

June 23, 2017

Physician-Focused Payment Model Technical Advisory Committee
C/o U.S. Department of Health and Human Services
Assistant Secretary for Planning and Evaluation Office of Health Policy
200 Independence Avenue, S.W.
Washington, D.C. 20201
PTAC@hhs.gov

**RE: Renal Physicians Association Incident ESRD Clinical Episode Payment Model
– May 2017**

Dear Committee Members:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comment on the Renal Physicians Association (RPA) Incident ESRD Clinical Episode Payment Model. ASN represents nearly 17,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of people with kidney diseases. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care and ensuring access to optimal patient-centered quality care, regardless of socioeconomic status, geographic location, or demographic characteristics.

ASN commends RPA for submitting a proposal on an incident end-stage renal disease (ESRD) clinical episode payment (CEP) model and encourages the PTAC to recommend testing of the model to the Secretary. RPA outlines the severity of the burden of ESRD on the American public and on the entire Medicare system. Patients with kidney failure are among the sickest and most complex in the Medicare system resulting in a disproportionately high utilization of Medicare resources. As outlined by the RPA proposal, “the typical adult ESRD patient has 2.0 hospital admissions per year, or on average 12 hospitalization days per year, and an approximate readmission rate of 36%. Thus, ESRD patients are among the sickest and most vulnerable patient sub-populations in Medicare.”

The proposed CEP focuses on one of the most precarious periods for patients with kidney diseases from both outcomes and cost perspectives: the transition to dialysis and the first six months of that period. RPA highlights that “costs in the first 6 months of ESRD care are disproportionately higher than annualized costs” and that improvements in incident dialysis – in the first six months – could yield improvements in patient care and reduce costs.

RPA's proposed model takes incident dialysis and builds a straightforward care approach based on a well-defined episode that is not only highly feasible but ready for testing in the immediate future. RPA's CEP model streamlines ESRD patient care oversight by nephrologists, alleviates the need for new administrative infrastructure, and allows flexibility for implementation by various practice sizes and geographic locations.

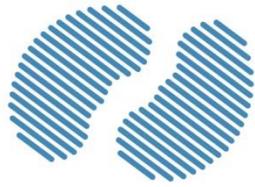
ASN hopes that this model, addressing a critical transition in care associated with high risk for patients with kidney failure, can serve as the basis for, or yield lessons that support, the creation of a broader kidney care model that spans the spectrum of care for individuals with advanced chronic kidney disease up to and across their disease transitions, including patients not treated with dialysis, dialysis patients, and kidney transplant recipients.

ASN thanks the Members of the PTAC for this opportunity to comment on the RPA CEP model and endorses that model for testing.

Sincerely,

A handwritten signature in black ink, appearing to read "Eleanor D. Lederer". The signature is fluid and cursive, with a large initial "E" and a long, sweeping tail.

Eleanor D. Lederer, MD, FASN
President



American Society of Pediatric Nephrology

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June 26, 2017

Physician-Focused Payment Model Technical Advisory Committee (PTAC)
c/o US DHHS Assistant Secretary for Planning and Evaluation Office of Health Policy
200 Independence Avenue SW
Washington, DC 20201

Re: Renal Physician Association Incident ESRD Clinical Episode Payment Model

Dear PTAC Committee Members:

On behalf of the American Society of Pediatric Nephrology (ASPN), I am writing to express our support for the above referenced proposal submitted by the Renal Physicians Association (RPA) that is currently under consideration. ASPN believes that RPA's condition-specific, episode-of-care payment model targets a particularly vulnerable population where there is an opportunity to improve care and simultaneously significantly reduce costs.

Founded in 1969, ASPN is a professional society composed of pediatric nephrologists and affiliate healthcare professionals whose goals are to promote optimal care for children with kidney disease and disseminate advances in the clinical practice and basic science of pediatric nephrology. The ASPN currently has over 700 members, making it the primary representative of the pediatric nephrology community in North America.

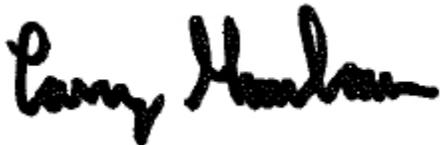
More than 670,000 Americans have end-stage renal disease (ESRD). An estimated 200,000 children and adolescents have kidney disease, with about 15,000 of them suffering from ESRD and currently receiving dialysis or living with a kidney transplant. While not of Medicare age, children and adolescents with ESRD who require dialysis or transplantation have access to Medicare coverage, requiring ASPN members to participate in Medicare quality programs, including the ESRD Quality Incentive Program (QIP) and the Quality Payment Program (QPP).

