

**The PTAC Preliminary Review Team's Questions on  
Incident ESRD Clinical Episode Payment Model**

**Submitted by the Renal Physicians Association (RPA)**

**Questions for the Submitter**

- 1) Please give a quantitative example of how this model would work for a nephrologist in a small practice.

**A 1-3 physician nephrology practice would, on average, contain 20-60 incident ESRD patients annually. Extrapolating from USRDS epidemiologic data, approximately 50% of these patients would have Medicare coverage when initiating dialysis. This number is likely to rise in coming years due to a recent uptick of individuals aged 65-74 initiating dialysis.**

**Additionally, while this is a small absolute number of patients, this cohort accounts for more than \$1 of every \$100 Medicare dollars spent in total. For this reason, the RPA's patient-centric model is likely to financially benefit providers and taxpayers, while improving the quality of care and quality of life for beneficiaries.**

**Because the RPA's Incident Dialysis PFFM requires no additional up-front infrastructure investment, a small practice would have equal opportunity for shared savings compared to a medium or large nephrology practice. Additionally, compared to the current ESCO model, there are three distinct advantages of this alternative payment strategy for small practices. First, ESCOs require at least 350 patients, greatly limiting small practice participation. Second, patients in an ESCO model do not have choice of dialysis provider. Third, current ESCO models are available in limited geographies, including those most concentrated with larger nephrology practices.**

**In contrast, small and larger nephrology practices that participate in the RPA's PFFM would not need to restrict their patients' choice of dialysis provider. Without any financial investment, small practices could implement a system for ensuring all CKD Stage 4 patients receive CKD education (available as a community service throughout the United States). Pre-emptive CKD education has been repeatedly demonstrated to increase home dialysis modality preference, AV fistula rates and reduced hospitalization. Similarly, small nephrology groups can reduce dialysis spending by offering conservative non-dialysis medical management, and by referring appropriate patients to regional kidney transplant centers prior to starting dialysis to optimize the chance for a pre-emptive transplant**

- 2) On page 3, the proposal states that the model would "span the initial six months of dialysis for established Medicare beneficiaries," but this restriction is not referenced in the description of eligible patients on page 12. Please clarify whether this model is restricted to those incident ESRD patients who are already enrolled in Medicare prior to initiating dialysis.
  - a) If it is not restricted to those already on Medicare, please describe how the model would work for those who become eligible for Medicare during the first 6 months of their dialysis.

**Expenditure for ESRD patients is greatest in the first 4-12 weeks after initiating dialysis. In order to accurately determine expenditures related to HCC-adjusted benchmarks, patients who become eligible for Medicare coverage AFTER initiating dialysis would not be eligible for this PFFM.**

Notably, entitled patients that initiate home dialysis are eligible for Medicare coverage on day 1 of dialysis and therefore would be eligible to participate in this alternative payment model, further incentivizing home dialysis choice.

*RPA is open to additional discussion on how patients who become eligible for Medicare after day 1 of dialysis could be incorporated into this PFPM. This would likely require CMS to perform further benchmarking on the costs associated with a less than six-month span of eligibility in the model.*

- b) If it is restricted to those already on Medicare, does it matter how long they have been on Medicare?

The RPA's PFPM was designed to enroll patients with primary Medicare coverage on day 1 of dialysis. There is no requirement for these patients to have Medicare coverage prior to initiating dialysis, nor does this model preferentially treat patients based upon their pre-dialysis beneficiary time on Medicare. As noted above, a major secondary benefit of this decision is to promote the utilization of home dialysis, a modality demonstrated to improve quality of life and reduce expenditure for all dialysis patients. Non-insured patients with incident ESRD who opt to begin home dialysis therapy are eligible for Medicare coverage upon initiating treatment.

- 3) The PRT wants to better understand why the RPA focused on a procedure (e.g. starting dialysis) rather than measure of disease severity (e.g. GFR) to identify the eligible population. Did you consider a clinical measure of severity and, if so, why did you choose a procedure-based approach instead?

The RPA focused on an "Episode of Care" model with precisely defined start and stop time points. While dialysis is a procedure, it represents a diagnosis of End Stage Renal Disease and, importantly, triggers completion of *Form 2728*, certifying eligibility in the Medicare program for entitled individuals. This required form differentiates between patients with acute kidney injury temporarily requiring dialysis from those with ESRD and designates the first day of outpatient dialysis. Therefore, the 2728 form, and by extension, the diagnosis of ESRD, triggers enrollment in the RPA's APM.

In contrast, there are no established "clinical measures" that could replicate the specific output of the Form 2728 and dialysis. A collateral benefit of the use of the 2728 form is that it resolves any possible ambiguities regarding a start date in the model or with attribution, as the patient will be assigned to the nephrologist submitting the first Monthly Capitated Payment (MCP) claim for professional services to Medicare.

Additionally, within CKD, clinical measures of severity are inherently unreliable and flawed for several reasons:

- A. There are no reasonable measures of true glomerular filtration rate (GFR, a measure of kidney function), only measures of estimated GFR. Those estimates vary in their accuracy based upon patient-specific characteristics, and can be adversely influenced by certain patient medications and nutritional status. Current models include Crockcroft Gault, MDRD, CKD-EPI, along with newer models based upon a novel biochemical marker, cystatin-C. Future estimated GFR (eGFR) is likely to be based upon an amalgamation of two or more current estimating equations. These equations are not optimal for all age groups and racial backgrounds, nor do they prospectively estimate the trajectory of

longitudinal GFR change, which can vary substantially between patients. Additionally, eGFR is not a precise estimate of disease severity, mortality risk nor symptoms.

- B. Common CKD-related medications alter the eGFR further. These include anti-hypertensive medications, common antibiotics, and gastrointestinal medications among others.
- C. Transient clinical situations also may alter the eGFR. This situation could lead to unintended consequences of early enrollment into an alternative payment model based solely on an estimated GFR number.

Because true quantification of uremia is inherently inaccurate, the RPA felt that an episode of care, based on the diagnosis of End-Stage Renal Disease, as defined by the initiation of dialysis (or by pre-emptive renal transplantation) was a more uniform approach. Additionally, by focusing on optimal transition to dialysis, the RPA's PFPM indirectly incentivizes and is intended to invigorate upstream CKD management, especially with regard to modality education, non-dialysis options and renal transplantation.

4) How does this model relate to the Comprehensive ESRD Care (CEC) model?

a) What specific gaps in the CEC model does this proposal address?

**The CEC model has 3 constraints which this model addresses:**

- i) CEC requires a minimum of 350 ESRD beneficiaries
- ii) CEC limits participation to a single dialysis organization (DO)
- iii) CEC constrains the geographic size of the ESCO (limited to 3 CBSAs)

By eliminating these constraints, the RPA model permits all nephrologists, especially those in small or rural practices, to participate. Today less than 1,300 nephrologists (15%) participate in an ESCO and few if any are in small practices or rural markets.

b) What is the advantage of creating a new payment model rather than adapting existing models to better manage incident ESRD?

Existing models for ESRD and CKD care are quite limited. Currently, the CEC (ESCO) model exists in limited geographies and require a minimum of 350 eligible patients, which significantly limit participation by the majority of nephrology groups nationwide. While some expansion of currently existing ESCOs may occur in the next two years, the addition of new ESCO markets is unlikely within that timeframe. Further, absent change in regulations, the CEC model is scheduled to sunset in 2020.

c) Please provide more information about how providers could participate in both the incident ESRD model and an ESCO (p. 12, "participation in this model does not preclude participation in other AAPMs such as ESCOs").

The RPA model would be first in the alignment hierarchy in markets where both models exist. Nephrologists participating in both models would take risk in the RPA model for the first 6 months of dialysis for patients receiving treatment in an ESCO clinic. Beginning with the "first touch" in an ESCO clinic during month 7, the ESRD beneficiary would be aligned with the nephrologist's local ESCO. The advantages for the beneficiary and for CMS is the RPA model creates direct and indirect incentives for better CKD care prior to starting dialysis, incentives which currently do not exist within the CEC model. It is important to note this alignment

**hierarchy may necessitate a slight change within the CEC model financial benchmark calculation.**

- 5) Page 10 of the proposal states, “Key opinion leaders and experts in measurement science in the nephrology community worked with RPA to develop custom, clinically-relevant measures that best reflect quality, patient-centered care.” What other quality measures did you consider and why did you not include them? Please provide an explanation for how weights were assigned to the proposed quality measures.

**CAHPS Scores—While these scores of patient satisfaction are used to evaluate dialysis centers as a whole, we opted not to use this measure as incident dialysis patients make up a relatively small percentage of a dialysis facility’s population. Therefore, the CAHPS score may have limited relevance.**

**Anemia Management and Bone Mineral Disease Metrics--While these items are a major component of overall ESRD patient care, they do not translate directly to reductions in hospitalization. Additionally, physicians already focus heavily on these metrics for all dialysis patients, based upon CMS “scoring criteria” of dialysis facilities (such as the Dialysis Facility Compare Five-Star Quality Rating System and QIP programs). Therefore, utilization of these metrics with the RPA’s PFFM would have limited additive value.**

**The weights were assigned to the quality measures based on a group consensus process of the members of our workgroup responsible for creation of the proposal.**

- 6) Quality Measure “Optimal Start: Day 1 of outpatient dialysis with no catheter in place or initiate dialysis on PD”—please explain how this measure would apply for patients who begin dialysis in the hospital before transitioning to outpatient dialysis.

**This metric would measure the first day of outpatient dialysis. While many of those patients who urgently or emergently initiate hemodialysis in the inpatient setting ultimately transition to outpatient hemodialysis, there are significant patient-centric and financial advantages of those patients initiating outpatient dialysis either on a home modality, such as peritoneal dialysis (PD), or with a maturing vascular access in place. In fact, an urgent PD start is an effective and patient-centric way that hospital starts can transition to home PD directly.**

- 7) How does this model avoid creating an incentive to place patients on dialysis earlier in the disease process, so that they are healthier and less expensive during the Medicare payment episode?

**The RPA would like to emphasize that the decision to initiate maintenance dialysis is fundamentally a clinical decision, including evaluation of volume status, uremic symptoms, uncontrolled electrolyte disorders, acid/base abnormalities, or neurologic manifestations. Although most patients do not initiate dialysis prior to advancing to Stage V CKD with an estimated GFR of 15 ml/min/1.73m<sup>2</sup> or less, there is no absolute level of eGFR used by nephrologists to decide on starting dialysis.**

**Based upon lack of specific evidence, the RPA was very sensitive to potential unintended consequences of any alternative payment model that further incentivizes dialysis. We have therefore recommend monitoring estimated GFR for all patients participating in this model. Our group of experts, however, opted not to include estimated GFR at time of dialysis initiation as a quality metric for three reasons for the reasons mentioned above.**

**Additionally, some patients initiate dialysis after an episode of acute on chronic renal failure. In this case, the eGFR is not an accurate representation of their true renal function. Similarly, there**

are currently no national standards by which to “grade” physicians on dialysis initiation. Other than a potential penalty for initiating dialysis on patients with eGFR above a threshold (i.e., 10 or 15ml/min/m<sup>2</sup>), we could not identify a fair and patient-centric way to include this in the quality metrics. This concern, and RPA’s effort to mitigate it, is additionally balanced by the inherent incentive to not offer dialysis to patients likely to do poorly.

