Renal Physicians Association
Incident ESRD Clinical Episode Payment Model
May 2017

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Abstract

The first months for adult patients transitioning from Chronic Kidney Disease (CKD) to End Stage Renal Disease (ESRD) therapies are associated with increased mortality and complication rates, frequent hospitalizations, and notably higher payer costs. RPA proposes a condition-specific, episode-of-care payment model (Clinical Episode Payment—CEP) that would span the first six months of dialysis therapy for established Medicare beneficiaries. Specifically, this model: (1) incentivizes coordination of care for incident dialysis patients; (2) promotes renal transplantation (both pre-emptive and after the initiation of dialysis (3) removes obstacles and disparities for patient choice in dialysis modality; (4) encourages upstream CKD patient education; (5) promotes quality of life, medical management and advanced care planning; and (6) improves overall quality at reduced cost. Additionally, this CEP requires little additional infrastructure creation that renders it feasible in urban, suburban and rural regions. For simplicity purposes specifically to attract participation by groups of all sizes, the model is built upon utilization of the current Medicare Physician Fee Schedule billing. The financial incentives or penalties would be determined in a reconciliation period following the episode of care and would constitute shared savings or shared losses when benchmarked against a risk-adjusted target cost. This CEP, with an upside/downside risk option, would allow participants to be afforded Advanced APM status. The upside only option of this APM model would be expected to allow credit to a participating physician under the MIPS Quality Payment Program. Evidence-based quality metrics as well as processes that represent surrogates for improved outcomes (permanent dialysis vascular access, for example) will be utilized to assure quality. An emphasis on hospital admission and re-admission avoidance, care coordination, and home therapies, as well as expanded use of palliative care where appropriate will impact payer spending. Given that this model is built upon established infrastructures and billing mechanisms, it is anticipated that nephrologists and nephrology groups of all sizes, both in rural and urban areas, would be eligible participants and attracted to this CEP.

Background and Model Overview—RPA ESRD CEP Model

According to the United States Renal Data System (USRDS) 2016 Annual Data Report (based upon patient data from 2014), more than 661,000 Americans have kidney failure, described in statute as end-stage renal disease (ESRD). Of these, 468,000 individuals are on dialysis, and approximately 193,000 live with a functioning kidney transplant. In 1972 Medicare eligibility was extended to persons with ESRD who required dialysis or transplantation. Thirty-five years ago approximately 10,000 Medicare beneficiaries received dialysis therapies; by 2014 the number had grown to nearly half a million.

Importantly, ESRD expenditures and disease burden include:

- In 2013 total Medicare costs for the ESRD program were $30.9 billion, representing a 1.6% increase from 2012. While ESRD patients account for 1% of the Medicare population, their care accounts for 7% of Medicare expenditures. In aggregate, the cost of ESRD care equates to 1% of the total annual federal budget;

- Hospitalization costs to Medicare for ESRD patient care rose to over $10.3 billion in 2013;
- Annual Medicare costs for prevalent ESRD patients average ~$86,000 per patient;
- Costs in the first 6 months of ESRD care are disproportionately higher than annualized costs, due in part to sub-optimal and unmanaged transitions (crashes) to renal replacement therapy;
- Historically, estimates have conservatively ranged from $56,000-$65,000 for the first 6 months of dialysis care. USRDS estimates from 2007 suggested costs of $15,000 per month for the first several months of dialysis. These incident dialysis costs are likely to have risen considerably over time and are substantially higher in the commercial insurance arena;
- Patients receiving in-center hemodialysis (HD) cost the Medicare program $15,000 more annually compared to patients receiving peritoneal dialysis. Similarly, patients who opt for home hemodialysis tend to have lower overall annual costs as well. This cost disparity may be greatest in the incident dialysis population; and
- The typical adult ESRD patient has 2.0 hospital admissions per year, or on average 12 hospitalization days per year, and an approximate readmission rate of 36%. Thus, ESRD patients are among the sickest and most vulnerable patient sub-populations in Medicare.

RPA believes that the daunting patient presentation and fiscal circumstances of the current entrance into ESRD (defined as "incident dialysis") offer a discernible and viable opportunity to improve patient choice of treatment modality, clinical outcomes and quality of life, while reducing the overall 'spend' for these patients in both the Medicare program and with private insurers. Given that the first six months for adult patients transitioning from chronic kidney disease (CKD) to ESRD and facing the need for renal replacement therapy are associated with the highest mortality and complication rates, frequent hospitalizations, and significantly higher costs, this period in a patient's kidney disease journey offers the prospect of enhanced patient-centric care and cost savings through nephrology-specific medical management of their disease.

RPA proposes a condition-specific, episode-of-care payment model (Clinical Episode Payment—CEP) for incident dialysis patients, for which there are nearly 121,000 new patients annually across the US. This proposed model would commence in the first month of dialysis therapy and would span the initial six months of dialysis for established Medicare primary beneficiaries. With pre-specified outcomes that align closely with CMS-accepted quality metrics, this model would serve to improve: (1) upstream preparation for dialysis, (2) equality of access to modality types and shared decision making (3) access to renal transplant, (4) healthy transition to dialysis, and (5) well-being during the first several months of dialysis. This model could easily be adapted to non-CMS payers as well.

This CEP should meet the standards as defined in the Federal Register (June 30, 2016) for a nephrology specific AAPM that includes the three fundamental requirements for an AAPM (use of certified electronic health records technology—CEHRT, quality measurement similar to that found in the Merit-based Incentive Payment System (MIPS) and greater than nominal financial

risk for participants). Specifically, this model: (1) incentivizes coordination of care for incident dialysis patients; (2) promotes renal transplantation (both pre-emptive and after the initiation of dialysis); (3) removes obstacles and disparities for patient choice of dialysis modality; (4) encourages more focused upstream CKD patient care and care coordination; (5) promotes quality of life, medical management and advanced care planning; and (6) improves overall quality at reduced cost. Additionally, this CEP requires little additional infrastructure creation that renders it feasible in urban, suburban and rural regions. For simplicity purposes and specifically to attract participation by groups of all sizes, the model is built upon utilization of the current Medicare Physician Fee Schedule billing and has low infrastructure burden, which will make this suitable for small and large practices alike. The financial incentives or penalties would be determined in a reconciliation period at the conclusion of the episode of care and would constitute shared savings or shared losses when benchmarked against a risk-adjusted target cost. Within this model of care providers could select to participate in the shared savings option, avoiding downside risk. In this circumstance the model would function as a MIPS APM within CMS' Quality Payment Program (QPP) framework.

