

Centers for Medicare & Medicaid Services (CMS)
Center for Medicare and Medicaid Innovation (CMMI)
Kidney Care Choices (KCC) Model

Request for Applications (RFA)

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I. The Kidney Care Choices (KCC) Model Overview

A. Background and Introduction

Chronic kidney disease (CKD) is the ninth leading cause of death in the United States, based on 2016 figures from the National Center for Health Statistics. According to 2017 data from the Centers for Disease Control and Prevention (CDC), CKD impacts over 30 million or 15% of Americans, and most of them are unaware that their kidneys have reduced function or are failing. While there are certain factors predisposing people to CKD, such as age and race, most causes of CKD are acquired rather than inherited. Diabetes and hypertension accounted for up to two-thirds of all cases, followed by diseases that damage the kidney's filtration units.

According to the United States Renal Data System (USRDS), in 2016 Medicare beneficiaries with CKD accounted for \$79 billion in Medicare spending, in addition to \$34 billion for the end-stage renal disease (ESRD) population, for approximately \$114 billion in total expenditures.

Once an individual has progressed to stage 4 CKD, when their glomerular filtration rate (GFR) has decreased to 15-30ml/min, kidney disease has become severe enough that the individual will likely experience specific symptoms and need to consider planning for dialysis or kidney transplantation. Those in stage 4 CKD are likely to develop more severe complications such as hypertension, anemia, bone disease, heart disease, ischemic stroke, and other cardiovascular diseases (CVDs). Once an individual's GFR drops below 15ml/min, they have progressed to stage 5 CKD. During this advanced stage, the kidneys have lost nearly all function. Without intervention, the patient will progress to ESRD, at which point dialysis or a kidney transplant is required for survival (National Kidney Foundation, 2018).

A major challenge in the study and treatment of CKD is the heterogeneity of the condition. For most patients, CKD is asymptomatic and can only be detected with laboratory studies. The time of progression to ESRD requiring renal replacement is variable depending on the patient and comorbidities. Early intervention can sometimes slow the progression of CKD and ESRD.

The best renal replacement therapy for most beneficiaries with ESRD is kidney transplantation, which replaces the failed kidneys with a more functional, healthy kidney from either a living or deceased donor. In 2015, 18,805 kidney transplants were performed in the United States, more than half of which were from deceased donors. Patients who have received a kidney transplant still have kidney disease and still require long term medications and medical care to ensure the health and function of their transplanted kidney. However, kidney transplant is associated with improved quality of life, reduced cardiovascular complications, improved morbidity and mortality, and reduced oxidative stress relative to dialysis. If the transplanted kidney stops functioning, dialysis or another transplant is needed.

As patients with CKD are educated about their treatment options, some patients consider transplantation before, and others after, the initiation of dialysis. In 2016, the Organ Procurement and Transplantation Network (OPTN) deceased donor kidney transplant waiting list held about 121,678 patients. With a wait time of about 3.9 years, approximately 3,000 new patients are added to the wait list each month, while approximately 390 individuals die each month waiting for a donor. Despite a 25% increase in the number of kidney transplants since 2015, the demand for kidney transplant still far exceeds the supply. Other barriers to transplantation include: financial burdens, poor communication between provider and patient, poor patient education regarding transplantation, lack of access to high quality health care services, and the absence of a committed care taker.

The Comprehensive ESRD Care (CEC) Model began in October, 2015, and will run through December 31, 2020. The CEC Model provides financial incentives for dialysis facilities, nephrologists, and other

Medicare providers and suppliers to work together to improve outcomes and reduce per capita expenditures for aligned ESRD beneficiaries in an accountable care organization (ACO) framework. Key features of the CEC Model include: 1) total cost of care accountability; 2) comprehensive and coordinated care delivery; and 3) improved access to care.

Evaluation of the first performance year of the CEC Model for the 13 ESRD Seamless Care Organizations (ESCOs) that began participating in the CEC Model in 2015 (October 1, 2015 through December 31, 2016) demonstrated promising findings, showing lower spending and improvements on some utilization and quality measures. Savings for ESCO beneficiaries were primarily attributed to a reduction in hospitalizations and post-acute care. The CEC Model has also shown improvement in quality of care as demonstrated through a decline in catheter utilization among aligned beneficiaries relative to the comparison (non-ESCO beneficiary) group.

While the CEC Model has shown some preliminary positive results, the current design has several limitations. Based on lessons learned from the first three years of the CEC Model, we have identified the following areas for potential improvement. We plan to incorporate these areas in the design of a new kidney disease-focused model, the Kidney Care Choices Model, which includes the CMS Kidney Care First (KCF) & Comprehensive Kidney Care Contracting Options:

- Including beneficiaries with CKD stage 4 and 5 before they progress to ESRD in the model to promote later and better starts on dialysis, or to avoid dialysis entirely.
- Including beneficiaries after they receive a transplant and incorporating financial incentives to promote greater utilization of transplants.
- Empowering nephrologists to take the lead in coordinating care for beneficiaries across the care spectrum.
- Including Medicare Benefit Enhancements to support improved utilization of skilled nursing facilities (SNFs) and hospice care, telehealth services, and the kidney disease education (KDE) benefit
- Addressing nephrologist payment in order to and better align payments with care.

The Kidney Care Choices (KCC) Model will address these limitations in its test of whether a model of care in which a single set of health care providers with aligned incentives are responsible for a patient's care from the later stages of CKD to and through dialysis, transplantation, or end of life care will improve overall quality of care and reduce the cost of care for beneficiaries with kidney disease. The KCC model designs draw on benchmark and payment methodologies in the CEC Model, the Direct Contracting (DC) Model, and the Primary Care First (PCF) Model.

B. Statutory Authority

Section 1115A of the Social Security Act (added by section 3021 of the Affordable Care Act) (42 U.S.C. 1315a) authorizes the CMS Innovation Center to test innovative payment and service delivery models that have the potential to lower Medicare, Medicaid, and CHIP spending while maintaining or improving the quality of beneficiaries' care. Under the law, preference is to be given to selecting models that also improve coordination, efficiency and quality of health care services furnished to beneficiaries. Section 1899 of the Social Security Act establishes the Medicare Shared Savings Program, and authorizes CMS to share Medicare savings with participating accountable care organizations under certain circumstances.

The KCC Model described in this Request for Applications (RFA) will use the CMS Innovation Center's authority to test a new model of care delivery and payment for Medicare beneficiaries with late stage

CKD and ESRD that is based on the PCF and DC Models. CMS will test whether the financial risk arrangements outlined in this RFA will improve quality of care for beneficiaries with CKD and ESRD and reduce Medicare costs.

C. The KCC Model

For the KCC Model, the Innovation Center builds upon and improves the structure of the financial and payment elements used in the CEC Model to address areas for potential improvement that have been identified through testing the CEC Model. The KCC Model designs draw on benchmark and payment methodologies present in the CEC Model, the DC Model, and the PCF Model. These Models are a condition-specific companion to the DC Model and the PCF Model, fitting in with the Innovation Center's suite of total cost of care models. These models will test whether these design elements reduce Medicare spending and improve the quality and coordination of care for beneficiaries with late stage CKD, ESRD, and kidney transplants.

For the CMS Kidney Care First (KCF) Option, nephrologists and nephrology practices will receive adjusted capitated payments for managing beneficiaries with CKD stages 4 and 5 and ESRD, and will be eligible for upward or downward payment adjustments based on the quality of their performance and improvements in their performance over time. This model is designed to emulate the basic design of the PCF Model, in which participating practices will be accountable for managing the care of attributed Medicare beneficiaries. The KCF Option will include Benefit Enhancements to enable nephrologists to strengthen care coordination for beneficiaries with CKD stages 4 and 5, as well as new financial mechanisms to enable participants to manage cash flow. The KCF Option will be a Merit-based Incentive Payment System (MIPS) Alternative Payment Model APM and an Advanced Alternative Payment Model (Advanced APM) beginning in 2021.

For the CKCC Options, nephrologists and nephrology practices must partner with transplant providers, and may partner with dialysis facilities and other providers and suppliers to become Kidney Contracting Entities (KCEs). KCE nephrologists will receive adjusted capitated payments for managing beneficiaries with CKD stages 4 and 5 and ESRD. The KCE will select a total cost of care accountability framework, and their payments under the model will be adjusted based on their performance on quality measures. As discussed further below, the CKCC Options are built on the frameworks of the DC Model and the CEC Model. KCEs participating in the CKCC Options will be able to participate in the Graduated Option, the first year of which is modeled off of the CEC one-sided risk track in the CEC Model, or the Professional Option or the Global Option, both of which are based on the Professional Population-Based Payment and Global Population-Based Payment options of the DC Model. Each Option will use the same benchmark process, based on the prospective benchmark calculation used in the Professional Population-Based Payment and Global Population-Based Payment options of the DC Model for the standard Direct Contracting Entities (DCEs). The CKCC Options will be Advanced APMs beginning in 2021, with the exception of the Graduated Option. The CKCC Graduated Option will be an Advanced APM in Level 2, as described in greater detail below. All of the CKCC Options, including the one sided Level 1 of the Graduated Option, will be MIPS APMs beginning in 2021. KCEs will also have access to Benefit Enhancements to strengthen care coordination for aligned beneficiaries and alternative payment mechanisms to manage cash flow.

D. Timeline

The Implementation Period of the KCC Model will occur in 2020. The Performance Period of the KCC Model will run from January 1, 2021, through December 31, 2023, with the option for the performance period of the Model to be extended for a period of one or two additional Performance Years (PYs), in which case the implementation and performance period of the Model will run through December 31, 2024, or December 31, 2025.

KCF practices and KCEs will apply to participate in the Model by January 22, 2020, and if selected and execute their respective Participation Agreements with CMS, would begin Model participation in 2020. However, Medicare payment adjustments based on quality and utilization and capitated payments will not begin until PY1. During the Implementation Period, which is the period between the effective date of the Implementation Period- Participation Agreement and the beginning of Medicare payment adjustments and accountability for care furnished to aligned beneficiaries under the Model (which begins in PY1), KCF practices and KCEs will focus on building necessary care relationships and infrastructure. The Performance Period- Participation Agreement will cover PY1 and subsequent performance years.

KCF practices and KCEs will sign their respective an Implementation Period- Participation Agreement that will outline the responsibilities and obligations of CMS and the KCF practices or KCEs during the Implementation Period. To continue participation in the model beyond the Implementation Period, a KCF Practice or KCE must execute a Performance Period- Participation Agreement with a term of three initial PYs (2021, 2022, and 2023). To the extent that CMS extends the entire performance period of the Model, as described above, CMS, in its sole discretion, will determine whether to extend each such Participation Agreement for a term of one or two additional 12-month PYs (2024 and 2025) and will notify participants in advance of each such PY whether CMS is exercising this extension authority. CMS’ determination to extend the performance period of the Model or Models, as a whole, and to extend each Participation Agreement will be based, in part, on whether participants are able to generate savings and/or meet performance standards or other Model requirements during PY1 (2021) and PY2 (2022). Additionally, CMS may terminate a Participation Agreement at any point due to a KCF practice or KCE’s non-compliance with its respective Participation Agreement and/or performance- or program integrity-related issues. CMS also reserves the right to modify or terminate the Model or Models at any time if it is determined that the Model or Models is not improving the quality of care without increasing spending or reducing spending without reducing the quality of care, or otherwise achieving the goals and aims of the initiative.

CMS also expects to add more KCF practices and KCEs to the Models with another solicitation in 2020 or 2021, for participation starting in PY1 (2021) or PY2 (2022). These new participants would not have an Implementation Period and their financial accountability under the Model would begin at the start of their first PY in the Model. The decision to conduct additional solicitations will depend on a variety of factors, including response to the original solicitation, and preliminary Model results. Table 1 provides a high-level timeline of key milestones in the Models.

Table 1. Milestone Timeline

TARGET DATE	MILESTONE
October 24, 2019	Request for Applications for the KCC Model Released
January 22, 2020	Application Responses Due from Potential KCF practices and KCEs
Winter, 2020	Final Application Decisions Made and Acceptances Sent to KCF Practices and KCEs
Spring, 2020	Approved KCF Practices and KCEs sign Implementation Period Participation Agreements
2020	KCC Model Implementation Period
2021	KCC Model PY1
2022	KCC Model PY2

TARGET DATE	MILESTONE
2023	KCC Model PY3
2024	Potential KCC Model PY4
2025	Potential KCC Model PY5

II. General Provisions

A. Monitoring and Oversight

The purpose of monitoring is to ensure that implementation of the KCC Model is occurring safely and appropriately. CMS has developed a multi-pronged approach to program monitoring and oversight that includes a robust performance measurement design complemented by additional oversight-specific metrics, and eligibility criteria and Model participation requirements.

The Innovation Center is collaborating 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’s strategies may include, but not be limited to, the following:

- Analysis of specific financial and performance data reported by the KCF practice or KCE.
- Analysis of beneficiary and provider/supplier complaints including, but not limited to, those submitted through 1-800-MEDICARE, surveys, and internal processes established and supported by the KCF practice or KCE for managing such complaints.
- Audits, including claims data mining, medical chart review, beneficiary survey data, coding audits, and on-site compliance reviews.

In addition, CMS will monitor for inappropriate care – including the withholding of necessary services, inappropriate steering of patients, and non-adherence to clinical guidelines – through claims data analysis and quality data trends. CMS will immediately address any anomalies or indicators of care delivery problems so appropriate action can be taken.

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.

When program monitoring efforts reveal potential non-compliance with the terms and conditions of the applicable Participation Agreement or other grounds for remedial action, CMS will employ a variety of corrective actions based on the level and type of issue identified, including, but not limited to:

- Notices of Non-compliance.
- Warning Letters.

- Requests for Corrective Action Plans (CAPs).
- Termination of a KCF practice or KCE.
- Requiring the KCF practice or KCE to terminate a provider/supplier.
- Recoupment or repayment of monies from signatories of the Participation Agreement via financial guarantees (KCEs) or the Performance-Based Adjustment (KCF practices).
- Referral to the Secretary for consideration under Sec. 1881(c)(3) of the Act.
- Referral to law enforcement.

CMS may add additional program integrity safeguards to the Models as it further develops the Model design, assesses applications for participation in the Models, and determines the terms and conditions to be included in the Participation Agreements.

B. Screening

CMS may reject an application or terminate a Participation Agreement on the basis of the results of a PI screening regarding the applicant, its affiliates, and any other relevant individuals or entities. The PI screening may include, without limitation, the following:

- Confirmation of current Medicare enrollment status and history of adverse enrollment actions;
- Identification of delinquent debt;
- Review of performance in, and compliance with the terms of, other CMS models, demonstration programs, and initiatives;
- Review of compliance with Medicare program requirements;
- Review of any administrative audits, investigations, or other activities conducted regarding suspicious billing or other potential program fraud and abuse; and
- Review of any civil or criminal actions related to participation in a federal health care program.

C. Evaluation

In accordance with Sec. 1115A(b)(4) of the Act, an evaluation of the KCC Model will be conducted to determine whether the Model results in improved quality of care and reduced Medicare spending. Pursuant to section 42 CFR 403.1110(b), participants must cooperate with CMS's evaluation contractor and provide data as requested. CMS's model evaluation contractor will perform rigorous quantitative and qualitative analysis to assess the impact of the KCC Model. A combination of administrative, claims, and registry data, beneficiary surveys and focus groups, and interviews with providers and suppliers will inform the research questions for the Model. The CMS Office of the Actuary (OACT) and the HHS Secretary will take into account this evaluation in determining whether the criteria have been met to expand to the Model. Specifically, the Model may be expanded only if the Secretary determines that expansion is expected to either reduce Medicare expenditures without reducing care quality or maintain the level of Medicare expenditures while enhance the quality of care while not increasing the level of Medicare expenditures; OACT certifies that such expansion would reduce (or would not result in any increase in) net Medicare program expenditures; and the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits.

D. Learning and Diffusion Resources

The Innovation Center is working with national healthcare experts to develop resources and activities to support the KCC Model and its primary aims. The Innovation Center will support KCEs and KCF practices in accelerating their progress by providing them with opportunities to learn how care delivery

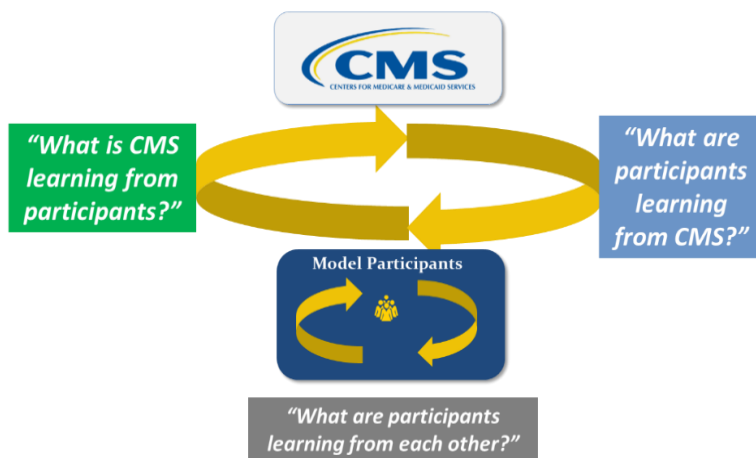
organizations can achieve performance improvements quickly and effectively, and opportunities to share their experiences with one another and with participants in other Innovation Center initiatives. The Innovation Center will test various approaches to group learning and exchange, helping Model participants effectively share their experiences, track their progress, and rapidly adopt new ways of achieving improvements in quality, efficiency and population health.

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.

The aim of the learning and diffusion strategy will be to establish an infrastructure to support shared learning, improvement efforts, and innovations in care delivery among KCC participants by addressing the following areas:

1. Assisting participants in applying improvement methods, with rigorous measurement that guides rapid cycle, iterative testing to achieve results.
2. Development of affinity groups among the participants for focused collaboration and sharing on common strategies and topics, leveraging resources, and accelerating learning.
3. Disseminating good ideas and effective practices for both KCEs and KCF practices as they emerge, thus allowing all participants to benefit from the work of their peers. These efforts will result in structured case studies, useful and practical metrics, and prepared packages of change concepts, and best practices.

Figure 1. Learning System



Participants will be required under the terms of the respective Participation Agreements to actively participate in and shape Learning System activities as part of their participation in the KCF and CCKC Models. The Learning System will facilitate peer learning and information sharing around how best to achieve quick and effective performance improvement. The Learning System will allow participants to glean promising practices from their peers and to further develop their own programs throughout the term of their Participation Agreement. The Innovation Center will undertake various approaches to group learning and exchange, helping participants to effectively share their experiences, track their progress, and rapidly adopt new ways of achieving improvements in care quality, as well as reductions in Medicare FFS expenditures. Potential Learning System activities include virtual learning sessions, topic-specific webinars, group-specific virtual collaboration, access to data dashboards, a learning collaborative virtual platform, case studies/toolkits, and an annual face to face collaborative.

Each participant will be required to:

1. Participate in targeted learning on Driver Diagrams, and during the Pre-Implementation Period (Year 1), develop and submit to CMS, or its contractors, an individualized participant Driver Diagram (after submission to CMS, the awardee Driver Diagram should be maintained and updated by the awardee throughout the life of the grant as a framework to guide and align the intervention design and implementation activities and shared with CMS upon request).
2. Upon request, answer surveys, participate in interviews or engage in other activities to assist CMS and its contractors in identifying their learning needs.
3. Participate in the identification and dissemination of practices that are showing positive outcomes by sharing lessons learned with other Model participants (e.g. presenting on webinars).
4. Participate in at least one virtual KCF or CCKC model learning activity every quarter during the 5-year model period, beginning Year 1.
5. Share with CMS, its contractors, and if relevant, other model participants, information on state and federal programs that complement the KCF and CCKC model interventions in the communities they serve.
6. Develop, track, and report to CMS on quality improvement efforts, activities, and program measures, at regular intervals.
7. Participate in in-person events during some years of the model (TBD). These in-person events will be held in the Baltimore/District of Columbia area and will be geared towards participant learning, collaboration, and dissemination of KCF and CCKC Model promising practices and other participant needs.

E. Interoperability Requirements

The CMS Interoperability and Patient Access Notice of Proposed Rulemaking (NPRM) sets forth CMS' proposed goals in promoting interoperability for all providers, suppliers, and CMS-funded payers and health plans across multiple programs and models. If finalized, participants will benefit from the use of interoperable health IT systems, and will see the value of data sharing, both between providers/suppliers and with patients.

In addition to the proposed requirements currently outlined in the Interoperability and Patient Access NPRM, under the terms of the applicable Participation Agreement, Model participants must:

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.
 - a. All participants must use 2015 Edition Certified EHR Technology, including secure messaging, transition of care document exchange and standards-based Application Programming Interfaces (APIs) to eliminate the use of faxes for health information exchange.
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.