We are acutely aware of the high cost of treating ESRD patients, who account for 7 percent of Medicare expenditures, but are only 1 percent of the Medicare population. Medicare costs for prevalent ESRD patients average \$86,000 per patient annually. In the first six months of dialysis care, costs tend to be significantly higher, ranging from \$56,000 - \$65,000.

In recognition of the high costs associated with this patient population, RPA has designed a payment model to improve health outcomes and reduce costs for these vulnerable patients making the transition to dialysis. Regardless of whether the patient is an adult, adolescent or a child, patients benefit from encouraging earlier referrals, incentives for referral for kidney transplant, fewer hospitalizations, more home dialysis utilization and earlier planning for fistulas or peritoneal dialysis access. If this model works as anticipated, it will promote the value of care over the volume of care while increasing quality and reducing costs. Furthermore, the lessons learned from this model will likely be helpful in tailoring payment models in the future for the unique needs of the pediatric ESRD population.

Thank you for the opportunity to provide comments on RPA's proposed model. Please do not hesitate to contact ASPN's Washington Representative, Erika Miller at emiller@dc-crd.com or (202) 484-1100, if you have any questions or require further information.

Sincerely,

A handwritten signature in black ink that reads "Larry Greenbaum". The signature is written in a cursive, slightly slanted style.

Larry Greenbaum, MD, PhD
President



June 26, 2017

Physician-Focused Payment Model Technical Advisory Committee (PTAC)
c/o Angela Tejada
Office of the Assistant Secretary for Planning and Evaluation
200 Independence Avenue SW
Washington, DC 20201

Re: Public Comment on Renal Physicians Association Incident ESRD Clinical Episode Payment Model

Dear Committee Members:

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer comments on the proposed Renal Physicians Association (RPA) Incident End Stage Renal Disease (ESRD) Clinical Episode Payment Model. NKCA represents five nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Clinic, Inc. (DCI); 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 5,000 patients with chronic kidney disease (CKD), with the goal of avoiding, or at least delaying, onset of end stage renal disease. Approximately 85 percent of our patients are covered by Medicare, including Medicare Advantage plans. Four of our five members also participate in the Comprehensive ESRD Care (CEC) Model through the Centers for Medicare and Medicaid Innovation (CMMI). Collectively we are responsible for 10 ESRD Seamless Care Organizations (ESCOs) across the country in both one-sided and two-sided risk models.

Approximately 26 million Americans suffer from kidney disease, at an estimated cost to the Medicare program of \$99 billion¹. Our goal is to improve patients' quality of life by providing the best care, not just for dialysis patients but also for those with chronic kidney disease, to reduce the risk and slow the progression of kidney disease to avoid, or at least delay, the onset of ESRD, and increase the number of patients who can benefit from kidney transplants. Kidney disease (both CKD and ESRD) is a chronic illness that doesn't exist alone. It is often accompanied by multiple co-morbidities, including diabetes, congestive heart failure, and high blood pressure. Kidney disease also exists over many years, making it a particularly appropriate candidate for coordinated care models.

While many of the tenets of the Clinical Episode Payment (CEP) model match our own, we are concerned the model does not go far enough to address CKD and does not include the appropriate providers to be meaningful. We offer our comments based on our experience in the current ESCO model and our CKD programs.

¹ USRDS. 2014 Annual Report

Addressing CKD Upstream for Better Outcomes

The NKCA believes the single most important change that can occur for patients with kidney disease is to better align the incentives of the current reimbursement system and metrics to encompass care for patients with kidney disease, at whatever stage of their journey, rather than focus predominately on patients on dialysis. 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. 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.

We are pleased to see in the proposed CEP Model a focus on appropriate transitions that support better outcomes and lower costs. We believe that transplant is the optimal therapy for individuals with kidney disease. For those individuals who need dialysis as a therapy, it is critical to work with the patient early enough that the patient can make the best decision for his or her own care. Unfortunately, too many patients start dialysis in the emergency room unaware until then that they had kidney disease, or at least are ill-prepared. By preparing patients early, and following them closely, there are many positive results for patients dealing with this disease. Several of our members have programs specific to CKD in which we see the following:

- **More patients receive a pre-emptive kidney transplant and avoid dialysis.** Nationwide the pre-emptive transplant rate is 2.6%. In The Rogosin Institute’s CKD program, patients have a 14% pre-emptive transplant rate.
- **Patients are educated on medical management without dialysis and when appropriate patients choose this option.** In the DCI CKD program in Spartanburg, SC, more than 15% of patients are choosing medical management without dialysis.
- **More patients receive education on and then choose home dialysis.** In the Northwest Kidney Centers’ Choices CKD program in Seattle, WA, 31% of patients start dialysis at home.
- **More patients start hemodialysis with a permanent access.** In the Northwest Kidney Centers’ Choices CKD program, more than 76% of patients start hemodialysis or peritoneal dialysis with a permanent access and never have a catheter.
- **More patients receive their first dialysis treatment as an outpatient and avoid an 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 programs avoided a hospitalization for their first treatment.
- In the DCI REACH program 500 (out of 4500 patients in 29 sites) are now being cared for at CKD Stage 5 and are being kept off dialysis.