Specifically, under this model, regional cost benchmarks will be set for the first six months of dialysis care for patients with ESRD, as determined by the date indicated on the CMS 2728 form. Physicians may design care plans, strengthen clinic infrastructure, deploy innovative models of care coordination and actively educate patients in an effort to meet or exceed cost savings based upon the above-mentioned regional cost benchmarks.

In order to qualify for a portion of the cost savings, participating physicians must meet several quality metrics designed to improve treatment options, quality of life and overall health of incident dialysis patients. Physicians will receive a total quality score (0-100) based upon performance on pre-specified, patient-centric quality metrics. That score will determine the percentage of overall shared savings that the physician qualifies to receive. Similarly, choice of participation in the MIPS APM vs. the Advanced APM will define the scope of upside shared savings and downside risk.

As described by the PTAC, this RPA proposal controls healthcare spending and improves health care quality by holding the APM entity accountable for cost and quality. Payments in this APM will enable physicians to: (1) improve care for patients receiving dialysis; (2) provide care across the care continuum for a combination of conditions related to ESRD; and (3) deliver more coordinated, efficient care. Additionally, payments will be designed to enable physicians to care for a specific subgroup of patients with an emphasis on early education in late stage CKD, which might be able to alter progression or prevent certain complications. Finally, payment for shared savings will be based upon recognized, evidence-based patient outcomes.

This Physician Focused Payment Model (PFPM) will fundamentally alter physician payment related to a specific health condition (incident ESRD) and will address care delivery to these patients via evidence-based services and quality measures. This proposal also identifies numerous potential unintended consequences and seeks to limit or eliminate as many as possible.

The advanced APM version of this proposal will require physicians to accept more than nominal financial risk. In this model, risk is structured in such a way to be feasible for physicians to participate, even for those in smaller practices, and will encourage appropriate changes in care delivery.

In short, the overarching goal of this model of care is to improve quality of life while lowering the total cost of care. By promoting patient-centered care coordination, increased upstream CKD patient education, enhanced access to dialysis modality options including renal transplant, patient-centered shared decision making including advanced care planning, and reductions in hospitalizations, this stated goal is considered achievable.

With proper upstream patient education, financial incentives for pre-emptive renal transplant, indirect incentives for non-dialysis, medical management of patients with short life-expectancy and objective evaluation of residual renal function at dialysis initiation, this APM has the potential to provide significant value to patients and payers alike.

II. Scope of Proposed Physician-Focused Payment Model

By focusing attention on the incident dialysis patient, this proposed CEP APM model promotes attention on the transition of care from CKD to ESRD. Building upon the current payment structure for dialysis care, this model provides for a greater breadth of services with fewer limitations than the current payment model, including a waiver to assist patients with transportation to dialysis and vascular access services. Additionally, with a greater focus on upstream physician efforts during the latter stages of advanced CKD, patients will experience improved care coordination, greater options for care based upon individual health goals and reduced risks for dialysis-associated complications that are highly prevalent among incident dialysis patients in the first 6 months. Given these patient-centered benefits, the RPA expects patients to experience fewer hospitalizations and for the payer to experience lower overall costs with physician shared savings. Moreover, outside of the finite number of Comprehensive ESRD Care (CEC) Models known as ESRD Seamless Care Organizations (ESCOs), there are no other nationwide opportunities for Advanced APM participation by nephrologists involving similar models.

Given the focus of care noted above, and the fact that ~85% of all monthly dialysis services billed to Medicare are provided by nephrologists, this group of physicians or physician practices will represent the vast majority of participants in this model. However, Internal Medicine and other physicians caring for ESRD patients will not be excluded from participation, as in some locations, non-nephrologist practitioners provide advanced CKD and dialysis services. RPA has only anecdotal information regarding the numbers of physicians who might have an early interest in participation.

USRDS data notes that the number of newly reported ESRD cases in 2014 was 120,688, representing an unadjusted incidence rate of 370 per million per year, with these figures rising

since 2011. The exact number of patients who might benefit from this proposed CEP model remains unknown and is related to the number of physician participants and the population they serve. With a conservative cost estimation of $57,000-$65,000 attributed to the first six months of dialysis for Medicare patients, the potential cost savings from this APM are significant. Based upon an estimate of 20% participation in this APM and 10% savings, this model could save CMS and other payers over $72 million after shared savings to the physicians (assuming 50% of providers participate in a MIPS APM and 50% participate in an AAPM).

The characteristics of this model include:

1. Nephrologist control of ESRD patient care oversight.
2. Design simplicity alleviating the need for new administrative infrastructure or burden.
3. Flexibility for implementation by various practice sizes and geographic locations.
4. Potential participation by non-CMS payers.
5. Potential for nationwide implementation by physicians.

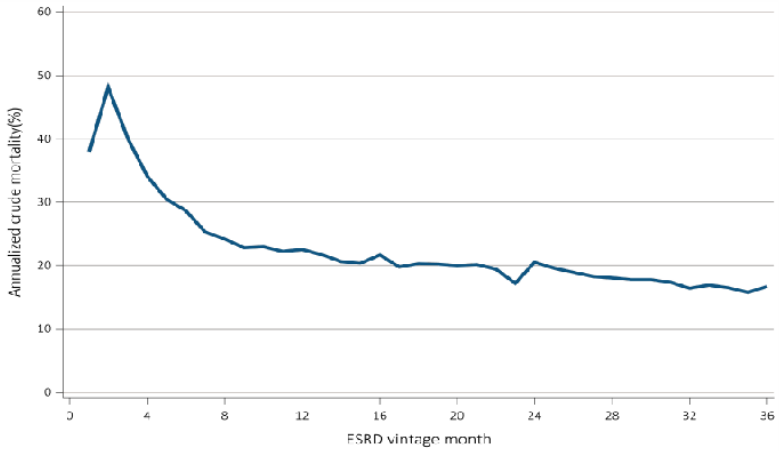
As most of this model's payment mechanisms are built upon the existing services within the Medicare Physician Fee Schedule with subsequent reconciliation of cost and determination of shared savings or losses, there is likely no need for a separate APM business entity aside from the participating physician(s) or physician practice. As such, this model is conceived to work for physicians practicing in single- and multi-specialty medical practices and includes both employed and "partner" physicians alike. In either scenario, the participating APM entity would be financially responsible for any shared savings or losses. Also, as noted earlier, this model would have applicability to practices of all sizes and in all population areas. As outlined in the MACRA final rule, physicians in smaller practices would have the opportunity to coordinate and form a joint APM entity in order to share resources and risk.