F. Waivers

The authority for the KCC Model is section 1115A of the Social Security Act (SSA). Under section 1115A(d)(1) of the SSA, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b). CMS plans to issue waivers of Medicare payment requirements as may be necessary solely for purposes of testing the KCF and CKCC Options. These payment rule waivers, also referred to as “Benefit Enhancements” will be detailed in Table 8 (KCF Option) and Table 18 (CKCC Option)..

For this Model and consistent with this standard, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the SSA. Waivers are not being issued in this document; waivers, if any, would be set forth in separately issued documentation. Thus, notwithstanding any other provision of this RFA, all individuals and entities must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to section 1115A(d)(1) specifically for the KCC model. Any such waiver would apply solely to the KCC Model and could differ in scope or design from waivers granted for other programs or models.

Execution of a Participation Agreement to participate in the KCF Option is not intended and shall not be construed as a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS Office of the Inspector General, or CMS of any right to institute any proceeding or action against an KCF practice or any of its affiliated entities for violations of any statutes, rules or regulations administered by the government, or to prevent or limit the rights of the government to obtain relief under any other federal statutes or regulations, or on account of any violation of the respective Participation Agreement or any other provision of law. The KCF Participation Agreements shall not be construed to bind any government agency except CMS and binds CMS only to the extent provided therein.

III. CMS Kidney Care First (KCF) Option

In the CMS KCF Option, nephrology practices and their participating nephrologists will receive adjusted capitated payments for the care management services furnished to aligned beneficiaries with late stage CKD (stage 4 and 5) and ESRD. The capitated payments will be adjusted based on the KCF practice's performance on quality and utilization measures. Once the KCF Participation Agreement is executed, KCF practices and their participating nephrologists will not be able to move from the KCF Option to the CKCC Option for the duration of the Participation Agreement term. If the KCF practice would like to join the CKCC Option as a CKCC Participant, the KCF practice can do so only after its Participation Agreement expires.

A. Legal Entity

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 Option 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.

Governance Structure Requirements

A practice participating in the model (hereinafter a "KCF practice") can be governed through the existing organizational structure of the practice, as long as the existing structure meets the requirements stated in this RFA and the applicable KCF Participation Agreement. A separate governing body or governance structure is not required for participation in the KCF Option.

B. Applicant Eligibility

Practices and their nephrologists are the only entities and individuals eligible to participate in the KCF Option. Dialysis facilities and other non-nephrologist supplier and provider types are not eligible to participate in the KCF Option.

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 located entirely in 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.

Nephrologists participating in the KCF Option are not eligible to participate contemporaneously in a KCE, as the services they furnish will be used for purposes of aligning beneficiaries to their KCF practice. A nephrology practice may apply as both a KCF practice and a KCE participant. If both applications are accepted, the practice would have to ultimately decide its participation pathway (KCF or CKCC) before signing a Participation Agreement. The nephrology practice's decision could have an impact on the eligibility of the KCE if the nephrology practice was the only nephrology participant in the KCE. Nephrologists, KCF practices, and beneficiaries will be able to overlap between a KCF practice and an ACO participating in the Shared Savings Program. However, nephrologists and KCF practices participating in the KCF Option that are also participating in a Shared Savings Program ACO will be required to have a letter signed by the ACO acknowledging that the nephrologist or practice is simultaneously participating in the KCF Option and that payments under the KCF Option for beneficiaries assigned to the ACO will be included in the ACO's expenditure calculations under the Shared Savings Program. KCF practices will not be able to participate in the DC Model. Overlap with other ACO models, including the CEC Model, will be allowed during the Implementation Period (2020), but under the terms of the KCF Participation Agreement, KCF Option participants will be precluded from participating in these other ACO models during PY1 and future years of the Model.

C. Beneficiary Alignment

The patient population for the KCF Option is Medicare beneficiaries with late stage CKD (stages 4 and 5), ESRD, and kidney transplants. It is important to note that the alignment of beneficiaries to KCF practices is for Model test purposes only. Beneficiary alignment is relevant for each KCF practice's expenditure calculations, quality performance measurement, and CMS monitoring of claims data. Beneficiary alignment to a KCF practice does not inhibit beneficiaries' freedom to choose to receive care

from other Medicare providers and suppliers within Medicare Fee-For-Service (FFS). Similar to other CMS programs and models, CMS will not allow beneficiaries that have been aligned to a KCF practice to opt out of alignment, but beneficiaries may opt out of CMS sharing certain information about them with the KCF practice.

Beneficiary Eligibility

To be eligible for alignment and to remain aligned to a KCF practice for a performance year, beneficiaries must meet all of the following criteria, except where otherwise noted:

- Have either late stage CKD (stage 4 or 5) or ESRD, or be a transplant recipient with a functioning kidney who was previously aligned to the KCF practice while the beneficiary had late stage CKD or ESRD.
- 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.

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. Under the terms of the KCF Participation Agreement, CMS will not require the KCF practice to furnish health services to a minimum number of aligned transplant beneficiaries. Aligned transplant beneficiaries do not count towards the minimum number of aligned CKD or ESRD beneficiaries.

The Innovation Center will prospectively align eligible beneficiaries to KCF practices through a claims-based process. The beneficiary alignment process (described in detail in the *Alignment Process* section below) identifies the Medicare beneficiaries with late stage CKD (stages 4 and 5), ESRD, and a kidney transplant for whom CMS will hold a KCF practice clinically and financially accountable under the terms of the KCF Participation Agreement.

Alignment Process

CMS will align beneficiaries to KCF practices based on nephrologist services and the beneficiary's stage of kidney disease (CKD stages 4 and 5, ESRD, or transplant recipient). This is different than the CEC Model, where beneficiaries are aligned through the dialysis facility.

CMS believes that aligning beneficiaries through the nephrologist has the following advantages:

- Prioritizes the nephrologist relationship as the most important one for beneficiaries with late stage CKD, ESRD, or kidney transplant.
- Protects the continuity of care by aligning a beneficiary with CKD stage 4 or 5 with the same nephrologist who might then be treating them for ESRD, although it does not have to be the same nephrologist.
- Allows for beneficiaries who only dialyze at nursing facilities, instead of outpatient dialysis facilities, to be aligned to KCF practices and included in the Model test, given that they are still seen by nephrologists.

Alignment will be as prospective as is feasible for each payment mechanisms, as summarized in Table 2 below, and will be retrospectively finalized as part of a reconciliation process after each performance year, allowing for a minimum of three months claims run-out. CMS will identify the final aligned beneficiary population for the KCF practice. Beneficiaries will be de-aligned from a KCF practice’s list of aligned beneficiaries if, at some point during the performance year, they no longer satisfy the KCF alignment eligibility criteria, do not receive certain health services from a KCF practice nephrologist during the performance year, or receive the majority of certain health services outside of the KCF practice’s market area.

De-alignment criteria, including de-alignment based on a beneficiary not receiving care from a KCF practice nephrologist during the performance year and receiving the majority of the E&M visits or MCP treatments outside the practice’s market area, are designed to ensure an accurate measure of the cost and quality of the beneficiary care in the model test. The de-alignment criteria are based on the care relationship between the KCF practice and the aligned beneficiaries. While there may be some incentive for a KCF practice to refer aligned beneficiaries outside of the market area in order to de-align them from the practice (and in doing so, take advantage of the de-alignment criteria), experience in the CEC Model has shown that the market areas, as defined above, tend to be large enough that seeking care outside of the market area truly represents a change in beneficiary residence rather than strategic referrals. This approach balances predictability in beneficiary populations, accuracy in alignment, and the unique way CKD and ESRD beneficiaries interact with the health care system.

KCF practices will receive a list at the start of the performance period with the aligned beneficiaries whose care they will be accountable for based on visits in the past year. New beneficiaries who satisfy the alignment eligibility criteria will be added to each KCF practice’s alignment list on a quarterly basis. Once aligned, beneficiaries remain aligned to the KCF practice until they meet one of the criteria for de-alignment.

Table 2. Alignment Criteria by Beneficiary Type

	Beneficiaries with CKD	Beneficiaries with ESRD	Beneficiaries who Receive Kidney Transplants
Aligning Participant	Nephrologist	Nephrologist	N/A – Must have been previously aligned by virtue of CKD or ESRD
Criteria for Alignment	Diagnosis of CKD stage 4 or 5; 2 or more Evaluation & Management (E&M) visits within a 6 month period with a KCF nephrologist	Diagnosis of ESRD; 2 or more Monthly Capitation Payment (MCP) visits within a 3 month period with a KCF nephrologist	Being previously aligned to the KCF practice as a CKD or ESRD beneficiary and receiving a kidney transplant

Criteria for De-alignment	Beneficiaries no longer meet the criteria for alignment; receiving the majority of E&M visits from a non-KCF nephrologist, from a different KCF practice in the market area, outside the KCF practice market area	Beneficiaries no longer meet the criteria for alignment; receiving the majority of MCP visits from a non- KCF nephrologist, from a different KCF practice in the market area, or outside the KCF practice market area	Beneficiaries no longer meet the criteria for alignment; kidney transplant failure (the beneficiary may be aligned as a CKD or ESRD beneficiary post-transplant failure if the applicable requirements for alignment are met)
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When an aligned CKD or ESRD beneficiary receives a transplant they 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, but the beneficiaries’ expenditures will no longer be counted toward financial calculations and the beneficiary will not be included in the quality assessment for the KCF practice. If the transplant fails, the beneficiary will be de-aligned from the KCF practice. It is possible for a transplant beneficiary to be realigned as a CKD or ESRD beneficiary in the event their transplant fails (either to the original KCF practice or to a different KCF practice). It is also possible that an aligned beneficiary that progresses from CKD to ESRD switches alignment “type” when they progress, assuming they meet alignment criteria for ESRD beneficiaries. When the alignment type changes, it changes the number of aligned CKD and ESRD beneficiaries and changes the criteria for de-alignment per the chart above.

As previously noted, during each performance year, KCF practices must have a minimum of 500 aligned Medicare beneficiaries with late stage CKD and 200 ESRD beneficiaries. If at any point a KCF practice drops below the minimum aligned beneficiary threshold, the KCF practice will be required to submit a corrective action plan (CAP) explaining the steps it will take to meet the minimum threshold for CMS’ review and approval. CMS may offer the KCF practice the opportunity to add nephrologists to the KCF practice list of participating nephrologists for purposes of increasing the number of aligned beneficiaries. Under the terms of the KCF Participation Agreements, KCF practices will otherwise be prohibited from adding suppliers to their KCF practice list of participating nephrologists during a performance year and will only be able to do so prior to the start of a performance year at a time and manner specified by CMS. If the nephrologists or nephrology practice does not meet this threshold, they will be required to aggregate their performance with other nephrologists or practices on financial and quality measures for calculations. If the minimum threshold remains unmet prior to the start of the next performance year, CMS may pursue additional compliance actions including, but not limited to, termination of the practice’s KCF Participation Agreement.

Finalizing Alignment

Alignment will be retrospectively finalized as part of a reconciliation process after each performance year. CMS will identify the final aligned population for the KCF practice after the performance year allowing for a minimum of three months claims run-out. In certain cases, a beneficiary may become de-aligned from the KCF practice alignment list for the entire performance year at reconciliation if they:

- Received the majority of their E&M visits or MCP treatments outside of the KCF practice’s market area.
- Received the majority of their E&M visits or MCP treatments at a different KCF practice within the KCF practice’s market area.
- Did not receive the required E&M or MCP visits from a KCF practice nephrologist during the performance year.

As a result of the quarterly alignment review and/or the reconciliation process, an aligned beneficiary may be removed from a KCF practice's list of aligned beneficiaries for certain months (e.g., months of and after transplant or months following a beneficiary's death).

Beneficiary Protection

All KCF practices will be required to share with aligned beneficiaries certain details about their alignment to the KCF practice. CMS must approve written materials and marketing plans prior to use in a manner that is reasonable in terms of standards, time frame, and procedure. For KCF practices' ease, CMS will consider providing templates that participants must use. If CMS provides a template to be used for these notification requirements, such template will include all of the required information described below and prior CMS review/approval of the template will not be needed. The KCF practice must also comply with all applicable federal laws regarding interaction with Medicare FFS beneficiaries.

Specifically, KCF practices will be required to share information with aligned beneficiaries, informing them of the initiative and the beneficiary's alignment to a KCF practice participating in the Model.

The notification must include the following elements:

- A short description of the KCF Option and what that means for their care.
- An explanation that the beneficiary retains full Medicare FFS benefits and the freedom to choose his or her providers and suppliers.¹
- Details of the KCF practice's Benefit Enhancements.
- Information on how to opt out of CMS sharing certain information about them with the KCF practice (described in more detail in the *Data Sharing* section, below).
- Contact information for the KCF practice and 1-800-MEDICARE for questions and/or concerns.

CMS will reserve the right to review any Marketing Materials and Activities to ensure that the materials comply with the terms of the KCF Participation Agreement, including that they are not inaccurate or misleading, are not discriminatory or used in a manner that is discriminatory, and make clear that alignment to a KCF practice does not remove or otherwise affect a beneficiary's freedom to choose a provider or supplier. Additional requirements concerning this review process will be provided in the KCF Participation Agreement.

Data Sharing

CMS 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. All information will be provided consistent with all applicable laws and regulations, including HIPAA and the Part 2 regulations governing the disclosure and use of certain substance use disorder patient records.

Specifically, under appropriate agreements (e.g., the KCF Participation Agreement) and upon a KCF practice's request, CMS will make available several types of Medicare data for the sole purposes of developing and implementing activities related to coordinating care and improving the quality and efficiency of care for beneficiaries aligned to the KCF practice under the KCF Option.

¹ The beneficiary maintains the right to see any Medicare participating healthcare provider at any time under the traditional Medicare FFS benefit structure. Example language may read "You still have the right to visit any dialysis facility, doctor, hospital, or healthcare provider that accepts Medicare" and/or "This is not a Medicare Advantage Plan or any kind of managed care plan".

Upon request from the KCF practice, CMS will provide (1) data on aligned beneficiaries that will include individually identifiable demographic and Medicare eligibility status information and various summary reports with data relevant to the KCF Option operations and performance in the Model (such as data related to quality, expenditures, etc.); and (2) detailed claims data files that will include individually identifiable claim and claim line data for services furnished by Medicare-enrolled providers and suppliers to aligned beneficiaries. Historical data files for aligned beneficiaries will be limited to three years of historical data, consistent with the approach under the CPC+ Model and shared savings models and programs.

The claims data provided to the KCF practice will not include individually identifiable data for aligned beneficiaries who have opted out of data sharing. Moreover, the KCF Option will honor the data sharing opt out decisions by beneficiaries who were previously given that choice while an aligned beneficiary in a Medicare ACO initiative. KCF practices will be required to notify newly aligned beneficiaries at the beginning of each performance year regarding the organization's intent to request their claims data from CMS and to provide information or forms regarding the opportunity to decline data sharing. Beneficiaries may opt-out of data sharing by calling 1-800-MEDICARE.

KCF practices may inform each newly-aligned beneficiary, in compliance with applicable laws and regulations, that he or she may elect to allow the KCF practice to receive beneficiary-level data regarding the utilization of substance use disorder treatment services, the mechanism by which the beneficiary can make this election, and contact information for answers to any questions about data sharing of data regarding substance use disorder services. CMS will provide KCF practices with a Substance Use Disorder Treatment Opt-In Form.

D. Finance and Payment

KCF practices will receive adjusted capitated and other payments for treating beneficiaries with CKD stages 4 and 5, and ESRD. KCF practices will receive the following payments:

- CKD Quarterly Capitation Payment (CKD QCP)
- Adjusted Monthly Capitation Payment (AMCP)
- Kidney Transplant Bonus (KTB)

Payment Types

CKD Quarterly Capitated Payment

Under the KCF Option, CMS will pay KCF practices through an innovative per-beneficiary CKD Quarterly Capitation Payment (CKD QCP), which combines payment for several different outpatient Evaluation and Management (E/M) codes, and other care management codes listed below, into a single capitated payment for the care of CKD aligned beneficiaries with CKD stage 4 or 5. The CKD QCP will allow flexibility in care delivery based on clinical benefits, rather than administrative requirements. The CKD QCP is designed to allow flexibility in care delivery and to give KCF practices a more stable payment stream to deliver advanced care for aligned CKD beneficiaries with late-stage CKD. For the beneficiary, this may result in increased access to nephrologist care for their CKD, improved efficiency and coordination in addressing health issues, and improved patient experience. The predictability of the CKD QCP payments will help the nephrologists in the KCF practice to coordinate care for aligned beneficiaries with other specialists in order to better address their renal needs. The CKD QCP is intended to provide an upfront payment to facilitate delivery of care for aligned beneficiaries with CKD.

KCF Practices will receive the CKD QCP payment instead of regular payments for those services included in the development of the CKD QCP. 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 or 5.

Table 3. Services Included in the CKD QCP

Services Included in the Development of the CKD QCP	CPT²/HCPCS Codes
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

KCF practices receiving the CKD QCP will continue to receive normal fee-for-service payments for services that are not included in the CKD QCP, such as procedures and inpatient visits, and for caring for beneficiaries with ESRD or who have received transplants. KCF practices will also continue to receive normal fee-for-service payments, and not CKD QCP, for services furnished to beneficiaries not aligned to the KCF practice. Beneficiary cost sharing for the services included in the CKD QCP will be set at the normal Medicare FFS cost sharing amounts for such services, which a beneficiary would have paid for the services they receive that are billed under the E&M codes that are subsumed into the CKD QCP, rather than at the cost amount for the amount of the CKD QCP.

The CKD QCP amount will be paid in the amount of one third of the AMCP rate (described below) on a per-beneficiary, per-month basis. The CKD QCP for one aligned CKD beneficiary paid each quarter will be the same amount as the AMCP for one aligned ESRD beneficiary paid each month. The CKD QCP will be the same amount for a CKD stage 4 or CKD stage 5 beneficiary. The payments will not be risk adjusted, given the very similar risk profiles in the CKD stages 4 and 5 populations.

The CKD QCP will be adjusted quarterly to account for “leakage rates” based on the aggregate CKD nephrology services included in the CKD QCP (see Table 3) furnished outside of the KCF practice to the practice’s aligned CKD beneficiaries. Under this leakage rate construct, we assume that beneficiaries will tend to increase the amount of nephrology care they seek elsewhere if they are not satisfied with the care they receive from the KCF practice. Thus, increases in services delivered outside of the KCF practice to aligned beneficiaries with late-stage CKD will lead to a reduction in the KCF practice’s future CKD QCPs. CMS will calculate a practice’s leakage rate by dividing the number of primary care visits that aligned beneficiaries received from the KCF practice in the prior performance period, with adequate

² CPT codes, descriptions and other data only are copyright 2019 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

claims run-out, by the total number of primary care visits that these beneficiaries received from any practice in the same time period.

Adjusted Monthly Capitation Payment for Dialysis (AMCP)

Currently, Medicare pays physicians and other practitioners who manage dialysis care for beneficiaries receiving dialysis through the Medicare capitation payment (MCP). The per-patient-per-month MCP payment is for all outpatient visit services related to the dialysis patient's renal condition. The amount of the MCP varies based on several criteria:

- The location where the beneficiary dialyzes (at home or in center).
- The number of face-to-face visits with the beneficiary for beneficiaries who dialyze in center (one monthly visit, two or three monthly visits, or four or more monthly visits).
- The age of the beneficiary.

Under the KCF Option, CMS will modify payments made to KCF practices under the current MCP payment structure. KCF practice nephrologists will continue to bill the MCP as they ordinarily would, but will receive the Adjusted MCP (AMCP) amount in lieu of the MCP amount for aligned beneficiaries with ESRD that they see at least once a month. The AMCP will include payment for all services included in the MCP and the same requirements will apply, but payment will not vary based on the number of nephrologist visits as the current MCP does. The AMCP, combined with the other payment and quality features of the model, is designed to provide strong incentives to KCF practices and their nephrologists to deliver appropriate care that is not based only on the number of visits for a beneficiary. AMCP Payments will still vary based on a beneficiary's age as they do now. The payment rate for the AMCP will be based on the current MCP rate for managing an in-center dialysis beneficiary with 2-3 visits during the month, which is equivalent to the current MCP rate for managing a beneficiary who dialyzes at home. Cost sharing for beneficiaries would remain unchanged, and would be assessed based on what amount the beneficiary would have paid were the AMCP not in place.

