On October 24 CMMI released the long-awaited Request for Applications (RFA) for what is now being called the Kidney Care Choices model, which is comprised of Kidney Care First (KCF—the nephrologist/nephrology practice only model) and the Kidney Care Entities (KCE—the risk-bearing models that require the participation of a transplant provider in addition to the nephrology component).

The RFA document presents a series of general provisions that apply to both the KCF and KCE models, followed by more detailed discussions of both models. However, many of the topics or provisions outlined in both the separate KCF and KCE discussions are identical, including the descriptions of the CKD Quarterly Capitation Payment (CKD QCP), the Adjusted Monthly Capitation Payment for Dialysis (AMCP) for ESRD patients (which as we were aware is set at the 2-3 visit level of the current MCP), and a list of benefit enhancements on issues such as application of the kidney education benefit, telehealth for home patients, home health, and hospice. Also, both the KCF and KCE sections include an application template for potential participants.

A summary of the key points outlined in the general provisions and both models is provided below. More detailed analysis and guidance for RPA members on the benefits and challenges of participating in the voluntary models will be forthcoming soon.

The full RFA is available at the following link:

https://innovation.cms.gov/Files/x/kcc-rfa.pdf

General Provisions

Timeline

- Application responses due January 22, 2020
- Application decisions made and participants informed-- Winter 2020
- Agreements to be signed-- Spring 2020
- Implementation Period--2020
- Performance year 1—2021; Performance year 2—2022, etc.
Monitoring and Oversight

CMMI will be working along with the Center for Program Integrity and the Office of Financial Management to monitor and assess the performance of individuals and entities participating in the Models.

CMS monitoring activities may include:

- Audit of samples of medical charts.
- Monitoring of beneficiary complaints and surveys.
- Analysis of claims and quality data.
- Vetting of model participants and their providers/suppliers and affiliated individuals and entities on the basis of program integrity issues.
- Review of warranted versus unwarranted inpatient services.
- Monitoring of external sources for sanctions, lawsuits, and investigations.
- Monitoring for appropriate use of Medicare Benefit Enhancements.

Screening, Evaluation, and Learning and Diffusion Resources

The RFA contains separate sections on screening, evaluation, and ‘learning and diffusion resources’. The screening section outlines the elements of the screening process (such as current Medicare enrollment status, identification of delinquent debt, and performance in other CMS models). Regarding evaluation, the RFA notes that CMS is legally required to conduct an evaluation of the KCC Model to determine whether the Model results in improved quality of care and reduced Medicare spending, while the ‘learning and diffusion’ passage discusses how CMMI will be helping participants succeed and the methods for sharing information among participants. In this section, CMS states that “All selected KCF practices and KCEs are required to participate in periodic conference calls and meetings, and actively share resources, tools, and ideas with each other via an online collaboration site being developed by the Innovation Center.”

Interoperability Requirements

As expected, interoperability capabilities among participants will be required, and CMS notes in the RFA that there is an “Interoperability and Patient Access Notice of Proposed Rulemaking (NPRM) that sets forth CMS’ proposed goals in promoting interoperability for all providers, suppliers, and CMS-funded payers and health plans across multiple programs and models.”

In addition to what gets finalized from the Interoperability NPRM, KCC model participants will be required to (1) make full electronic health data available to all patients within 24 hours of an encounter; (2) support electronic, interoperable data exchange with other providers/suppliers and health systems, using 2015 CEHRT; and (3) connect to regional and/or national/vendor-mediated health information exchange (HIE) to send and receive electronic alerts for patient transitions of care from hospitals or other providers, for all patients.
Waivers

On the issue of waivers, CMS includes a table in the RFA with the payment rule waivers they will be allowing; these are the ‘benefit enhancements’ referred to earlier on KDE, telehealth and home dialysis, home health, etc. However, CMS also notes that the Secretary will consider issuing fraud and abuse waivers at a later juncture, but they are not being issued in the RFA. That is not surprising in that the Office of Inspector General (OIG) and the Department of Justice are much more circumspect in allowing fraud and abuse waivers and waiting for those would have further delayed the release of this RFA.

Kidney Care First Option

The KCF option can be used by nephrologists and nephrology practices solely, and as noted has many features that are identical to the KCE model that also requires participation of a transplant provider and involves varying levels of risk. Key points from each section of the rule are provided below.