- 8) Did you consider a quality measure for the proportion of ESRD patients who are on dialysis?

**The diagnosis of ESRD is most often made upon the initiation of dialysis or renal transplantation, upon completion of the Form 2728. When medical management is chosen, rather than dialysis, those patients are often referred to as CKD stage 5, rather than ESRD. Regardless of actual or estimated GFR, this difference in nomenclature persists within EHR documentation and ICD-10-CM records on CMS claims. Due to this semantic nuance, it is difficult to accurately measure the proportion of patients at any level of advanced renal disease receiving dialysis compared to all eligible.**

- 9) Please address how you arrived at a risk adjustment model using HCCs (as described on page 13) that is normalized to the average Medicare beneficiary. Is this appropriate for comparing differences in risk between two groups of ESRD patients? Have you assessed the average risk scores for the population of potential patients?

**The RPA model uses an HCC-based risk adjustment procedure similar to the approach taken by the CEC ESCO model. This risk adjustment is used to accurately establish the financial benchmark for the specific patients participating in this model rather than to compare differences in risk between the populations of dialysis patients in our model compared to those outside our model. Medicare calculates HCC risk scores for all program beneficiaries. Within the CEC ESCO model, HCC risk scores are divided by a renormalization factor which ensures that all CMS risk scores are scaled so that the average risk score is 1.0. Normalizing the individual patient’s risk score provides an objective method to stratify expected medical costs. While we have not assessed the average risk scores for the incident ESRD population, we take comfort in the fact that a similar approach is in place today for approximately 46,000 Medicare ESRD beneficiaries aligned with the CEC model. To summarize, the RPA’s intent was to take the individual’s HCC score and “normalize” it, like the mechanism within the ESCO model, to serve as a financial benchmark. This could be achieved by normalizing in comparison to geographically similar ESRD patients or nationally to all other Medicare ESRD beneficiaries.**

- 10) Page 14 of the proposal states “a patient...who receives a kidney transplant during the episode of the model is thereafter excluded from the model.” Please explain why these patients are excluded and clarify whether Medicare expenditures for these patients up to the time of transplant are included in the APM Episode Adjusted Patient Cost.

**Transplant patient expenditures are excluded from the RPA model based on the same rationale they were not included in the CEC ESCO model, in that an unintended consequence of including these would create a financial disincentive for transplantation when early renal transplantation may represent the best course of treatment for an individual patient. Moreover, given the anticipated lower numbers of Medicare beneficiaries enrolling in this PFPM compared to an ESCO, including these lofty costs would likely render the model actuarially unsound and probably not even financially feasible for participants who choose to assume risk. RPA is not explicitly opposed to including transplant patients in the model, but the challenge is ensuring the actuarial analysis is correct.**

11) The pre-emptive transplant bonus (p.15) would accrue to providers for Medicare patients who, by definition, are not part of the eligible population because the transplant occurs before dialysis begins. Participants could also receive a bonus for transplants during the episode. Are there any restrictions on the patient population, or would participants receive a transplant bonus for all of their Medicare patients who receive a transplant?

**Physicians who participate in the proposed model would receive a bonus for all of their eligible Medicare beneficiaries who receive a transplant. There are no restrictions. Similarly, even transplants with primary failure would be eligible for the bonus.**

**Successfully transplanted patients ultimately cost less to care for compared to matched patients who remain on maintenance dialysis. Since pre-emptively transplanting these patients keeps them off dialysis, they would not otherwise be included in this alternative payment model. Therefore, the designated bonus for pre-emptive transplant helps offset any disincentive that might exist associated with advocating timely renal transplant. As noted above, the RPA spent tremendous time and effort minimizing any unintended consequences of this PFFM and the pre-emptive and early renal transplant bonuses accomplish this goal in a patient-centric manner.**

12) Please describe the rationale for selecting 30 as the total quality score threshold.

**Given the fact that some of the quality metrics are reporting metrics, the RPA chose not to set the quality score threshold lower than 30. Similarly, to encourage physicians to participate and experience early success with shared savings and patient-centered improvements, we opted not to set the threshold too high. For this reason, the minimum threshold of 30 was chosen.**

13) What is the business case for a nephrologist to participate in this model?

a) What costs would a practice incur to undertake the types of activities described on page 17 of the proposal? Do nephrologists treat adequate numbers of incident ESRD patients to make this investment feasible based on anticipated shared savings payments?

**The RPA feels that the business case for participation are multiple. The cost of entry into this type of entity would be minimal. CKD education and optimal transition can be achieved without significant infrastructure changes within a medical group. The activities described on page 17 require no major infrastructure investments and are considered standard of care (best practices) for patients and physicians.**

**Potential expenses or activities resulting in increased cost for a physician or practice to optimize savings and patient-centric outcomes in this model could include:**

- **Protocol design to ensure all patients with CKD stage for receive education;**
- **While CKD education is available for free in most communities, physician practices may choose to design and implement their own education. Currently, CKD education is reimbursed by CMS. Therefore, any upfront costs for CKD education design would be quickly offset by current fee-for-service payments outside of the APM.**
- **Physicians may choose to have some clinic availability to evaluate ill ESRD patients in their office, rather than having those patients sent from the dialysis facility to the Emergency Department. While there are no up-front costs for designing such a system, the payment from many of these visits would fall under the capitated MCP rate payment that physicians already receive for caring for dialysis-dependent ESRD patients.**
- **Most physicians and physician practices already employ EHRs that will suffice for this PFFM. However, any physician not currently utilizing an EHR would incur that expense, as EHR utilization is mandated under MACRA for participation in Advanced APMs.**

- **Some physicians may opt to formally invest in greater care coordination. This could include systematic changes to their workflow or could include utilizing non-physician work-force to ensure sharing of documentation and closer communication among specialists and primary care providers caring for this patient population.**

**Overall, we feel that this model will help align incentives between patients, physicians and dialysis providers. Currently, dialysis providers are incentivized under 5-Star and QIP to reduce hospitalizations and optimize transition to dialysis. Similarly, patients have an intrinsic incentive to receive the highest-quality care and share in the decision making for dialysis modality choice. This model ensures that nephrologists now share in the financial rewards of providing lower cost, higher quality, patient-focused care.**

- b) **Is the model more feasible or appropriate for certain kinds of physician practices (e.g. small and rural providers), particularly in comparison to CEC?**

**This model was designed to be feasible for nephrology practices of all sizes. Because upfront infrastructure investments would be minimal in this model, the RPA anticipates that practices of all sizes and geographic locations would equally have ability to participate**

14) **What kind of organization does RPA anticipate would serve as the APM Entity?**

- a) **How would the nephrologist integrate with primary care, surgical care for transplantation and vascular access, specialist care for co-morbid conditions, and other providers?**

**There are multiple options for participation in the APM entity. In the simplest form, a single nephrology group would serve as 100% of the entity. Alternatively, groups may opt to share risk and coalesce into a larger, shared APM entity. One mechanism for this risk-sharing would be through a convener method, like what exists currently within the Bundled Payment for Care Improvement (BPCI) program. Similarly, some groups may prefer to form an entity with hospital groups, dialysis organizations and/or other specialists. However, while this latter approach may be practical for larger, metropolitan groups, the RPA opted not to mandate any specific approach, thereby allowing flexibility in this PFMP to suit the specific needs of individual physicians and their patient population.**

**We anticipate that a successful APM entity would have incentives to invest greater time and effort into care coordination, both during pre-ESRD CKD care and when the patient ultimately transitions to dialysis.**

- b) **How might shared savings be distributed to compensate other providers for their investment?**

**In an APM entity governed entirely by one nephrology group, there would be no need for such shared savings. Alternatively, groups consisting of multiple providers could utilize the BPCI mechanism for sharing costs and distributing savings.**

**While geographic variations occur, the greatest obstacle to optimal dialysis transition is not lack of access to specialists, but rather, lack of adequate education and planning. Therefore, the RPA does not see interactions with other providers serving as a major barrier to increasing the rates of home dialysis, increasing AV fistula or graft placement or referral to a renal transplant center.**

**The RPA would advocate for a waiver or similar process to allow APM entities a mechanism to create financial arrangements with other providers or entities who are not direct participants**

**in the model. As an example, within the ESCO model, there is a waiver allowing for patient transportation to and from dialysis.**

- 15) How does the model address additional Medicare spending for activities like surgery for vascular access and pre-emptive transplantation? These expenditures are excluded from a model that uses dialysis as the beginning of the episode but they would offset the savings from fewer complications after initiation of dialysis.

**The RPA does not anticipate additional overall CMS spending for vascular access or pre-emptive transplant. Transplant rates in the United States are related to organ supply. Shifting transplants from later in the patient’s course to earlier will ultimately save CMS resources, rather than increase expenditures. Similarly, we do not anticipate significant additional utilization of vascular access surgeries, but rather a shift to earlier placement. This shift would reduce interventional radiology/interventional nephrology expenditures associated with placement and replacement of tunneled vascular catheters.**

**That these expenditures will not be directly incurred by model participants is intentional. By placing the nephrologist at risk for the first 6 months of dialysis, the model creates incentives to ensure all beneficiaries are optimally prepared for dialysis. As these services are performed earlier for beneficiaries who need them, the rate of optimal transition to dialysis will increase. This patient-centric approach is better for the beneficiary and will reduce the cost of care for this population.**

**Moreover, the benefits of early renal transplantation, optimal transition to dialysis and increased utilization of home dialysis therapies will have ongoing benefits long after this “Episode of Care” alternative payment model ends. This model is designed to have long-standing financial and patient-centered benefits for participants after the six-month point. The RPA also estimates a beneficial “spill-over effect” for non-eligible patients of physicians who participate in this model. Not only is this model expected reduce hospitalization rates and improve patient choice for those that do participate, but we anticipate greater coordination of care and upstream education even for non-eligible patients, as enhanced attention to assuring that dialysis as opposed to conservative, non-dialytic care is the best option for each individual patient.**

- 16) Why does the model focus on a 6-month episode? Did you consider other timeframes for defining incident ESRD?

**The RPA did consider different time-frames, including 90-day and 365-day timeframes. We ultimately chose 6-months because this time period is associated with the highest overall expenses for ESRD care. Ultimately, 90 days does not allow for maximal savings. Similarly, additional cost savings after 6 months are unlikely to be based upon upstream decision making and optimal dialysis transition. Additionally, longer term PFPs could potentially decrease the complimentary nature of the incident dialysis PFP with the CEC in geographies where both would coexist.**

- 17) Page 13 of the proposal (“included Medicare Costs”) notes that expenditures related to kidney transplant will be excluded from the model. Please specify which transplant-related expenditures will be excluded.

**Since this aspect of the RPA model uses the CEC/ESCO program as a template, cited below is the language included in the ESCO participation agreement.**

***“All financial calculations will exclude expenditures related to kidney transplant services in order to avoid creating an incentive for the ESCO to limit kidney transplant services. These services fall into each of the following stages:***

- Evaluation of the recipient and donor
- Blood and tissue typing of the recipient and donor
- Organ acquisition
- Execution of the transplant itself
- Services following the transplant”

18) Did you consider alternative mechanisms such as a fee-based approach with performance metrics to address incident ESRD? Why did you select a shared savings model?