CMS will utilize an AMCP to pay KCF practices for renal care furnished to aligned beneficiaries with ESRD for several reasons:

- Studies that have analyzed the implementation of the MCP show that there is no clear relationship between the number of nephrologist visits per month and beneficiary outcomes. The implementation of the MCP saw an increase in visits, but without any corresponding change in results for beneficiaries who received increased visits.³
- The current structure of MCP payments, under which nephrologists are paid more for seeing beneficiaries more times, creates a financial incentive for nephrologists to furnish four visits per month to beneficiaries who dialyze in center to maximize payment, regardless of whether the beneficiary needs four visits a month. Utilizing an AMCP payment rate that is the same amount regardless of the number of beneficiary visits reduces provider/supplier burden and enables them to focus on quality of care, rather than the number of visits.
- The current payment structure of the MCP creates a bias toward in-center hemodialysis because the highest MCPs are available for beneficiaries who dialyze in-center and receive four in-person visits a month. According to a 2015 GAO report, equalizing nephrologist payments for home and

³ Evaluating the Evidence behind Policy Mandates in US Dialysis Care; Kevin F. Erickson, Wolfgang C. Winkelmayr. JASN Dec 2018, 29 (12) 2777-2779; DOI: 10.1681/ASN.2018090905

in-center dialysis could remove a financial disincentive for prescribing home dialysis and supports beneficiaries dialyzing at home.⁴

KCF Performance-Based Adjustment (PBA)

In addition to the CKD QCP and AMCPs, the KCF Option will include a Performance-Based Adjustment, or PBA, which 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.

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.
- Utilization Measures - aimed at incentivizing efficient and appropriate provision of health care services for the patient population.

These measures are described in detail under Quality Strategy.

Under the PBA methodology, financial rewards and penalties for KCF practices will be based on two separate comparisons of performance, each using the Quality Gateway and utilization measures. These two components of the PBA are:

- *Relative Performance (RP) Component* – each KCF practice is assessed first according to the Quality Gateway measures, and then its performance on the utilization measures relative to other KCF practices. Depending on this relative performance, the KCF practice's performance on the utilization measures may also be compared to that of all nephrology practices nationwide. As a distinct component of the PBA, this financial adjustment based on relative performance could be either positive or negative.
- *Continuous Improvement (CI) Component* – each KCF practice that meets the Quality Gateway threshold of the overall PBA is evaluated on its improvement on utilization measures relative to an earlier period of model participation.

For each of the RP and CI Components of the PBA, performance level comparisons will be made according to 6-month performance periods. CMS will begin calculating each KCF practice's RP Component during PY1, while CMS will begin calculating the CI Component, which depends on previous experience in the model, in PY2. CMS will calculate the KCF practice's PBA (consisting of the sum of the RP and CI Components) during the 6-month period following the respective performance period. This calculated amount (in sum either positive or negative) will be applied subsequent to this 6-month period, to the CKD QCP and AMCP amounts determined for that following period. The following chart illustrates the recurring sequence of performance measurement, calculation, and payment adjustment.

⁴ End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis. GAO-16-125: Published: Oct 15, 2015. Publicly Released: Nov 16, 2015.

Table 4. Timeline for Applying PBA to Model Payments

	PBA Performance, Calculation, and Payment Adjustment Period							
PBA Performance Period	PY1 Q1-Q2	PY1 Q3-Q4	PY2 Q1-Q2	PY2 Q3-Q4	PY 3 Q1-Q2	PY3 Q3-Q4	Q1-Q2*	Q3-Q4*
PY1 - Q1 and Q2 (for RP only)	Measure	Calculate	Adjust Payment					
PY1 - Q3 and Q4 (for RP only)		Measure	Calculate	Adjust Payment				
PY2 - Q1 and Q2 (for RP and CI)			Measure	Calculate	Adjust Payment			
PY2 - Q3 and PY2 Q4 (for RP and CI)				Measure	Calculate	Adjust Payment		
PY3 - Q3 and Q4 (for RP and CI)					Measure	Calculate	Adjust Payment	
PY3 – Q3 and Q4 (for RP and CI)						Measure	Calculate	Adjust Payment
Measurement Period	Data collection on measure performance concludes at end of PBA performance period							
Calculation Period	PBA amount calculated during PBA calculation period based on performance during PBA performance period							
Adjustment Period	Performance-based adjustment applied to CKD QCP and AMCP during the PBA payment adjustment period							
	* Calculation and application of the PBA during the 6-month periods following upon PY3.							

For each KCF practice, determination of the PBA will proceed according to a sequence of steps: the Relative Performance Component will be the only calculation that factors into the PBA in PY1; starting in PY2, CMS will calculate the KCF practice’s RP Component and CI Component, and the overall PBA will consist of the sum of these two amounts.

1. *Relative Performance (RP) Component Calculation* – Each KCF practice will be placed into one of eight PBA performance levels, based on the following determinations:

Starting in PY1, for each 6-month performance period, CMS will calculate the KCF practice’s performance on quality measures to determine if the KCF practice achieved the Quality Gateway threshold and will calculate the practice’s performance on the PBA utilization measures.

- If the practice achieves the Quality Gateway threshold, then it will be placed in PBA Performance Levels 1 through 7;
- If the practice does not meet the Quality Gateway threshold, it will be placed in Performance Level 8.

For KCF practices that achieve the performance threshold for the Quality Gateway, the PBA performance level (1 through 7) will be determined by performance on the utilization measures. First, the practice’s performance on the PBA utilization measures will be compared to all other KCF practices.

- If the practice’s performance on the utilization measures falls among the top 50 percent of all KCF practices, then it is placed within PBA Performance Levels 1 through 5, with the specific level depending on the practice’s relative performance. The RP adjustment for these performance levels will be positive, with the magnitude of adjustment increasing with relative performance.
- If the practice’s performance on the utilization measures falls among the bottom 50 percent of all KCF practices, then the PBA performance level will be determined by its performance in comparison to all nephrology practices nationwide. If the specific KCF practice’s performance on the utilization measures falls:
 - Within the top 50 percent of nephrology practices nationwide, then the KCF practice will be placed in PBA RP Performance Level 6. (No RP-specific adjustment for the PBA).
 - Between the 50th and 25th percentile of nephrology practices nationwide, then the KCF practice will be placed in PBA Performance Level 7. (Negative RP adjustment for the PBA).
 - In the bottom 25 percent, or below the 25th percentile, of nephrology practices nationwide, then the practice will be placed in PBA Performance Level 8. (The largest negative RP adjustment for the PBA).

Table 4 summarizes the PBA performance levels, along with the resulting either positive or negative RP adjustments.

Table 5. Magnitude of the RP Component by PBA Level

PBA Performance Level	Percent Adjustment to CKD QCP and AMCP
Top 50 Percent of Performers – Compared to All KCF Practices	
Level 1 – Top 10% of KCF Practices	+20%
Level 2 – 11 – 20% of KCF Practices	+16%
Level 3 – 21% – 30% of KCF Practices	+12%
Level 4 – 31% – 40% of KCF Practices	+8%
Level 5 – 41% – 50% of KCF Practices	+2%
Bottom 50 Percent of Performers – Compared to All KCF Practices	
Group 6 – Bottom 50% of KCF practices and the top 50% of nephrology practices nationally	0%
Group 7 – Bottom 50% of KCF practices and 51% – 75% (25 th to 50 th percentile) of nephrology practices nationally	-6%
Group 8 – Bottom 50% of KCF practices and bottom 25 percent (below the 25 th percentile) of nephrology practices nationally <i>or</i> did not pass Quality Gateway	An amount sufficient to equal 8% of estimated revenue, which CMS believes will be a maximum of -20% ⁵

⁵ This amount will be set at a level sufficient to meet the 8% nominal risk standards necessary for the KCF to qualify as an Advanced APM in the QPP, the amount will be set based on the exact model participants. This amount will

2. Continuous Improvement (CI) Component Calculation

For each 6-month period, starting in PY2, CMS will calculate each KCF practice's performance in terms of the Quality Gateway measures.

- If the practice meets the Quality Gateway threshold, then it will be eligible for the CI Component. The extent of improvement needed to receive a CI-specific payment adjustment, as well as the magnitude of the adjustment, will depend on the PBA Performance Level for the KCF practice.
- If the practice does not meet the Quality Gateway threshold, then it will not be eligible for the CI Component.

Improvement will be based on comparing the KCF practice's performance on the utilization measures to a previous 6-month period. The target improvement for a KCF practice will range from 3 to 5 percent.

The CI Component's contribution to the overall PBA amount will also depend on the KCF practice's PBA performance level. KCF practices that qualify for the CI Component will receive in between a 4 and 10 percent increase in the PBA. Table 5 details the percent improvement in utilization measures needed for each PBA performance level, and the amount of the positive adjustment, as a percentage of the CKD QCP and AMCP.

Table 6. Magnitude of CI Component and percent improvement on PBA utilization measures needed by PBA performance level

PBA Performance Level	Target: Percent Improvement on PBA Utilization Measures needed to be eligible for CI Component	Percent Adjustment to CKD QCP and AMCP
Level 1	+3%	+10%
Level 2	+3.5%	+8%
Level 3	+3.5%	+6%
Level 4	+4%	+4%
Level 5	+4%	+4%
Level 6	+4.5%	+4%
Level 7	+4.5%	+4%
Level 8	+5%	+10%

To mitigate the possibility that change in utilization measure performance over time might be due to random variation and not actual change, especially for small KCF practices, we will utilize statistical approaches to improve the reliability of the measurement of improvement. A potential strategy would be to adjust practices' scores by the average score for similar practices for characteristics such as low patient volume. Such an approach would represent an alternative to aggregating aligned beneficiaries for small KCF practices in order to reach a minimum beneficiary threshold.

not exceed 20%, but the KCF Option may not qualify as an Advanced APM if an amount greater than 20% is required in order for the Option to qualify as an Advanced APM under the 8% nominal risk standard.

Magnitude of the PBA

Starting with PY2, the PBA for each KCF practice will be the sum of its RP- and CI-specific adjustments. For PY1, the PBA will be based solely on the RP Component. Therefore, starting in PY2, the PBA will range from +30 percent (maximum upside potential) to -20 percent (downside risk) adjustment to the CKD QCP and AMCP for the measurement period. We believe that this risk structure, along with the frequency of assessment, will provide an incentive for continuously improving health outcomes for aligned beneficiaries and reducing unnecessary utilization.

Table 7. PBA Magnitude by PBA Group –Starting in PY2

PBA Performance Level	PBA Components (Percent Adjustment to CKD QCP & AMCP)		Total PBA Impact (% Adjustment to CKD QCP and AMCP)	
	Relative Performance RP Component	Continuous Improvement CI Component	RP + CI (Maximum Upward PBA Adjustment)	RP Only (Does not qualify for CI)
Level 1	+20%	+10%	+30%	+20%
Level 2	+16%	+8%	+24%	+16%
Level 3	+12%	+6%	+18%	+12%
Level 4	+8%	+4%	+12%	+8%
Level 5	+2%	+4%	+6%	+2%
Level 6	0%	+4%	+4%	0%
Level 7	-6%	+4%	-2%	-6%
Level 8				
Cleared Quality Gateway	-20%*	+10%	-10%	-20%
Failed to Clear Quality Gateway	-20%*	0%	-20%	-20%

* Note: This number is subject to adjustment annually based on final QPP determinations to ensure that the KCF Option qualifies as an Advanced APM.

Kidney Transplant Bonus (KTB) Payment

In addition to the payment adjustments described above, 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. The KTB will create a direct incentive for model participants to support beneficiaries through the transplant process, including continued care management of patients to support graft success. CMS recognizes the lack of supply of available kidneys and that nephrologists do not control access to the transplant wait list, but CMS believes that this payment could better incentivize health care providers to get more beneficiaries onto the waitlist, assist beneficiaries with the living donation process, and support beneficiaries after they receive a transplant in maintaining the health of the transplanted organ.

CMS 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.

Payment Mechanism

For KCF practices, payments for the CKD QCP and AMCP are scheduled to begin at the start of Performance Year 1, and last until the end of the performance period of the Model. The CKD QCP will be paid quarterly and the AMCP will be paid monthly to KCF practices for their aligned beneficiaries during a given quarter, and are subject to the PBA, with adjustments to the CKD QCP and AMCP beginning in Performance Year 2.

E. Quality Strategy

There are two sets of measures for practices in the KCF Option: Quality Gateway measures and utilization measures. The Quality Gateway measure set includes measures that indicate appropriate clinical care and engagement for the patient population. These measures are directly and indirectly related to the beneficiary's kidney disease, and applicable to both late stage CKD patients and ESRD patients. The utilization measure set includes measures of health care utilization that are direct outcomes of quality clinical care, care management, and care coordination. These will be adapted for the Model context from existing measures with demonstrated reliability and validity, if adaptations are necessary. Numerators, denominators, and performance thresholds would be based on beneficiaries aligned to the participating nephrology practices, as well as stipulated inclusion and exclusion criteria.

Both Quality Gateway and utilization measures will be used to determine the RP and CI components of the PBA. As described above in PY1, the PBA will be based on the RP component, and starting in PY2 (with the availability of PY 1 data on quality performance) the CI component will also factor into the PBA.

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. During PY0, CMS will consider whether any 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.

CMS will develop new performance measures for the specific patient population that incentivize providers to optimal care management that delays progression to ESRD/dialysis and lowers mortality. The measures under development – i.e., Standardized Mortality Ratio for Late Stage CKD and ESRD, Measure of Delay or Reduction of Progression to ESRD (or dialysis), and Home Dialysis and Transplant Rates would be incorporated into the Quality Gateway or the utilization measures as they became available.

F. Benefit Enhancements

The KCF Option will issue several payment waivers, or benefit enhancements, which will test whether allowing KCF practices additional flexibilities in the services they can provide will improve the quality of care and reduce the cost of care. With the exception of the Kidney Disease Education Benefit Enhancement, these benefit enhancements will not be available in PY1 unless the TPCC measure is included in the utilization measure set in PY1.

Table 8. Benefit Enhancements

Name	Description
Kidney Disease Education Benefit Enhancement	<p>Medicare currently covers up to six 1-hour sessions of kidney disease education (KDE) services for beneficiaries that have Stage 4 chronic kidney disease (CKD). While the KDE benefit is intended to ensure beneficiaries are informed about the effects and treatment of kidney disease, diet and nutrition, transplantation, dialysis modalities, and vascular access, the uptake of this service has been exceptionally low at less than two percent of eligible patients. In the KCC Model, beneficiary education is a crucial component to increasing rates of transplants and home dialysis and delaying the onset of end-stage renal disease (ESRD). Therefore, CMS will conditionally waive certain KDE requirements under Innovation Center authority as necessary to test ways to increase the provision of the KDE benefit under the KCC Model. CMS is proposing to waive a similar set of KDE requirements solely for purposes of testing the proposed ESRD Treatment Choices Model.</p> <p>The programmatic waivers would:</p> <ul style="list-style-type: none"> • Waive the requirement that the KDE be performed by a physician, physician assistant, nurse practitioner, or clinical nurse specialist and allow qualified clinicians not currently allowed to bill for the benefit to furnish the services incident to the services of a participating KCF or CKCC nephrologist. • Waive the requirement that a beneficiary have Stage 4 CKD in order to test furnishing the KDE benefit to beneficiaries with CKD stage 5 and those in the first 6 months of ESRD, who can also benefit from KDE. • Waive the requirement that KDE sessions cover the topic of delaying initiation of dialysis to allow participating nephrologists to cover this topic as “as applicable” rather than mandated, as it is not

Name	Description
	<p>relevant to beneficiaries with ESRD who have already begun dialysis.</p> <ul style="list-style-type: none"> • Waive the requirement that an outcomes assessment be conducted during one of the KDE sessions; and instead to test the provision of this assessment during a subsequent evaluation and management visit with the nephrologist.
Telehealth Benefit Enhancement	<p>CMS will make available to qualified KCF practices a conditional waiver of the interactive telecommunications system requirement under section 1834(m)(1) of the Act and 42 CFR 410.78(b) for services including otherwise covered dermatology and ophthalmology services furnished using asynchronous store and forward technologies.</p> <p>Asynchronous telehealth includes the transmission of recorded health history (for example, retinal scanning and digital images) through a secure electronic communications system to a practitioner, usually a specialist, who uses the information to evaluate the case or render a service outside of a real-time interaction. Asynchronous telecommunication systems in single media format do not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patients' condition and adequate for rendering or confirming a diagnosis or treatment plan.</p> <p>Payment will be permitted for services including dermatology and ophthalmology services furnished to eligible beneficiaries using asynchronous telehealth in single or multimedia formats that is used as a substitute for an interactive telecommunications system. Distant site practitioners will bill for these services using CMMI specific asynchronous telehealth codes. The distant site practitioner must be a KCF participant who has elected to participate in this benefit enhancement.</p> <p>The Bipartisan Budget Act of 2018 amended Section 1899 of the Social Security Act to provide accountable care organizations the ability to expand the use of telehealth services if the accountable care organization is participating in a two-sided model tested or expanded under section 1115A of the Act. Subject to approval, CMS will issue a waiver to also provide KCF practices the same ability as the accountable care organizations to which the Bipartisan Budget Act of 2018 refers, to expand the use of telehealth services for beneficiaries aligned to the KCF practice. Additionally, subject to approval, CMS will conditionally waive certain Medicare telehealth requirements for qualified entities to allow them to furnish telehealth services using asynchronous telecommunications systems. The waivers will apply only for beneficiaries aligned to KCF practices approved by CMS.</p>
Post-Discharge Home Visits Benefit Enhancement	<p>Subject to approval, CMS will conditionally waive certain supervision requirements for qualified entities in order to allow payment for home visits to non-homebound aligned beneficiaries when furnished "incident to" a practitioner's professional services by "auxiliary personnel" as defined in 42 CFR §410.26(a)(1), under general supervision- instead of direct supervision.-</p>

Name	Description
	<p>Payment for these visits will only be allowed when visits are furnished following the beneficiary’s discharge from an acute inpatient hospital, inpatient psychiatric facility, inpatient rehabilitation facility, long-term care hospital, or skilled nursing facility. Also, under this benefit enhancement, a beneficiary is eligible to receive up to nine post-discharge home visits within 90 days following discharge. The nine services do not accumulate across multiple discharges; if the beneficiary is admitted within 90 days of the initial discharge and before receiving nine home visits, the beneficiary may receive only nine home visits in connection with the most subsequent discharge.</p> <p>We will waive the direct supervision requirement and require only general supervision for these home visits only when furnished by approved participants and Preferred Providers to beneficiaries under the following circumstances, including:</p> <ul style="list-style-type: none"> • The beneficiary does not qualify for Medicare coverage of home health services (or qualifies for Medicare coverage of home health services on the sole basis of living in a medically underserved area); • The beneficiary is an aligned beneficiary at the time the services are furnished; and • The services are furnished in the beneficiary’s home after the beneficiary has been discharged from an inpatient facility.
Home Health Benefit Enhancement	<p>The proposed Benefit Enhancement is currently under consideration by CMS to waive the homebound requirement to allow for modified application for beneficiaries aligned to the entity in order to receive home health services. The entity would have greater flexibility to ensure special populations (as specified in the KCF Participation Agreement) have access to home health services in appropriate cases. Given the risk borne by the entity, the entity would be incentivized only to do so where such care would improve quality and be cost-effective from a Total Cost of Care perspective. We expect this flexibility would aid KCF Practices in reaching their own alternative payment arrangements with home health agencies and promote innovation and greater ability of beneficiaries to return to, remain in, and receive care in their home.</p> <p>There is evidence demonstrating high quality outcomes for non-homebound patients receiving support in their home environment. There are some models that use health coaches to follow patients in their home and telephonically.⁶ Critical elements of those models are its self-management underpinnings and its emphasis on medication reconciliation. Outcomes include a 20-50% reduction in readmissions, and increased likelihood of achieving self-identified goals related to symptom management and functional recovery. Other models are multi-disciplinary in hospital planning processes that lead to in-home follow-</p>

⁶ <http://caretransitions.org/evidence-and-adoption/>

Name	Description
	<p>up and services.⁷ Those models have resulted in reductions in preventable hospital readmissions for both primary and co-existing health conditions; improvements in health outcomes; enhanced patient experience with care; and a reduction in total health care costs. The Best Practice Intervention Package (BPIP)⁸ provides tools for home care to improve health literacy, self-care, and cross setting coordination. Participating Home Health agencies report improvement, with reductions in readmission rates compared to other agencies not using enhanced tools and models available.</p>
<p>Home Health Services Certified by Nurse Practitioners</p>	<p>The proposed Benefit Enhancement is currently under consideration by CMS to allow nurse practitioners who are participating in a KCF practice to certify that beneficiaries aligned to a KCF practice meet the requirements to receive home health services. Currently, Medicare Part A or Part B may pay for home health services if and only if a physician certifies or recertifies that the patient meets the requirements to receive home health services. However, several states, Maryland for example, allow nurse practitioners to certify or recertify that a beneficiary meets the requirements for home health services as part of their scope of practice. A beneficiary who lacks access to a community-based primary care physician must be admitted to a facility and placed under the care of facility-based physicians before home health services can be ordered even if the beneficiary is under the care of a nurse practitioner who is serving as their primary care provider. This limitation can result in a higher total cost of care and unnecessary utilization. This benefit enhancement would allow nurse practitioners (if allowed under their state’s scope of practice laws) to make home health services certifications to test whether this flexibility can prevent unnecessary utilization and reduce the total cost of care.</p>
<p>Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit</p>	<p>The proposed Benefit Enhancement currently under consideration by CMS allows entities to waive the requirement that beneficiaries who elect the Medicare Hospice Benefit give up their right to receive curative care (sometimes referred to as “conventional care”) as a condition of electing the hospice benefit. All expenditures incurred by Medicare on behalf of such beneficiaries, whether for hospice or other non-hospices services would be included as part of Total Cost of Care for the relevant performance year.</p> <p>Similar to the operation of the 3-Day Skilled Nursing Facility Rule Waiver, KCF Practices will identify the hospices with which they will partner in this Benefit Enhancement. Through the application and implementation plan, entities will be asked to describe how the identified KCF practices have the appropriate staff capacity and necessary</p>

⁷ <http://www.transitionalcare.info/>

⁸ <http://www.homehealthquality.org/Education/Best-Practices.aspx>

Name	Description
	<p>infrastructure to carry out proposed care coordination activities, and consistent with existing Hospice Conditions of Participation,⁹ will be asked to explain their process for how they will ensure working with partner hospices and other non-hospice providers that an appropriate plan of care will be developed for beneficiaries receiving concurrent care and ensure that the beneficiary is fully informed of what care or services are included in the care plan, what is not, what clinician or organization will be providing which services, how care coordination will be achieved, and whether there are any limitations, including services provided for transitional purposes only.</p> <p>Medicare will retain its existing claims-based edits to prevent non-hospice claims from being processed while a beneficiary is under hospice election. As such, it will be the entity’s responsibility to make payment arrangements with and process claims submitted by its partner hospices or other non-hospice organizations to pay for services not paid for through Medicare’s payment for hospice services. Entities utilizing this payment waiver are expected to have the operational capacity to carry out this function in order to ensure high levels of care coordination and service integration.</p> <p>For purposes of this payment waiver, a KCF practice may not partner with any hospice that has existing condition level deficiencies that have not been remediated, and all hospices an entity partners with must readily offer beneficiaries access to the four levels of hospice consistent with clinical need.</p>

G. Termination

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 or required by section 1115A(b)(3)(B) of the Social Security Act.