Similar to other patient populations, the 2016 USRDS Annual Data Reports highlighted the point that mortality of US military veterans with ESRD was notably highest in the first few months of dialysis therapy (incident dialysis), noted in Figure 8.4 below. Also, the number of hospitalizations for arterio-venous graft complications and septicemia (presumably a result of large numbers of hemodialysis catheters being utilized for treatments) were clearly highest in the early months after initiation of dialysis (Figure 8.8). Results for the general patient population are likely similar to that seen in this study population of US military veterans, as evidenced by USRDS Figure 6.3.b below. Moreover, the distinction between mortality rates in the patients treated with hemodialysis compared to those treated with peritoneal dialysis is profound, an observation not lost among policymakers in general and the proposers of this model. Data from USRDS in 2007 noted that the cost of Medicare patients on average was $15,000 PPPM in the first months following dialysis initiation, a rate that has likely increased over the past decade. Achievement of the patient-centric, evidence-based quality metrics assigned to this CEP model proposal would likely reduce hospitalization rates and mortality during this treatment episode. Furthermore, it is expected that the positive clinical outcomes would have a lasting beneficial impact long after the CEP timeframe expires. Therefore, this PFPM is not only expected to reduce Medicare costs during the shared-savings timeframe, but thereafter as well.

In further support of the above observations, Lukowsky et al (Am J Nephrology 2012; 35:548-558) noted that incident hemodialysis patients had the highest mortality during the first 6 months of dialysis, including an 80% higher death risk in the first 2 months. The presence of a central venous catheter and hypoalbuminemia <3.5 g/dl each explained one third of all deaths in the first 90 days (see figure below). Fortunately, upstream education with subsequent optimal transition to dialysis enhances the likelihood that a central venous catheter and its attendant complications can be avoided as well as the predictive adverse outcomes associated with poor nutritional status and chronic inflammation.

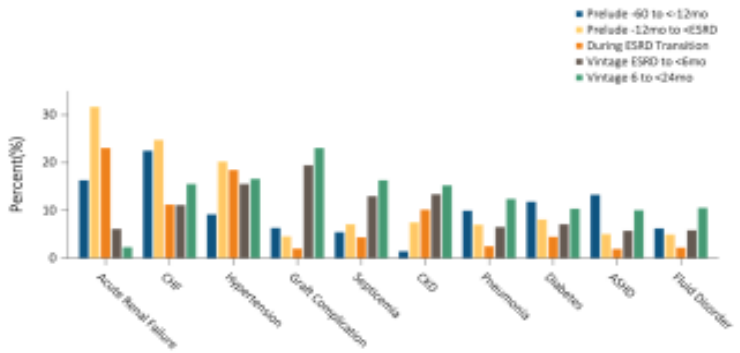
Thus, this CEP APM model proposal seeks to improve desired patient outcomes of improved mortality, fewer hospitalizations, and reduce total costs. In addition to the outcomes measures being proposed, this model includes a set of Monitoring Metrics, designed to provide insight on variables including estimated GFR during dialysis initiation and provide both a mechanism assessing the standard of practice as well as a disincentive to nephrologists to start patients too early. The inclusion of Advance Care Planning as a weighted quality metric in this proposal is anticipated to indirectly provide safeguards, and encourage robust and frank discussions among physicians, families and patients regarding desired goals of therapy, including quality of life and support conversations regarding the options for dialysis therapy or medical management.

Figure 8.4 Annualized unadjusted mortality of incident ESRD veterans who transitioned to ESRD during 10/1/2007-3/31/2014 and who were followed for up to 36 months (N=85,505)



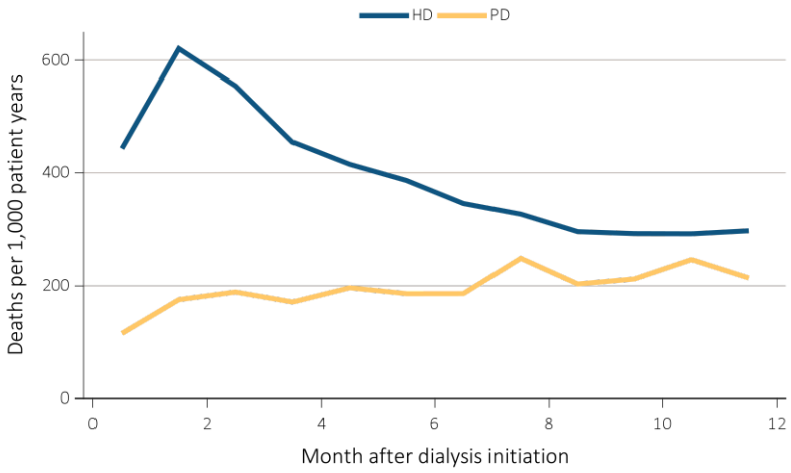
Data Source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data.
Abbreviations: ESRD,end-stage renal disease.

Figure 8.8a Top 20 causes of hospitalizations in 74,382 incident ESRD veterans who were hospitalized at least once during the 60 months prior to ESRD transition (prelude) up to 24 months after ESRD transition (vintage).