**The RPA focused on a shared savings model due to simplicity and nephrologist familiarity with this approach, mirroring that of the CEC model.**

19) On page 17 of the proposal, the third example references medical management for patients unlikely to benefit from dialysis. How does the proposed model promote this, if these patients are not included in the eligible population?

**The RPA acknowledges that this portion of the PFPM is somewhat nuanced. For several reasons, the RPA did not feel it was feasible to directly or overtly incentivize medical management, as this could pose a conflict of interest. However, the subset of patients most likely to benefit from medical management over dialysis therapy are also likely to be high utilizers of hospital services if they opt for dialysis. Therefore, by encouraging appropriate nephrology, patient, and family member discussions, these potentially high-resource utilizers may appropriately opt not to enter dialysis. Indirectly, this leads to savings within the PFPM. Additionally, it is a patient-centric approach, as this subset of patients likely does not benefit clinically from dialysis.**

**Stated another way, this approach helps physicians and patients choose a less expensive, but equally effective and patient-centric treatment modality. The PFPM entity then benefits by including fewer high-expense/high utilization patients. Similarly, this subset of patients may be more likely to have a disproportionately negative impact on the entity’s quality metrics, due to their numerous comorbidities.**

20) (Question sent via email on 11/14) As it develops its report, the PRT had one clarification question on the RPA proposal. It is possible that Medicare beneficiaries who have had a kidney transplant that subsequently fails will then need to start dialysis (or restart dialysis). This dialysis initiation would occur at a much later point after first being diagnosed with end-stage renal disease than most ESRD patients. The PRT interpreted the proposal’s focus on “incident ESRD” to mean that it would be limited to those who are initially transitioning from chronic kidney disease to ESRD and who are receiving dialysis as their first form of renal replacement therapy, rather than those who initiate dialysis after a transplant. Is this correct, or would Medicare beneficiaries who are starting dialysis after previous renal replacement therapy—for example, after a kidney transplant failed--also be included in the group of patients with a qualifying clinical episode?

**(response received via email dated 11/16)**

**RPA’s proposal consciously focused on patients making their initial transitional entry into the ESRD program, and did not include patients who have experienced a failed transplant. This is because these patients tend to be under the care of the transplant community rather than private nephrology**

**practitioners, thus limiting the ability of nephrologists who would be participating in our model to impact their care during the subsequent transition. That said, we are open to reevaluating this consideration as the model gains experience in future years.**



December 8, 2017

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

Dr. Paul Casale and members of the PTAC Preliminary Review Team (PRT),

The Renal Physicians Association greatly appreciates your committee's review of our Clinical Episode Payment (CEP) incident dialysis payment model. As your committee noted in its report, the transition to dialysis is a complicated and expensive endeavor. Nearly one-third of patients who begin dialysis either received no or very limited chronic kidney disease care prior to their transition. This leads to suboptimal patient modality choice, limited access to transplant referral, and poor health beyond the incident dialysis period.

Current financial incentives are misaligned between payers, physicians and dialysis providers. The existing reimbursement environment does not promote optimal dialysis transition, referral to renal transplant, patient experience or care coordination as a means of reducing hospitalization rates. For those reasons, the RPA designed this alternative payment model to improve alignment between patient-specific needs, societal goals and physician compensation.

The RPA appreciates the invitation to join the PTAC review meeting on December 18<sup>th</sup> and we are looking forward to addressing the members of this committee directly. We also greatly appreciate the constructive preliminary review provided by Dr. Casale, Dr. Bailet and Mr. Miller. In the interim, we would like to take this opportunity to highlight key aspects of our proposal including items that did not meet the PRT's rating as acceptable as well as the issues raised by the outside expert.

Items that did not meet the Secretarial criteria:

- 1. Payment Methodology (High Priority): Transplant bonus component.** While it has been well documented that pre-emptive renal transplantation greatly impacts the health and well-being of patients with advanced CKD, the RPA understands the PRT's concern that up-front payments for early transplantation do not address lack of organ availability. We would therefore advocate for the addition of a transplant referral metric within the clinical outcomes required for shared savings. RPA would recommend use of the CMS-approved 2017 Qualified Clinical Data Registry (QCDR) Transplant Referral quality measure.
- 2. Integration and Care Coordination:** With input from nephrologists around the country, in 2014 RPA published a position paper, "*Nephrology Scope of Practice*" which highlighted the

nephrologist's role as the *principal care provider* (pcp) for ESRD patients. While this *pcp* model differs from the traditional Primary Care Physician (PCP) role, it is nonetheless a care model to which many nephrologists adhere. The current CMS capitated monthly payment model present since the 1970s has extensively influenced the development of this scope of practice. Within the opening paragraph of that publication, the RPA notes "The use of collaborative practice models in CKD care is essential to meet the needs of this rapidly expanding patient population."

Based upon this premise, our APM was designed to not dictate specific care coordination strategies. It is our intent to permit local care teams to establish integration and care coordination strategies that will work in local markets. If the APM mandated specific care coordination requirements, we are concerned certain providers, specifically small nephrology practices or those practicing in rural locations, may not participate. This APM intentionally maintains flexibility within this realm to foster local innovation.

#### Issues raised by outside expert:

- 1. Utilization of estimated GFR (eGFR) to monitor trends in utilization:** Our APM design committee has leveraged the use of eGFR in two ways within this model. Ultimately, we do not believe that an absolute metric or eGFR cutoff would be appropriate for determining patient entry into this CEP Model. As described in our original proposal, eGFR is highly variable for individuals near the start of dialysis. Nutritional status, diuretic use, patient race and medications all influence eGFR. Development of uremic symptoms remains the gold standard for initiating dialysis.

While we have purposefully designed a system that does not utilize eGFR as a trigger for entrance into the APM, we do believe that the eGFR, when evaluated for populations, is helpful for identifying treatment trends. Throughout this design process, we have maintained focus on the risk of unintended consequences. As such, we have recommended using eGFR as a means of monitoring the population of patients within the APM to ensure the APM has not created an incentive to start dialysis prematurely. We believe that this use of eGFR represents a balanced approach given both the weaknesses and usefulness of this estimated numerical value.

- 2. Ability to achieve savings and improved clinical outcomes without moving further upstream into CKD care:** As the RPA developed this APM, we evaluated several potential payment models including a *per member per month* model that would begin during stages 3 or 4 of chronic kidney disease. The RPA continues to believe that such a model could, in the future, be viable for this patient population. Potentially, we foresee future models working in complement with one another, beginning early in CKD care focusing on prevention of progression, later in CKD care focusing on management of cardiac and endocrine comorbidities, and so on. Unfortunately, given the heterogeneity of dialysis transition and the large percentage of patients that present to dialysis without prior nephrology care (and in some cases, minimal prior medical care), no single APM will meet the needs of all patients or all providers in this space today.

In order to develop, deliver and implement a model that would work at scale for the vast majority of patients transitioning to dialysis, we opted to focus on the date of dialysis initiation

as the trigger to enter the APM. With simplicity in mind, the RPA's shared savings model is designed for clarity to encourage widespread participation among providers. Although this model does not overtly focus on late stage CKD, success within the APM requires dedicated attention to late stage CKD. Providing patients with education and choice prior to the initiation of renal replacement therapy leads to improved patient engagement with better care at lower costs.

- 3. Lack of direct care coordination among nephrologists:** As the vast majority of nephrologists serve as principal care providers for their ESRD patients, we believe that care coordination is inherently embedded into this type of shared savings program. By design, this APM does not establish rigid care coordination requirements. Instead the APM provides flexibility to address local variability, permitting each individual care team to test innovative interventions to improve quality and reduce costs during the first six months of dialysis.
  
- 4. Exclusion of transplant-associated costs:** Renal transplant remains the undisputed gold standard for most patients with ESRD. In design of this APM, the RPA utilized the Comprehensive ESRD Care (CEC ESCO) rules, which specifically carve out these costs rather than attributing them to the APM entity. As mentioned above, the RPA has remained highly focused on eliminating any unintended consequences of a novel payment model. The burden of high transplant-related costs could serve as a disincentive for physicians to refer patients and act as an advocate for renal transplantation during the first six months of dialysis.

The RPA greatly appreciates this committee's dedication to the PFPM process. We look forward to discussing any concerns that the PRT and PTAC members may have with the proposed model, and to collaborating further to finalize an alternative payment model geared towards positively affecting this very vulnerable and costly patient population.

Thank you for your consideration.



Michael Shapiro, MD, MBA, FACP, CPE  
President, Renal Physicians Association

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2 PHYSICIAN-FOCUSED PAYMENT MODEL  
3 TECHNICAL ADVISORY COMMITTEE (PTAC)  
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9 PRELIMINARY REVIEW TEAM (PRT)

10  
11 CONFERENCE CALL

12  
13 INCIDENT END-STAGE RENAL DISEASE (ESRD)  
14 CLINICAL EPISODE PAYMENT MODEL  
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16 SUBMITTED BY  
17 RENAL PHYSICIANS ASSOCIATION (RPA)  
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22 Monday, September 25, 2017  
23 6:00 p.m.  
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27 PRESENT:

28  
29 JEFFREY W. BAILET, MD, PTAC Committee Member  
30 PAUL N. CASALE, MD, MPH, PTAC Committee Member  
31 HAROLD D. MILLER, PTAC Committee Member  
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33 SARAH SELENICH, Office of Assistant Secretary  
34 for Planning and Evaluation (ASPE)  
35 MARY ELLEN STAHLMAN, ASPE  
36

37 ADELE SHARTZER, PhD, Urban Institute  
38

39 MICHAEL SHAPIRO, MD, President, RPA

40 ROBERT E. BLASER, Director of Public Policy, RPA

41 JEFF GIULLIAN, MD, Vice President of Medical Affairs and  
42 National Group Medical Director Company, DaVita  
43 Healthcare Partners

44 ROBERT KENNEY, MD, Vice President of Medical Operations for  
45 Baton Rouge General/General Health System

46 TERRY KETCHERSID, MD, MBA, Board Member, RPA and Chief  
47 Medical Officer, Integrated Care Group at Fresenius  
48 Medical Care

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P R O C E E D I N G S

[6:00 p.m.]

DR. CASALE: So, thank you for getting on the phone, and we will go around so everyone can introduce themselves. But before that, I'll just remind everyone that the phone call will be transcribed, but we appreciate everyone getting on the call today.

And so, that said, I'm Paul Casale. I'm a cardiologist, and I'm in New York. I lead the ACO (accountable care organization) for New York-Presbyterian/Weill Cornell and Columbia.

Harold, I'll let you introduce yourself next.

MR. MILLER: This is Harold Miller, Center for Healthcare Quality and Payment Reform. I'm also a member of the PRT with Paul.

DR. CASALE: And then, Mary Ellen, if you could introduce everyone who's there from ASPE, and then we'll go on to the submitters.

MS. STAHLMAN: Sure. This is Mary Ellen Stahlman, ASPE staff supporting PTAC, and I'm joined by Sarah Selenich and Adele Shartzter, who is an Urban Institute employee working on this project

1 with us. And for the transcriber, we'll get you  
2 the names and spelling of all the folks on the  
3 call.