To determine whether KCF practices can succeed in improving quality and reducing costs over a longer period of time, KCF practices will be incentivized to participate in the Model for a minimum of two performance years (PY1-PY2), in addition to the Implementation Period. KCF practices that provide a notice of termination to CMS by February 28 of a Performance Year, with an effective date 30 days following the notice of termination, will be able to leave the model and revert to receiving Medicare Fee-For-Service payments effective as of the effective date of the notice. If a KCF practice provides a notice of termination to CMS after February 28 of a Performance Year, the effective date of the termination will be December 31st of the Performance Year, and the practice will continue to be paid under the terms of

⁹ The beneficiary maintains the right to see any Medicare participating healthcare provider at any time under the traditional Medicare FFS benefit structure. Example language may read “You still have the right to visit any dialysis facility, doctor, hospital, or healthcare provider that accepts Medicare” and/or “This is not a Medicare Advantage Plan or any kind of managed care plan”.

the Model for the remainder of that Performance Year. KCF Practices will have an opportunity to withdraw their notice of termination before the Performance Year ends (“Reconsideration Period”). KCF practices that proceed to terminate from the Model after the Reconsideration Period expires may not be able to participate in another CMMI Model for one year, to be determined at CMS’s discretion. In addition, CMS may consider the duration of a KCF practice’s participation in the KCF Option when reviewing any future applications by the practice to participate in other CMMI Models.

H. Application for KCF Option

Practices interested in participating in the KCF Option must file an application by no later than January 22, 2020, at 11:59pm. To file an application, applicants may access an electronic portal via the KCC Model website at <https://innovation.cms.gov/initiatives/voluntary-kidney-models/>. An application template is provided below for response from applicants.

Applicants must create a username and password in order to access the application portal. Applicants will be asked to respond to a series of questions on the description and nature of the entity, primary contact information, legal and organizational structure, and more.

CMS reserves the right to request additional information (interviews, site visits, or additional information related to application responses) from applicants in order to assess their applications.

Applicants seeking to withdraw their application must submit an electronic withdrawal request to CMS via the following mailbox: KCF-CKCC-CMMI@cms.hhs.gov. The request must be submitted as a PDF on the organization’s letterhead and must be signed by an authorized corporate official authorized to bind the applicant. It should include: the applicant organization’s legal name; the organization’s primary point of contact; the full and correct address of the organization; and a description of the nature of the withdrawal. Applicants seeking to withdraw only specific CMS Certification Numbers (CCNs) and/or National Provider Identifier (NPI) numbers from a pending application must follow the same process outlined above. Note that withdrawal of CCNs and/or NPIs from an application will require CMS to reassess the applicant’s eligibility in terms of its ability to meet the minimum number of beneficiaries eligible for alignment to be in the Model.

Application Template for KCF Option

Practices should include the requested information for all of their suppliers that they intend to include in the Model along with the initial application submission. There will not be an opportunity to submit additional suppliers after the application is submitted and before applications are adjudicated. Prior to the signing of the KCF Participation Agreement, selected applicants must have all of their suppliers identified and CMS-vetted through the Center for Program Integrity.

Questions about the application should be directed to KCF-CKCC-CMMI@cms.hhs.gov.

Section A – Applicant KCF Information and Eligibility Requirements

1. Applicant is a(n):
 - Individual Nephrologist(s) Professional Corporation
 - Nephrology Physician Practice
2. KCF Practice Contact Information (Required)

- KCF Practice Legal Name:
 - Mailing Address (Street, City, State, Zip Code):
3. Is your practice owned and operated by a larger health care organization or other parent organization, such as a health system or a group practice?
- Yes; if yes, respond to Question 4 and skip Question 5:
 - No; If no, Skip Question 4 and respond to Question 5:
4. What is the name of the parent organization?
- Corporate Street Address:
 - Corporate County:
 - Corporate State:
 - Corporate Zip Code:
 - Corporate Phone Number:
 - Name of primary organizational contact. We will use this information to link practices within the same larger health care/parent organization.
- First Name:
Last Name:
Email:
Phone Number:
5. If organization is not owned by outside entity, who owns this practice? Select all that apply.
- Physicians in the practice
 - Non-physician practitioners (nurse practitioners or physician assistants) in the practice
 - Another physician organization
 - Public or private hospital, health system, or foundation owned by a hospital
 - Insurance company, health plan or HMO
 - Medical school or university
 - Other (please specify)
6. Does your practice share a TIN for billing with other practices that are part of the same health group or system?
- Yes
 - No
7. KCF Primary Contact (Required) and Secondary Contacts: Submit contacts' information (name, title, phone number, and email)

- KCF Executive:
- CMS KCF Option Liaison with CMS:
- Applicant Primary Contact (required):
- Applicant Secondary Contact (optional):
- Health Information Technology Contact:

8. Are any of the KCF Organization’s nephrologists currently participating in the CEC Model?

- Yes
- No

If so, please describe the nature of their participation in the CEC Model (ex. participant owner or participant non-owner, etc.) _____

9. Please indicate if any of the Model organization’s nephrologists have participated in or are participating in any of the following:

- Accountable Health Communities
- ACO Investment Model
- Advance Payment ACO Model
- Bundled Payments for Care Improvement (model)
- Comprehensive Care for Joint Replacement
- Comprehensive Primary Care Initiative
- Comprehensive Primary Care Plus
- Independence at Home Demonstration
- Maryland All-Payer Model
- Maryland Total Cost of Care Model
- Medicare Care Choices Model
- Medicare Shared Savings Program
- Medicare ACO Track 1+ Model
- Next Generation ACO Model
- Oncology Care Model
- Pioneer ACO Model
- Private, For-Profit Demo Project for the Programs of All-Inclusive Care for the Elderly (PACE)
- State Innovation Models Initiative
- Transforming Clinical Practice Initiative
- Other (please specify)
- Not Applicable

10. Please use the spreadsheet template attached to provide your practice and provider information regarding your proposed suppliers so CMS can conduct a program integrity screen for your practice and proposed nephrologists and determine the market area where you plan to operate a

KCF practice under the model. You must include all the states, counties and zip codes of the Applicant Practice's organization's proposed nephrologists. The attachment is titled "KCF Participant Add Template.xlsx".

11. Please describe the Applicant's performance under prior or current risk sharing arrangements, if any. Risk sharing arrangements must include: (1) financial accountability; (2) evaluation of patient experiences of care; and (3) substantial quality performance incentives. If applicable, please include performance under CMS programs, and demonstrations, and models that meet the definition of outcomes-based contracts (No more than 2 pages). Provide an "N/A" response if no prior or current risk sharing arrangements.
12. I certify that my organization is a recognized legal entity formed under applicable state, federal, or tribal law and authorized to conduct business in each state in which it operates or will be by the time the Participant Agreement is signed.
 Yes

Section B – Organizational Structure, Leadership and Management, and Governance Structure

13. Please provide a paragraph summarizing your KCF Practice. This may include: the practice's history, mission, and organization, including your practice's affiliations; the practice's composition, geographic service area including where most of the practice's patients reside, if the service area encompasses urban, suburban, and/or rural locations, if the area includes underserved beneficiaries, and if the practice will work with other community-based organizations under the KCF Option if selected to participate (e.g., care management organization, ESRD networks, quality improvement organization, etc.). Please include any other applicable narrative describing the KCF practice.
14. By checking the box below, you attest that your compliance plan identifies a compliance officer, who must not be legal counsel to the applicant, must not be in a direct reporting relationship to legal counsel for the applicant, and must report directly to the applicant's governing body, and that the compliance plan includes a description of the following:
 - a. A quality assurance strategy that, at the very least, includes a peer review process to investigate cases of potentially suboptimal care;
 - b. The internal process for addressing a request for corrective action plan (CAP) by CMS and a description of the circumstances under which the organization would terminate an agreement with a participating nephrologist;
 - c. The remedial processes that apply when participating nephrologists fail to comply with the KCF Participation Agreement, Medicare regulations, and/or internal procedures and performance standards including correction action plans (CAPs) and circumstances for termination; and,
 - d. An antitrust compliance plan sub-section that describes appropriate firewalls, or other safeguards against, improper exchanges of prices or other competitively sensitive information among competing participant that could facilitate collusion and reduce competition in the provision of services outside the KCF Practice organization.
 - e. Compliance training programs for the KCF practice participating nephrologists.
 - f. A method for KCF practice nephrologists to anonymously report suspected problems related to the nephrologist/KCF practice to the compliance officer.

- g. A requirement for the KCF practice to report probable violations of law to an appropriate law enforcement agency.
- h. The KCF practice compliance plan must be in compliance with all applicable laws and regulations and be updated periodically to reflect changes in those laws and regulations.
 - I attest that my compliance plan meets the listed criteria. I further certify that the information contained within the compliance plan is true and correct and that the compliance plan is in compliance with all applicable laws and regulations and be updated periodically to reflect changes in those laws and regulations.

Section C – Care Model Patient Centeredness

- 15. Please provide a narrative explanation of 1) why the Practice wishes to participate in the KCF Model, 2) the Practice’s proposed nephrologists, and 3) how the Practice will achieve the goals of better health and better care for Medicare beneficiaries with CKD, ESRD, and transplants (No more than 2 pages).
- 16. Please provide a narrative description of the KCF applicant’s plan for engaging with CKD and ESRD beneficiaries and their caregivers. At a minimum, please address the following (No more than 10 pages):
 - a. Managing the progression of CKD
 - b. Modality options and transition onto dialysis
 - c. Coordination of care with different providers and suppliers
 - d. Transplant process and Managing post-transplant care
 - e. Health I.T. and data interoperability
 - f. Social determinants of health
 - g. Prescription drug utilization
 - h. Shared decision-making, self-management and self-care skill development
 - i. Managing care for dually eligible beneficiaries

Section D – Attestation and Signature

I have read the contents of this application. By my signature, I certify to the best of my knowledge, information, and belief that the information contained herein is true, correct, and complete, that I am authorized to sign this application on behalf of the applicant organization, and that I authorize the Centers for Medicare & Medicaid Services (CMS) to verify this information. If I become aware that any information in this application is not true, correct, or complete, I agree to notify CMS of this fact immediately and to provide the correct and/or complete information. This authorization is on behalf of the KCF Applicant Organization.

Printed Name Applicant Contact

Date

Signature of Applicant Contact

Date

IV. The Comprehensive Kidney Care Contracting (CKCC) Options

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. KCEs will focus on improving the quality of care, reducing total cost of care, delaying the progression of kidney disease, and increasing the transplant rate.

The CKCC Options will include: 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 DC Model, and a Global Option based on the Global Population-Based Payment option of the DC Model. In all three Options, the health care providers participating in the KCE will receive adjusted capitated payments for managing care for beneficiaries with CKD stages 4 and 5, and ESRD. The KCE will select a payment option, and will be accountable for quality outcomes. KCEs will be able to move from a lower risk option to a higher risk option at the start of each performance year, but would not be able to move to a lower risk option from a higher risk option. For instance, a KCE can move from Level 1 of the Graduated Option to the Professional Option in the following PY or from the Professional Option to the Global Option, but not vice versa.

A. Legal Entity and Contracting Requirements

Each KCE must be identified by a single TIN and be a separate and unique legal entity that is recognized and authorized to conduct business under applicable federal, state, or tribal law. The KCE should be formed by KCE Participants, which are Medicare-enrolled providers and suppliers who have a participant agreement in place with the KCE. The KCE may be an existing legal entity if it conforms to all of the relevant requirements set forth in this RFA and the CKCC Participation Agreement (e.g., governance and structure requirements). To be eligible for Model participation, the KCE must be capable of:

- Receiving and distributing shared savings payments or other payments received from CMS under the one of the CKCC Payment Options.
- Collecting and repaying shared losses, if applicable.
- Establishing reporting mechanisms and ensuring KCE compliance with applicable Model requirements, including but not limited to reporting on quality measures.
- Securing a financial guarantee, if applicable.

To ensure beneficiary freedom of choice, the KCE must not interfere with its KCE participants' ability to refer their Medicare beneficiaries to any dialysis facility or other Medicare-enrolled provider or supplier or otherwise prevent full beneficiary freedom of choice of providers and suppliers.

KCEs must include as KCE participants at least one nephrologist or nephrology group practice, and at least one transplant provider (i.e., transplant center, transplant surgeon, transplant nephrologist, and/or organ procurement organization (OPO)). Nephrologists may only participate in one KCE, while transplant providers may participate in multiple KCEs. A transplant nephrologist would participate in the KCE in their capacity as a transplant provider and could participate in multiple KCEs if they do not identify themselves as an alignment eligible nephrologist. If the transplant nephrologist self-identifies as an alignment eligible nephrologist, they may only participate in one KCE.

Other providers and suppliers may participate in multiple KCEs and other CMS initiatives, if consistent with the rules governing the other initiative. Other Medicare enrolled providers and suppliers (other than

DMEPOS suppliers, ambulance suppliers and drug/device manufacturers) are able to join the KCE as KCE participants, but their participation is not mandatory for KCE eligibility. We note that the Shared Savings Program does not allow ACOs to include providers or suppliers that participate in Innovation Center Models that involve shared savings as ACO participants. Overlap with the Shared Savings Program would be allowed during the Implementation Period (2020), but under the CKCC Options, KCE participants will be precluded from participating in the Shared Savings Program during PY1 and future years of the Model.

The KCE may also contract with other community-based organizations (e.g., care management organizations, quality improvement organizations, etc.) that are not KCE participants or Preferred Providers (described below) (e.g., because they have not entered into an arrangement with the KCE to participate in the CKCC Participation Agreement). These organizations (hereinafter referred to as “KCE partners”) are not considered KCE participants, but will nonetheless likely be helpful to the KCE as it the KCE works to address the clinical elements in the Model.

KCE Governance Structure Requirements

A KCE must maintain a separate and unique identifiable governing body with sole and exclusive authority to execute the functions and make the final decisions on behalf of the KCE. The governing body may be a board of directors, board of managers or any other governing body structure that provides a mechanism for shared governance and decision making. The KCE governing body must:

- Have authority to execute the functions of the KCE including defining the processes to promote evidence-based medicine and patient engagement, reporting on quality and cost measures and coordination of care, and the appointment and removal of an executive officer.
- Have authority for final decision-making for the KCE, including responsibility for oversight and strategic direction of the KCE and responsibility for holding the KCE management accountable for the KCE’s activities.
- Have a conflict of interest policy that applies to members of the governing body, requires disclosure of all relevant financial interests and other conflicts of interest, identifies processes for resolution of conflicts of interest, and sets forth remedial processes for non-compliance.
- Have a transparent governing process to ensure CMS ability to monitor and audit as appropriate.
- Receive regular reports from the designated compliance official of the KCE, who is not legal counsel to the KCE and who must report directly to the governing body.

The KCE governing body must be structured as follows:

- Decision-making must be KCE participant-driven, as evidenced by KCE participants having at least 75% control of the KCE’s governing body. The beneficiary representative shall not be included in either the numerator or denominator when calculating percent control. The KCE may seek an exception from the 75 percent control requirement by submitting a proposal to CMS describing the current composition of the KCE's governing body and how the KCE will involve CKCC Participants in innovative ways in KCE governance. Any exception to the 75 percent control requirement will be at the sole discretion of CMS.
- Nephrologists or representatives of nephrology practices must represent at least 30% of the membership of the governing body.
- Members of the governing body must place their fiduciary duty to the KCE before the interests of any KCE participant or other individual or entity and act consistent with that fiduciary duty.

- The governing body must ensure representation of patient interests by including an independent Medicare beneficiary with CKD or ESRD as a member and/or a trained or experienced non-affiliated, independent consumer advocate on the governing body. This representative must not have a conflict of interest with the KCE or have an immediate family member with a conflict of interest with the KCE. The representative must not be a participant in the KCE and not have a direct or indirect financial relationship with the KCE or its KCE participants, except that the person may be reasonably compensated by the KCE for his or her duties as a member of the governing body of the KCE.
- At least one governing body member must be an employee or executive of a transplant provider.

B. Applicant Eligibility

Together, the following types of providers/suppliers are required participants to form a KCE:

- Nephrologists and/or nephrology practices.
- Transplant Centers, transplant surgeons, transplant nephrologists, and/or OPOs.

Transplant providers may participate in multiple KCEs. 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. In addition, any of the following optional Medicare-enrolled providers or suppliers may participate in a KCE with the required KCE participants:

- Medicare-certified dialysis facilities, including facilities owned by large dialysis organizations (LDOs), facilities owned by small dialysis organizations (SDOs), or independently-owned dialysis facilities. All dialysis facilities in a single KCE must be owned by the same dialysis company to avoid anticompetitive practices. Additionally, if the KCE includes dialysis facilities as KCE participants, it must include greater than 85% of the dialysis facilities owned in whole or in part by the dialysis company in the KCE market area as described below.
- Other Medicare-enrolled providers and suppliers.

All types of providers and suppliers other than nephrologists/nephrology practices and transplant providers, including dialysis facilities, are optional KCE participants. DMEPOS suppliers, ambulance suppliers, and drug/device manufacturers are prohibited from participating in a KCE. While the KCE will not be required to be a Medicare-enrolled provider or supplier, all KCE participants under the KCE must be a Medicare-enrolled provider or supplier by a date specified by CMS.

All KCE participants must be physically located in the KCE's market area. Generally, a KCE's market area is defined as no more than four core-based statistical areas (CBSAs), with permissible inclusion of rural counties that are not included in a Medicare CBSA that are within the same state or states as the KCE market. The CBSAs need not be contiguous, but must be connected by rural counties or with no more than one CBSA in between KCE CBSAs. The only exception to this requirement would be in the case of rural applicants not included in any Medicare CBSA. For rural applicants not included in any Medicare CBSA, the market area of the KCE market area will be defined based on a geographic unit no larger than the state that the KCE is located in, and will be composed of the rural counties in which KCE participants are located. CMS will also consider an exception for certain providers/suppliers who deliver telehealth services for KCE beneficiaries given their national geographic reach, such that these providers/suppliers can participate in the KCE even if they are not located in the KCE's market area. Dialysis facilities and nephrologists/nephrology practices would not be subject to this exception and

would need to be physically located in the KCE's market. Medicare providers/suppliers in the state of Maryland will be able to apply to participate in a KCE.

Similar to the DC Model, the CKCC Option clearly defines categories of Medicare providers/suppliers and their respective relationships to the KCE. The two primary categories are KCE participants and Preferred Providers and they apply to all three payment options:

- KCE participants are the core providers/suppliers in the Model. The services furnished by nephrologists that are KCE participants are used for purposes of aligning beneficiaries to the KCE and these KCE participants are responsible for, among other things, reporting quality measures through the KCE.
- Preferred Providers contribute to KCE goals by promoting better care for beneficiaries by extending and facilitating valuable care relationships beyond the KCE. Services furnished by Preferred Providers will not be considered in beneficiary alignment and Preferred Providers are not responsible for reporting quality through the KCE.