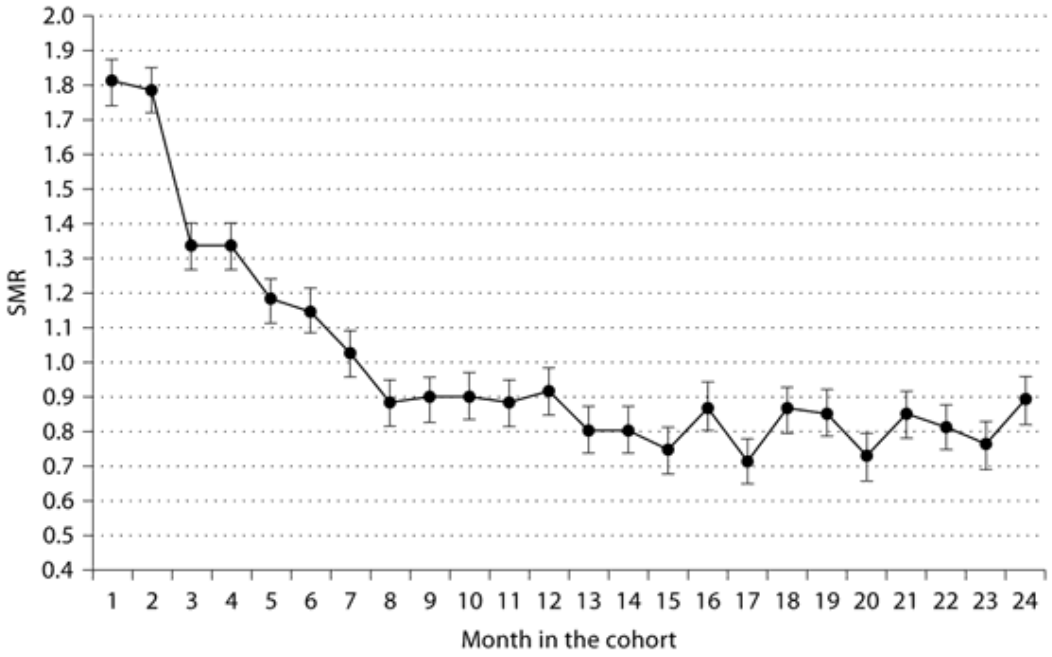


Data source: VHA Administrative data, USRDS ESRD Database, CMS Medicare Inpatient and Outpatient data. Abbreviations: ASHD, atherosclerotic heart disease; CHF, congestive heart failure; CKD, chronic kidney disease; CVD, acute cerebrovascular disease; ESRD, end-stage renal disease; GI Hem, gastrointestinal hemorrhage; MI, myocardial infarction; mo, month; Resp Fail, respiratory failure; Skin inf, skin infection; surg, surgical.

Figure 6.3.b Adjusted mortality (deaths per 1000 patient-years) by treatment modality and number of months after treatment initiation among ESRD patients, aged 65 and over, 2013



Data Source: Special analyses, USRDS ESRD Database. Adjusted (age, race, sex, ethnicity, and primary diagnosis) mortality among 2013 incident ESRD patients during the first year of therapy. Reference population: incident ESRD patients, 2011. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis.



Monthly standardized mortality ratios (SMRs) during the first 2 years for 18,707 incident dialysis patients who during this timeframe were treated only with hemodialysis. (Lukowsky, IBID)

III. Quality and Cost

The value proposition for this model is related to a heightened focus on patient-centered modality choice, enhanced coordination of care and improved quality outcomes, which if successful, will result in lower costs of care.

Numerous studies, including the USRDS Special Study Center on Transitions of Care in CKD, have noted that 75-80% of incident hemodialysis patients start dialysis with central venous hemodialysis catheters. The preponderance of incident hemodialysis patients who start dialysis without permanent vascular access is a major source of costly outcomes including problems with dialysis adequacy, catheter dysfunction, bloodstream infections, sepsis, increased hospitalizations, added cost, and higher mortality rates. The current payment system has failed to encourage efforts to overcome existing barriers to orderly transition to dialysis and/or kidney transplantation, even among those CKD patients followed by nephrologists for prolonged timeframes prior to development of ESRD. Efforts by others (Fishbane, Kaiser) have demonstrated that orderly transition from CKD to ESRD is associated with higher rates of permanent vascular accesses, reduced hospitalizations, and decreased costs of care. The opportunity is such that even a relatively small percentage of improvements in quality outcomes translate into significant savings.

Hazards of this model include: (1) financial incentives with shared savings even if successful may not be enough to encourage continued efforts at orderly transitions to

ESRD/transplantation/home dialysis therapies; (2) relatively small numbers of incident dialysis patients annually per nephrologist may not provide a large enough risk pool for actuarial precision; (3) nephrologists may not be willing to invest in more robust care coordination activities, particularly in some areas where demographics adversely impact patient inclination toward home therapies; and (4) nephrologists frequently see some patients for the first time just before the onset of ESRD requiring dialysis leaving little time for adequate preparation.

Despite longstanding evidence that the best outcomes in transitioning patients from CKD to ESRD involve early transplantation, avoidance of hemodialysis catheters, encouraging more home dialysis utilization, care coordination with patient education, and use of palliative care programs where appropriate, tangible or intangible barriers continue to exist given the current state in this area. Although the intent of CMS has been to support such efforts, the question arises as to whether current policies might be insufficient to address whatever barriers may be present. This CEP model proposes to alter and re-focus physician incentives to break down barriers that might exist. A unique aspect of this APM is the creation of a mechanism and one-time physician financial incentive for achievement of kidney transplantation, either pre-emptively or during the episode of this APM. Success in both quality and cost in this model will necessitate a more intense focus on patients in the latter stages of CKD, particularly regarding avoidance of hemodialysis catheters and in situations which involve patients who present in dire need and abruptly start dialysis. The use of home dialysis therapies is also incentivized in this model. Where appropriate for patients with multiple co-morbidities and unclear favorable prognoses, the provisions in this model may encourage physicians to consider palliative care programs, which as yet are considered underutilized but valuable for select individuals.

APM: Quality Outcomes

The RPA sponsors the Kidney Quality Improvement Registry, the only nephrology-specific CMS-certified Qualified Clinical Data Registry (QCDR). The RPA Registry gathers data from across a variety of practices and geographies, allowing for meaningful benchmarking, comparison and insights at a national level. Currently, the RPA Registry is used to report components of MIPS including quality measures. 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. Several of the metrics chosen for the quality component of this APM mirror those approved by CMS and included in the RPA QCDR. Below is a chart outlining the quality metrics for this model.