4 DR. CASALE: Okay, great. So if those  
5 from RPA could just introduce themselves, I'd  
6 appreciate it.

7 DR. GIULLIAN: Sure. I'll go ahead and  
8 start. This is Jeff Giullian. I am a nephrologist  
9 from Denver and one of the members of the RPA  
10 committee that designed this PFPM (Physician-  
11 Focused Payment Model).

12 DR. CASALE: Great.

13 MR. BLASER: And my name --

14 DR. SHAPIRO: Yeah. Hi. I'm Mike -- go  
15 ahead, Rob.

16 DR. KENNEY: Oh, sorry, Michael.

17 My name is Robert Kenney, K-e-n-n-e-y, and  
18 I'm a nephrologist in Baton Rouge, Louisiana, and  
19 along with Jeff helped author this proposal.

20 DR. CASALE: Great.

21 DR. SHAPIRO: My name is -- my name is  
22 Michael Shapiro. I'm the RPA president, also a  
23 nephrologist.

24 DR. KETCHERSID: Terry Ketchersid, a

1 nephrologist, RPA board member, Southern Virginia,  
2 also helped participate in putting the program  
3 together.

4 MR. BLASER: And this is Rob Blaser. I'm  
5 RPA's director of public policy.

6 DR. CASALE: Great.

7 And, Mike, where are you a nephrologist?  
8 I know you mentioned you're the president, but --

9 DR. SHAPIRO: Oh, yeah. I'm in La Jolla,  
10 California.

11 DR. CASALE: Ah, okay. Great.

12 Okay. Well, again, we appreciate  
13 everyone. I know everyone's got busy schedules.  
14 We appreciate you getting on the call, and we  
15 appreciate the -- you know, submitting answers to  
16 our questions. What we thought we'd -- we were  
17 interested in some further discussion on some of  
18 the questions, and then other questions may arise.

19 But I thought I would start off -- you  
20 know, one of the areas that we've been talking  
21 about and we're just trying to understand better in  
22 the model is, you know, there's several areas that  
23 the model will impact, you know, in terms of pre-  
24 emptive CKD (chronic kidney disease) education,

1 having people, you know, start on perineal dialysis  
2 rather than hemodialysis, getting grafts in place,  
3 et cetera. And I think one of the things we're  
4 trying to understand is how that can be achieved  
5 when the model starts with the first outpatient  
6 dialysis.

7 DR. GIULLIAN: Yeah. So this is Jeff  
8 Giullian, and I'll take that. And I will just kind  
9 of start by saying that our overarching philosophy  
10 was really to keep this payment model as simple as  
11 possible, so that it could be undertaken by  
12 practitioners of all size groups.

13 And, the second philosophy we had was this  
14 needed to be something that worked for the patients  
15 that ultimately have CKD education and transition  
16 into dialysis along with the very large population  
17 of patients that ultimately crash into dialysis for  
18 any number of reasons, either because they develop  
19 some other medical problem in the hospital, develop  
20 acute renal failure, and then their kidneys never  
21 recover, or because they just never sought out or  
22 were given upstream CKD education. So we wanted  
23 some type of treatment -- excuse me -- some type of  
24 payment model that would sort of address all of

1 that.

2           We also felt fairly strongly that we could  
3 influence upstream CKD education and upstream  
4 choices by incentivizing in the downstream or  
5 actual dialysis population, and by that, we meant  
6 that because we're incentivizing for optimal  
7 transition into dialysis, anybody who chooses to  
8 participate in this payment model would want to put  
9 into place some sort of infrastructure -- both in  
10 their clinic for education or discussion of  
11 conservative therapy or discussion of pre-emptive  
12 transplant and also implement within their hospital  
13 some means of transitioning those -- what we call  
14 "crasher patients." And I realize that's not an  
15 optimal statement, but that's sort of colloquially  
16 what they're called. Those crasher patients  
17 develop a way that they could transition, if not  
18 optimally, at least more optimally than they do  
19 now.

20           So, ultimately, we felt like it's a very  
21 easy-to-define population, the incident dialysis  
22 population, because we have a very specific start  
23 date that is recorded by CMS (Centers for Medicare  
24 and Medicaid Services) when the physician signs the

1 Form 2728. So we know the exact start date, we  
2 know the exact end date, and by using that sort of  
3 episode of care, we felt strongly we could  
4 positively influence upstream care.

5 DR. CASALE: Okay. And I guess one of the  
6 -- as a follow-up to that question and in your  
7 experience, in terms of the -- let's --  
8 theoretically, the nephrologist who's doing that  
9 work may ultimately not be the nephrologist who  
10 does the dialysis, given maybe the patients'  
11 geographic location, et cetera. How would that  
12 work?

13 DR. GIULLIAN: Yeah. I mean, anybody else  
14 can chime in here, since you all practice in  
15 different regions.

16 In my region, it was almost always the  
17 nephrologist doing the CKD work that ultimately  
18 cared for the patient on dialysis, or one of his or  
19 her partners, meaning it stayed in the same group.

20 To be blunt about it, CKD care isn't  
21 something that would keep most nephrologists in  
22 practice financially, and so what's sort of the  
23 bread and butter in terms of our income, is that  
24 care of the patient on ESRD. And so while

1 occasionally there are geographic reasons --  
2 somebody might move -- move in with a family  
3 member, or do something else where they transition  
4 their geographic location when they go on to  
5 dialysis, I would say that that's the minority of  
6 patients and, in fact, the slim minority, at least  
7 in my own clinical experience.

8 DR. CASALE: I don't know if others want  
9 to -- I was thinking more in an urban setting,  
10 particularly, where they may be followed, you know,  
11 in a city, but they may live out in a more suburban  
12 area, and then the -- you know, the nephrologist  
13 who's been following them may be, you know,  
14 potentially at an academic center or whatever,  
15 would then not be -- they wouldn't be coming in  
16 just for convenience sake for the dialysis. So I  
17 was thinking it might not be -- it might be more  
18 than just a minority that would fall into that --

19 DR. GIULLIAN: Yeah. Again, I mean, I can  
20 only speak for Denver, where I practice here, but  
21 even the academic physicians have privileges in the  
22 outlying dialysis centers and typically tend to  
23 follow their patients. I'm sure there are some  
24 outlying patients that, you know, may be traveling

1 20, 25, 30 miles to see the academic physician and  
2 then ultimately when they transition to dialysis  
3 choose not to do that.

4           Although, quite honestly, you know, it's,  
5 in that case, all the more incentive to do home  
6 dialysis, which is a better overall treatment, we  
7 think, from a payer's standpoint and from a  
8 patient-centric standpoint. And so, it would  
9 still, I think, in the long run, incentivize those  
10 patients to do a home dialysis modality, if that's  
11 appropriate, and stay with their primary physician.

12           MR. MILLER: So this is Harold Miller.

13           Take an example, though, for me -- you're  
14 kind of describing what, in a sense, is the ideal.  
15 So the ideal is the patient's being seen by the  
16 nephrologist, who then is -- can manage, improve  
17 their care, before they go on to dialysis. Take  
18 some of the examples, for me, where it's not ideal  
19 -- which kind of Paul's question was along the same  
20 lines -- is -- there may be different places in the  
21 country where it doesn't happen the way you're  
22 describing. Maybe they're managed by their primary  
23 care physician, maybe they're -- who's tried to  
24 refer them to a nephrologist, and they don't want

1 to go because of their denying their kidney  
2 disease. They don't want to pay the copay. They  
3 don't want to do whatever. And so, they end up  
4 getting to the point where they need dialysis. And  
5 it was somebody else managing them or maybe nobody.  
6 Take some of those cases and describe -- Are you  
7 just going to view them as being the, "We have no  
8 opportunity there?" Are you imagining that  
9 somehow, all of a sudden, some new kind of outreach  
10 will be developed to go upstream for the ones that  
11 aren't already part of your practice?

12 DR. GIULLIAN: Yeah. Actually, somewhere  
13 in between. So I'll take one of those less-  
14 fortunate individuals that didn't transition well  
15 into dialysis.

16 In the current situation, what happens  
17 most often is those patients start dialysis in the  
18 hospital. They get a dialysis catheter placed in  
19 them. First, a temporary catheter, just to dialyze  
20 and stabilize them in the hospital, and then what  
21 we can -- what we call a "tunnel dialysis  
22 catheter," and then they're sent out to do in-  
23 center dialysis, which is the most expensive  
24 dialysis. And they're sent out typically without

1 much of a plan or dialysis access or CKD education  
2 or anything else, and that patient population,  
3 unfortunately right now, tends to kind of follow  
4 the path of least resistance, which is the one I  
5 just mentioned.

6           And they then end up being in center  
7 dialysis, which again is about \$90,000 a year.  
8 They tend to have the highest rehospitalization  
9 rate because of their catheter. The average  
10 dialysis patient spends about 12 days a year in the  
11 hospital. That group with catheters spend at least  
12 27 days in the hospital. So it's a very, very  
13 different situation.

14           That being said, we know that there are  
15 significant opportunities for utilization of best  
16 demonstrated practices that are underutilized right  
17 now. So, very specifically, that crasher patient  
18 could, again, have a temporary dialysis catheter  
19 placed in the hospital, receive a couple of  
20 episodes of urgent or emergent dialysis to  
21 temporize and stabilize them.

22           They could then receive CKD education in  
23 the hospital and choose to do what we call "urgent  
24 start peritoneal dialysis." So rather than going

1 out of the hospital with a dialysis catheter,  
2 intravascular catheter in their neck, which is an  
3 infection risk, they could go out with a peritoneal  
4 dialysis catheter and start PD training,  
5 peritoneal dialysis, and urgent start PD on Day One  
6 of being an outpatient.

7           That's something that happens not  
8 routinely right now, mainly because it's extra work  
9 for the nephrologist, a fair amount of extra work,  
10 and quite honestly, it pays worse than the path of  
11 least resistance, which is the one I described  
12 first.

13           Another option would be for that patient  
14 to receive that same CKD education in the hospital,  
15 still choose to do in-center dialysis, now making  
16 an informed decision, and now perhaps get what we  
17 call "vessel mapping," which is an evaluation of  
18 the veins in the arm, perhaps even an initial AV  
19 (arteriovenous) fistula or AV graft placed before  
20 leaving the hospital.

21           That patient would still leave the  
22 hospital with one of the tunnel intravascular  
23 dialysis catheters, but that catheter likely would  
24 only need to stay in them for four to six weeks as

1 opposed to now, where it's staying in on average 12  
2 to 16 weeks. And we know that every extra week  
3 that a patient has one of those tunnel dialysis  
4 catheters, there's a significantly increased risk  
5 for readmission and increased costs.

6           So I think that there's opportunity both  
7 with that well-treated, upstream CKD population  
8 that's the ideal patient, but I think there's a  
9 fair amount of opportunity here as well for the  
10 less-than-ideal patient, the one I just described  
11 that sort of meets the nephrologist for the first  
12 time when they're ready to start dialysis.

13           MR. MILLER: So it sounds like you're not  
14 envisioning, though, the nephrologist trying to  
15 build new or different relationships with PCPs  
16 (primary care physicians) or whatever -- upstream  
17 to try to be able to get to more patients earlier.  
18 You're either imagining that the nephrologist  
19 already has them and is going to be doing something  
20 different than they're doing today with them, to  
21 try to facilitate the transition, or they're going  
22 to do something differently once they -- the  
23 patient starts dialysis.