While we appreciate the intention to encourage these modalities in the CEP model, we believe it does not go far enough or capture patients early enough in the progression of CKD to have the impact necessary for these patients. In their proposal, RPA notes that many nephrologists only see patients for the first time just before the onset of ESRD, making the structure of this model initiating at the start of dialysis difficult.

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 United States Renal Data System (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.

We recommend that a model going upstream to address transitions in ESRD care must identify the eligible population based on their Glomerular Filtration Rate (GFR). We believe the most appropriate GFR level for a model should be a GFR less than 45, or CKD stage 3b, in order to provide 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) data²:

- 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)

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 difference in cost of care for a patient with stage 5 CKD not on dialysis and a patient on dialysis. For every month that the start of dialysis is delayed, there is not only a decrease in the cost of care for Medicare by more than \$4,000 per patient but also for some a better quality of life. These costs can also be compounded since many CKD patients also have diabetes and hypertension.

² 2015 USRDS

Role of the Nephrologist and Other Partners

We believe that the role of the nephrologist is the most important aspect of any model addressing CKD or ESRD. We consider them to be the captain of the ship and should always be the one to make the clinical decisions for the patient and take on a leadership role within the APM entity. With that in mind, based on the CEP proposal, we are concerned that there is no discussion, and even an exclusion of other providers in the model. Without any other partners in the administration of the model, nephrologists and nephrology practices may not have the necessary infrastructure to administer the model. ***We believe that others, including dialysis providers, hospitals, or others are necessary to carrying out this model to encompass all care services for these patients, while also providing the structural support necessary for success.***

We believe having various partners, such as in the current ESCOs, is incredibly valuable in order to coordinate services, provide financial and administrative support, and share in the decision-making of the entity. For instance, in the ESCO, nephrologists are owners in the model, along with dialysis and other providers who sit on a board for the organization to promote coordinated decision-making and support, while still keeping the nephrologist at the center of patient care. Our members have also utilized less formalized partnerships in the ESCOs with hospitals, primary care physicians, hospice providers, and local community groups to expand their reach and the services provided to patients. We feel strongly that any model moving forward should include all providers responsible for the care of patients with kidney disease.

Conclusion

Thank you for the opportunity to comment on the proposed Renal Physicians Association Incident ESRD Clinical Episode Payment Model. We would be happy to discuss any of our comments further if that would be of assistance to PTAC members. If you have any questions, please feel free to contact me at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,



Martin Corry
Executive Director

June 26, 2017

Physician-Focused Payment Model Technical Advisory Committee (PTAC)
c/o Angela Tejada
Office of the Assistant Secretary for Planning and Evaluation
200 Independence Avenue SW
Washington, DC 20201

Re: Public Comment on Renal Physicians Association Incident ESRD Clinical Episode Payment Model

Dear Committee Members:

On behalf of Dialysis Clinic, Inc. (DCI), I write to offer comments on the proposed Public Comment on Renal Physicians Association (RPA) Incident End Stage Renal Disease (ESRD) Clinical Episode Payment Model. DCI is a nonprofit provider of care for patients with kidney disease. We currently care for more than 15,000 patients in more than 230 clinics in 28 states. In addition, we run three Organ Procurement Organizations, located in Tennessee, New Mexico and Northern California. Because of the hard work of the staff at DCI Donor Services, more than 600 people received a kidney transplant in 2016. In addition, DCI currently runs 6 ESRD Seamless Care Organizations (ESCOs) across the country in a two-sided risk model.

DCI has established a chronic kidney disease (CKD) care coordination program called “Reach Kidney Care” to provide education and clinical services to individuals at an earlier stage of kidney disease with the goal of delaying or eliminating the need for dialysis. Through Reach Kidney Care, we currently care for more than 4,200 patients in 29 different communities. Our primary goals for this care are to either avoid dialysis or delay the start of dialysis. In this program, we currently care for more than 600 patients with stage 5 CKD (glomerular filtration rate (GFR) \leq 15) and are keeping them off dialysis.

We believe that it is critical to focus “upstream” on patients with CKD so that fewer patients need dialysis, or delay the start, and are better transplant candidates. By counseling patients earlier on their treatment options, patients have more time on the transplant wait list and are more likely to receive a pre-emptive transplant. This also allows additional time to have discussions with friends and family members to increase the likelihood of a living donation.