Metric	National Benchmark	Measurement Goal	Performance Metric	Weighting/ Maximum Points	Sliding Scale for Points Linear point distribution	How to Measure
Advanced Care Planning	Unknown	Mirror ESCO, (HEDIS). Hybrid with entity attestation, updated annually.	Pay for reporting year 1 Pay for Performance year 2: 100% ACP on file (Consider formal State regulatory form such as MOST or POST)	15 points	Year 2: Linear point distribution from 75% ACP on file (0 points) up to 100% ACP on file (15 points)	Hybrid: Claims & EHR
Catheter % for ICHD (90 day)	70-75% (Internal data) 80% day 1 CVC rate (2014 USRDS)	Reduction in catheter rate compared to day 1 rate or absolute target	≥25% relative reduction (RR) from day 0 rate or ≤60% absolute (A) catheter rate	5 points	10% relative rate reduction or 75% absolute catheter rates (0 points) up to 25% RR or down to 60% A (5 points)	EHR
Catheter % for ICHD (180 day)	55-60% (Internal data) ~18.8% total prevalent patients (2014 USRDS)	Reduction in catheter rate compared to day 1 rate or absolute target	≥50% relative reduction (RR) from day 0 rate or ≤40% absolute catheter rate by day 180	5 points	25% relative rate reduction or 60% absolute catheter rates (0 points) up to 50% RR or down to 40% A (5 points)	EHR
Optimal Start: Day 1 of outpatient dialysis with no catheter in place (ICHD/HHD) or initiate dialysis on PD	Total 29.6%: 20% for HD (2014 USRDS); 9.6% for PD (2014 USRDS)	Increase in overall optimal starts	≥50% for Max points	20 points	30% optimal starts (0 points) up to 50% optimal starts (20 points)	Hybrid: Claims and EHR
Fistula Rate of all permanent vascular access for ICHD & HDD (180 day)	70% AVF/(AVF +AVG) 63.1% total prevalent patients AVF, 18.1% AVG (2014 USRDS)	Maintain "Fistula First" goals for permanent vascular access	≥70% AVF/Total permanent access	10 points	60% AVF/Total permanent access (0 points) up to 70% (10 points)	EHR
Home dialysis % (PD and HHD)	9.6% for Incident PD and <1% for Incident HHD (2014 USRDS)	Increase total monthly home dialysis penetration	≥20% total patient months on home dialysis modality (any day in a month on home dialysis counts for full month)	15 points	10% home dialysis (0 points) up to 20% home dialysis (15 points)	Claims
Referral to Transplant	Unknown		Reporting	10 points		EHR
Patient Centeredness: Karnofsky Functionality Score	Unknown		Reporting	10 points		EHR
Patient Experience: PROMIS (Pt Reported Outcomes Meausurement Information systems – Adult/Peds)	Unknown		Reporting	10 points		EHR

IV. Payment Methodology

One attraction of this model to nephrologists in large and small practices, both rural and urban, is the intentional use of the current physician fee schedule payment methodology. Physician-provided, Medicare-covered services would continue to be reimbursed as they have been

traditionally. This alternative payment proposal involves the sharing of Medicare savings that may be achieved over the entire episode of care during the 6 months following the initiation of dialysis therapy for treatment of ESRD. Unique to this model is the proposal to create a mechanism for a one-time bonus payment to nephrologists for efforts facilitating a patient receiving a kidney transplant either pre-emptively or during the episode of care. This component has been added in order to encourage and recognize the influence, time and effort of nephrologists. This payment structure will facilitate greater access to treatments that results in superior outcomes and improved quality of life with lower costs over time compared to maintenance dialysis.

While this payment model offers opportunities for physicians not otherwise participating in an ESRD-designed APM, the shared savings payment methodology bears striking resemblance to that associated with the ESCOs. This was intentionally done to make efficient use of the regulatory infrastructure already in place for ESCOs. Unlike the ESCO model, which includes both incident and prevalent dialysis patients over prolonged periods of time, the proposal under evaluation focuses on the specific cohort of new ESRD patients beginning dialysis therapies. Participation in this model does not preclude participation in other AAPMs such as ESCOs. As this specific group historically has exhibited higher mortality and hospitalization rates, as well as higher costs to payers, distinct opportunities for improvements in these areas exist. Moreover, the current payment methodology for care during this defined episode for these patients has not resulted in widespread improvements in these important outcomes nor has it incentivized utilization of home dialysis therapies to the extent sought by CMS. This model appears to be easily adaptable to other payers, which is particularly important, given that a sizable number of incident dialysis patients begin renal replacement therapy before they become eligible for Medicare benefits.

This APM model proposal relies on nephrologists and nephrology practices (who most likely will be the APM entities) for success, in that it creates greater incentives for patient-centric, value-added care, defined as improved quality outcomes, patient choice and care coordination with attention to overall cost of care during this episode. By design, a CEP based on the first six months of dialysis will encourage physicians to act upstream to prepare and educate their CKD patients. By extension, we anticipate greater access to home dialysis options (peritoneal dialysis and home hemodialysis) and to pre-emptive renal transplantation. We also anticipate a deeper consideration of medical management, conservative care and palliative options for patients in whom dialysis therapies may not yield improved quality or longevity of life.

Two APM models are being proposed, giving model participants the option to select an upside-only (MIPS) APM, or a two-sided Advanced APM. In other aspects, the models are essentially identical.

Components of the payment methodology are:

- **Eligible Patients** – Patients with ESRD requiring transition to dialysis therapies are eligible to participate in this care model.