24           DR. GIULLIAN: Yeah. I think in a perfect

1 world where there was a much larger supply of  
2 nephrologists, exactly what you're saying makes  
3 sense, going upstream, trying to care for these  
4 patients at a CKD 3A, trying to develop stronger  
5 relationships with the primary care population, so  
6 that these patients aren't slipping through the  
7 cracks is absolutely, I think, a model that makes  
8 sense.

9           Unfortunately, we're in a situation right  
10 now where there's a significant limitation in most  
11 parts of the country on the number of nephrologists  
12 available. We have several areas of the country,  
13 especially more rural areas and out West,  
14 basically, unfortunately, anything that's outside  
15 of the Northeast, that has a significant lack of  
16 nephrologists.

17           And we believe that sort of this lack of  
18 manpower has really led to the significant number  
19 of non-optimal starts. Eighty percent of patients  
20 in this country currently start with that tunnel  
21 dialysis catheter that I mentioned above -- or  
22 mentioned previously, and I think that we need to  
23 be thinking right now in terms of optimizing that  
24 transition, in the longer term thinking in terms

1 of, how do we recruit more and more people into the  
2 training of nephrologists?

3 MR. MILLER: So let me just stick with  
4 that for one more minute. So if there is diversity  
5 around the country in that -- that would mean that  
6 some nephrologists, the ones that have a higher  
7 proportion of upstream patients, would look better  
8 in this model than others. So how would you  
9 imagine trying to adjust for that, or would you  
10 imagine trying to adjust for that? I mean, is  
11 there some sort of a risk adjustment notion where  
12 you would say, "this nephrologist didn't have  
13 upstream contact, and so they get a lower -- or  
14 higher benchmark in terms of spending or whatever,"  
15 and does that create any -- if you did that, does  
16 that create any strange incentives?

17 DR. GIULLIAN: Yeah. So I'll take a first  
18 crack at that, and then, Terry, if you want to jump  
19 in or Dr. Kenney.

20 We, first and foremost, were very  
21 cognizant about both the fact that there are these  
22 geographic differences and the risk of unintended  
23 consequences or incentivizing something that  
24 ultimately isn't good for society, patients, or the

1 payer.

2           So one of the things that we did in  
3 looking at the metrics overall is define two ways,  
4 in essence, to reach each metric. So one would be  
5 an absolute threshold benchmark, you know, X  
6 percentage of home dialysis patients or X  
7 percentage of optimal starts, meaning starting  
8 without that catheter, or not having a catheter in  
9 place at Day 180, which is the end of the episode.

10           But the second way we did it is to say,  
11 "Okay. There could also be quality points for an  
12 overall improvement," so that way, we are not dis-  
13 incentivizing the group that starts out with the  
14 more difficult patient population. We're also not  
15 dis-incentivizing those groups of physicians that  
16 have really been working hard at this for the past  
17 several years.

18           So maybe, Terry, do you want to discuss a  
19 little bit more --

20           DR. KETCHERSID: Yeah.

21           DR. GIULLIAN: -- on what we were thinking  
22 in terms of geographic modeling and things like  
23 that?

24           DR. KETCHERSID: Yeah. Yeah, happy to,

1 Harold.

2           You know, we actually begged, borrowed,  
3 and stole a few of the good things that we see in  
4 the CEC (Comprehensive ESRD Care) Model, and one of  
5 the things that you could argue that they got right  
6 in that model is the establishment of local  
7 benchmarks.

8           And so, in that circumstance, to Jeff's  
9 point, you know, we're identifying places where the  
10 cost of care is already high, largely because of  
11 challenges with transitions, perhaps, so there's  
12 opportunity for improvement. And yet, in the -- in  
13 the areas where the care is optimal, we still think  
14 -- and we're seeing this today in the ESCO (ESRD  
15 Seamless Care Organization) Model -- we still think  
16 there's opportunity for those local markets to  
17 improve as well.

18           Getting back to a point that was made  
19 earlier, there are -- by design, there are specific  
20 pathways or plans that are part of this model. If  
21 there's a region in the country that has a well-  
22 established process for modality education and  
23 optimal starts, fantastic. If there are places,  
24 whether they be rural or urban, where those don't

1 exist and there haven't -- you know, there really  
2 haven't been the -- well, for lack of a better  
3 word, the financial incentives to go out and put  
4 those in place, we think this model produces that  
5 kind of opportunity.

6 I think the one last thing to mention, to  
7 get back to Paul's point about the patients coming  
8 in from the urban -- or from the rural area to see  
9 the academic folks and then starting dialysis and  
10 letting the rural folks take advantage of the care  
11 that was provided, one of the things we're seeing  
12 in the nephrology space, largely because of the  
13 ESCO program, is a high demand on the nephrology  
14 provider-side for these models of care. And if the  
15 model that we're proposing is flexible enough and  
16 accessible enough, there's a decent chance that a  
17 substantial number of nephrologists around the  
18 country would participate. So that the patient that  
19 is seeing the academic -- at the urban center and  
20 then goes back into the rural community, there's a  
21 decent chance that both of those nephrology  
22 practices or providers are participating.

23 DR. SHARTZER: Hi. This is Adele.

24 If I could please remind folks to

1 introduce yourself each time you speak, and also,  
2 if anyone has joined the line, since we did  
3 introductions, please let us know who you are.

4 Thanks.

5 DR. BAILET: Yeah. Adele, this is Jeff  
6 Bailet. I joined about five minutes after the  
7 hour. I appreciate -- appreciate you guys, the  
8 submitters, joining the call. I'm sorry I was  
9 late.

10 DR. CASALE: Well, thanks, Jeff, for  
11 joining.

12 If I could just follow up on the --  
13 because you mentioned the CEC Model, and one of --  
14 and I know we asked the question about how the CEC  
15 relates [unintelligible], this model relates to  
16 that. And then you did list, you know, sort of the  
17 criteria which are different, but I'm still -- I  
18 still, I guess, would like to follow up.

19 I'm trying to understand -- Is there a  
20 potential to blend the model so that we -- so that  
21 there don't need to be separate models, or are they  
22 so different in your view that they -- that they  
23 are that distinct? I guess I'm wondering if we --  
24 if it's possible, since they already have the CEC

1 Model, can that be revised in a major way, so that  
2 more nephrologists could be part of it and include  
3 many of the things that you are proposing as  
4 opposed to a totally separate model?

5 DR. GIULLIAN: Sure. So this is Jeff  
6 Giullian, and I'll start and then let Terry and Dr.  
7 Kenney jump in.

8 But I think that the models are  
9 sufficiently different, that while they complement  
10 one another, I don't see, at least in the near  
11 term, a way of significantly changing the ESCO or  
12 CEC Model to incorporate this for a couple of  
13 reasons.

14 So, the first is just the sheer number of  
15 patients that are required to be in a CEC Model.  
16 So in my own practice in Denver, when I -- when we  
17 were looking at that model, we did not qualify for  
18 a CEC Model. We were a seven-physician practice,  
19 and we did not have enough nephrologists to  
20 qualify.

21 And then, secondarily, there's a  
22 significant amount of up-front potential cost. The  
23 nephrologist has to be an owner in the CEC Model,  
24 and for that reason, it really precluded us, for

1 example, from being a member.

2           Similarly, most rural areas would not have  
3 the numbers of patients ultimately to make a run at  
4 that.

5           So I think this is sufficiently different  
6 in the types of nephrologists, the geography, the  
7 size of practices, that it probably warrants being  
8 its own model.

9           And then, secondarily, even though,  
10 obviously, there's an overlap in the patient  
11 population, the incident dialysis population really  
12 is a unique population. CMS currently treats them  
13 differently than the prevalent dialysis population.  
14 They have a different set of needs. They have a  
15 different set of -- a different cost structure in  
16 general, and so I think, fundamentally, although  
17 it's all dialysis, it's not quite the same  
18 population. And I think that what is beneficial  
19 for an ESCO population in general, you know, may or  
20 may not be the exact same things that are perfectly  
21 beneficial for somebody who's moving from CKD into  
22 dialysis.

23           And, Terry and Robert, I'll turn it to you  
24 guys.

1 DR. KENNEY: Yeah. This is Terry.

2 Just to build on what Jeff said, I think  
3 they are certainly unique enough. One of the --  
4 one of the interesting, we think, benefits of  
5 focusing on that incident population is, unlike the  
6 ESCO, where basically all of the eligible Medicare  
7 beneficiaries are attributed to the model, in the  
8 case where I have the patient for the first six  
9 months, now there is a tremendous incentive for me  
10 to pay attention to what happens just before that  
11 patient starts.

12 The other -- the other piece of that  
13 puzzle is the ESCO Model. One of the things,  
14 frankly, that the authors of the Model didn't quite  
15 get right, is it explicitly ignores transplant,  
16 right? Those costs are carved out of the program  
17 if, in fact, the incident model under discussion is  
18 in play, not that people are not trying to  
19 transplant patients, but suddenly, there's -- there  
20 are increased incentives to do so.

21 So they're definitely separate. They'd be  
22 available, as Jeff pointed out, to far more  
23 nephrologists around the country than can  
24 participate in the CEC Model, and much the way the

1 CEC model intersects with the ACO that you operate,  
2 Paul, up in New York City -- the way CMMI (Center  
3 for Medicare & Medicaid Innovation) is explaining  
4 the hierarchy -- today, if I'm a Medicare  
5 beneficiary and I'm attributed as a CKD patient to  
6 your ACO, if I start dialysis during the year, I  
7 stay in your ACO until the calendar year changes.  
8 And if I have a first touch after the first of the  
9 year in an ESCO clinic in that market, now I'm  
10 aligned with the ESCO.

11           And so there's a precedent to have the  
12 separate models appropriately hand off patients,  
13 depending on what episode or model of care is most  
14 appropriate for them.

15           DR. KENNEY: Yeah. This is Robert Kenney.

16           I'd like to just add, and I absolutely  
17 agree with Jeff and Terry about the need for  
18 separation of these two nephrology payment models.

19           But I do want to just point out, as Terry  
20 mentioned, that our model actually, hopefully,  
21 creates an intent, a little bit more intent to  
22 focus on the care of these high-risk, high-  
23 morbidity, high-mortality patients, whether they  
24 are going from CKD into dialysis by one provider or

1 they have just started by a single provider on  
2 dialysis.

3           And it's worth pointing out that we're not  
4 advocating doing anything different in terms of  
5 evidence-based than what already exists. It's just  
6 for whatever reason, the lack of number of  
7 nephrologists or lack of priority given to this  
8 high-risk population or whatever -- it's not being  
9 accomplished.

10           So we're really interested in seeing  
11 what's just this added incentive, these added  
12 financial incentives, might do to this very high-  
13 risk population.

14           DR. GIULLIAN: Yeah. And this is Jeff  
15 Giullian again, and I'll just add one more thing  
16 that I think is somewhat different, and that is  
17 that, within this model, although there's not a  
18 direct incentive to consider conservative  
19 management of certain patients, we believe there's  
20 a strong indirect incentive.