Legal Entity

The RFA states that the applicant must be a Medicare-enrolled entity (i.e., physician practice or professional corporation) that bills Medicare for physician services rendered by one or more nephrologists. In the case of a physician practice, the application must identify each nephrologist in the entity that has reassigned his or her right to receive Medicare payments to the entity. At least 80% of nephrologists in the entity that have reassigned the right to receive Medicare payments to the entity must participate in the Model. Each entity must be recognized and authorized to conduct business under applicable state law. To be eligible for KCF participation, the entity must be capable of:

- Receiving the payments under the KCC Model from CMS;
- Repaying any required reconciliation payments to CMS, if applicable;
- Establishing reporting mechanisms and ensuring compliance with program Model requirements, including but not limited to reporting on quality measures.

Additionally, the RFA states that generally, a specific governance structure for the purposes of the KCF is not required, as long as the practice can fulfill all of the obligations set forth in the RFA.

Applicant Eligibility

Nephrologists in KCF practices must meet all of the following requirements for the duration of their participation in the Model:

- Must be enrolled in Medicare;
- Must self-identify as nephrologists for the purposes of this Model. CMS will verify this information against PECOS, or through other means, including claims data.
Practices must meet all of the following requirements in order to be eligible to participate in the KCF Option and for the duration of their participation:

- A practice is defined as all individual National Provider Identifiers (NPIs) billing under a single TIN at a practice site’s physical address. To be eligible to participate in the KCF Option, the practice will need to demonstrate that at least 50% of the practice’s total revenue from the previous 6 months comes from nephrology services;
- At least 80% of all nephrologists that have reassigned their rights to receive Medicare payment to the practice must participate in the Model.
- The practice must receive at least 50% of its Medicare payments for services furnished to beneficiaries with CKD, ESRD, or a functioning transplant.
- The practice must provide certain services to a minimum of 500 late stage CKD and 200 ESRD aligned Medicare beneficiaries over the course of the previous 6 months. There is no requirement that the KCF practice furnish services to a minimum number of transplant beneficiaries.
- The practice must use the 2015 Edition Certified Electronic Health Record Technology (CEHRT), support data exchange with other providers and health systems via Application Programming Interface (API), and connect to their regional health information exchange (HIE).
- The practice must demonstrate the ability to assume financial risk and make any required repayments to the Medicare program.
- The practice and its locations must be entirely within a single KCF market area. A KCF market area is a geographic area which contains no more than four Medicare Core Based Statistical Areas (CBSAs), and any rural counties not included in Medicare CBSAs within the same state or states as the included CBSAs. The CBSAs included in the KCF market area need not be contiguous but must be connected by rural counties and/or have no more than one CBSA in between CBSAs included in the KCF market area. Alternatively, a KCF practice may be located in rural counties only, in which case all included rural counties must be located in the same state. Nephrology practices in the state of Maryland will be able to apply to participate in a KCE.

Individual nephrologists cannot participate in the KCE model, but nephrology practices can apply to be in both the KCF and KCE models, and if both applications are approved, choose the model in which to participate. Further detail is provided in the RFA on the interactions between KCFs and other shared savings programs.

Beneficiary Eligibility and Alignment

CMS provides a long list of criteria for a beneficiary to be eligible for inclusion in the model, provided below:

- Be enrolled in Medicare Parts A and B.
• Not be enrolled in a Medicare Advantage plan, cost plan, or other non-Medicare Advantage Medicare managed care plan.
• Reside in the United States.
• Receive the plurality of their Monthly Capitation Payments (MCPs) billed in the KCF practice’s market area, defined in section III.B of this RFA (ESRD beneficiaries only).
• Receive the plurality of their CKD care in the KCF practice’s market area (CKD beneficiaries only).
• Be 18 years of age or older.
• Be alive.
• Not have acute kidney injury (AKI).
• Not have already been aligned to a Medicare Accountable Care Organization (ACO) or another participant in a Medicare program/demonstration/model involving shared savings as of the date of alignment for the KCF Option (please refer to Section 14, Overlap, for additional information).
• Not have Medicare as a secondary payer.

One participation requirement that seems likely to exclude some potential participants is that during each performance year, KCF practices must have a minimum of 500 aligned Medicare beneficiaries with late stage CKD and 200 aligned Medicare ESRD beneficiaries. Also, CMS will prospectively align beneficiaries to KCF practices based on claims data and nephrology services. A lengthy description of how alignment and de-alignment of patients to a practice is provided, but long story short, it is based on E&M and/or nephrology services provides to a beneficiary, and how that might fluctuate. Transplant patients will remain aligned to their KCF practice for 3 years from the month of transplant in order for the KCF practice to be eligible to receive Kidney Transplant Bonus payments.