Both KCE participants and Preferred Providers must have agreements in place with the KCE that satisfy the requirements of the CKCC Participation Agreement. Both KCE participants and Preferred Providers have the opportunity to participate in the CKCC Option's Benefit Enhancements.

While various combinations of eligible Medicare-enrolled providers and suppliers are permitted to participate in a KCE, CMS has established several limitations on KCE composition to protect against further consolidation of the dialysis market. Dialysis facilities owned in whole or in part by different dialysis companies are prohibited from applying or participating as part of the same KCE—meaning that only facilities owned by one a single dialysis company are permitted to participate in a KCE.

KCEs will be incentivized to participate in the KCC Model for a minimum of two performance years (PY1-PY2). This incentive and the consequences of voluntary termination prior to completing PY2 can be found in Section V.G below. In addition to these safeguards, existing antitrust rules will apply and KCE applicants should consider the potential impact of those requirements when structuring their organizations. CMS approval of an applicant to participate in the CKCC Option does not constitute a determination that the arrangements comply with existing antitrust law. All KCE organizational and provider/supplier arrangements must satisfy the legal entity and contracting requirements described in detail in Section IV.A.

C. Beneficiary Alignment

The patient population for the CKCC Option is Medicare beneficiaries with CKD stages 4 and 5, ESRD, and kidney transplants. It is important to note that the alignment of beneficiaries to KCEs is for Model test purposes only. Model activities for which beneficiary alignment under this Model is relevant includes each KCE's expenditure calculations, quality performance measurement, and CMS' monitoring of claims data. Beneficiary alignment to a KCE does not inhibit beneficiaries' freedom to choose to receive care from other Medicare providers and suppliers within Medicare FFS. Similar to other programs and models, the CKCC Option does not include provisions for beneficiaries that have been aligned to a KCE to opt out of alignment, but they may opt out of certain data sharing with the KCE. Aligned beneficiaries may obtain nephrology services from health care providers not participating in a KCE, which could exclude them from being aligned to a KCE retroactively during alignment reconciliation.

Beneficiary Eligibility

To be eligible for alignment and to remain aligned to a KCE for a performance year, beneficiaries must meet all of the following criteria, except where otherwise noted:

- Have either late stage CKD (stage 4 or 5) or ESRD, or be a transplant recipient with a functioning kidney who was previously aligned to the KCE while the beneficiary had late stage CKD or ESRD.
- 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 MCPs billed in the KCE's market area (ESRD beneficiaries only).
- Receive the plurality of their CKD care in the KCE'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 CKCC Option (please refer to Section 14, Overlap, for additional information).
- Not have Medicare as a secondary payer.

Upon application approval and throughout each year thereafter, the KCE must provide health services to a minimum of 1,000 aligned Medicare beneficiaries with late stage CKD and 350 ESRD beneficiaries. There is no Model requirement that the KCE furnish services to a minimum number of aligned transplant beneficiaries. Aligned transplant beneficiaries do not count towards the minimum number of aligned CKD or ESRD beneficiaries.

The Innovation Center will prospectively align eligible beneficiaries through a claims-based process. The beneficiary alignment process (described in detail in the *Alignment Process* section below) identifies the Medicare beneficiaries with late stage CKD (stages 4 and 5), ESRD, and a kidney transplant for whom CMS will hold a KCE clinically and financially accountable under the terms of the CKCC Participation Agreement.

Alignment Process

Initial and continued alignment for the CKCC Options will occur through the nephrologist for each stage of kidney care (CKD stages 4 and 5, ESRD, or transplant recipient) and will differ based on the beneficiary's stage of kidney disease. This is different than the CEC Model, where beneficiaries are aligned through the dialysis facility.

CMS believes that aligning beneficiaries through the nephrologist has the following advantages:

- Prioritizes the nephrologist relationship as the most important one for beneficiaries with late stage CKD, ESRD, or kidney transplant.
- Protects the continuity of care by aligning a beneficiary with CKD stages 4 or 5 with the same nephrologist who might then be treating them for ESRD, although it does not have to be the same nephrologist.
- Allows for beneficiaries who only dialyze at nursing facilities, instead of outpatient dialysis facilities, to be aligned to KCEs and included in the Model test, given that they are still seen by nephrologists.

Alignment will be as prospective as is feasible given particular mechanisms, summarized in the table below, and will be retrospectively finalized as part of a reconciliation process after each performance year, allowing for a minimum of three months claims run-out. CMS will identify the final aligned beneficiary population for the KCE. Beneficiaries will be de-aligned from the list of aligned beneficiaries if, at some point during the performance year, they no longer satisfy the KCE alignment eligibility criteria, do not receive certain health services from a KCE nephrologist during the performance year, or receive the majority of certain health services outside of the KCE’s market area.

De-alignment criteria, including not receiving care from a KCE participant who is a nephrologist during the performance year or receiving the majority of certain health services outside the KCE’s market area, are designed to ensure an accurate measure of the cost and quality of the beneficiary care in the model test. The de-alignment criteria emphasize the care relationship between the KCE participant who is a nephrologist and the aligned beneficiary. While there may be some incentive for a participant to refer aligned beneficiaries outside of the market area in order to de-align them from the KCE (and in doing so, take advantage of the de-alignment criteria) – experience in the CEC Model has shown that the market areas, as defined above, tend to be large enough that seeking care outside of the market area truly represents a change in beneficiary residence rather than strategic referrals. This approach balances predictability in beneficiary populations and accuracy in alignment, while reflecting the unique way CKD and ESRD beneficiaries interact with the health care system.

KCEs will receive a list at the start of the Model with the aligned beneficiaries whose care they will be accountable for based on visits in the past year. New beneficiaries who satisfy the alignment eligibility criteria will be added to each KCE’s alignment list on a quarterly basis. Once aligned, beneficiaries remain aligned to the KCE until they meet one of the criteria for de-alignment.

Table 9. Alignment Criteria by Beneficiary Type

	Beneficiaries with CKD	Beneficiaries with ESRD	Beneficiaries who Receive Kidney Transplants
Aligning KCE Participant	Nephrologist	Nephrologist	N/A – Must have been previously aligned by virtue of CKD or ESRD
Criteria for Alignment	Diagnosis of CKD Stage 4 or 5; 2 or more Evaluation & Management (E&M) visits within a 6 month period with a KCE nephrologist	Diagnosis of ESRD; 2 or more Monthly Capitation Payment (MCP) visits within a 3 month period with a KCE nephrologist	Being previously aligned to the KCE as a CKD or ESRD beneficiary and receiving a kidney transplant
Criteria for De-alignment	Beneficiaries no longer meet the criteria for alignment; receiving the majority of E&M visits from a non-KCE nephrologist, from a different KCE nephrologist in the market area, or outside the KCE market area	Beneficiaries no longer meet the criteria for alignment; receiving the majority of MCP visits from a non- KCE nephrologist, from a different KCE nephrologist in the market area, or outside the KCE market area	Beneficiaries no longer meet the criteria for alignment; kidney transplant failure (the beneficiary may be aligned as a CKD or ESRD beneficiary post-transplant failure if the applicable requirements for alignment are met)

When an aligned CKD or ESRD beneficiary receives a transplant they will remain aligned to the KCE for 3 years from the month of transplant in order for the KCE to be eligible to receive Kidney Transplant Bonus payments, but the beneficiaries' expenditures will no longer be counted toward financial calculations and the beneficiary will not be included in the quality performance sample for the KCE. If the transplant fails, the beneficiary will be de-aligned. It is possible for a transplant beneficiary to become realigned as a CKD or ESRD beneficiary in the event their transplant fails (either to the original KCE or to a different KCE). It is also possible that an aligned beneficiary who progresses from CKD to ESRD switches alignment "type" when they progress, assuming they meet alignment criteria for ESRD beneficiaries. When an aligned beneficiary's alignment type changes, the KCE's number of aligned CKD and ESRD beneficiaries also changes (i.e., where an aligned beneficiary's kidney disease progresses from CKD to ESRD, the beneficiary would count towards the KCE's number of aligned ESRD beneficiaries and no longer count towards the KCE's number of aligned CKD beneficiaries, assuming the beneficiary meets the requirements for alignment by virtue of their ESRD).

In order to continue with participation in the Model, the KCE must maintain at least 1000 late stage CKD and 350 ESRD aligned beneficiaries throughout the life of the Model. There is no minimum number of aligned transplant beneficiaries required. Aligned transplant beneficiaries do not count towards the number of CKD or ESRD aligned beneficiaries. If at any point a KCE drops below the minimum threshold, the KCE will be required to submit a Corrective Action Plan (CAP) explaining the steps it will take to meet the minimum threshold for CMS' review and approval. This will allow the KCE the opportunity to add KCE participants for purposes of increasing its number of aligned beneficiaries. KCEs are prohibited from adding KCE participants during a performance year and will only be able to do so prior to the start of a performance year at a time and manner specified by CMS. This prohibition does not extend to preferred providers. If the minimum threshold remains unmet prior to the start of the next performance year, CMS may pursue additional compliance actions including, but not limited to, termination of the KCE from the Model.

Finalizing Alignment

Alignment will be retrospectively finalized as part of a reconciliation process after each performance year. CMS will identify the final aligned population for the KCE, including each beneficiary's months of alignment within the performance year, and will allow for a minimum of three months claims run-out. In certain cases, a beneficiary may become de-aligned from the KCE alignment list for the entire performance year at reconciliation if they:

- Lost alignment eligibility;
- Received the majority of their E&M visits or MCP treatments outside of the KCE's market area;
- Received the majority of their E&M visits or MCP treatments at a different KCE within the aligning KCE's market area; or
- Did not receive the requisite services from a KCE participant who is a nephrologist during the performance year.

Select beneficiary months may be removed from alignment reconciliation (e.g., months following a beneficiary's death).

Beneficiary Protection

All KCEs will be required to share with aligned beneficiaries certain details about their alignment to the KCE. CMS must approve written materials and marketing plans prior to use in a manner that is reasonable in terms of standards, time frame, and procedure. For KCEs' ease, CMS will consider

providing templates that participants must use. If CMS provides a template to be used for these notification requirements, such template will include all of the required information described below and prior CMS review/approval of the template will not be needed. The KCE must also comply with all applicable federal laws regarding interaction with Medicare FFS beneficiaries.

Specifically, KCEs will be required to share information with aligned beneficiaries, informing them of the initiative and the beneficiary's alignment to a KCE participating in the Model.

The notification must include the following elements:

- A short description of the CKCC Option the KCE is participating in and what that means for their care;
- An explanation that the beneficiary retains full Medicare FFS benefits and the freedom to choose his or her providers and suppliers;¹⁰
- Details of the KCE's Benefit Enhancements;
- Information on how to opt out of CMS sharing certain information about them with the KCE (described in more detail in the *Data Sharing* section, below); and
- Contact information for the KCE and 1-800- MEDICARE for questions and/or concerns.

CMS will reserve the right to review any Marketing Materials and Activities to ensure that the materials comply with the terms of the CKCC Participation Agreement, including that they are not inaccurate or misleading, are not discriminatory or used in a manner that is discriminatory, and make clear that alignment to a KCE does not remove or otherwise affect a beneficiary's freedom to choose a provider or supplier. Additional requirements concerning this review process will be provided in the CKCC Participation Agreement.

Data Sharing

CMS will provide historical and monthly claims data to KCEs, consistent with data sharing practices in other comparable models and programs. All information will be provided consistent with all applicable laws and regulations, including HIPAA and the Part 2 regulations governing the disclosure and use of certain substance use disorder patient records.

Specifically, under appropriate agreements (e.g., the CKCC Participation Agreement) and upon a KCE's request, CMS will make available several types of Medicare data for the sole purposes of developing and implementing activities related to coordinating care and improving the quality and efficiency of care for beneficiaries aligned to the KCE under the CKCC Options.

Upon request from the KCE, CMS will provide (1) data on aligned beneficiaries that will include individually identifiable demographic and Medicare eligibility status information and various summary reports with data relevant to the CKCC Options operations and performance in the Model (such as data related to quality, expenditures, etc.); and (2) detailed claims data files that will include individually identifiable claim and claim line data for services furnished by Medicare-enrolled providers and suppliers to aligned beneficiaries. KCEs in the CKCC Global Model that elect the TCC payment mechanism will receive claims and payment information from CMS for the services furnished to aligned beneficiaries by KCE participants and Preferred Providers. Historical data files for aligned beneficiaries will be limited to

¹⁰ The beneficiary maintains the right to see any Medicare participating healthcare provider at any time under the traditional Medicare FFS benefit structure. Example language may read "You still have the right to visit any dialysis facility, doctor, hospital, or healthcare provider that accepts Medicare" and/or "This is not a Medicare Advantage Plan or any kind of managed care plan".

three years of historical data, consistent with the approach under the CEC Model and other shared savings models and programs.

The claims data provided to the KCE will not include individually identifiable data for aligned beneficiaries who have opted out of data sharing. Moreover, the CKCC Options will honor the data sharing opt out decisions by beneficiaries who were previously given that choice while an aligned beneficiary in another Medicare ACO initiative. KCEs will be required to notify newly aligned beneficiaries regarding the organization's intent to request their claims data from CMS and to provide information or forms regarding the opportunity to decline data sharing. Beneficiaries may opt-out of data sharing by calling 1-800-MEDICARE.

KCEs may inform each newly-aligned beneficiary, in compliance with applicable laws and regulations, that he or she may elect to allow the KCE to receive beneficiary-level data regarding the utilization of substance use disorder treatment services, the mechanism by which the beneficiary can make this election, and contact information for answers to any questions about data sharing regarding substance use disorder services. CMS will provide KCEs with a Substance Use Disorder Treatment Opt-In Form.

D. Finance and Payment

Nephrologists and nephrology practices who participate in a KCE will receive adjusted capitated payments for managing beneficiaries with CKD stages 4 and 5, and ESRD. KCEs will be eligible for the following payments:

- CKD Quarterly Capitation Payment (CKD QCP)
- Adjusted Monthly Capitation Payment (AMCP)
- Kidney Transplant Bonus (KTB)
- Shared savings/shared losses under one of the following options:
 - CKCC Graduate
 - CKCC Professional Option
 - CKCC Global Option

General Payment Model Provisions

CKD Quarterly Capitation Payment

As part of the KCE CKCC Options, CMS will pay KCEs through an innovative per beneficiary CKD Quarterly Capitated Payment (CKD QCP), which combines payment for several different outpatient Evaluation and Management (E/M) codes, and other care management codes listed below, into a single capitated payment. The CKD QCP is intended to provide an upfront payment to facilitate delivery of care for aligned beneficiaries with CKD stages 4 or 5. The CKD QCP payment is mandatory for Participants and Preferred Providers in the KCE. KCEs (including their preferred providers) will have their Medicare FFS payments for these included services reduced by 100% and instead receive the CKD QCP payment from CMS, instead of regular Medicare payments, for included services delivered to aligned beneficiaries. KCEs will have arrangements with their CKCC Participants and their Preferred Providers, and any requirements of such arrangements will be detailed in the PA. Nephrologists and other providers and suppliers will still be required to submit claims with the relevant codes for data collection and quality purposes, but CMS will only pay the CKD QCP for included services furnished to aligned beneficiaries with late-stage CKD stages 4 or 5. The CKD QCP is designed to allow flexibility in care delivery and to give providers/suppliers a more stable payment stream to deliver advanced care for aligned CKD beneficiaries with late-stage CKD. For the beneficiary, this may result in increased access to nephrologist care for their CKD, improved efficiency and coordination in addressing health issues, and improved

patient experience. The model will test whether upfront, predictable revenue will help the nephrologist coordinate care for aligned beneficiaries with other specialists to better address their renal needs.

Table 10. Services Included in the CKD QCP

Services Included in the CKD QCP	CPT¹¹/HCPCS Codes
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

KCEs that receive the CKD QCP will continue to receive normal fee-for-service payments for services furnished to aligned beneficiaries that are not included in the CKD QCP, such as inpatient visits, and services for beneficiaries with CKD Stages 4 and 5 or who have received transplants. KCE participants will also continue to receive normal fee-for-service payments, rather than CKD QCPs, for services furnished to beneficiaries not aligned to the KCE. Beneficiary cost sharing for the services included in the CKD QCP will be set at the cost-sharing amount which a beneficiary would have paid for the particular E&M or care coordination service furnished to the beneficiary during a particular encounter, rather than the amount the beneficiary would have had to pay based on the CKD QCP amount. The CKD QCP amount will be approximately one third of the Adjusted Monthly Capitated Payment (AMCP) rate for aligned ESRD beneficiaries, described below, and will be paid on a per beneficiary per month basis. The CKD QCP payment amount will be the same amount for a CKD stage 4 or CKD stage 5 beneficiary. These payments will not be risk adjusted, given very similar risk profiles in the CKD stages 4 and 5 populations.

Modeled off of the leakage methodology from the PCF Model, the CKD QCP will be adjusted quarterly to account for “leakage rates” based on the aggregate CKD nephrology services included in the CKD QCP (see Table 10) furnished outside of the KCE for the KCE’s aligned late-stage CKD beneficiaries. Under this leakage rate construct, we presume that beneficiaries will tend to increase the amount of nephrology care they seek elsewhere if they are not satisfied with the care they receive from the KCE. Thus, increases in services delivered by nephrologists outside of the KCE to aligned beneficiaries with late-stage CKD will lead to a reduction in future CKD QCPs.

Operationally, CMS will calculate a KCE’s leakage rate by dividing the number of primary care visits that aligned beneficiaries received from the KCE in the prior performance period, with adequate claims

¹¹ CPT codes, descriptions and other data only are copyright 2019 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

run-out, by the total number of primary care visits that these beneficiaries received from any practice in the same time period.

Adjusted Monthly Capitation Payment (AMCP)

Currently, Medicare pays physicians and other practitioners who manage dialysis care for beneficiaries receiving dialysis through the MCP. The per-patient-per-month MCP payment is for all routine outpatient physicians' services related to the dialysis patient's renal condition. The amount of the MCP varies based on several criteria:

- The location where the beneficiary dialyzes (at home or in center).
- The number of face-to-face visits with the beneficiary for beneficiaries who dialyze in center (one monthly visit, two or three monthly visits, or four or more monthly visits).
- The age of the beneficiary.

Under the CKCC Options, CMS will modify the current MCP payment structure. KCEs will continue to bill the MCP as they ordinarily would, but will receive the AMCP amount in lieu of the MCP amount for aligned beneficiaries with ESRD. The AMCP will include payment for all services included in the MCP and the same requirements will apply, but payment will not vary based on the number of nephrologist visits as the current MCP does. The AMCP, combined with the other payment and quality incentive features of the model, is designed to provide strong incentives to KCE participants to deliver appropriate care that is not based only on the number of visits for a beneficiary. AMCP payment rates will still vary by patient age as they do now. The payment rate for the AMCP will be based on the current MCP rate for managing an in-center dialysis beneficiary with 2-3 visits during the month, which is equivalent to the current MCP rate for managing a beneficiary who dialyzes at home.

CMS will utilize an AMCP to pay KCE participants for renal care furnished to aligned beneficiaries with ESRD for several reasons:

- Studies that have analyzed the implementation of the MCP show that there is no clear relationship between the number of nephrologist visits per month and beneficiary outcomes. The implementation of the MCP saw an increase in visits, but without any corresponding change in results for beneficiaries who received increased visits.¹²
- The current structure of the MCP, under which nephrologists are paid more for treating beneficiaries who have more frequent visits, creates a financial incentive for nephrologists to furnish four visits per month with beneficiaries who dialyze in center to maximize payment, regardless of whether four visits per month is the best treatment for the beneficiary. Utilizing an AMCP payment rate that is the same amount regardless of the number of beneficiary visits per month reduces provider/supplier burden and enables them to focus on quality of care, rather than the number of visits.
- The current payment structure of the MCP creates a bias toward in-center hemodialysis because the highest MCPs are available for beneficiaries who dialyze in-center and receive four in-person visits a month. According to a 2015 GAO report, equalizing nephrologist payments for home and in-center dialysis removes the financial disincentive for prescribing home dialysis and supports beneficiaries dialyzing at home¹³.

¹² Evaluating the Evidence behind Policy Mandates in US Dialysis Care; Kevin F. Erickson, Wolfgang C. Winkelmayr. JASN Dec 2018, 29 (12) 2777-2779; DOI: 10.1681/ASN.2018090905

¹³ END-STAGE RENAL DISEASE: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis. GAO-16-125: Published: Oct 15, 2015. Publicly Released: Nov 16, 2015.