Approximately 26 million Americans suffer from kidney disease, at an estimated cost to the Medicare program of \$99 billion¹. Our goal is to improve patients’ quality of life by providing the best care not just for dialysis patients but also for those with chronic kidney disease, to reduce the risk and slow the progression of kidney disease to avoid, or at least delay, the onset of ESRD, and increase the number of patients who can benefit from kidney transplants. Kidney

¹ USRDS. 2014 Annual Report

disease (both CKD and ESRD) is a chronic illness that doesn't exist alone. It is often accompanied by multiple co-morbidities, including diabetes, congestive heart failure (CHF), and high blood pressure. Kidney disease also exists over many years, making it a particularly appropriate candidate for coordinated care models.

Based on our experience caring for patients with late stage CKD, and based on what we have learned from our partners, we recommend that a program addressing late stage CKD and the transition to the next step in care include:

1. All patients receiving a pre-emptive kidney transplant or a transplant during the first year of dialysis
2. All patients in the first 120 days of dialysis (with the option to exclude these patients if there is an ESCO or other population health model for patients on dialysis in the same market as the program)
3. All patients with stage 5 CKD ($GFR \leq 15$), not on dialysis
4. All patients with stage 4 CKD ($GFR 30-15$)
5. Patients with $GFR 45-30$ with either moderately increased albuminuria ($30-300$ mg/g or $3-30$ mg/mmol) or severely increased albuminuria (>300 mg/g or > 30 mg/mmol)
6. Patients with $GFR 60-45$ with severely increased albuminuria (>300 mg/g or > 30 mg/mmol)

We also recommend that a model focused on improving care for these patients addresses both their current care and the possible transition to either transplant or dialysis.

While many of the tenets of the Clinical Episode Payment (CEP) model match our own, we are concerned the model does not go far enough to address CKD and does not include the appropriate providers to be meaningful. We offer our comments based on our experience in the current ESCO model and our CKD programs.

I. We Support Any Effort To Improve Transition To Transplant and Dialysis

We commend the RPA for proposing a new model to improve care for patients starting dialysis. We agree that the transition to dialysis can be greatly improved. We also greatly appreciate that the RPA explicitly notes the benefit of transplant and offers a financial incentive to nephrologists for both patients who receive a pre-emptive transplant and a transplant during the first six months of dialysis.

A. Transplant

We consider transplant to be the optimal therapy for many patients with kidney failure. A patient with a transplant is more likely to have the life that s/he would have had, but for that person's poorly functioning kidney. A person with a kidney transplant is more likely to be able to work and more likely to live a longer life than a patient on dialysis. In addition, the cost of care for a patient with a kidney transplant is substantially lower than a patient on dialysis. Excluding the cost of the transplant surgery, the cost of care for a patient with a transplant is more than \$50,000 less per year than the cost of care for a patient on dialysis.

Yet, only 2.6% of patients receive a kidney transplant and avoid dialysis. We need to do better. At DCI, our goal is to quadruple the pre-emptive transplant rate to 11%. We know this goal is attainable – at The Rogosin Institute CKD program in New York City, the pre-emptive transplant rate is 14%.

B. Home Dialysis

A patient dialyzing at home has more independence, is more likely to work, has more satisfaction in his/her care, and is able to avoid going to the dialysis clinic for a four hour treatment three days a week. In addition, the cost of care for a patient dialyzing at home is less than the cost of care for a patient dialyzing in an outpatient clinic. According to our internal analysis of claims data from our first three ESCOs, the cost of care for a patient dialyzing at home is more than \$5,000 less per year than a patient dialyzing with a permanent access in a dialysis clinic. [DCI Internal Analysis, results subject to change.²]

Currently less than 10% of patients nation-wide start dialysis at home. By providing better care for patients with CKD, we can make home dialysis available to more patients. In Spartanburg, SC, we manage the care for more than 900 patients with chronic kidney disease. For those patients in this program who started dialysis in 2015, 37% started dialysis at home.

C. Dialysis With A Permanent Access

A patient dialyzing with a fistula or a graft is less likely to have an infection, less likely to be in the hospital, and more likely to live than a patient dialyzing with a hemodialysis catheter. In addition, according to our internal analysis of claims data from our first three ESCOs, the cost of care for a patient dialyzing with a permanent access is more than \$29,000 less per year than a patient dialyzing with a hemodialysis catheter. [DCI Internal Analysis, results subject to change]

Unfortunately, nationwide only 20% of patients start dialysis with a permanent access. By working with patients early, and allowing their access to be placed and to mature, we can make it more likely that a patient will start dialysis using a permanent access and never use a hemodialysis catheter. In our Spartanburg program in 2015, 68% of patients from the CKD program started dialysis with a permanent access, avoiding the need to use a hemodialysis catheter.