Beneficiary Protection and Data Sharing

There are sections in the RFA on beneficiary protection and data sharing, with the beneficiary protection section focused mainly on the educational materials that a practice will be required to provide to a patient aligned to their practice, and addresses marketing materials and activities. In the data sharing section, CMS notes that it will provide historical and monthly claims data to KCF practices, consistent with data sharing practices in the CPC+ Model and in shared savings models and programs, and that all information will be provided consistent with all applicable laws and regulations.

Finances and Payment

The RFA outlines the previously promulgated payment types of a CKD quarterly capitated payment (QCP), an adjusted MCP (AMCP), and the kidney transplant bonus (KTB). For the CKD QCP, it is designed to give a predictable upfront payment for CKD services; but in lieu of the typical E&M services that would be provided to these patients. As such, the following code families are included in the QCP and thus not separately billable:
Office/Outpatient Visit E/M 99201-99205, 99211-99215
• Prolonged E/M 99354-99355
• Transitional Care Management Services 99495-99496
• Advance Care Planning 99497-99498
• Welcome to Medicare and Annual Wellness Visits G0402, G0438, G0439
• Chronic Care Management Services 99490

CMS states in the rule that:

*KCF practices will still be required to submit claims with the relevant codes for data collection and quality purposes, but the CKD QCP will be the only payment to the KCF practice for the included services furnished to aligned beneficiaries with CKD stage 4/5.*

So, this means that KCF practices will be expected to submit claims for these E&M code families but will not be paid for them.

With regard to the payment, CMS states that the CKD QCP it will be the same as the AMCP, which is to be set at the current 2-3 visit level of the MCP, so this quarterly payment figure would be approximately $242.

As for the AMCP, the $242 payment would occur regardless of the number of visits the nephrologist has with the patient in a month, unlike the current fee-for-service MCP. The rationalization that CMS provides for this decision is that: (1) that studies show there is no relationship between the number of MCP patient visit and outcomes; (2) the current structure creates an incentive to pursue 4 visits every month, while the revised structure will reduce provider burden and allow nephrologists to focus on care quality rather than the number of visits; and (3) the current payment structure of the MCP creates a bias toward in-center hemodialysis.

For the kidney transplant bonus (KTB), CMS states that:

*KCF practices are eligible for a bonus payment for every aligned beneficiary who receives a kidney transplant, whether from a living or deceased donor, and does not return to dialysis. KCF practices would also receive the KTB payment when an aligned beneficiary receives any future FDA-approved products that replace physiological kidney function.*

As noted in CMS’ press releases on the KCF from July, it will set the amount of the KTB payment at $15,000 per transplant, paid to the KCF practice. The KTB will be disbursed to the KCF practice as follows: $2,500 one year after transplant, $5,000 two years after the transplant, and $7,500 three years after the transplant, as long as the transplant remains successful.

Like the mandatory ETC model, the KCF model utilizes a performance-based adjustment (PBA) system for determining bonus payments based on quality and utilization of services. CMS notes in the rule that the PBA could increase a KCF practice’s revenue by up to 30 percent of its
combined CKD QCP and AMCP, or, on the other hand, reduce that revenue by as much as 20 percent of those payments, with details in an included table.

Two distinct sets of performance measures will be used in calculating the PBA:

- **Quality Gateway** – a set of quality measures, with performance thresholds, designated to reflect appropriate clinical care and patient experience for the affected population, and
- **Utilization Measures** - aimed at incentivizing efficient and appropriate provision of health care services for the patient population.

Within the PBA, participants will be evaluated on a Relative Performance (RP) Component (both with other KCF practices and possibly with all nephrology practices nationally), and a Continuous Improvement (CI) Component based on improvement measures relative to prior performance. As with the ETC, the performance periods would be continually adjusted six-month periods, with a table included displaying the periods over the three performance years currently scheduled. CMS also provides detail on the magnitude of the bonuses or penalties, but in short there are 8 levels of penalty or bonus, with the top six being positive or upward adjustments and the bottom two downward, with as noted the range extending from +30 percent (maximum upside potential) to a -20 percent (downside risk) adjustment.

**Quality Strategy**

In the Quality Strategy section of the document, CMS outlines the two types of measures it will use, the Quality Gateway measures and the Utilization Measures.

The measures included in the Quality Gateway are:

- Gains in Patient Activation (PAM) Scores at 12 Months; NQF #2483
- Depression Remission at Twelve Months – Progress Towards Remission; NQF #1885
- Controlling High Blood Pressure; NQF #0018

The utilization measures are:

- **Optimal End Stage Renal Disease (ESRD) Starts; NQF #2594** – The percentage of new ESRD patients during the measurement period who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, by initiating home dialysis, or by initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft.
- **Hospitalization Costs** – This measure assesses the risk-adjusted ratio of observed-to-expected inpatient admission and observation stay discharges during the measurement year based on an average cost measure per hospitalization, adapted from the Standardized Hospitalization Ratio (SHR) measure approved by NQF. During PY0, CMS will consider whether any additional adjustments to its current specifications would be needed given the specific characteristics of the Model’s patient population. In that case,
CMS would determine whether re-specifications would be appropriate for the Model, and, accordingly, whether to include the revised measure in the utilization measure set in PY1 or PY2 and subsequent years.