21           So what has, I think, been shown fairly  
22 robustly over the past four to five years, is that  
23 there is a subset of population of patients that  
24 really ought not start dialysis. They don't

1 necessarily have a prolonged length of life by  
2 starting dialysis. They don't have an improvement  
3 on quality of life by starting dialysis, and yet,  
4 frequently, those patients do start. And, quite  
5 honestly, there's an incentive right now, fee-for-  
6 service-wise, for doctors to start them on  
7 dialysis, and I don't mean to imply that docs start  
8 them for the payment. I don't mean to say that at  
9 all. But there's not a lot of incentive to really  
10 work with patients themselves and family members to  
11 understand the current level of evidence that's out  
12 there and to choose not to start dialysis.

13           And we think that this model actually  
14 does, as I mentioned, indirectly incentivize having  
15 those, you know, modality discussions, advanced  
16 care discussions, prior to starting dialysis, such  
17 that patients who probably aren't going to do well  
18 on dialysis and patients who probably aren't going  
19 to achieve the benefits, ultimately, don't go down  
20 that path.

21           DR. CASALE: So this is Paul.

22           Just one last quick follow-up on that.

23 Thank you for that.

24           And I understand the numbers, you know,

1 needed in the CEC Model, et cetera, but it's my  
2 understanding that the ESCOs have a similar thought  
3 process. That they understand that people who come  
4 in crashing to the hospital will turn out to be  
5 high risk in their ESCO, and so one of their  
6 focuses would be similarly on education and  
7 potentially, you know, directing people to  
8 transplant when appropriate or peritoneal dialysis  
9 in order to prevent their ESCO -- you know, to  
10 prevent them from crashing and burning and then,  
11 all of a sudden, now they're in their ESCO. Do I -  
12 - is that -- do I not have that right?

13 DR. KETCHERSID: Paul, this is Terry  
14 Ketchersid.

15 So the issue is, in the ESCO Model --

16 DR. CASALE: Yeah.

17 DR. KETCHERSID: -- you're talking about  
18 10 to 15 percent of the patient population, right?

19 In the model under discussion, 100 percent  
20 of the patients in that model are new-start  
21 dialysis patients. So that even though -- even  
22 though 10 to 15 percent sounds like a big number  
23 and they're extensive patients, I can tell you  
24 that's not a huge focus in the ESCOs that I'm

1 familiar with.

2 DR. CASALE: I see.

3 DR. GIULLIAN: Additionally, within the  
4 ESCO, you know, you need to be aligned with a given  
5 dialysis provider. So, quite honestly, if one  
6 provider does better with home therapy or home  
7 chemo or PD or something like that, that may  
8 ultimately determine what type of care you offer to  
9 a given patient that's either entering or not  
10 entering your ESCO.

11 Whereas, in this Model, the patient could  
12 go to any dialysis provider and, in fact, could  
13 then dialyze in the facility that the nephrologist  
14 feels is either closest to their home or provides  
15 the best care for the modality choice that they  
16 made. So I think that's another fundamental  
17 difference.

18 DR. CASALE: Okay.

19 DR. SHAPIRO: And this is Mike. Yeah,  
20 this is Michael Shapiro.

21 Just to add on to that just a little bit.  
22 The requirement, again, as was mentioned earlier,  
23 for physician buy-in financially into the ESCO,  
24 even though it's a potential opportunity with a

1 potential number of patients, sometimes it keeps  
2 some nephrologists, nephrology practices, from  
3 entering into that CEC Model.

4           Whereas, in this -- in an incidence model  
5 that we're proposing, there really is no  
6 substantial requirement for buy-in. Yes, there are  
7 some potential infrastructure changes that a  
8 practice might want to make to enhance education --  
9 diet, education, medication review, et cetera, for  
10 those patients, but without the requirement to  
11 actually buy into a high-risk model.

12           DR. CASALE: Mm-hmm.

13           DR. SHAPIRO: You can make it just part of  
14 the practice.

15           So even a small one- or two-doc practice  
16 could do this without the substantial added cost.

17           DR. BAILET: This is -- Harold? Paul? Do  
18 I have -- this is Jeff. Do I have a chance to jump  
19 in and ask a question?

20           DR. CASALE: Please do. Yep, jump. Thank  
21 you.

22           DR. BAILET: Yeah. So, you know, it's a  
23 sort of a two-part question. The first one is, I  
24 caught the discussion about the fact that at least

1 in your experience and what you think happens in  
2 most part of the country -- in most parts of the  
3 country, that the physician who starts dialysis on  
4 these patients is typically the doctor who is  
5 seeing them upstream when they're a chronic kidney  
6 patient. And I want -- I'll stop there and just  
7 check that. Is that, in fact -- is that, in fact,  
8 what was said?

9 DR. SHAPIRO: Yeah. So, typically, it's  
10 somebody of the same practice. It may not be the  
11 same --

12 DR. BAILET: Okay.

13 DR. SHAPIRO: -- physician. That, of  
14 course, doesn't hold true 100 percent of the time.  
15 Patients move, or occasionally, patients were  
16 receiving care in one geography and ultimately  
17 dialyzed in another geography.

18 But, in general -- and I'll defer to my  
19 colleagues if they have a different experience --  
20 in general, in my experience, for the patients that  
21 we took care of in CKD, we did our darned best to  
22 make sure we were taking care of them as ESRD  
23 patients.

24 DR. BAILET: Okay.

1 DR. KENNEY: This is Robert Kenney.

2 That's been my experience as well.

3 DR. BAILET: All right. Great. So thank  
4 you for that.

5 So then the second part of my question is  
6 it seemed like the upstream activities -- I  
7 understand that the starting point is when they  
8 begin dialysis, but it seems like the -- you know,  
9 for a really best practice for these patients,  
10 there's a lot of upstream activities that your  
11 model addresses, but I'm -- I just need some  
12 clarity on why these kinds of things aren't already  
13 happening, given the economics related to dialysis  
14 and the focus on end-stage renal disease patients.

15 For example, we know -- you said it  
16 earlier -- the catheter in the neck, every day that  
17 is in there, is the time bomb for infection and  
18 downstream complications. You were very eloquent  
19 in your description of the state of the union  
20 relative to cost for these patients, particularly  
21 when they don't do well. But the first six months  
22 of their dialysis consumes tremendous amounts of  
23 dollars and resources.

24 I just -- I guess I'm a little puzzled on

1 why these practices, relative to getting patients  
2 educated, making sure that the decision for or  
3 actually not to receive dialysis, that that's  
4 thought through, getting them the appropriate time  
5 to put an AV fistula in so that they can start with  
6 a fistula versus a catheter. I'm just -- help me  
7 understand why that's really not -- and maybe I'm  
8 overreaching by using the word "common practice,"  
9 but why is that not seen more ubiquitously through  
10 the practice of nephrology today?

11 DR. GIULLIAN: Yeah. I think the answer  
12 to that is multifactorial, and I'll be just a  
13 little bit cynical when I say that, quite honestly,  
14 it's not incentivized. I, as a physician, would  
15 have to work very, very hard to get my patients to  
16 do stuff upstream to make sure that their  
17 transition is optimal, and I am not paid for that.  
18 And that doesn't mean that I'm thinking that way  
19 consciously, but with so many competing priorities,  
20 sometimes that's not priority number one.

21 I will tell you, though, that when I  
22 personally changed my thought process on that and  
23 really redoubled my efforts for a multipronged CKD  
24 educational approach, I was able to achieve 40

1 percent home dialysis penetration for my personal  
2 patients, and so I know that it can be done.

3           There are a number of reasons why we've  
4 been stuck at 80 percent catheter rate for Day One  
5 of dialysis for the past several years, and, you  
6 know, some of it is that patients crash into  
7 dialysis. Some of it is that patients get a little  
8 bit of upstream education but not enough for them  
9 to ultimately make the decision to do peritoneal  
10 dialysis or to get an AV fistula. And some of it  
11 is, as I mentioned, there are just a number of  
12 competing priorities out there with nephrologists  
13 focusing on, you know, diabetic care and  
14 hypertension and their hospital patients and making  
15 dialysis rounds and doing so much else, that for  
16 the subset of patients that ultimately do  
17 transition into dialysis, for whatever reason,  
18 there hasn't been the emphasis that there should be  
19 on getting them the transitions that are -- that  
20 are optimal.

21           I think by incentivizing physicians,  
22 giving them skin in the game, for lack of a better  
23 term, that they are paid on -- you know, they're  
24 reimbursed based on these optimal transitions -- I

1 think that will shift their focus and make this a  
2 priority.

3 DR. KENNEY: Yeah. Jeff, this is Terry.

4 I'll just add and put a fine point on that  
5 cynical piece. I had the opportunity to help --  
6 help shop the ESCOs early on, 2015 or so, and it's  
7 interesting -- So, as we talked to these nephrology  
8 practices, who again are among some of the best  
9 nephrology practices in the country. If not on the  
10 first visit, on the second, or the third visit,  
11 somebody in the room would say, "Okay, I understand  
12 this. The ESCO does well financially largely by  
13 avoiding unnecessary hospital admissions. How are  
14 you going to make up the income that I miss out on  
15 because I'm not seeing those patients in the  
16 hospital?" Right? And it's just a perfect example  
17 of that perverse incentive that exists in a fee-  
18 for-service world.

19 If the focus of the model is taking very  
20 good patient -- very good care of patients in the  
21 first six months of dialysis, that calculus changes  
22 dramatically.

23 DR. GIULLIAN: Yeah. I mean, I hate to --  
24 I hate to admit it, but, you know, right now under

1 the fee-for-service model, the way that a  
2 physician, unfortunately, would make the most  
3 amount of money, is to see their patient in the  
4 outpatient setting just on the first of the month  
5 and then put them in the hospital, and seeing them  
6 in the hospital for the next, you know, 28 or 29  
7 days in the month.

8           Now, no physician does that. I don't  
9 think any physician thinks like that, but really,  
10 this model is meant to change that incentive  
11 entirely to reimburse for the great care of keeping  
12 somebody out of the hospital as opposed to, in  
13 essence, reimbursing them for having them in the  
14 hospital.

15           DR. BAILET: Great. I appreciate that.

16           And you can understand -- I mean, there's  
17 a couple of rabbit holes I could go down, but I  
18 don't want to. But it is -- I guess my editorial  
19 comment is it -- and maybe I'm just naïve, but it  
20 is a little heartbreaking that, you know -- that  
21 the economics, that we need to -- we need to amp up  
22 the economics in particular areas for what I still  
23 think are fairly foundational components of a  
24 nephrology practice.

1           And, again, I'm not a nephrologist.

2           DR. GIULLIAN:   Yeah.

3           DR. BAILET:   But I just thought I'd  
4 clarify that.   So your comments are very helpful.  
5 Thank you.

6           DR. GIULLIAN:   So let me also just say  
7 that you're exactly right.   We share your heartache  
8 on that.

9           There is a difference between the ESRD  
10 population, though, and the general population, and  
11 that, you know, in the general population, I think  
12 physician payments, Medicare Part B payments,  
13 account for about one-sixth or maybe even one-  
14 eighth of the total cost of care of a given  
15 patient.

16           For the ESRD patient, in general, not even  
17 including the incident ESRD patients who spend more  
18 time in the hospital, but just the in general --

19           DR. BAILET:   Yeah.

20           DR. GIULLIAN:   -- the physician only  
21 accounts for about one-twelfth of the -- of the  
22 annual cost and, in some cases, about one-fifteenth  
23 of the annual -- of the cost.