D. Avoid Hospitalization Before First Dialysis

Although not explicitly mentioned in the RPA proposal, we note that care can be improved, and the cost of care decreased, if more patients avoided the hospitalization before their first dialysis treatment.

² The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The author assumes responsibility for the accuracy and completeness of the information contained in this document.

Nationwide, almost two-thirds of patients receive their first dialysis treatment in the hospital. [Wong SPY, Kreuter W, O'Hare AM: Healthcare intensity at initiation of chronic dialysis among older adults. J Am Soc Nephrol 25:143–149, 2014] We estimate that the cost of a hospitalization (including post-acute care) for a patient on dialysis can be as high as \$25,000. [DCI analysis of 5% Medicare claims data from 2013.]

We have found that by following patients closely, we can allow for a better transition to dialysis and drop this hospitalization rate in half. For our CKD program in Spartanburg, only 33% of patients starting dialysis in 2015 received their first dialysis treatment in the hospital.

E. Delaying Start Of Dialysis

We note that one gap in the current model is that it does not provide an incentive to start a patient later in the progression of kidney disease. We see this as a weakness of the model and strongly recommend that any model addressing the transition to dialysis or transplant provide both a financial incentive for appropriate start later in progression of CKD and establish a quality metric that evaluates GFR at start, and patient symptoms justifying the need to start dialysis.

In our opinion, nation-wide patients are starting dialysis too early in the progression of their CKD. Patients should only be started on dialysis when they have symptoms that cannot be treated without dialysis care; they should not be started on dialysis merely because they reach a certain GFR number.

Nation-wide, 12% of patients are starting dialysis with a $GFR \geq 15$. This represents more than 14,000 people in 2014 alone. If we are able to better manage these patients, and keep them off dialysis until they have symptoms that can only be treated with dialysis care, we can provide a great benefit to these patients, since they will not need to go to a dialysis clinic for a four hour treatment three times a week. In addition, the cost of care for these patients is more than \$4,000 less for each month that the start of dialysis is delayed.

In our Spartanburg CKD program, we have been effective at safely starting patients later in the progression of their kidney disease. Since 2014, not a single patient has started dialysis with a $GFR > 15$. In fact, most patients start dialysis with a GFR between 5 and 10. In this program, we do not start a patient on dialysis until that patient has symptoms that can only be treated with dialysis care. We partner with the patient's nephrologist so that the patient is seen twice as frequently as if they were followed by their nephrologist alone. Some patients are seen every week so that we can closely follow and treat symptoms and safely determine the time that it is necessary to start dialysis care. We provide additional services beyond nursing care coordination, including social work and dietitian services. We have seen that with this intensive management, patients are able to have a smooth and safe start of dialysis care later in the progression of their kidney disease and nephrologists are more comfortable starting patients later in the progression of their kidney disease.

We are also seeing that by following this process patients have more time to choose their optimal therapy and, for those who start hemodialysis, patients are more likely to have their permanent access ready to be used when they start dialysis. As noted above, patients starting dialysis from

the CKD program in Spartanburg are three times more likely to start dialysis at home, and, if starting in center, are three times more likely to start using a permanent access.

II. The Proposed Model Is Limited Because It Does Not Take The Opportunity To Improve Care For Patients With CKD While They Have CKD

We strongly believe that any program that only addresses the transition to dialysis care is an incomplete model. Patients with late stage CKD have high clinical needs and a high cost of care. They should be cared for as a patient with CKD and not only seen as patients who may need dialysis or a kidney transplant.

A. Opportunities To Improve Care For Patients With Late Stage Kidney Disease

Patients with late stage CKD have high clinical needs and a high cost of care. The hospitalization rate for a patient with stage 4 or 5 CKD, not on dialysis, is more than 3½ times higher than the typical patient with Medicare coverage. [2016 USRDS ADR. Vol. 1. Figure 3.13] The average total Medicare cost of care for a patient with stage 4 or 5 CKD, not on dialysis, is \$28,541, more than 2½ times the average cost of care for a patient with Medicare; the cost of care for a patient with stage 4 or 5 CKD, not on dialysis, with CHF is \$40,904, nearly four times the average cost of care for a patient with Medicare. [2016 USRDS ADR, vol. 1, table 6.3; table 6.4]

From a patient-centric point of view, shouldn't we build a better system of care to improve their care now, instead of when they may need dialysis? From a population health point of view, shouldn't we work to ensure that these patients receive the best, most cost effective care possible?