- Total Per Capita Costs (TPCC) – This measure is a payment standardized, annualized, risk adjusted, and specialty adjusted measure that evaluates the overall cost of care provided to beneficiaries attributed to solo practitioners and groups, and is currently used as a cost measure in MIPS.

**Benefit Enhancements**

The waivers or ‘benefit enhancements’ that CMS provides in the RFA are in the following areas: (1) KDE; (2) Telehealth; (3) Post-Discharge Home Visits; (4) Home Health; (5) Home Health Services Certified by Nurse Practitioners; and (6) Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit. As noted, any fraud and abuse waivers that might be provided by the OIG or DOJ are yet to come, but some provisions from the recent proposed rules on physician self-referral and anti-kickback statutes may be applicable to the KCF activities.

**Termination and Application**

Concluding the KCF section of the RFA are provisions on termination and guidance on how to submit an application. The termination section notes that CMS reserves the right to terminate a KCF Practice’s Participation Agreement or require the KCF practice to terminate its agreement with a participating nephrologist at any point during the Model for reasons associated with poor performance, program integrity issues, non-compliance with the terms and conditions of the Model, or if otherwise specified in the KCF Participation Agreement. The application component of the RFA provides functional instructions on how to submit the application, and also includes a template for how to develop an application.

**The Comprehensive Kidney Care Contracting (CKCC) Options (for KCE Entities)**

As noted above, there are numerous provisions in both the KCF and the KCE sections of the RFA, including the CKD QCP, the AMCP, Benefit Eligibility, and the Benefit Enhancements that are very aligned if not identical, and thus will not be re-summarized below.

Regarding what is different, this section opens by noting that “KCEs must be comprised of nephrologists and/or nephrology practices, and transplant providers (i.e., a transplant center, transplant surgeon, transplant nephrologist, and/or organ procurement organization (OPO)), and may include other providers and suppliers that help to coordinate the care for beneficiaries with late stage CKD (stages 4 and 5) and ESRD, including dialysis facilities.”

CMS states that it will be creating a Graduated Option loosely based on the existing one-sided risk track of the CEC Model in its first year, a Professional Option based on the Professional Population-Based Payment option of the CMMI Direct Contracting (DC) Model, and a Global Option based on the Global Population-Based Payment option of the DC Model.
Sections addressing the Legal Entities, Contracting Requirements, Governance and Applicant Eligibility seem to mirror closely what was developed for the ESCO program. The Applicant Eligibility section does note that transplant providers may participate in multiple KCEs, while nephrologists and dialysis facilities may only participate in a single KCE and can be added to the model as KCE participants only at the beginning of each performance year, a restriction that does not apply to other types of participants. Also, All KCE participants must be physically located in the KCE’s market area.

CMS also lays out the three options potential applicants can utilize to participate in the CKCC: the Graduated Option that has no downside risk, the Professional Option where participants take on 50% risk, and the Global Option where participants will be at risk for 100% of the total cost of care for all Medicare Part A and B services for aligned beneficiaries.

Each payment model will use the same benchmark process, which will include the following steps: (1) Determine the baseline/historical expenditure; (2) Apply trending and geographic adjustment factor (GAF); (3) Incorporate regional expenditures; (4) Risk adjust; and (5) Discount and quality adjustments. The benchmarks will be calculated prospectively and given to KCEs at the start of each performance year and may be adjusted to account for CKD progression.

One other substantial difference between what was outlined for KCFs versus KCEs in the RFA is the depth to which financial issues such as assets, minimum savings rates, minimal loss rates, risk corridors, financial assurances, and stop loss are addressed, which is understandable given that in the KCF CMS will be reimbursing nephrology practices similarly to how this has been done in the past, while administering the program for the KCE entities will be much more similar to the more complex arrangements associated with the ESCOs.

Next Steps

Considering that this is not a proposed rule, no formal comment process is in place, so it remains to seen to what extent CMS may consider any modifications to the RFA. However, since these are voluntary models being proposed, the Agency may not be willing to make refinements, and nephrology practices will have the option to pass on participation. RPA will continue to further review the RFA to help nephrology practices determine the appropriateness of participating in any of the models.