Kidney Transplant Bonus (KTB) Payment

In addition to the payments described above, KCEs are eligible for up to three kidney transplant bonus (KTB) payments for every aligned beneficiary who receives a kidney transplant, whether from a living or deceased donor, and does not return to dialysis. KCEs would also receive the KTB payment when an aligned beneficiary receives any future FDA-approved products that replace physiological kidney function. The KTB will create a direct incentive for model participants to support beneficiaries through the transplant process, including continued care management of transplant recipients to support graft success. CMS recognizes the lack of supply of available kidneys and that nephrologists do not control access to the transplant wait list, but CMS believes that this payment could better incentivize providers and suppliers to move beneficiaries onto the waitlist, assist beneficiaries with the living donation process, and process, and support beneficiaries after they receive a transplant in maintaining the health of the transplanted organ.

CMS will make up to \$15,000 in KTB payments per transplant, paid to the KCE at set intervals following the transplant. In particular, the KTB will be disbursed to the KCE 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 at each of these points (i.e., – the beneficiary is alive and has not returned to dialysis).

At least 20 percent of KTB payments must be shared with KCE participants who are transplant providers (e.g., transplant surgeons, OPOs, etc.), and an additional 20 percent of the KTB payment must be shared with KCE participants who are nephrologists/nephrology practices in order to ensure that the work of these KCE participants in the transplant process is recognized and to ensure that the KTB payments are used for more than repaying the KCE's operating costs. The distribution of the remaining 60% of the KTB payments is at the discretion of the governing body of the KCE, subject to the requirements of applicable law.

CKCC Options

KCEs in the CKCC Options have three sources of income or losses from CMS. First, KCEs receive the CKD QCP and AMCP and can be eligible to receive the KTB discussed earlier. Second, KCEs that select to participate in the CKCC Global Option, described in more detail below, will have the opportunity to receive a capitated payment monthly covering all Medicare Part A and Part B expenditures, the Total Care Capitation (TCC). Third, KCEs can be eligible for shared savings or (with the exception of Level 1 of the Graduated Option) be liable for shared losses. CMS will calculate a prospective total cost of care benchmark based on total Medicare Part A and Part B expenditures for aligned beneficiaries. CMS will reconcile the total cost of care for the aligned beneficiaries against the performance year benchmark, giving KCEs the opportunity to be eligible to earn shared savings or be liable for shared losses depending on their expenditures compared to the benchmark. The amount that a KCE can retain or owe to CMS varies depending on the CKCC Option in which the KCE participates. The CKD QCP, AMCP and TCC count as expenditures against the performance year benchmark, while the KTB does not. More details on the financial methodology can be found below.

KCE's will have the option to select from among the following options:

CKCC Graduated Option: KCEs participating in this payment option will enter into a path that has one-sided risk in the first PY and transitions to two-sided risk with subsequent downside risk in the following PYs. The first year of this option is based on the one-sided risk track in the CEC Model. Here, KCEs have the option to begin participation under a lower-reward one-sided option and incrementally phase in risk and additional potential reward. This option is intended for KCEs with either no dialysis facility participants or only dialysis facility participants with small dialysis organization ownership (i.e., dialysis

organizations with 35 or fewer dialysis facilities). KCEs with dialysis facility participants owned by dialysis organizations that own, in whole or in part, more than 35 dialysis facilities will not be allowed to participate in this option. This path of increased risk includes two levels: Level 1 (a one-sided, 40% shared savings arrangement available only for the KCE's first performance year); and Level 2 (a shared savings rate of up to 50% based on cost and quality performance with a shared losses rate of a flat 30%). KCEs entering into the Graduated Model option may select either level of risk (Levels 1 or Level 2) at the start of their first performance year. If the KCE selects Level 1 for their first performance year, the KCE will automatically graduate to Level 2 for their second performance year. Following participation in Level 2 of the Graduated Option for one performance year, KCEs will automatically transition into the CKCC Professional Option for each subsequent performance year, sharing in 50% of savings and losses in the total cost of care for Medicare Part A and B services for aligned beneficiaries relative to a benchmark (see more detailed information in the following section on the CKCC Professional Option). The TCC is not available to Graduated Option KCEs.

CKCC Professional Option: KCEs participating in this payment option will share in 50% of savings or losses in the total cost of care for Medicare Part A and B services for aligned beneficiaries relative to a benchmark calculated in the manner specified below. The TCC is not available to Professional Option KCEs.

CKCC Global Option: KCEs participating in the Global PBP Option will be at risk for 100% of the total cost of care for all Medicare Part A and B services for aligned beneficiaries relative to a benchmark calculated in the manner specified below. This option will include the total care capitation (TCC) arrangements described in greater detail below. TCC, which offers a capitated, risk-adjusted monthly payment to KCEs for services that KCE participants furnish to aligned beneficiaries, will build on innovative financial arrangements currently available in the NGACO Model. KCE Participant Providers and Preferred Providers will have the option of participating in the capitated arrangement and reducing their claims amounts between 1 and 100 percent (while continuing to process claims) for services furnished to aligned beneficiaries by such KCE participants. CMS will continue to pay claims for services furnished by providers and suppliers outside of the KCE and for any Preferred Providers who do not opt into FFS claims reductions.

While the payment methodology and degree of risk varies across CKCC options, a common benchmarking methodology will apply across all three models. In this section, the benchmarking methodology will be described first, then the differences between the payment methodologies under the three payment options will be discussed.

Benchmarking Methodology

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
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. The benchmark will be calculated separately for CKD and ESRD beneficiaries¹⁴ for each of the three payment options and cover all Medicare Part A and

¹⁴ No separate benchmark will be calculated for kidney transplant beneficiaries.

B costs, including those not related to kidney disease, with a few exceptions. These exceptions are designed to avoid negative cost incentives for behaviors CMS wishes to promote and include:

- Dialysis access installation.
- Kidney transplant-related costs, including: evaluation of the recipient and donor, blood and tissue typing of the recipient and donor, organ acquisition, execution of the transplant itself, and services following the transplant.

CMS reserves the right to change financial model provisions to respond to specific circumstances in a particular market, such as a natural disaster or other emergency.

Step 1: Determine the baseline / historical expenditure

For all three CKCC payment options, the baseline period will be a fixed three-year period for the duration of the KCC model: 2017, 2018, & 2019. This period represents the most recent full calendar years for which full experience and claims run-out will be complete prior to PY1 (2021). These base years will be weighted to give additional weight to the most recent base year, recognizing that the population of base year-aligned beneficiaries for the most recent base year is likely more comparable to the KCE's performance year population of aligned beneficiaries. The model will incorporate the weighting scheme used in the Shared Savings Program for ACOs in their first agreement period (BY1 [2017] at 10%, BY2 [2018] at 30%, BY3 [2019] at 60%) in determining the performance year benchmark. The *baseline period* will be static across all of the performance years of the model. However, the *baseline expenditures* will be updated each year, as CMS will use a KCE's most recent Participant List to identify the beneficiaries that would have been aligned to the KCE for each of the base years and their associated expenditures. For example, the baseline expenditures that will apply for purposes of calculating the PY1 benchmark will be determined based on the KCE's Participant List for PY1. For PY2, the same baseline period will be used, but the baseline expenditures will be determined based on the KCE's Participant List for PY2.

Step 2: Apply trending and geographic adjustment factor (GAF)

Trending will be determined by the year-over-year projected percent change of the U.S. Per Capita Cost (USPCC). The USPCC is developed annually by the CMS Office of the Actuary and announced in the annual Announcement of Calendar Year (CY) Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies released the first Monday in April of the prior calendar year. The CKCC Options will use the USPCC's general FFS trend rate for the CKD benchmarks and the USPCC's ESRD trend rate for the ESRD benchmarks. CMS will make adjustments, such as an adjustment based on a comparison of the projected USPCC to the experience and trend for specific populations, to take into account differences in the expenditure trend of the FFS population as a whole compared to the subset of FFS beneficiaries eligible to be aligned to KCEs. Under limited circumstances, CMS may use an adjusted projected trend figure in response to unforeseeable events that have a substantial impact on Medicare FFS expenditures. Adjustments to the trend projections would be intended to prevent KCEs from being unfairly penalized or rewarded for major payment changes beyond their control.

The USPCC growth trend will be adjusted to reflect the anticipated impact of changes in the regional Geographic Adjustment Factors (GAFs) applied to payment amounts under the Medicare FFS payment systems. This GAF adjustment is intended to prevent the benchmark from being unfairly understated (or overstated) because of differences in the local geographic price adjustments that Medicare uses to calculate provider and supplier payments between the baseline period and the performance year. This

process accounts for variations in the cost-of-doing-business adjustments that Medicare applies under most its FFS fee schedules (e.g., the Medicare area wage index, the geographic practice cost index), which are typically updated annually.

Step 3: Incorporate regional expenditures

CMS will incorporate regional expenditures into the historical baseline to generate the performance year benchmark. Incorporating regional expenditures will enable performance year benchmarks to better reflect the KCE’s regional environment while also providing a simple and predictable methodology synchronized with other Medicare payment policy programs. To that end, CMS will test the use of an adjusted version of the Medicare Advantage (MA) Rate Book to establish regional expenditures for the CKCC Options. These county level benchmarks will be established prospectively and published in advance of the performance year. CMS will make use of the most recently available MA Rate Book data to derive these rates and incorporate regional expenditures with the KCE’s historical baseline expenditures, which have been trended forward to the performance year.

Use of regional expenditures in the CKCC Options will depart from the use of regional expenditures in previous ACO initiatives, in that an adjusted version of the MA Rate Book will be used to derive the regional expenditures. This approach, which departs from the CEC methodology of developing an ESCO-specific calculation of regional expenditures, is intended to be responsive to stakeholder feedback that the existing CEC model’s benchmarking methodology is too complex and gives rise to uncertainty throughout the performance year. In making use of an adjusted version of the MA Rate Book, CMS will be able to capitalize on an existing rate setting methodology.

CMS will make adjustments to the MA Rate Book figures to ensure that the rates used for this model serve as an accurate representation of the regional costs for purposes of benchmarking. First, CMS will remove the impact of certain adjustments that are incorporated into the MA Rate Book for purposes of MA plan payment, but that are not relevant to the CKCC Options, such as the Quality Bonus Payment (QBP) percentage based on star ratings. Second, CMS will make adjustments to account for differences in expenditure types that are included for purposes of the MA rate book but are not relevant for purposes of the CKCC Options. Third, CMS will make adjustments to account for differences between the subset of FFS beneficiaries eligible to be aligned to KCEs and Medicare FFS beneficiaries generally.

Once CMS makes its adjustments to the MA Rate Book for purposes of this model, a specified percent of the KCE’s regional expenditures would be “blended” into the KCE’s benchmark. The percentage of regional baseline expenditures and the KCE’s baseline expenditures for each performance year of the model is described in the Table 11, below.

Table 11. Regional and KCE Historical Blend for KCE Benchmarks by Performance Year

	Benchmark Component	PY1 (2021)	PY2 (2022)	PY3 (2023)	PY4 (2024)	PY5 (2025)
Composition of the KCE Benchmark	Baseline: Historical Expenditure	65%	65%	60%	55%	50%
	Regional Expenditure: adj MA Rate Book	35%	35%	40%	45%	50%

For purposes of incorporating regional expenditures into a KCE's benchmark, a KCE's region will include all counties (or states) where one or more beneficiaries aligned to the KCE in the baseline period reside. Regional expenditure is calculated using a beneficiary-month weighted average of county-level or state-level FFS expenditures for the KCE's aligned beneficiaries in each county or state. General MA rates for the Aged & Disabled (i.e. non-ESRD) population are calculated at the county level, while ESRD MA rates are calculated at the state level. Specifically, CMS will calculate a beneficiary month-expenditure weighted average of each county's (or state's, for ESRD) adjusted MA rate for which the KCE has aligned beneficiaries; the weights will be a product of the proportion of the KCE's beneficiaries residing in that county and the proportion of that county's FFS expenditures among all of the KCE's counties. Note that the "region" for purposes of the financial benchmark methodology is separate and distinct from the KCE's "service area" that is used for purposes of alignment.

We will establish limits on the maximum upward and downward adjustment that can result from incorporating regional expenditures into the benchmark. To align with the DC Model, we will limit the overall upward adjustment from incorporating the regional expenditures to a flat dollar amount equal to 5 percent of the FFS USPCC described above for the Performance Year (e.g., PY 2021 will use the 2021 MA Rate Book USPCC Rate adjusted as described above). We will limit the overall downward adjustment from incorporating the regional expenditures to a flat dollar amount equal to 2 percent of the FFS USPCC for that Performance Year. For example, in a hypothetical performance year in which the FFS USPCC rate for Aged and Disabled beneficiaries was \$891.07, then this rate would result in a maximum upward adjustment of +\$44.55 ($=\$891.07 * 5\%$) PBPM to the historical benchmark (Aged and Disabled) and a maximum downward adjustment of -\$17.82 ($=\$891.07 * -2\%$) PBPM to the historical benchmark (Aged and Disabled).

Limiting the impact of the regional expenditures in calculating the benchmark accomplishes three goals. First, the upward limit serves as a buffer against excessive increases to the benchmark that would stem solely from the incorporation of regional expenditures. The regional expenditures can otherwise provide an overly inflated benchmark for KCEs that are relatively low-spending compared to their region. Second, the downward limit recognizes that higher-cost KCEs may be particularly sensitive to the inclusion of regional expenditures into the baseline. KCEs with higher spending compared to the region may choose not to participate in the Model when otherwise faced with significantly lower benchmark. Third, the use of a flat dollar cap, rather than a cap based on a percentage of benchmark, provides a relatively higher adjustment for those lower spending KCEs and a relatively lower adjustment for higher spending KCEs. As we would expect most KCEs to be efficient relative to their region, this would have the effect of providing a greater relative adjustment for low risk KCEs than higher risk KCEs.

Limitations on the maximum upward/downward adjustments stemming from inclusion of regional expenditures have previously been introduced in ACO benchmarking, including in the NGACO Model and in the Shared Savings Program benchmarking methodology as part of the December 2018 final rule. This limit would impose clear parameters on the maximum adjustment that can result from incorporating regional expenditures into the benchmark.

Step 4: Risk adjustment

Risk adjustment is necessary in the CKCC Options to ensure that benchmarks and TCCs account for differences in the risk of beneficiaries aligned to the KCE in the base and performance years. Existing ACO Risk adjustment models used in current Medicare ACO initiatives are based on the prospective CMS Hierarchical Condition Category (HCC) risk model, which relies on provider-supplied diagnostic

codes for the prior calendar year to predict costs in the performance year (e.g., diagnoses from 2018 to predict 2019 costs).

CMS will test a different risk adjustment approach in the CKCC Options across all of the payment options to determine if this approach would address certain concerns with the existing approach from the Shared Savings Program and NGACO Model. CMS will design the risk adjustment methodology to achieve two primary goals:

1. Mitigate the influence of coding intensity on risk adjustment.
2. Improve accuracy of risk adjustment for organizations specializing in serving complex, high-risk patients.

This methodology mirrors the approach that we expect to use under the DC Model and is dependent upon the necessary analyses being completed. Additional information regarding this risk adjustment methodology will be provided in subsequent financial methodology papers. CMS anticipates publishing a risk adjustment methodology technical methods paper in late 2019. This technical paper will address various aspects of the risk adjustment methodology.

Step 5: Apply discount and quality adjustments

The KCE payment pathways will incorporate a discount to the trended, risk adjusted benchmark for KCEs participating in the Global Option. KCEs participating in the Global Option will be responsible for 100% of expenditures, and as such, the discount to the benchmark represents the only mechanism for CMS to obtain savings from the model (e.g., CMS does not “share” in the savings generated by the KCE). This discount effectively reduces the total benchmark expenditures by a specified percentage, in an effort to ensure that savings accrue to CMS from the KCC Model. The discount will only apply to the ESRD portion of the benchmark and not the CKD portion. The discount will be set at 3% of the ESRD portion of the benchmark for the first two performance years. Subsequently, the discount will increase by a percentage point each year, subject to the adjustments described below, thereby requiring continuous improvement from the Global Option KCEs. No discount will apply to the benchmarks for KCEs participating in the CKCC Graduated or the CKCC Professional Options.

Discounts on the ESRD portion of the benchmark for KCEs that select the Global Option could be reduced by 0.5% for the performance year if greater than 90% of the dialysis facilities owned in whole or in part by a dialysis company in the KCE’s market area are included in KCEs across the country, or if the KCEs participate in future multi-payer payment strategies still to be developed, if a multi-payer component is added to the model in future years. Because the majority of beneficiaries with CKD are not on Medicare, CMS believes that coordination across multiple payers is important to fully address CKD. KCE participation will be evaluated annually to determine if the threshold is met.

Additionally, if a beneficiary has remained with CKD Stages 4 and 5 for over a year, CMS will apply an upward adjustment of 1% to the KCE’s CKD portion of the benchmark to reward the KCE for keeping the beneficiary off dialysis.

Finally, adjustments will be made to the benchmark to account for the KCE’s performance on quality measures. KCEs are subject to a quality withhold, a reduction in their performance year benchmarks. KCEs in Graduated Option Level 1 do not have a quality withhold, KCEs in Level 2 have a quality withhold of 2.5%, and KCEs in Professional and Global have quality withholds of 5%. KCE’s can recoup a portion or all of their quality withhold based on their performance on the quality measures. This true up of the portion of the quality withhold that the KCE recoups is done at final reconciliation. High

performing KCEs can further increase their benchmark if they qualify for the High Performers Pool. Additional details on the quality program and its impact on the benchmark are discussed in the quality section of the RFA.

Features of Payment Methodologies Specific to the CKCC Graduated Option

Minimum Savings Rate (MSR)/Minimum Loss Rate (MLR)

The MSR is the minimum percentage of the total performance year expenditure benchmark that the KCE must have in preliminary savings to be able to receive for shared savings. Conversely, to be required to pay back shared losses, preliminary losses must exceed the minimum loss rate or the MLR.

For KCEs participating in Level 1 (under a one-sided risk arrangement) of the Graduated Model, preliminary savings must exceed the MSR to be eligible to receive shared savings. CMS will use a sliding scale, based on the number of beneficiaries aligned to the KCE to establish the MSR for the KCE.

Once KCEs transition into taking on downside risk (Level 2 of the Graduated Model and during participation in Professional Model), the MSR/MLR threshold will be set for first dollar savings/losses. If the KCE terminates participation from the model before the completion of the full performance year, the KCE’s MSR and MLR will be identical to the MSR and MLR applicable in a full performance year.

Aggregate Savings/Losses Cap (Risk Corridor)

For Graduated Level 1, shared savings will be capped at 10% of the KCE’s performance year benchmark. In Graduated Level 2, the aggregate amount of shared savings that KCEs will be eligible to receive if their actual performance year expenditures are lower than their performance year (PY) benchmark will be limited, or “capped” using a series of caps that are set as a percent of the PY benchmark. Similarly, in the event that KCEs generate shared losses, those shared losses will also be capped.

Table 12. Series of Shared Savings and Shared Losses Caps (Level 2 of the Graduated Model)

Shared savings/losses cap as a % of the PY benchmark	Portion of savings/losses above the cap accruing to the KCE’s shared savings/losses	Portion of savings/losses above the cap accruing to the CMS’ shared savings/losses
Gross Savings/Losses Less than 5%	50% of Saving 30% of Losses	50% of Savings 70% of Losses
Gross Savings/Losses Between 5% and 10%	35% of Savings 20% of Losses	65% of Savings 80% of Losses
Gross Savings/Losses Between 10% and 15%	15% of Savings 10% of Losses	85% of Savings 90% of Losses
Gross Savings/Losses Greater than 15%	5% of Savings 5% of Losses	95% of Savings and Losses

Truncation and Optional Stop-Loss

For expenditure calculations, CMS will truncate annualized expenditures at the 99th percentile for CKD/ESRD beneficiaries aligned to KCEs participating in the Graduated Model at Level 1. For KCEs participating in Level 2 of the Graduated Model and through transition into the Professional Model, a stop-loss arrangement will be available as an optional feature that may be selected by KCEs at the start of each PY beginning with PY2 (or PY1 if the KCE selects to enter the Graduated Option in Level 2 of the Model beginning in their first performance year).

The purpose of the stop-loss arrangement is to reduce financial uncertainty associated with infrequent, but high-cost, expenditures at the level of the individual aligned beneficiary. Stop-loss protects KCEs from financial liability on individual beneficiary expenditures that are above the stop loss “attachment points.” An attachment point is the dollar threshold at which stop-loss protection begins. CMS will develop the stop loss attachment points prospectively, prior to the start of each performance year, based on expenditure data derived from a national reference population of Medicare FFS beneficiaries, adjusted to reflect Medicare payment rates in the KCE’s region, using the GAF. A portion of the expenditures accrued above each attachment point and below the next highest attachment point will be included in the KCE’s performance year expenditure calculations. The percent of expenditures for each of the four attachment points will be 30%, 20%, and 10% respectively (See Table 13).

KCEs that choose the stop-loss arrangement are effectively charged for this protection. CMS will apply a PBPM stop loss “charge” to the KCE’s final performance year benchmark, which will be based upon the percent of expenditures above each of the KCE’s attachment points in the baseline period.