Many interventions can be implemented to improve the care, and decrease the cost of care for these patients, including –

1. Avoiding NSAIDS, to slow progression of CKD;
2. Ensuring that these patients are on an ACE Inhibitor or an ARB, slowing progression of their CKD;
3. Improving control of diabetes;
4. Improving control of hypertension;
5. Encouraging smoking cessation;
6. Encouraging increased activity;
7. Having open discussions with the patient and his or her family about end of life and documenting the patient's wishes for intensity of care at end of life;
8. Treating fluid overload, and delaying the start of dialysis; and
9. Treating hyperkalemia, and delaying the start of dialysis

All of the above interventions improve the current care of patients with late stage CKD and likely provide additional savings regardless of whether the patient needs dialysis or receives a transplant. Yet none of these opportunities are addressed by a model that only addresses the transition to transplant or dialysis. Shouldn't a model addressing patients with late stage CKD also take the opportunity to improve these aspects of their care?

B. We Need To Improve The Transition To End of Life For Patients With CKD

Many patients with late stage CKD will die before they reach dialysis. The mortality rate for patients with stage 4 or 5 CKD, not on dialysis, is more than four times higher than a patient without CKD. [2016 USRDS ADR Figure 3.2] Despite this high risk of mortality, we are not aware of any systematic approach to improve end of life care for patients with late stage CKD.

It has recently been shown that patients with ESRD are much more likely to die in the ICU than patients with cancer or patients with dementia. [Wachterman et al. Quality of End-of-Life Care Provided to Patients With Different Serious Illnesses. JAMA. Published online June 26, 2016] We are not aware of a similar analysis looking at intensity of end of life care for patients with CKD in the US. However, a recent analysis of end of life care for patients with CKD in England found that only 10.7% of people with CKD died at home, compared to 17.2% for a comparable population without CKD. For patients with CKD, the cost of outpatient and inpatient care for the last 12 months of life was £11,916; compared to £7,832 for comparable patients without CKD. [Kerr et al. NDT. 2016]

A model addressing late stage CKD should create a better transition to end of life care. In our opinion, any model that does not address the transition to end of life for this high risk population is incomplete.

C. Importance Of Addressing The Option To Not Start Dialysis

Many patients with late stage CKD would do just as well if they received medical management without dialysis instead of starting dialysis. According to a recent publication, patients over 80 years of age who chose conservative care have similar survival rates to those who chose dialysis. In addition, patients over 70 years of age with poor functional status (WHO score of 3+) who choose conservative care have similar survival to those who start dialysis. Finally, patients over 70 years of age with other comorbid illnesses (Charlson Comorbidity Index 8+) who choose conservative care have similar outcomes to those who start dialysis. [Hussain. Palliative Medicine. Vol. 27. Issue 9. 2013]

In 2014, more than 25,000 patients aged 75 and older started dialysis. We do not know how many of them were educated about the possibility of receiving medical management without dialysis. However, we strongly believe that any model addressing care for late stage CKD should ensure that patients are informed of the possibility of not starting dialysis. These patients should also know that we will not abandon them if they choose to not start dialysis and that they can change their mind at any time. If they choose medical management without dialysis, they should be followed closely and should be offered a broad spectrum of non-dialytic treatment, ranging from pure palliation to a very active effort to do everything except dialysis.

We have followed this process in our CKD program in Spartanburg, SC. We have seen that more than 10% of our patients choose medical management without dialysis. Although they know that they can change their decision at any time, 96% of patients choosing medical management without dialysis have not started dialysis.

III. Role of the Nephrologist and Other Partners

We believe that the role of the nephrologist is the most important aspect of any model addressing CKD or ESRD. We consider the nephrologist to be the captain of the ship and should always be the one to make the clinical decisions for the patient and take on a leadership role within the APM entity. With that in mind, based on the CEP proposal, we are concerned that there is no discussion, and even an exclusion of other providers in the model. Without any other partners in the administration of the model, nephrologists and nephrology practices may not have the necessary infrastructure to administer the model. ***We believe that others, including dialysis providers, hospitals, or others are necessary to carrying out this model to encompass all care services for these patients, while also providing the structural support necessary for success.*** We believe having various partners, such as in the current ESCOs, is incredibly valuable in order to coordinate services, provide financial and administrative support, and share in the decision-making of the entity.

For instance, in the ESCO, nephrologists are owners in the model along with dialysis and other providers who sit on a board for the organization to promote coordinated decision-making and support, while still keeping the nephrologist at the center of patient care. Our members have also utilized less formalized partnerships in the ESCOs with hospitals, primary care physicians, hospice providers, and local community groups to expand their reach and the services provided to patients. We feel strongly that any model moving forward should include all providers responsible for the care of patients with kidney disease.

To ensure that nephrologists remain the captain of the ship in a model that addresses CKD and early ESRD care, we support including a restriction that non-nephrologists must have less than 50% of the control of the operations of the model. In our six ESCOs, the average governing board has ten members. DCI has only two voting representatives in each ESCO board. We have seen that this model allows for more collaboration among providers and increases the likelihood that each owner in the ESCO is maximally engaged in improving care for patients with kidney disease.