24           So I think unlike -- unlike anywhere else,

1 we have a population in where, if we truly do  
2 change the incentives for the physician, that can  
3 have a huge lever effect in bringing down the  
4 entire cost of care to a much greater extent than  
5 with, you know, a gastroenterology patient --

6 DR. BAILET: Yeah.

7 DR. GIULLIAN: -- or, you know, a routine  
8 primary care-type patient. So that lever is pretty  
9 big here for incentivizing the physicians and  
10 really driving down hospitalizations and driving up  
11 cost savings.

12 DR. BAILET: Yeah. Well, that's an  
13 important point. Thank you.

14 DR. CASALE: So just on another point, I  
15 know one of the questions we -- and we've talked  
16 about it -- was, you know, to keep the model  
17 simple, you know, in one sense starting with the  
18 first dialysis and filling out Form 2728, et cetera  
19 -- but we asked about, well, wouldn't ideally,  
20 given this model, to start further upstream, and  
21 you described how GFR (glomerular filtration rate),  
22 the measure of GFR, you know, the accuracy -- it's  
23 not perfect -- or other models, et cetera, which I  
24 certainly understand.

1           But then on the other -- on one of the  
2 other questions in terms of "how do you avoid  
3 creating an incentive to place patients on dialysis  
4 earlier?" The -- part of the answer was "Well, I  
5 think it would be important to monitor estimated  
6 GFR."

7           DR. GIULLIAN: Yeah.

8           DR. CASALE: So, I just wondered if you  
9 could respond to that.

10          DR. GIULLIAN: Yeah. So, certainly, we  
11 don't get to have both sides of that argument, and  
12 we understand that.

13           I think going back to, again, one of our  
14 main considerations when we designed this was how  
15 do we design something that, as we mentioned, could  
16 have as broad appeal as possible, but also not have  
17 undesirable consequences, such as overly  
18 incentivizing people to start dialysis when kidney  
19 function really doesn't -- doesn't call for that.

20           So the first thing we said was, "you know,  
21 we really need to make sure we're focusing on  
22 transplant." Transplant obviously has very high  
23 up-front costs, but the cost savings begins  
24 somewhere in the 30th month, in general, and so we

1 wanted to make sure that that was first and  
2 foremost.

3           And then, secondly, we -- because we don't  
4 have a great model for knowing the exact GFR or  
5 exact kidney function, for the reasons that you  
6 just mentioned, we opted not to put that in our  
7 quality metrics but rather to use that as something  
8 to monitor over time.

9           I think that regardless of how accurate it  
10 is, the trend could be very useful. So if, for  
11 instance, this model rolled out in, say, 2018 and  
12 you said, "Gosh, in general, incident dialysis  
13 patients started with an MDRD (Modification of Diet  
14 in Renal Disease) estimated GFR of 12.5 milliliters  
15 per minute, and over the next year or two years,  
16 that went up to 13.5 or 14.5," that would give you  
17 real-time, or just slightly lagging-time,  
18 indication that there really is an unintended  
19 consequence of earlier dialysis.

20           On the other hand, if what you saw with  
21 those average estimated GFRs, even though they may  
22 not be perfect numbers, but you see the trends  
23 staying the same, year over year, then I think we  
24 can confidently say that this did not

1 inappropriately incentivize people to start  
2 dialysis earlier.

3           So, really, that -- using it as sort of a  
4 dashboard metric to monitor, is really monitoring  
5 the trend over time as opposed to an absolute  
6 number.

7           DR. CASALE: But that trend over time, you  
8 don't think is accurate enough to use -- to move  
9 the whole model upstream, rather than just one  
10 [unintelligible] -- this trend of GFR to trigger?  
11 Again, putting aside the simplification of using  
12 Form 2728 -- I'm just trying to understand in the  
13 ideal --

14           DR. GIULLIAN: Yeah.

15           DR. CASALE: -- situation.

16           DR. GIULLIAN: Yeah. So the difference  
17 really is that that upstream, that GFR changes  
18 significantly, and there's significant noise. So,  
19 by adding an ACE (angiotensin-converting-enzyme)  
20 inhibitor or stopping an ACE inhibitor, by adding a  
21 loop diuretic or decreasing a loop diuretic, we see  
22 enough noise bounce around, and quite honestly,  
23 we've seen, to some extent, other places where that  
24 gets abused. And maybe "abused" is the wrong word,

1 but used for maybe not the right purposes, and so  
2 we wanted to really make sure that we were staying  
3 away from that.

4 In general, if there was a way to truly  
5 slow down the progression of CKD 4 and reduce the  
6 rate at which somebody went to dialysis and that  
7 was well-established and proven and underutilized,  
8 I think it would be worthwhile going upstream.

9 We didn't feel like there were -- there  
10 were significant opportunities right now to make  
11 that impact in advance to CKD, to justify the noise  
12 of using different estimated GFR levels.

13 And I'll defer to anybody else that may  
14 want to answer as well.

15 DR. KENNEY: Yeah. This is Robert Kenney.

16 I agree with what Jeff said about that,  
17 and we really struggled to try to see if we could  
18 come up with some type of outcome measure in CKD.  
19 And, yes, we could say, "Okay, if one does this  
20 process measure and that process measure and  
21 another process measure," but how do you judge  
22 success?

23 And it's like one of our members said,  
24 "How do you define a non-event?" In other words,

1 how can we define keeping somebody longer off  
2 dialysis? We just -- we just could not come up  
3 with something to --

4 DR. CASALE: Yeah.

5 DR. KENNEY: -- accomplish that.

6 DR. KETCHERSID: Yeah. I think the --  
7 this is Terry.

8 Just to add on to that, because we did --  
9 we did debate this, and in addition to adding  
10 complexity, there's a remarkable variability in  
11 terms of CKD progression, and the timeframes can be  
12 remarkably long.

13 If you -- if you're looking at a patient  
14 population that's small and you're waiting years,  
15 in many cases, that's -- that just adds a layer of  
16 complexity that we didn't think we could accurately  
17 get our arms around in a model that nephrologists  
18 would be willing to participate in.

19 DR. CASALE: Right. That's very helpful.

20 DR. GIULLIAN: And I just want to clarify  
21 -- When I was talking about GFR trends, you know,  
22 in CKD, using GFR, that's a single individual  
23 patient's GFR trend --

24 DR. CASALE: Right.

1 DR. GIULLIAN: -- as opposed to looking at  
2 a population of patients --

3 DR. CASALE: Yeah.

4 DR. GIULLIAN: -- that start in the model.

5 DR. CASALE: Right, right.

6 MR. MILLER: So this is Harold Miller.

7 Let me switch subjects a bit. So, I  
8 wanted to get a little bit more of your thoughts  
9 about the six-month episode, because that's  
10 inherently an arbitrary number. You know, in other  
11 places, the notion of an episode is that there's  
12 some clinical end point that's being reached.  
13 Here, it seems like it's an arbitrary number. You  
14 said you looked at different timeframes.

15 The challenge is that once you create a  
16 cutoff, then -- and you're saying, "I'm going to  
17 reward you for savings that occur before that  
18 cutoff and not afterwards," there's a concern that  
19 you might find ways to shove costs past the six-  
20 month time period.

21 And I wanted you to talk a little bit  
22 about how you would imagine -- why six months, why  
23 that wouldn't happen, why, for example, you  
24 wouldn't say, "Well, this patient, yeah, we could

1 try to start a fistula for them, but they're going  
2 to have lots of complications. And maybe we'd be  
3 better just living with catheters and trying to  
4 make sure they don't have catheter-related  
5 infections for six months and defer the vascular  
6 surgery until six months plus one day."

7 DR. GIULLIAN: Sure. I think that is --  
8 it's a great question, and it goes to, again, the  
9 unintentional consequences that we thought of.

10 So, the first reason that we chose six  
11 months is that's really the time point in which  
12 costs start to flatten out. So what we see is a  
13 huge spike in cost in the first six weeks that  
14 starts to trend down over the next, you know,  
15 approximately 18 to 20 weeks, and once you reach  
16 the six-month mark, not only are patients at that  
17 point really, I think - they fundamentally have  
18 chosen which modality that they're going to do for  
19 the long period, but they become more chronically  
20 stable. And that's probably not a great term  
21 because these patients are inherently unstable, but  
22 meaning we see very little variability over the  
23 population from, say, month six through even month  
24 48. The big variation in terms of hospitalizations

1 is earlier.

2           The second thing is about that -- you  
3 know, pushing the cost off past six months -- the  
4 two largest drivers of cost for an ESRD patient,  
5 that together account for between 65 and 70 percent  
6 of the total costs, are, number one, the cost of  
7 dialysis itself, and so there's no way to push that  
8 off. Just by definition, that is the cost of doing  
9 dialysis. That's about 30 percent of the overall  
10 cost, and the --

11           MR. MILLER: But you're also -- you're not  
12 going to necessarily reduce that.

13           DR. GIULLIAN: Right. So that part  
14 probably won't, but the other part, which accounts  
15 for about 30 to 40 percent of the cost, is  
16 hospitalizations. And, hospitalizations -- 40  
17 percent of hospitalizations are due to  
18 cardiovascular issues, and another approximately 25  
19 to 30 percent of hospitalizations are due to  
20 infections.

21           So, while I guess in some ways you're  
22 right, you could say, "Gosh, I want to -- I want to  
23 not do that \$1,200 fistula procedure until month  
24 six and one day," likely, that would be offset by

1 significantly higher risk of hospitalization for an  
2 infection, or hospitalization for volume-related  
3 issues by not choosing the right modality, not  
4 dialyzing in an optimal way.

5           And so, I think that in broad terms --

6           MR. MILLER: But let me just pause you  
7 there. So I'm assuming that you're really good at  
8 your job, and you have a better able -- ability to  
9 predict which patients are going to have problems  
10 and which ones aren't -- than just kind of doing as  
11 a random thing that you'd say, "I have no way of  
12 controlling or predicting this, so I better give  
13 them all a fistula because that'll do better." I'm  
14 asking, so how do I know that you're not going --  
15 and maybe it's okay to say, you know, "I can do an  
16 okay job of predicting it." But, it would seem to  
17 me that, you know, you could potentially -- if  
18 you're good -- "I know my patients. I know which  
19 ones are likely to be able to do -- to do better  
20 and which ones worse," that you would try to  
21 stratify yourself.

22           DR. GIULLIAN: Yeah. I don't think  
23 there's any way to do that with a fistula. I  
24 think, you know, a healthy patient with a catheter

1 is at significantly high risk for an infection, and  
2 an unhealthy patient with a catheter is as well.

3           So where it comes down to, I think, is,  
4 How do you stratify which patients maybe should  
5 stay on hemodialysis, as opposed to which patients  
6 ought to transition to peritoneal dialysis?" And,  
7 that is additionally inherently tricky because,  
8 quite honestly, the healthiest patients do better  
9 on PD, but the unhealthiest, those with low  
10 ejection fractions, poor cardiac output, also do  
11 very, very well on peritoneal dialysis. So, you've  
12 got sort of a bimodal distribution.