- **Episode of Care Duration** – Episode will encompass the first 6 months of dialysis therapy. The start date will be the 1st day of the month in which outpatient dialysis begins. However, if the first day of dialysis falls on or after the 16th of that month, for purposes of this APM the start date will be the 1st day of the following month.
- **Payer type** – This model initially is restricted to patients with traditional Medicare as the primary payer. However, the model should be readily adaptable to other payer types.
- **Attribution event** – The date of first dialysis treatment as entered on CMS Form 2728 and subsequent Medicare Part B claims (CPT codes 90960 through 90970) for that patient by a nephrologist or nephrology practice group participating in this APM will determine attribution of the incident dialysis patient.
- **Risk Adjustment Methodology** – An individual Medicare beneficiary's most recent Hierarchical Condition Category (HCC) risk score normalized such that an average risk patient would have a score of 1.0 will be used for risk adjustment. This value as described herein represents the normalized HCC and is virtually identical in methodology to that already in use in ESCOs. A value >1.0 would indicate co-morbidities that are associated with higher costs of care, whereas a value <1.0 is indicative of the converse.
- **Truncation**— All expenditure values will be subject to truncation in order to limit financial risk posed by high-cost beneficiary outliers analogous but not necessarily identical to the methodology utilized for ESCOs. The truncation methodology, yet to be determined, will focus on the timeframe of the first 6 months of dialysis therapy.
- **Financial Benchmark** – This is the dollar amount of included Medicare Part A and Part B costs representing the local historical expenditures for the first 6 months of incident dialysis patient care based on Medicare claims data. This figure is based on that derived from the Healthcare Referral Region of the APM participant based on the most recent two years of claims data. If numbers are insufficient to yield an actuarially sound target cost, then data from contiguous healthcare referral regions may be used to the extent necessary to yield valid figures. Adjustments to this figure will occur through a trending exercise similar to that used within the ESCO program in order to account for changes in health care costs over time. This value is also subject to truncation due to high-cost outliers as described above. This average historical dollar amount is then divided by the average of normalized HCC scores of these same patients in order to arrive at the Financial Benchmark for the average risk patient within the local market.
- **APM Episode Adjusted Patient Cost –** The included Medicare costs for the episode of care of patients attributed to APM participants are determined following the appropriate reconciliation date. The total monies expended, subject to truncation due to high-cost outliers, are then divided by the number of attributed patients during the period to arrive at an average spend. This figure is then divided by the average normalized HCC score in order to adjust for severity of illness. This final calculated dollar amount represents the APM Episode Adjusted Patient Cost.
- **Included Medicare Costs** – All Medicare Part A and Part B costs with the exception of those attributable to transplant and those described in the following paragraph.

- **Excluded Medicare Costs** – This APM model's financial calculations will exclude both the capital and operating components of Medicare's Indirect Medical Education and Disproportionate Share Hospital payments applicable to Part A claims. Uncompensated care payments will also be excluded from calculations of actual costs. All kidney transplant-related services will also be excluded, including costs for care of delayed graft function. A patient already attributed to an APM participant on the basis of ESRD and who receives a kidney transplant during the episode duration of the model is thereafter excluded from the model. Actual costs occurring prior to the transplant can be "semi-annualized" against the episode target cost such that the nephrologist would not lose the financial opportunities from efforts resulting in the transplant. The 2% sequestration calculation will likewise be excluded from calculations; however, it will be applied to any payout of shared savings as required by law.
- **Total Quality Score Threshold** – This represents the APM participant's minimum total quality score below which no shared savings may be paid to the participant for the current reconciliation period. This score is by consensus established to be 30.
- **Reconciliation Periods** – This APM proposes two reconciliation periods annually, demarcated by June 30th and December 31st. For attributed patients whose episodes of care overlap those dates, reconciliation periods for those patients will occur following one of the above dates after which the episode has ended. As claims for patients may continue to occur in the weeks thereafter, expectations for reconciliation and calculations of shared savings or losses may take up to 4 months thereafter, following which time payment for shared savings or payback arrangements for shared losses should occur.
- **Savings (or Losses) Calculations** –The difference between the Financial Benchmark and the APM Episode Adjusted Patient Cost described above multiplied by the number of patients attributed during the episode determines the total Savings or Losses dollar amount.
- **Minimum Savings Rate –** For the MIPS APM (with no downside risk), the minimum amount of savings that must be achieved in order for an APM participant to be eligible to share in those savings is 3% of the Financial Benchmark. For the Advanced APM, this minimum savings rate is 1%.
- **Shared Savings Split** – If shared savings are found to have occurred, then the participant(s) responsible for those savings will be allotted a portion of those dollars. For either the MIPS or Advanced APM options the shared savings split will be 75% for APM participants and 25% for CMS.
- **Quality Adjusted Dollars –** This represents the final step in determination of the dollar amount of shared savings payable to the APM participant in a given reconciliation period. This is calculated by multiplying the Total Quality Score expressed as a percentage by the dollar figure of Shared Savings Split due the APM participant.
- **CEHRT Utilization –**Certified EHR Technology is required for use in this PFPM APM as described in the MACRA Final Rule.
- **Risk –** No downside risk occurs in the MIPS APM model option. For the Advanced APM, the model complies with the requirements in the MACRA final rule to expose

participants to at least nominal financial risk. This model establishes a minimum loss rate of 4%. That is, if the actual costs do not exceed 4% of the Episode Target cost, the participants will not share in the losses. However, if actual costs exceed 4% of the Episode Target cost, participants will be responsible for at least 50% of those losses and as much as 75% of the losses. The actual percentage of the loss paid by the participant will be directly dependent of the Total Quality Score. Importantly, the participants' downside risk is capped at 8 percent of the average estimated total Medicare Part B revenues received for attributed patients during this episode of care by participating providers.

- **Payback Mechanism –** In the event shared losses requiring payback occur in the Advanced APM model option, then the MACRA final rule specifies that this may occur by either a withhold, or a specified reduction in future payments until the amount is recouped, or the participant may pay a lump sum. This model proposes to adjust the payback amount based on the level of Quality Score achieved, as long as the score exceeds the Total Quality Score Threshold, such that less payback may be required for achieving a higher Quality Score. The methodology for this conceivably could be similar to that already created for payback within the ESCO model.
- **Pre-emptive Transplant Bonus –** This model proposes a one-time bonus to the nephrologist participant for any Medicare eligible patient under the care of that nephrologist and who receives a kidney transplant prior to the initiation of dialysis therapy for treatment of ESRD. Upon the reconciliation period defining date following the transplant (date and occurrence documented by CMS Form 2728 done by the transplanting facility), the nephrologist participant will complete and sign an attestation statement documenting the physician participant's role in facilitating the transplant. Medicare claims data will be recognized as documentation substantiating that attestation. The nephrologist participant will then receive $3000 as a one-time bonus.
- **Transplant during Episode Bonus –** Should kidney transplantation occur after the patient has begun dialysis therapy for treatment of ESRD but prior to the end of the episode duration, the nephrologist participant responsible for facilitating the kidney transplant will be eligible for a one-time bonus of $1500.

The chart below provides hypothetical examples of how different nephrology practices might fare in the model based quality metrics scoring and the practice's cost/savings differential.