Additional details will be provided in future white papers.

Aggregation

The CEC Model uses aggregation as a tool for non-LDO ESCOs to facilitate participation in the model by smaller dialysis organizations. Smaller non-LDO ESCOs may have faced difficulty maintaining the minimum number of aligned beneficiaries required for participation in the CEC Model, and faced higher MSRs than larger ESCOs making it more difficult to achieve savings. Aggregation was used in the CEC Model to increase the size of the total beneficiary pool for participating ESCOs, which addresses these two issues. Non-LDOs may combine their aligned beneficiaries in order to increase the statistical validity of their results and reduce their one-sided MSR. In order to incentivize participation by smaller participants in the market, under CEC, only ESCOs with participation by dialysis facilities owned by non-LDOs are able to combine their financial results in order to achieve statistical significance.

As in the CEC Model, KCEs in the Graduated Model will be able to aggregate their expenditures in separate aggregation pools. The aggregation pools will be set up by CMS at its sole discretion. CMS will only group beneficiaries that are associated with smaller dialysis organizations (as defined above) that are participating in the same payment option within the model. In other words, beneficiaries who are aligned to KCEs participating in the same model will be grouped together for financial calculation purposes. Aggregation will be optional for all KCEs under the CKCC Options, but will be mandatory for KCEs that do not meet the minimum number of aligned beneficiaries. For instance, if at the start of a performance year a KCE participating in the Graduated Model has fewer than the minimum number of aligned beneficiaries, the KCE must participate in an aggregation pool, in addition to any Corrective Action Plan CMS requires the KCE to execute. For each KCE aggregation pool, CMS will calculate aggregate performance year benchmarks and performance year expenditures, weighting to account for the distribution of aligned beneficiaries across KCEs included in the aggregation pool. CMS will also calculate similar values for individual KCEs within each aggregation pool, for monitoring purposes and to support KCEs in their care improvement work. CMS will compare the resulting aggregate performance expenditures for a given pool to its aggregate benchmarks to determine a single overall savings percentage for the aggregated pool using the applicable MSR for the overall population of aligned beneficiaries in the aggregation pool. For each KCE aggregation pool, CMS will distribute aggregate savings to each individual KCE based on its number of aligned beneficiaries and its quality score for each individual KCE in the aggregation pool.

Payment Mechanisms

Payment Mechanism: The CKCC Graduated Option

KCEs' participant providers and preferred providers who elect to participate in the Graduated Model at Level 1 will be paid under FFS. CMS will subsequently reconcile the KCE's performance year expenditures against the KCE's performance year benchmark to determine the amount of the KCE's shared savings, as applicable with retrospective reconciliation. In addition, KCEs participating in the Graduated Model at Level 2 (i.e., with downside risk) must establish one of the following financial guarantees in an amount and by a deadline specified by CMS: an escrow account with an FDIC-insured institution, a surety bond from a company included on the U.S. Department of Treasury's List of Certified Companies, or a line of credit at an FDIC-insured institution.

Features of Payment Methodologies Specific to the Professional Model

MSR/MLR

No Minimum Saving Rate (MSR) or Minimum Loss Rate (MLR) will apply to aggregate savings/losses for either the Professional or Global Models. As such, KCEs will retain "first dollar" savings and be responsible for "first dollar" losses.

Aggregate Savings/Losses Cap (Risk Corridor)

The aggregate amount of shared savings that KCEs will be eligible to receive if their actual performance year expenditures are lower than their PY benchmark will be limited, or "capped" using a series of caps that are set as a percent of the PY benchmark. Similarly, in the event that KCEs generate shared losses, those shared losses will be capped, as shown in Table 12. KCEs will be eligible to receive a portion of shared savings, or liable for a portion of shared losses, above each threshold, with the portion decreasing with each threshold. The shared savings/shared losses caps will be set at the following amounts:

Table 13. Series of Shared Savings and Shared Losses Caps (Professional Model)

Shared savings/losses cap as a % of the PY benchmark	Portion of savings/losses above the cap accruing to the KCE's shared savings/losses	Portion of savings/losses above the cap accruing to the CMS' shared savings/losses
Gross Savings/Losses Less than 5%	50% of savings/losses	50% of savings/losses
Gross Savings/Losses Between 5% and 10%	35% of savings/losses	65% of savings/losses
Gross Savings/Losses Between 10% and 15%	15% of savings/losses	85% of savings/losses
Gross Savings/Losses Greater than 15%	5% of savings/losses	95% of savings/losses

Stop Loss Arrangement (Optional)

The purpose of the stop-loss arrangement is to reduce financial uncertainty associated with infrequent, but high-cost, expenditures at the level of the individual aligned beneficiary. Stop-loss protects KCEs from financial liability on individual beneficiary expenditures that are above the stop loss "attachment points." An attachment point is the dollar threshold at which stop-loss protection begins. CMS will develop the

stop loss attachment points prospectively, prior to the start of each performance year, based on expenditure data derived from a national reference population of Medicare FFS beneficiaries, adjusted to reflect Medicare payment rates in the KCE’s region, using the GAF. A portion of the expenditures accrued above each attachment point and below the next highest attachment point will be included in the KCE’s performance year expenditure calculations. The percent of expenditures for each of the four attachment points will be 30%, 20%, and 10% respectively (See Table 13).

KCEs that choose the stop-loss arrangement are effectively charged for this protection. CMS will apply a PBPM stop loss “charge” to the KCE’s final performance year benchmark, which will be based upon the percent of expenditures above each of the KCE’s attachment points in the baseline period.

Additional details will be provided in future white papers.

Table 14. Series of Stop Loss Attachment Points (Graduated and Professional Model)

Attachment Point	Percent of expenditures accruing to KCE	Percent of expenditures accruing to CMS
Below stop-loss attachment points	100%	0%
Above 1st attachment point	30%	70%
Above 2nd attachment point	20%	80%
Above 3rd attachment point	10%	90%

Features of Payment Methodologies Specific to the Global Model

Aggregate Savings/Losses Cap (Risk Corridor)

The aggregate amount of shared savings that KCEs will be eligible to receive if their actual performance year expenditures are lower than their PY benchmark will be limited, or “capped” using a series of caps that are set as a percent of the PY benchmark. Similarly, in the event that KCEs generate shared losses, those shared losses will be capped, as shown in Table 12. KCEs will be eligible to receive a portion of shared savings, or liable for a portion of shared losses, above each threshold, with the portion decreasing with each threshold. The shared savings/shared losses caps will be set at the following amounts:

Table 15. Series of Shared Savings and Losses Caps (Global Model)

Shared savings/loss cap as a % of the Final PY Benchmark	Portion of savings/loss above the cap accruing to the KCE’s shared savings/losses	Portion of savings/loss above the cap accruing to the CMS’ shared savings/losses
Under 25% of Benchmark	100% of savings/losses	0% of savings/losses
Gross Savings/Losses Between 25% and 35%	50% of savings/losses	50% of savings/losses
Gross Savings/Losses Between 35% and 50%	25% of savings/losses	75% of savings/losses
Gross Savings/Losses Greater than 50%	10% of savings/losses	90% of savings/losses

Stop Loss Arrangement (Optional)

The purpose of the stop-loss arrangement is to reduce financial uncertainty associated with infrequent, but high-cost, expenditures at the level of the individual aligned beneficiary. Stop-loss protects KCEs from

financial liability on individual beneficiary expenditures that are above the stop loss “attachment points.” An attachment point is the dollar threshold in at which stop-loss protection begins. CMS will develop the stop loss attachment points prospectively, prior to the start of each performance year, based on expenditure data derived from a national reference population of Medicare FFS beneficiaries, adjusted to reflect each KCEs’ regional differences in Medicare payment rates, using the GAF. A portion of the expenditures accrued above each attachment point and below the next highest attachment point will be included in the KCE’s performance year expenditure calculations. The percent of expenditures for each of the four attachment points will be 30%, 20%, and 10% respectively (See Table 15).

KCEs that choose the stop-loss arrangement are effectively charged for this protection. CMS will apply a PBPM stop loss “charge” to the KCEs final performance year benchmark, which will be based upon the percent of expenditures above each of the KCEs attachment points in the baseline period.

Additional details will be provided in future white papers.

Table 16. Stop Loss Attachment Points (Global Model)

Attachment Point	Percent of expenditures accruing to KCE	Percent of expenditures accruing to CMS
Below stop-loss attachment points	100%	0%
Above 1st attachment point	30%	70%
Above 2nd attachment point	20%	80%
Above 3rd attachment point	10%	90%

Alternative Payment Mechanism: Total Care Capitation (TCC)

The CKCC Global Option will test the use of a capitated monthly payment made from CMS to the KCE called the Total Care Capitation (TCC). Under this alternative payment mechanism, the capitation payment that is offered will encompass all Medicare Part A and Part B services furnished to aligned beneficiaries by KCE participants or Preferred Providers. Specifically, for KCE Practices that decide to participate in the Global option, KCE Participant Providers and Preferred Providers will have the option of participating in the capitated arrangement and reducing their claims amounts between 1 and 100 percent (while continuing to submit claims) for services furnished to aligned beneficiaries by such KCE participants. CMS will continue to pay claims for services furnished by providers and suppliers outside of the KCE and for any providers in the KCE who elect not to participate in the TCC.

The monthly TCC amount will equal one-twelfth of the discounted performance year benchmark (less adjustments for quality performed at final reconciliation) and will be risk adjusted. The amount of the monthly TCC will be reduced, or “withheld”, to account for any remaining FFS claims expenditures filed for services delivered to aligned beneficiaries. For example, it is expected that a portion of the total cost of care for aligned beneficiaries will be for services provided by providers and suppliers not participating in the TCC arrangement, therefore CMS will withhold a portion of the monthly TCC amount to offset the expected claims payments that will be made by CMS to these providers and suppliers. Furthermore, if any of the Participants or Preferred Providers are electing to participate in the TCC, but electing to reduce their FFS claims by less than 100%, CMS would withhold a portion of the TCC to account for the

remaining expected claims expenditures. These efforts are intended to avoid the need for significant year end recoupments from KCEs. CMS will determine the withhold amount for each KCE, prior to the start of the performance year, based upon historical utilization of aligned beneficiaries.

Following the performance year, CMS will perform reconciliation for the TCC. The TCC Withhold will be compared against actual claims expenditures incurred by aligned beneficiaries for services provided by providers and suppliers not covered under the capitation arrangement or remaining claims expenditures for providers who are only partially reducing FFS claims. Additional reimbursement to KCEs will be made if the withhold overestimated the expenditures for care delivered by providers not participating in the TCC. Likewise, if the withhold underestimated expenditures by non-participating providers, CMS will recoup the reimbursement amount overpaid to the KCE.

For example, if the performance year benchmark, for a KCE is \$1,000 PBPM and the Total Care Capitation Withhold is 40% (\$400 PBPM), the monthly capitated payment made to the KCE would be \$600 PBPM. If, through reconciliation, actual CMS payments to providers and suppliers not participating in Total Care Capitation accounted for \$350 PBPM, CMS would distribute the remaining \$50 PBPM that was “withheld” to the KCE (\$400 PBPM - \$350 PBPM). Alternatively, if actual CMS payments to providers and suppliers not participating in the Total Care Capitation accounted for \$450 PBPM, the KCE would owe \$50 PBPM to CMS, which represents payments that were made to non-participating providers and suppliers beyond the amount withheld by CMS under the Total Care Capitation Withhold.

Reconciliation

The CKCC Options will work to provide a more timely distribution of shared savings/shared losses through the use of a provisional reconciliation. This is in response to stakeholder feedback from ESCOs in the CEC Model, who have suggested that the timeline for final reconciliation is too delayed, complicating efforts to keep providers/suppliers engaged and to allow for more real-time results for care management efforts. For example, in the CEC Model, shared savings are dispersed (or shared losses repaid) approximately 20 months following the start of the applicable performance year.

Provisional Reconciliation

At the start of each performance year, CMS will provide KCEs participating in the Professional Model and Global Model the choice to be subject to a provisional reconciliation. Provisional reconciliation will occur shortly after the end of the performance year, with a target date of January 31st, thereby providing KCEs with a more timely payment of any monies owed to the KCE (savings) or a more timely requirement that the KCE pay any monies owed to CMS (losses), as compared to existing ACO models. This provisional reconciliation will include expenditures through the first half of the performance year (through June 30) with six months of claims run-out. CMS anticipates that a KCE’s expenditures through the first half of the year may differ significantly from expenditures at year end. For purposes of calculating any monies owed to the KCE or to CMS, as part of the provisional reconciliation, CMS will need to make several adjustments to the KCE’s expenditures to account for differences between the first and second halves of the performance year. For example, CMS will use an incurred but not reported (IBNR) estimate of performance year expenditures, and a seasonality adjustment to account for anticipated fluctuations in expenditures throughout the performance year. CMS may also use a default quality score (e.g., average quality score from prior year). The provisionally reconciled savings or losses will be distributed/recouped following the distribution of the provisional reconciliation report and a limited period of time allowing the KCEs to contest the results on the basis of mathematical error.

Table 17. Reconciliation Summary

	Preliminary Reconciliation Report (on or after January 31 after the PY)	Final Settlement Report (on or after July 31 after the PY)
Reconciliation Type	Provisional Reconciliation	Final Reconciliation
Claims Included in Reconciliation	Claims expenditures through Quarter 2 of the performance year (June 30)	Claims through Q4 of the performance year (Dec 31)
Run out on claims	6 months (through Dec. 31 of the performance year)	3 months (through March 31 of the subsequent calendar year)
Risk scores	Mid-Year Provisionally Resolved Risk Scores	Final Risk Scores
Incurred But Not Reported claims (IBNR) and seasonality estimate	Yes	No
Quality withhold	Yes – default score	Quality withhold and quality pool reconciliation
Net Stop-Loss Amount (Optional for KCEs)	Excluded	Included

Final Reconciliation

The final reconciliation will take place in the same timeframe as under the CEC model, with a final settlement target date of July 31 of the calendar year following the performance year. This lag in the final reconciliation is necessary in order to allow for claims run-out through March 31st of the calendar year following the performance year and for CMS to incorporate final risk scores and to determine the KCE's quality score. For organizations that select provisional reconciliation, the final reconciliation will update prior experience (e.g., will include full claims run-out and final risk scores) and monies owed payments or recoupments from savings or losses generated by the KCE.

CMS will reconcile adjusted payments including the CKD QCP and AMCP, as part of final settlement, as well as any discounted payment option under the TCC option alternative payment mechanism (discussed above).

Financial Assurances

Building on requirements developed in the CEC model, all KCEs will be required to hold a financial guarantee to ensure CMS is able to recover monies owed by the KCEs. This is especially important for KCEs that select no stop loss protection. The amount of the financial guarantee should be equal to at least 7.25% of the KCE's benchmark (including the expected TCC payments) for each Performance Year.

This guarantee should be in the form of funds placed in an escrow, a line of credit, or a surety bond. To permit CMS to recover funds using the guarantee, CMS will require the guarantee to remain in effect for a limited period of time after final reconciliation is completed for each performance year. Specific requirements for the financial guarantee will be specified in the CKCC Participation Agreement.

E. Quality Performance

Measures

A set of measures that indicate appropriate clinical care and engagement for the patient population, independent of the goal of altering the patient's pre-dialysis trajectory, will be adapted for the model context from existing measures with demonstrated reliability and validity. These measures will be tied to payment and applied to relevant providers and patients. Timing for implementation of pay-for-performance will depend on validating these measures and the exact specifications for the model context. Numerators, denominators, and performance thresholds would be based on beneficiaries aligned to the participating nephrology practices, as well as stipulated inclusion and exclusion criteria.

The measures that will be included 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
- *Optimal End Stage Renal Disease (ESRD) Starts*; NQF #2594

Measures to be developed

CMS aims to develop new performance measures for the specific patient population that incentivize providers to optimal care management that delays progression to ESRD/dialysis and lowers mortality. Because overall health care costs increase as patients progress to ESRD and dialysis, such incentives are supported by the model's financial methodology. In particular, we aim to implement during the life of the model an explicit reward/penalty mechanism based on comparison of observed experience to historical benchmarks.

The measures under development – i.e., Standardized Mortality Ratio for Late Stage CKD and ESRD, Measure of Delay or Reduction of Progression to ESRD (or dialysis), and Home Dialysis and Transplant Rates would be incorporated into the quality scores.

Performance Adjustments

Aligned with the Shared Savings Program's BASIC Track, the shared savings calculated for KCEs in Level 1 of the Graduated Option will reflect their quality score. KCEs in Level 1 will also have to achieve a minimum quality threshold in order to be eligible to receive shared savings. Level 1 KCEs will not be subject to a quality withhold.

For KCEs participating in Level 2 of the Graduated Option, 2.5% of the KCE's trended, risk adjusted, discounted performance year benchmark will be "withheld" to incentivize strong quality measure performance. For KCEs in the Professional or Global Options, 5% of the performance year benchmark will be withheld. The performance year benchmark will be reduced but KCEs will have the opportunity to recoup the amount withheld based on their quality score on the quality measure set for the performance year. The amount of the quality withhold that the KCE recoups will be calculated as a function of the KCE's quality score on the quality measure set multiplied by quality withhold percentage (e.g., a KCE in the CKCC Professional Option with a 95% quality score will recoup 4.75% of their benchmark (= 95% quality score x 5% quality withhold). A KCE that achieves a full (100%) quality score will fully recoup the entire quality withhold for the performance year.

Lastly, we will test the use of a quality pool, the High Performers Pool, to further incentivize high performance and continuous improvement on the quality measure set. KCEs may earn a quality bonus if

they meet a high level of performance on a subset of quality measures. The High Performers Pool will be funded from 50% of the remaining amount of the quality withhold that KCEs fail to recoup based on their performance on the quality measure set. For example, a Professional KCE that recoups 4.75% of its benchmark contributes the remaining 0.125% of their benchmark to the High Performers Pool (5% withhold less 4.75% recouped, divided by 2). As will be outlined in the CKCC Participation Agreement, any remaining High Performer Pool funds will be distributed to a subset of the highest performing KCEs, which may be determined based on the KCE’s relative performance on an additional set of more ambitious outcomes-based measures or the highest performance for the measures from the quality measure set. KCEs that fail to meet the model’s quality reporting requirements (thereby receiving earning back a 0% quality recoupment of the quality withhold) and organizations that fail to meet the continuous improvement component requirement will not be eligible for the High Performers Pool, and will have the remainder of their quality withhold or discount retained by CMS.

F. Benefit Enhancements

The CKCC Option will issue several payment waivers, or benefit enhancements, which will test whether allowing KCEs additional flexibilities in the services they can provide will improve the quality of care and reduce the cost of care. These waivers will not be available to KCEs participating in Level 1 of the Graduated Risk Option.

Table 18. Benefit Enhancements

Name	Description
3-Day Skilled Nursing Facility Rule	<p>CMS will make available to qualified KCEs a conditional waiver of the three-day inpatient stay requirement prior to admission to a skilled nursing facility (SNF) or acute-care hospital or CAH with swing-bed approval for SNF services (swing-bed hospital). This benefit enhancement will allow eligible CKCC beneficiaries to be admitted to qualified CKCC Participants or Preferred Providers either directly or with an inpatient stay of fewer than three days.</p> <p>A CKCC beneficiary will be eligible for admission under the terms of this benefit enhancement if (1) the beneficiary does not reside in a SNF or long-term care setting at the time of the admission to the SNF or swing-bed hospital; and (2) the beneficiary meets all other CMS criteria for SNF or swing-bed hospital admission, including that the beneficiary must:</p> <ul style="list-style-type: none"> • be medically stable; • have confirmed diagnoses (e.g., does not have conditions that require further testing for proper diagnosis); • not require inpatient hospital evaluation or treatment; and • have an identified skilled nursing or rehabilitation need that cannot be provided on an outpatient basis or through home health services.