13           So while I hear the question and I think  
14 it's a wise question, I think it would be really,  
15 really hard to stratify patients in such a way that  
16 you hold off doing things for them until six months  
17 and one day and not --

18           MR. MILLER: Mm-hmm.

19           DR. GIULLIAN: -- reach the negative  
20 effects of infection-related admissions and --

21           MR. MILLER: Okay.

22           DR. KETCHERSID: Jeff, this is --

23           DR. GIULLIAN: -- cardiovascular-related  
24 admission.

1 DR. KETCHERSID: Jeff, this is Terry.

2 I don't have the quality measures in front  
3 of me, but wasn't our fistula metric time-based? I  
4 don't recall.

5 DR. GIULLIAN: Yeah. It went through a  
6 few different iterations, but yes. Ultimately, it  
7 was.

8 MR. MILLER: So one more follow-up. What  
9 is it -- what is it that you think would happen  
10 between 90 days and six months? Because, you said  
11 90 days does not allow for optimal savings. So,  
12 what happens between 90 days and six months, in  
13 your mind?

14 DR. GIULLIAN: Those patients from 91 days  
15 to 180 still have higher than average costs.  
16 Secondly, we think that, you know, quite  
17 honestly, you want to make sure that we're doing  
18 everything possible to get these patients  
19 transplanted early and transitioning over to a  
20 whole modality.

21 Many patients, that sort of follow that  
22 path of least resistance and start in center  
23 dialysis, ultimately could still transition over to  
24 peritoneal dialysis, and that savings -- you know,

1 if somebody didn't get their PD catheter placed  
2 until one month in and we decided as a physician  
3 not to do urgent-start PD -- you let that PD  
4 catheter -- typically, you let it heal for a month.  
5 So now you're not even starting peritoneal dialysis  
6 in a patient like that until Day 60 or Day 90. And  
7 so to be able to make sure that the physician is  
8 continuing to evaluate these patients, continuing  
9 to do what's right for them in terms of that  
10 optimal transition to the right patient-centered  
11 modality and then reaping the rewards of those cost  
12 savings, to me that's -- that makes it the right  
13 timeframe.

14 MR. MILLER: So you're saying 90 to -- 90  
15 days to six months is kind of where a lot of the  
16 benefits get reaped, and then beyond that, it  
17 stabilizes out past that. And there would be no  
18 logical point to going beyond that to, say, nine  
19 months, 12 months, or whatever?

20 DR. GIULLIAN: Yeah.

21 So, I think CMS probably has a better  
22 ability to look at the exact cost per patient per  
23 month than we do. We obviously are limited to the  
24 analysis -- the analyses that are in the general

1 publications, and so we may be limited by the fact  
2 that people did economic analyses looking at six  
3 months and looking at one year, as opposed to  
4 looking at six months, seven months, eight months.

5 MR. MILLER: Mm-hmm. Okay.

6 DR. GIULLIAN: So, I think we'd be open  
7 to, you know, considering what you guys think is  
8 best based on maybe numbers --

9 MR. MILLER: Well, I was more -- yeah, and  
10 we could certainly do that. I was more just asking  
11 kind of from your own clinical perspective, you  
12 know, what happens in what time period, and you're  
13 basically saying that lots of stuff would happen in  
14 the first 90 days and in a sense wouldn't -- you  
15 wouldn't have the ROI (return on investment) appear  
16 until the second half of that. But, it kind of  
17 evens out after that.

18 I mean, we can -- we can -- we can think  
19 about whether there's a way to look at that more  
20 carefully. I just wanted to make sure that I was  
21 understanding why you thought six months versus 90  
22 days and why six months versus a longer period of  
23 time. So that -- that's helpful. Thanks.

24 DR. GIULLIAN: Yeah.

1 DR. KENNEY: Yeah. And this is Robert  
2 Kenney.

3 Just to add to that, in the proposal, we  
4 actually put a chart from USRDS (United States  
5 Renal Data System), and basically, the mortality,  
6 the standardized mortality is quite high at the  
7 start of dialysis and comes down, as Jeff  
8 mentioned, plateaus about six months. Although we  
9 don't have the cost data, I suspect that the cost  
10 data parallels that mortality risk data.

11 MR. MILLER: Mm-hmm. Okay. Thanks.

12 DR. CASALE: So, I know we're almost at  
13 the top of the hour. I have one more question,  
14 but, Jeff, I want to give you an opportunity  
15 because I feel like I've asked a lot of questions.  
16 I want to make sure if you have other questions,  
17 you get a chance to --

18 DR. BAILET: No. I'm actually good, Paul.

19 DR. CASALE: Okay.

20 DR. BAILET: I think you guys have covered  
21 a lot of waterfront here today.

22 DR. CASALE: Okay. Well, if you don't --  
23 I just had a question related to transplants and  
24 the bonus, in particular, and I'm sure you've given

1 a lot of thought to that.

2 Well, there's two questions. One is, It's  
3 my understanding that for people to sort of get on  
4 to dialysis, it's probably several months before  
5 they actually might get to the point where they're  
6 sort of -- you know, have everything in order to be  
7 referred to transplant or that kind of thing, so  
8 would a lot of - so, would a significant number of  
9 patients be beyond the six months before that  
10 happens -- is one question?

11 And then the other is, you know, whenever  
12 we think of bonus for a transplant -- and I know  
13 transplant is a good thing. I'm a cardiologist,  
14 but I do know that's a good thing. You -- I always  
15 ask, "Well, are there unintended consequences of  
16 paying a bonus for a transplant?"

17 So I wondered if you could address both of  
18 those questions.

19 DR. GIULLIAN: Sure.

20 So, I mean, I would say this is probably  
21 the most, I guess, out-of-the-box part of our  
22 recommendation, or our model, because it is  
23 completely different than a typical fee-for-service  
24 payment, even fee-for-service with shared savings.

1 And so, you know, we recognize that we went out on  
2 a limb requesting this and yet, again, it is the  
3 right thing for patients.

4           So, first and foremost, a preemptive  
5 transplant, a transplant that occurs before a  
6 patient ever touches dialysis --

7           DR. CASALE: Right.

8           DR. GIULLIAN: -- is absolutely the right  
9 thing, which is why we incentivize that the  
10 greatest. Patients can be placed on the kidney  
11 transplant list when their estimated GFR hits below  
12 20, and they typically don't start dialysis until  
13 they're somewhere around a GFR of 10.

14           So, assuming that patients could get  
15 referred earlier, we believe that there are a  
16 significant number of patients that could  
17 potentially get transplanted either before they  
18 start dialysis or, in essence, be transplanted  
19 right after they start dialysis.

20           And that's not an uncommon issue either.  
21 Where, you know, somebody is pretty darn on the  
22 edge of doing dialysis, not doing great, but, gosh,  
23 they're number four on the transplant list and this  
24 and that. And so we wanted to make sure that

1 somebody who needs to start dialysis ultimately  
2 starts dialysis, and then if that means they end up  
3 getting transplanted at Month One or Month Two, the  
4 physician gets zero benefit from having done all of  
5 the upstream work. So, really that's where we're  
6 looking.

7 DR. CASALE: Mm-hmm.

8 DR. GIULLIAN: And then, additionally, you  
9 have a subset of patients that ultimately crash  
10 into dialysis, and if they're referred early enough  
11 to dialysis -- excuse me -- early enough to  
12 transplant, and assuming they have a living donor,  
13 that process can be as short as 10 to 16 weeks.

14 And so somebody that maybe transitions on  
15 to dialysis, gets referred to a transplant center  
16 within the first couple of weeks as opposed to  
17 waiting months and months and months, has the  
18 opportunity to be transplanted within that six-  
19 month timeframe. And again, incentivizing the  
20 physician for doing the extra heavy lift of getting  
21 that patient over to a transplant center sooner  
22 rather than later, knowing that in the long run,  
23 that has significant benefits for the patient and  
24 for society.

1 DR. CASALE: Yeah.

2 And just one last thing -- and, again, I  
3 understand transplant is, you know, for sure the  
4 best path. In regards to the -- again, because I'm  
5 just thinking around a bonus payment and unintended  
6 consequences. So the living donor, is it because,  
7 you know, people live longer than they used to? Is  
8 there any -- not controversy, but data or concern  
9 around long-term risk for the donor, given people  
10 live longer than --

11 DR. GIULLIAN: Yes.

12 DR. CASALE: -- as far as --

13 DR. GIULLIAN: So far not. So right now,  
14 the two greatest risks for a living donor are a  
15 slightly increased chance of hypertension later in  
16 life -- a little bit difficult to elucidate exactly  
17 if that risk was because of the single kidney, or  
18 if those are patients that maybe would have been at  
19 risk for hypertension, anyway. And a slight  
20 increased risk for albuminuria later in life.  
21 Those have not translated, thus far, to increased  
22 risk of cardiovascular events or anything else that  
23 we sometimes attribute to albuminuria and  
24 hypertension, mostly because in the cases of a

1 typical patient with albuminuria and hypertension,  
2 there's actual damage to the kidneys, where in this  
3 case --

4 DR. CASALE: Right.

5 DR. GIULLIAN: -- it's just that they're  
6 living with a single kidney.

7 Obviously, you know, we won't know --  
8 given the fact that some of these patients are  
9 living to now 80 and 90, we won't know for several  
10 years, whether or not there is a change.

11 I can tell you as a transplant  
12 nephrologist myself, I have transplanted people  
13 that ultimately developed kidney failure that had  
14 been kidney donors themselves. In every case for  
15 me -- and this is anecdotal, not evidence --

16 DR. CASALE: Right.

17 DR. GIULLIAN: But in every case for me,  
18 those patients would have, in my opinion, developed  
19 ESRD, anyway, because what caused their ESRD would  
20 have attacked both kidneys --

21 DR. CASALE: Right.

22 DR. GIULLIAN: -- as opposed to attacking  
23 one. In one case, it was lupus. In another case,  
24 it was membranous nephropathy. And so --

1 DR. CASALE: Yeah.

2 DR. GIULLIAN: --you know, that may not be  
3 a perfect question -- a perfect answer, but I think  
4 living donation is still absolutely the gold  
5 standard for these issues.

6 DR. CASALE: Yeah. Okay.

7 Great. Well, Harold, are you good?

8 MR. MILLER: Yes. Thank you. Excellent,  
9 excellent. So, thank you.

10 DR. CASALE: Yeah. Well, great. Well,  
11 listen, thank you to everyone who is on the phone.  
12 It's been very informative and very helpful to us  
13 as we work through our evaluation, so thanks very  
14 much.

15 If we happen to come up with any follow-up  
16 questions, we would send them to you by e-mail, but  
17 thanks for getting on the phone.

18 MR. MILLER: And I would just say, Paul,  
19 too, I mean, if you guys have any follow-up  
20 information that you think would be helpful after  
21 the call, we would welcome seeing anything else you  
22 wanted to send.

23 DR. CASALE: Well, great. Thank you very  
24 much.

1 DR. SHAPIRO: We really appreciate the  
2 opportunity.

3 MR. MILLER: Thanks.

4 DR. CASALE: All right. Thank you. Have  
5 a good evening, everyone. Thanks very much.

6 DR. BAILET: Yes. Thank you, guys.

7 DR. CASALE: Yeah. Thanks, Jeff, Harold.  
8 Bye.

9 [Whereupon, at 7:03 p.m., the conference  
10 call concluded.]

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