Category	Baseline	Example Group 1	Example Group 2	Example Group 3
Type of APM	N/A	MIPS APM	AAPM	AAPM
Total number of incident dialysis patients annually	20	20	20	20
Total eligible number of incident dialysis patients	N/A	10	10	10
Advanced Care Planning	Unknown	100% 15 points	90% 9 points	80% 3 points
Catheter rates day 90 (In-Center)	75% on day 90 (80% on day 1)	65% 3.3 points	62% 4.3 points	68% 2.3 point
Catheter rates day 180 (In-Center)	60% on day 180	40% 5 points	45% 3.75 points	58% .5 point
Optimal Starts	29.6%	35% 5 points	40% 10 points	25% 0 points
Fistula rates, day 180 (of total perm access, HD)	71%	65% 5 points	70% 10 points	65% 5 points
Home Dialysis	6-10%	12% 3 points	15% 7.5 points	8% 0 points
Referral to Transplant Center	Unknown	Reporting 10 points	Reporting 10 points	Reporting 10 points
Patient Centered Functionality Evaluation	N/A	Reporting 10 points	Reporting 10 points	Reporting 10 points
Patient Experience	Unknown for Incident dialysis.	Reporting 10 points	Reporting 10 points	Reporting 10 points
Total Quality Score	N/A	66.3 points	74.6 points	40.8 points
Overall Cost of Care	$65,000 per patient (10 patients, $650,000)	$620,000	$610,000	$660,000
Total Savings	N/A	$30,000	$40,000	($10,000)
Percentage of savings from baseline	N/A	4.62%	6.15%	(1.54%)
Saving eligibility / Risk		MIPS APM 25%/75% 75% x 66.3% = %49.7	AAPM 25%/75% 75% x 74.6% = %56	Total costs <4% over baseline costs
Physician Shared Savings		$30,000 x 49.7% $14,910	$40,000 x 56% $22,400	None
CMS Shared Savings		$15,090	$17,600	None
Outcome		Quality improvement with cost savings	Quality improvement with cost savings	Quality improvement without cost savings
*Additional cost savings associated with pre-emptive transplant and renal transplant in the first 6 months of dialysis. Physicians would receive added payment for these transplants.				

V. Value over Volume

Nephrology practices that embrace this model conceptually will have greater incentives than exist currently to take every step possible to ensure that late stage CKD patients are appropriately prepared for the transition to ESRD; or, to choose conservative, medical management and to minimize both the difficulties patients encounter during this transition and adverse situations such as hospitalizations and infections. Given that the majority of care is provided locally, it is our belief that nephrologists will autonomously create solutions that improve patient care (which we believe would be a primary catalyst for innovation), patient choice and access to multiple modalities that fit with the geography in which they practice. This model will give them the latitude to do so.

While this CEC model does not prescribe specific process changes for physicians, there are numerous potential process improvements that physicians and their practices may adopt to succeed in this model. Examples might include:

1. Systematic referral of all appropriate patients with CKD stage 4 (eGFR <30ml/min) to one or more kidney education class(es);
2. Robust structure to identify patients who might not benefit from dialysis. This non-financial incentive could improve patient-centered care by allowing physicians, patients and caregivers to explore alternatives to dialysis when dialysis will neither improve the patients' longevity or quality of life;
3. For patients identified as unlikely to benefit from dialysis, development of medical management as a distinct care modality option. This option would focus on proactive management of the patient's co-morbid conditions to optimize their quality of life and would not necessarily encompass hospice or palliative care;
4. Formal and coordinated efforts to educate patients and family members regarding treatment options, patient wishes and advanced care planning and increased patient choice and access to home dialysis modalities;
5. Care coordination with vascular surgeons for streamlined and efficient placement of optimal dialysis vascular access. This might include collaboration with office or dialysis-facility vascular access managers;
6. Coordinated initiation of dialysis directly in the outpatient setting, bypassing the need for hospital admission to begin dialysis therapy;
7. Coordinated referral of all eligible and appropriate patients for pre-emptive renal transplant (before dialysis initiation) or early referral after starting dialysis;
8. Rapid office visits for ESRD patients with signs or symptoms of infection or other illness, including additional office days or hours; to reduce Emergency Department visits;
9. Process improvement for care coordination with other specialists and the patient's primary care physician, including enhanced evaluation after hospitalizations; and
10. Regular evaluation of patient satisfaction, perception of care, care goals and functional status.

VI. Flexibility

One of the primary positive attributes of the RPA Incident ESRD APM proposal is the degree of flexibility that it would provide prospective participants. The absence of a top-down structure that would otherwise dictate specific services and activities that must be provided in a payment model, provides the nephrology entity with the autonomy to determine the staffing arrangements, specialist relationships, health information technology (HIT) infrastructure, and services and interventions most appropriate for their patient populations and local circumstances.

Additionally, RPA recognizes that for a host of reasons, (small numbers, too little upside, or current participation in other APMs) nephrologists may determine that this model will not be suitable for their particular situation, and will not participate. Once the payment methodology has been thoroughly vetted, in an effort to facilitate adoption by smaller practices, a tool to assist physicians or practices in determining whether to participate or not can hopefully be developed. As noted previously, we believe this model will be adaptable for use in urban, suburban, and rural settings. Regarding operational burdens and reporting requirements, practitioners who have been participating successfully in CMS' incentive payment programs in recent years will not have significant difficulty adapting their practice activities or information systems to accommodate the needs posed by this ESRD CEP model. RPA also has created the only nephrology-specific Qualified Clinical Data Registry (QCDR), which will facilitate nephrologist participants' collection of real-time data, patient management including implementation of quality improvement programs, and project submission requirements.

VII. Ability to be Evaluated

This payment model meets the criteria put forth in the June 30, 2016 edition of the Federal Register for a nephrology-based APM. These criteria include: (1) incentivizing coordination of care for incident dialysis patients; (2) promoting renal transplantation; (3) removing obstacles and disparities for patient choice of dialysis modality; (4) encouraging more focused upstream CKD patient care and care coordination; (5) promoting quality of life, medical management and advanced care planning; and (6) improving overall quality at reduced cost. By virtue of its impact on total cost of care, hospitalization rates, and pre-specified, valid clinical metrics, CMS and other payers will be able to objectively measure the model's impact on quality and the cost of care for patients starting dialysis. Additionally, physician experience under this model could be evaluated both by direct survey to participating physicians and by monitoring adoption rates of the model.