For patients with CKD, we have seen that partnership with other providers, and in particular health systems, can greatly improve care. A few years ago, we noticed in Spartanburg, SC that many patients who crash into dialysis had been seen at the local hospital before they had kidney failure and their lab-work during the prior admissions showed evidence of kidney disease. In partnership with Spartanburg Medical Center, we started the Kidney Care Protocol in February 2016. Under this new protocol, any patient in the hospital with a GFR less than 60 receives an automatic referral to our CKD program. For the first three months of the program, we received more than 1,000 referrals to our CKD program. At the time of the start of the Kidney Care Protocol, we had 600 patients in our CKD program; we now care for more than 900 patients. By caring for more patients with CKD earlier in their progression of CKD, we hope to allow them to avoid dialysis, or at least be more prepared for the transition to dialysis if they need to receive this care. We also hope that more patients will have the opportunity to receive a pre-emptive transplant and avoid dialysis.

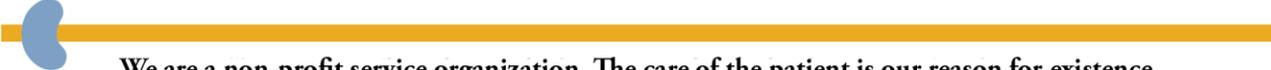
Conclusion

Thank you for the opportunity to comment on the proposed Renal Physicians Association Incident ESRD Clinical Episode Payment Model. We would be happy to discuss any of our comments further if that would be of assistance to the PTAC members. If you have any questions, please feel free to contact me at 615-342-0435 or Doug.Johnson@dcinc.org.

Sincerely,



Doug Johnson, MD
Vice Chairman of the Board



We are a non-profit service organization. The care of the patient is our reason for existence.



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June 26, 2017

Physician-Focused Payment Model Technical Advisory Committee
c/o U.S. Department of Health and Human Services
Assistant Secretary for Planning and Evaluation Office of Health Policy
200 Independence Avenue, S.W.
Washington, DC 20201
PTAC@hhs.gov

Dear Committee Members,

The National Kidney Foundation is pleased to comment on the proposed Incident ESRD Clinical Episode Payment Model submitted by the Renal Physicians Association. NKF is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, 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 has also submitted a letter of intent to propose a payment model to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) this August that would address critical gaps across the spectrum of kidney care – from early detection of those at highest risk to those who will transition to ESRD. We offer the following the comments on the proposed ESRD Clinical Episode Payment Model.

NKF appreciates the model's intent to improve incident ESRD patients' outcomes. NKF agrees, and the evidence supports, that the first 90-120 days on dialysis is the most critical time for dialysis patents – risk of mortality and hospitalizations are at their highest in this period. Nephrologists can serve a critical role in improving patients' outcomes by closely managing care prior to kidney failure, working to address comorbidities, and overseeing the delivery of patient education on all treatment options. This care management is critical to ensuring those patients who need renal replacement therapy have the opportunity to choose, in advance, the therapy that best meets their individual needs and goals. The Incident ESRD Clinical Episode Payment Model highlights these laudable goals, and promotes a needed focus on pre-emptive kidney transplantation and end of life care for those who are unlikely to benefit from dialysis. Yet, the model lacks criteria to ensure accountability for improved value and benefits delivered to patients.

The model relies on the assumption that the potential for shared savings to nephrologists is enough to change the current status of nephrology care, but does not address that some of these changes may require upfront investments. The model does not adequately address improving patient referrals from

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primary care providers to nephrologists and for that reason the potential for savings is limited given that 1/3 of CKD patients receive little to no nephrology care prior to kidney failure. While the model assumes the shared savings potential is enough to motivate new collaborations with primary care practitioners, and certainly there is evidence for potential savings through optimal ESRD starts that could be shared with PCPs, the lack of any upfront investment or structure for how collaborations would work in this model is likely to limit the potential for improved care. Shared savings models are not new, have many limitations, and have seen mixed results. For example, the most efficient practices have difficulty achieving ongoing savings when baselines are rebased and for these reasons have been viewed as not sustainable in the long-term.¹

The quality measure topics included in the model address important areas of patient care and the weighting of quality measures is likely to encourage an increased focus on these known gaps. However, many of the measures are process and reporting measures rather than measures of improvement in care. For example, the functional status measure only assesses whether an evaluation occurred--not the outcome of functional status. NKF questions the absence of measures related to hospitalization and readmissions, which can be improved with care coordination. We also note concern with a threshold of 30 points out of 100 serving as the benchmark for acceptable quality at which shared savings could be paid. This appears low even though the amount of shared savings increases with higher scores. The risk of shared savings models is that increases in payment can be realized through cost-cutting or limiting services with relatively little emphasis or gains in quality. NKF believes the threshold for quality should be higher, particularly with half of the measures being reporting or process measures.

The model leaves considerable flexibility to nephrologists in determining how they will improve care to meet shared savings and quality measure benchmarks. The model suggests, but does not establish criteria for delivering added value to patients. There are also no criteria or support systems in place for patient engagement in the model. The model does not emphasize the need to formulate a care plan tailored to best achieve individual patient goals. We believe engagement of patients will be necessary to achieve the model's stated goals of increased use of home dialysis, improved patient experience, advanced care planning, and even shared savings.

While the model could be improved to provide greater patient-centricity and tools and resources to physicians caring for CKD patients, NKF does believe the stated intent of the model to improve patients' transitions to ESRD is laudable and draws attention to an important gap in care. While NKF does intend to submit our own proposal to PTAC, which will address many of these same gaps, plus additional ones mentioned in these comments, we do think both models could operate simultaneously and offer nephrologists more opportunities to participate in alternative payment models.

¹ Muhlestein David, et al, Medicare Accountable Care Organization Results For 2015: The Journey To Better Quality And Lower Costs Continues, Health Affairs Blog, September 6, 2016.

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The National Kidney Foundation hopes that our comments are helpful to the committee's evaluation of the Incident ESRD Clinical Episode Payment Model and we would be pleased to answer additional questions from the committee.

Sincerely,

Kevin Longino

Kevin Longino
CEO and kidney patient

Michael Choi

Michael Choi, MD
President

June 26, 2017

Jeffrey Bailet, MD
Committee Chairperson
Physician-Focused Payment Model
Technical Advisory Committee
Office of the Assistant Secretary for
Planning and Evaluation
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Bailet:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide our strong support for the Renal Physicians Association (RPA) Incident End-Stage Renal Disease (ESRD) Clinical Episode Payment (CEP) Model proposal currently being reviewed by the Physician-Focused Payment Model Technical Advisory Committee (PTAC).

The ESRD CEP proposed model focuses on patients transitioning from chronic kidney disease (CKD) to ESRD, and includes treatments within the first six months of ESRD care. Costs in the first six months of ESRD care are disproportionately higher than costs in later stages of the condition, often due to suboptimal transitions to renal replacement therapy. The AMA has participated in several discussions with nephrologists and others who provide medical care to patients with CKD and ESRD, which have illuminated the numerous opportunities to improve the delivery of care for these patients and the barriers to making those improvements within the existing payment system. Given the potential for improved quality of care, quality of life, and reduced Medicare spending, the AMA agrees that treatment for the first six months of dialysis care for patients with ESRD is an ideal condition to be treated through a condition-based episode-of-care Alternative Payment Model (APM).

The RPA argues that the proposed model will increase physicians' focus on improving care during the latter stages of advanced CKD, before patients develop ESRD. In addition, the proposal states that once patients develop ESRD, factors such as starting incident hemodialysis without permanent vascular access can create costly complications and higher mortality rates. Also, greater access to home dialysis and palliative care options can improve the quality of life and outcomes for ESRD patients. Therefore, the AMA agrees the proposed ESRD CEP model will support nephrologists' efforts to improve care and reduce costs by emphasizing pre-dialysis treatment planning, increasing care coordination, reducing complications that can lead to hospital admissions, increasing access to kidney transplants and to home dialysis, and promoting advanced care planning.

Furthermore, the proposed model requires minimal infrastructure creation, allowing physicians in a variety of practice locations and sizes to participate. In addition, the model has two tracks, one which includes upside risk only, which would allow physicians to participate in an APM within the Merit-Based

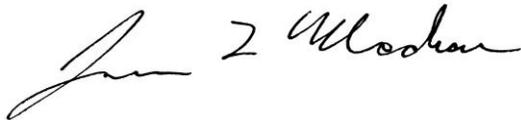
Jeffrey Bailet, MD
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Page 2

Incentive Payment System (MIPS). The second track includes both upside and downside risk, and would be considered an Advanced APM. The AMA supports allowing physicians the flexibility to participate in either MIPS APMs or Advanced APMs, and not requiring that they move to a two-sided risk model.

The ESRD CEP model could allow ESRD patients receiving the first six months of dialysis treatment to experience fewer hospitalizations and complications, which would significantly reduce Medicare costs for these beneficiaries. The proposed model provides an important opportunity to improve patient care and achieve cost savings for patients transitioning from CKD to ESRD.

The AMA urges the PTAC to recommend the RPA Incident ESRD Clinical Episode Payment Model as a high priority for adoption and implementation. We thank the Committee for the opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive, flowing style.

James L. Madara, MD