The clinical and patient-centered metrics that were chosen for this APM have been demonstrated to align with optimal patient care and align with those of the CMS-approved, kidney-specific RPA QCDR. Similarly, in spite of numerous nationwide attempts to improve these metrics, they each have remained relatively stagnant for the past decade. In some cases, such as home dialysis rates, there has even been regression over time even though home dialysis has been repeatedly

demonstrated to improve certain patient outcomes. The clinical metrics of this APM include nine metrics within three broad domains:

1. Patient-centered care coordination: Advanced care planning and referral to transplant center
2. Clinical outcomes: Catheter rates, Optimal Starts, Fistula rates, and Home dialysis
3. Patient functionality and experience: Karnofsky functionality score and PROMIS patient experience scores.

VIII. Integration and Care Coordination

Optimal transition to dialysis requires significant thoughtfulness and planning during mid and late stages of CKD. This includes patient and caregiver education; patient-centered, shared decision making; coordination among medical specialists; and coordination with dialysis providers. Patients may benefit substantially both from a quality of life standpoint and overall health status when they have an optimal transition to dialysis. This includes the option for home dialysis and beginning hemodialysis without an indwelling central venous catheter. Equally important, patients may benefit from the optimal non-transition to dialysis, including pre-emptive renal transplant or medical (conservative) management. These optimal transitions require substantial coordination in a patient-centered manner. Currently, this level of coordination is not reimbursed by the traditional Medicare fee schedule, thereby limiting effective optimal dialysis transition. Of potential utility in the care of patients with mid- to-late stage CKD would be the *RPA's Advanced CKD Patient Management Toolkit*, a field-tested suite of materials intended to promote awareness among primary care providers regarding the risk factors of CKD and to facilitate the transition from primary care to nephrology care. (Haley, et al, AJKD 2015; 65; 67-79).

IX. Patient Choice

RPA strongly believes that patient involvement is a key element in effective chronic disease management, and this commitment led the organization to develop and publish the *RPA Clinical Practice Guideline on Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis*. The catalyst for RPA's efforts in this area is the realization that while dialysis is a life sustaining therapy, it can also be a difficult and challenging journey that is not necessarily appropriate for or desired by all patients, and that decisions on whether or not to embark on this journey should be fully informed and carefully considered. This guideline provides 19 recommendations for initiating, withholding and withdrawing dialysis in adult and pediatric patients with acute AKI, CKD, or ESRD. The guideline represents consensus expert opinion informed by ethical principles, case and statutory law, and systematic review of scientific evidence.

In the current fee-for-service structure, the vast majority of patients do not start dialysis optimally. Currently, 80% of all hemodialysis patients start dialysis with a hemodialysis catheter, which vastly increases the likelihood for infection, hospitalization and death. These patients also incur higher costs of care compared to those patients that start optimally. Similarly,

the overall penetration of home dialysis in the United States remains flat at only 10-13%. Home dialysis is not only a less costly option for patients, but has been shown repeatedly to improve patient experience and quality of life.

By indirectly incentivizing physicians to enhance upstream patient education, patients and caregivers will experience greater understanding of treatment options and modality choice. Similarly, by monitoring and tracking advanced care planning, patients will continue to have a greater voice in their clinical treatment goals both during the six months while they are under the umbrella of this APM and when they become prevalent ESRD patients after they exit this APM.

X. Patient Safety

Dialysis patients are at great risk for hospitalization. The reasons for this are multifactorial and include both the prevalence of comorbid conditions and excess risks associated with non-optimal transition to dialysis (or renal transplant). Each hospitalization is associated with significant patient safety risk, including hospital-acquired infections, decrease in functional status and nutritional decline. The latter two items increase the risk for wound formation and reduction in self-care ability. Therefore, all interventions that reduce hospitalization have an immediate beneficial impact on patient safety.

Furthermore, patients that start dialysis without a hemodialysis catheter are at lower risk for catheter-related infections, inflammation, inadequate dialysis toxin clearance and inadvertent catheter dislodgement with blood loss. Other patient safety concerns include medication errors and insufficient medication reconciliation, which will compromise patient outcomes if left unaddressed. To address patient safety in renal care broadly, RPA created the *Keeping Kidney Patients Safe* website, a resource for nephrologists seeking to achieve and maintain optimum levels of kidney patient safety.

XI. Health Information Technology

As noted above all participants in either the non-risk APM or the downside risk AAPM would be required to utilize CEHRT, which should serve to address patient privacy concerns. Given that the model is not overly prescriptive, we anticipate that health information innovations such as telehealth and remote monitoring could be used as part of the health care delivery and monitoring structure, and that participating groups would have the flexibility to choose the HIT infrastructure most appropriate for their geography and practice. The RPA QCDR would be available to prospective model participants and would facilitate the collection of data for patient and disease tracking to foster improvement in the quality of care provided to the patients being treated as part of the model.

XII. Supplemental Information

1. United States Renal Data System 2016 Annual Report. https://www.usrds.org/adr.aspx
2. Karnofsky Performance Status Scale. http://www.hospicepatients.org/karnofsky.html
3. PROMIS® (Patient-Reported Outcomes Measurement Information System). http://www.healthmeasures.net/explore-measurement-systems/promis

4. Renal Physicians Association, Advanced CKD Patient Management Toolkit. http://c.ymcdn.com/sites/www.renalmd.org/resource/resmgr/Chronic_Kidney_Disease/How_to_Utilize_RPA's_Advance.pdf
5. Improving Care Coordination Between Nephrology and Primary Care: A Quality Improvement Initiative Using the Renal Physicians Association Toolkit. http://www.ajkd.org/article/S0272-6386(14)01061-0/abstract.
6. Renal Physicians Association, Clinical Practice Guideline on Shared Decision Making in the Appropriate Initiation of and Withdrawal from Dialysis. http://c.ymcdn.com/sites/www.renalmd.org/resource/resmgr/Store/Shared_Decision_Making_Toolk.pdf.
7. Renal Physicians Association, Keeping Kidney Patients Safe Website. http://www.kidneypatientsafety.org/
8. Renal Physicians Association, Kidney Quality Improvement Registry. http://www.renalmd.org/page/RPAkidneyquality.