Name	Description
	<p>KCEs will identify the SNFs and swing-bed hospitals with which they will partner in this benefit enhancement. Partner SNFs and swing-bed hospitals may be either CKCC Participants or Preferred Providers. Through the application and implementation plan, KCEs may be asked to describe how the identified CKCC Participants and Preferred Providers have the appropriate staff capacity and necessary infrastructure to carry out proposed coordination activities. In addition to the information the KCE includes in its implementation plan, a SNF must have an overall rating of three or more stars under the CMS 5-Star Quality Rating System in at least seven of the previous twelve months, as reported on the Nursing Home Compare website. This star standard is subject to change in response to changes in the scoring methodology.</p>
<p>Kidney Disease Education Benefit Enhancement</p>	<p>Medicare currently covers up to six 1-hour sessions of kidney disease education (KDE) services for beneficiaries that have Stage 4 chronic kidney disease (CKD). While the KDE benefit is intended to ensure beneficiaries are informed about the effects and treatment of kidney disease, diet and nutrition, transplantation, dialysis modalities, and vascular access, the uptake of this service has been exceptionally low at less than two percent of eligible patients. In the KCC Model, beneficiary education is a crucial component to increasing rates of transplants and home dialysis and delaying the onset of end-stage renal disease (ESRD). Therefore, CMS will conditionally waive certain KDE requirements under Innovation Center authority as necessary to test ways to increase the provision of the KDE benefit under the KCC Model. CMS is proposing to waive a similar set of KDE requirements solely for purposes of testing the proposed ESRD Treatment Choices Model.</p> <p>The programmatic waivers would:</p> <ul style="list-style-type: none"> • Waive the requirement that the KDE be performed by a physician, physician assistant, nurse practitioner, or clinical nurse specialist and allow qualified clinicians not currently allowed to bill for the benefit to furnish the services incident to the services of a participating KCF or CKCC nephrologist. • Waive the requirement that a beneficiary have Stage 4 CKD in order to test furnishing the KDE benefit to beneficiaries with CKD Stage 5 and those in the first 6 months of ESRD, who can also benefit from KDE. • Waive the requirement that KDE sessions cover the topic of delaying initiation of dialysis to allow

Name	Description
	<p>participating nephrologists to cover this topic as “as applicable” rather than mandated, as it is not relevant to beneficiaries with ESRD who have already begun dialysis.</p> <p>Waive the requirement that an outcomes assessment be conducted during one of the KDE sessions; and instead to test the provision of this assessment during a subsequent evaluation and management visit with the nephrologist.</p>
Telehealth Benefit Enhancement	<p>CMS will make available to qualified KCEs a conditional waiver of the interactive telecommunications system requirement under section 1834(m)(1) of the Act and 42 CFR 410.78(b) for services including otherwise covered dermatology and ophthalmology services furnished using asynchronous store and forward technologies.</p> <p>Asynchronous telehealth includes the transmission of recorded health history (for example, retinal scanning and digital images) through a secure electronic communications system to a practitioner, usually a specialist, who uses the information to evaluate the case or render a service outside of a real-time interaction. Asynchronous telecommunication systems in single media format do not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patients’ condition and adequate for rendering or confirming a diagnosis or treatment plan.</p> <p>Payment will be permitted for services including dermatology and ophthalmology services furnished to eligible beneficiaries using asynchronous telehealth in single or multimedia formats that is used as a substitute for an interactive telecommunications system. Distant site practitioners will bill for these services using CMMI specific asynchronous telehealth codes. The distant site practitioner must be a KCE participant who has elected to participate in this benefit enhancement.</p> <p>The Bipartisan Budget Act of 2018 amended Section 1899 of the Social Security Act to provide accountable care organizations the ability to expand the use of telehealth services if the accountable care organization is participating in a two-sided model tested or expanded under section 1115A of the Act. Subject to approval, CMS will issue a waiver to waive certain Medicare telehealth requirements for qualified entities to allow them to furnish telehealth services using asynchronous telecommunications systems. The waivers will apply only for beneficiaries aligned to KCEs approved by CMS.</p>

Name	Description
<p>Post-Discharge Home Visits Benefit Enhancement</p>	<p>Subject to approval, CMS will conditionally waive certain supervision requirements for qualified entities in order to allow payment for home visits to non-homebound aligned beneficiaries when furnished “incident to” a practitioner’s professional services by “auxiliary personnel” as defined in 42 CFR §410.26(a)(1), under general supervision- instead of direct supervision.</p> <p>Payment for these visits will only be allowed when visits are furnished following the beneficiary’s discharge from an acute inpatient hospital, inpatient psychiatric facility, inpatient rehabilitation facility, long-term care hospital, or skilled nursing facility. Also, under this benefit enhancement, a beneficiary is eligible to receive up to nine post-discharge home visits within 90 days following discharge. The nine services do not accumulate across multiple discharges; if the beneficiary is admitted within 90 days of the initial discharge and before receiving nine home visits, the beneficiary may receive only nine home visits in connection with the most subsequent discharge. We will waive the direct supervision requirement and require only general supervision for these home visits only when furnished by approved participants and Preferred Providers to beneficiaries under the following circumstances, including:</p> <ul style="list-style-type: none"> • The beneficiary does not qualify for Medicare coverage of home health services (or qualifies for Medicare coverage of home health services on the sole basis of living in a medically underserved area); • The beneficiary is an aligned beneficiary at the time the services are furnished; and <p>The services are furnished in the beneficiary’s home after the beneficiary has been discharged from an inpatient facility.</p>
<p>Home Health Benefit Enhancement</p>	<p>The proposed Benefit Enhancement is currently under consideration by CMS to waive the homebound requirement to allow for modified application for beneficiaries aligned to the entity in order to receive home health services. The entity would have greater flexibility to ensure special populations (as specified in the Participation Agreement) have access to home health services in appropriate cases. Given the risk borne by the entity, the entity would be incentivized only to do so where such care would improve quality and be cost-effective from a Total Cost of Care perspective. We expect this flexibility would aid KCEs in reaching their own alternative payment arrangements with home health</p>

Name	Description
	<p>agencies and promote innovation and greater ability of beneficiaries to return to, remain in, and receive care in their home.</p> <p>There is evidence demonstrating high quality outcomes for non-homebound patients receiving support in their home environment. There are some models that use health coaches to follow patients in their home and telephonically.¹⁵ Critical elements of those models are its self-management underpinnings and its emphasis on medication reconciliation. Outcomes include a 20-50% reduction in readmissions, and increased likelihood of achieving self-identified goals related to symptom management and functional recovery. Other models are multi-disciplinary in hospital planning processes that lead to in-home follow-up and services.¹⁶ Those models have resulted in reductions in preventable hospital readmissions for both primary and co-existing health conditions; improvements in health outcomes; enhanced patient experience with care; and a reduction in total health care costs. The Best Practice Intervention Package (BPIP)¹⁷ provides tools for home care to improve health literacy, self-care, and cross setting coordination. Participating Home Health agencies report improvement, with reductions in readmission rates compared to other agencies not using enhanced tools and models available.</p>
Home Health Services Certified by Nurse Practitioners	<p>The proposed Benefit Enhancement is currently under consideration by CMS to allow nurse practitioners who are participating in a KCE to certify that beneficiaries aligned to a KCE meet the requirements to receive home health services. Currently, Medicare Part A or Part B may pay for home health services if and only if a physician certifies or recertifies that the patient meets the requirements to receive home health services. However, several states, Maryland for example, allow nurse practitioners to certify or recertify that a beneficiary meets the requirements for home health services as part of their scope of practice. A beneficiary who lacks access to a community-based primary care physician must be admitted to a facility and placed under the care of facility-based physicians before home health services can be ordered even if the beneficiary is under the care of a nurse practitioner who is serving as their primary care</p>

¹⁵ <http://caretransitions.org/evidence-and-adoption/>

¹⁶ <http://www.transitionalcare.info/>

¹⁷ <http://www.homehealthquality.org/Education/Best-Practices.aspx>

Name	Description
	<p>provider. This limitation can result in a higher total cost of care and unnecessary utilization. This benefit enhancement would allow nurse practitioners (if allowed under their state’s scope of practice laws) to make home health services certifications to test whether this flexibility can prevent unnecessary utilization and reduce the total cost of care.</p>
<p>Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit</p>	<p>The proposed Benefit Enhancement currently under consideration by CMS is for entities to waive the requirement that beneficiaries who elect the Medicare Hospice Benefit give up their right to receive curative care (sometimes referred to as “conventional care”) as a condition of electing the hospice benefit. All expenditures incurred by Medicare on behalf of such beneficiaries, whether for hospice or other non-hospices services would be included as part of Total Cost of Care for the relevant performance year.</p> <p>Similar to the operation of the 3-Day Skilled Nursing Facility Rule Waiver, KCEs will identify the hospices with which they will partner in this Benefit Enhancement. Through the application and implementation plan, entities will be asked to describe how the identified KCEs have the appropriate staff capacity and necessary infrastructure to carry out proposed care coordination activities, and consistent with existing Hospice Conditions of Participation,¹⁸ will be asked to explain their process for how they will ensure working with partner hospices and other non-hospice providers that an appropriate plan of care will be developed for beneficiaries receiving concurrent care and ensure that the beneficiary is fully informed of what care or services are included in the care plan, what is not, what clinician or organization will be providing which services, how care coordination will be achieved, and whether there are any limitations, including services provided for transitional purposes only.</p> <p>Medicare will retain its existing claims-based edits to prevent non-hospice claims from being processed while a beneficiary is under hospice election. As such, it will be the entity’s responsibility to make payment arrangements with and process claims submitted by its partner hospices</p>

¹⁸ The beneficiary maintains the right to see any Medicare participating healthcare provider at any time under the traditional Medicare FFS benefit structure. Example language may read “You still have the right to visit any dialysis facility, doctor, hospital, or healthcare provider that accepts Medicare” and/or “This is not a Medicare Advantage Plan or any kind of managed care plan”.

Name	Description
	<p>or other non-hospice organizations to pay for services not paid for through Medicare’s payment for hospice services. Entities utilizing this payment waiver are expected to have the operational capacity to carry out this function in order to ensure high levels of care coordination and service integration.</p> <p>For purposes of this payment waiver, a KCE may not partner with any hospice that has existing condition level deficiencies that have not been remediated, and all hospices an entity partners with must readily offer beneficiaries access to the four levels of hospice consistent with clinical need.</p>

G. Termination

CMS reserves the right to terminate a KCE’s CKCC Participation Agreement at any point during the Model for reasons associated with poor performance, program integrity issues, non-compliance with the terms and conditions of the CKCC Participation Agreement, or if otherwise specified in the Participation Agreement or required by section 1115A(b)(3)(B) of the Social Security Act.

To determine whether KCEs can succeed in improving quality and reducing costs over a longer period of time, KCEs will be incentivized to participate in the Model for a minimum of two Performance Years (PY1 and PY2), in addition to the Implementation Period. KCEs will have two options under this Participation Commitment Incentive: Under the first option, during PY1 (CY2021), KCEs will be subject to a 2% “retention withhold,” in the amount of an additional 2% discount applied to the KCE’s Performance Year Benchmark. If the KCE’s Participation Agreement remains in effect at the time of PY1 final reconciliation, the 2% retention withhold will be removed from the benchmark, as part of PY1 final reconciliation. If, on the other hand, the KCE terminates its CKCC Participation Agreement before PY1 final reconciliation occurs, the 2% withhold will remain as part of PY1 final reconciliation.

Alternatively, under the second option, the KCE can elect to secure the “retention amount,” calculated to be equivalent to the retention withhold, with a financial guarantee from a third party guarantor. This secured amount would be in addition to the 7.25% of the KCE’s PY benchmark financial guarantee that the KCE needs to secure to ensure its ability to repay CMS Shared Losses or Other Monies Owed discussed in Section V.D. The KCE can secure the retention amount with the same financial guarantee as the 7.25% financial guarantee or secure the retention amount with a separate financial guarantee. If the KCE leaves the model before the end of PY2, the KCE will be required to pay CMS the retention amount. If the KCE fails to pay the retention amount to CMS, CMS would recover the retention amount under the terms of the financial guarantee. A KCE that selects to secure a retention amount would be required to have a financial guarantee that remains in effect for a brief period of time after the end of PY2, as later specified by CMS. If the KCE continues to participate in the model after the end of PY2, and it used a single financial guarantee to secure payment of the retention amount, the KCE would be permitted to reduce the financial guarantee amount by the value of the retention amount; if the KCE used a separate financial guarantee to secure payment only of the retention amount, it would be permitted to terminate the financial guarantee.

H. Application Scoring and Selection

KCEs interested in participating in the CKCC Options must file an application by no later than January 22, 2020 at 11:59pm. To file an application, applicants may access an electronic portal via the KCF and CKCC Options website at <https://innovation.cms.gov/initiatives/voluntary-kidney-models/>.

CMS reserves the right to request additional information (interviews, site visits, or additional information related to application responses) from applicants in order to assess their applications.

Applicants seeking to withdraw their application must submit an electronic withdrawal request to CMS before the distribution of the CKCC Participation Agreements via the following mailbox: KCF-CKCC-RFA-CMMI@cms.hhs.gov. The request must be submitted as a PDF on the organization's letterhead and must be signed by an authorized corporate official authorized to bind the applicant. It should include: the applicant organization's legal name; the organization's primary point of contact; the full and correct address of the organization; and a description of the nature of the withdrawal. Applicants seeking to withdraw only specific CMS Certification Numbers (CCNs) and/or National Provider Identifier (NPI) numbers from a pending application must follow the same process outlined above. Note that withdrawal of CCNs and/or NPIs from an application will require CMS to reassess the applicant's eligibility in terms of its number of beneficiaries eligible for alignment and in terms of having the minimum required types of KCE participants to be in the model.

Of important note, and described in the Legal Entity and Contracting Requirements section, applicants to the CKCC Option will not be expected to have their legal entity formed until after application selection and prior to executing the applicable CKCC Participation Agreement and beginning model participation in 2020. However, KCE applicants should include all of their proposed KCE participants and Preferred Providers in the application. Prior to the signing of the CKCC Participation Agreement, selected applicants must have 100% of their KCE participants on the proposed Participant List and Preferred Providers on the proposed Preferred Provider List identified and CMS-vetted. The KCE must certify in the form and manner prescribed by CMS that its Participant List and Preferred Provider List are true, accurate, and complete. An individual authorized to sign on behalf of the KCEs must sign the KCE's application to participate in the CKCC Options, and also must also be a signatory to the applicable CKCC Participation Agreement. While the KCEs will not be required to be a Medicare-enrolled provider or supplier, all participants and Preferred Providers under the KCE must be a Medicare-enrolled provider or supplier by the beginning of the Implementation Period.

Applications will be screened to determine eligibility for further review using criteria detailed in this RFA and in applicable law and regulations, including 2 CFR Parts 180 and 376. In addition, CMS may deny selection to an otherwise qualified applicant on the basis of information found during a program integrity review of the applicant, its KCE participants, Preferred Providers, or any other relevant individuals or entities. CMS may also deny individual KCE participants or Preferred Providers or any other relevant individual or entity participation in the CKCC Options based on the results of a program integrity review. Adverse results from PI screening may relate to issues with Medicare billing privileges, outstanding Medicare debt, or current administrative review or investigation by CMS or other federal government agencies.

Applicants will be required to disclose any investigations of, or sanctions that have been imposed on the applicant or individuals in leadership positions within the applicant in the last three years by an accrediting body or state or federal government agency. Individuals in leadership positions include key executives who manage or have oversight responsibility for the organization, its finances, personnel, and

quality improvement, including without limitation, a CEO, CFO, COO, CIO, medical director, compliance officer, or an individual responsible for maintenance and stewardship of clinical data.

Application Template for the CKCC Options

Important to note before outlining the requirements listed below is that applicants to the CKCC Option will not be expected to have their legal entity formed until after application selection and prior to the finalization of the applicable CKCC Participation Agreement. Practices and KCE applicants should include 100% of their KCE participants [and Preferred Providers] in the application. Prior to the signing of the applicable CKCC Participation Agreement, selected applicants must have 100% of their proposed KCE participants and Preferred Providers identified and vetted by CMS.

Questions about the application should be directed to [KCF-CKCC-RFA @cms.hhs.gov](mailto:KCF-CKCC-RFA@cms.hhs.gov).

Section A – Applicant KCE Information and Eligibility Requirements

1. KCE Contact Information (Required)
 - KCE Legal Name:
 - Dialysis Organization with ownership interest in participant dialysis facility/facilities (if applicable):
 - Mailing Address (Street, City, State, Zip Code):
2. What is the composition of Provider/Supplier types Eligible to Form the KCE as KCE participants (select all that apply):
 - Nephrologist(s)/ Nephrology practice(s) (required)
 - Dialysis facilities
 - Hospital(s)
 - Transplant Center(s)
 - Transplant Surgeon(s)
 - Organ Procurement Organization(s)
 - Rural Health Clinic(s)
 - Nursing Home(s)
 - Other Medicare-enrolled provider(s) and supplier(s): (Please specify)
3. KCE Primary Contact (Required) and Secondary (optional): Submit contacts' information (name, title, phone number, and email)
 - KCE Executive:
 - KCE Liaison with CMS:
 - Applicant Primary Contact (required):
 - Applicant Secondary Contact (optional):

4. Are any of the proposed KCE participants currently participating in the CEC Model?

- Yes
- No

If so, please describe the nature of their participation (e.g. participant owner, provider/supplier etc.)

5. Please indicate if any of the KCE participants have participated or are currently participating in any of the following:

- Accountable Health Communities
- ACO Investment Model
- Advance Payment ACO Model
- Bundled Payments for Care Improvement (BPCI) Initiative
- BPCI Advanced Model
- Comprehensive Care for Joint Replacement
- Comprehensive ESRD Care Initiative
- Comprehensive Primary Care Initiative
- Independence at Home Demonstration
- Maryland All-Payer Model
- Maryland Total Cost of Care Model
- Medicare Care Choices Model
- Medicare Shared Savings Program
- Next Generation ACO Model
- Oncology Care Model
- Pioneer ACO Model
- Private, For-Profit Demo Project for the Program of All-Inclusive Care for the Elderly (PACE)
- State Innovation Models Initiative
- Transforming Clinical Practice Initiative
- Other: (Please Specify)

Not Applicable

6. Please describe the applicant's performance under prior or current outcomes-based contracts, if any. Outcomes-based contracts must include: (1) financial accountability; (2) evaluation of patient experiences of care; and (3) substantial quality performance incentives. If applicable, please include performance under CMS programs, and demonstrations, and models that meet the definition of outcomes-based contracts (No more than 2 pages). Provide an "N/A" response if no prior or current risk sharing arrangements.

7. I certify that my KCE is a recognized legal entity formed under applicable state, federal, or tribal law and authorized to conduct business in each state in which it operates or will be by the time the applicable CKCC Participation Agreement is signed.

- Yes

By selecting YES, you certify that your KCE legal entity can, or will be able to:

- a) Receive and distribute shared savings;
- b) Repay shared losses or other monies determined to be owed to CMS;
- c) Establish, report, and ensure provider compliance with health care quality criteria, including quality performance standards; and

8. Please provide an executive summary describing your KCE. This includes: the KCE’s history, mission, and organization, including your KCE’s affiliations; the KCE’s: composition, including the number of hospitals, number of skilled nursing facilities, types of providers/suppliers (primary care and types of specialists); the KCE’s geographic service area, including the geographic area where most of the Applicant KCE's patients reside; whether the KCE’s service area encompasses urban, suburban, and/or rural locations; whether the KCE’s service area includes underserved beneficiaries; and whether the KCE will contract with other community-based organizations (e.g., care management organization, ESRD networks, quality improvement organization, etc.). Please include any other applicable narrative describing the KCE. (1-page max)
9. Please use the attached spreadsheet template to provide your proposed KCE participants’ and preferred providers information so CMS can vet conduct a program integrity screen for the each of the proposed KCE participants and determine the market area where you plan to operate the KCE. You must include all the states, counties and zip codes of the Applicant KCE’s proposed KCE participants and preferred providers. The attachment is titled “KCE Participant Add Template.xlsx”.

Section B – Organizational Structure, Leadership and Management, and Governance Structure

10. Please provide a proposed organizational chart for the KCE. It should depict the legal structure and governing body, the proposed composition of the applicant, and any relevant committees (2 pages).
11. Please complete the table below with information specific to the KCE's proposed leadership team. The leadership team may include, but is not limited to: key executives, finance, clinical improvement, compliance officers, information systems leadership, and the individual responsible for maintenance and stewardship of clinical data. If specific individuals have not yet been identified, please note that in the Name column and provide an anticipated date by which the individual will be identified. Please also include a brief description of the responsibilities associated with that each position/role.

Name	Practice/KCE Leadership Team Position/Role	Responsibilities

12. By checking the box below, you attest that your compliance plan identifies a compliance officer, who must not be legal counsel to the applicant, must not be in a direct reporting relationship to legal counsel for the applicant, and must report directly to the applicant’s governing body, and that the compliance plan includes a description of the following:
- a. A quality assurance strategy that, at the very least, includes a peer review process to investigate cases of potentially suboptimal care;

- b. The internal process for addressing a request for corrective action plan (CAP) by CMS and a description of the supplier termination circumstances;
- c. The remedial processes that apply when participating nephrologists fail to comply with the CKCC Participation Agreement, Medicare regulations, and/or internal procedures and performance standards including correction action plans (CAPs) and circumstances for termination; and,
- d. An antitrust compliance plan sub-section that describes appropriate firewalls, or other safeguards against, improper exchanges of prices or other competitively sensitive information among competing participant that could facilitate collusion and reduce competition in the provision of services outside the KCE.
- e. Compliance training programs for the KCE participating nephrologists.
- f. A method for KCE nephrologists to anonymously report suspected problems related to the Nephrologist KCE to the compliance officer.
- g. A requirement for the KCE to report probable violations of law to an appropriate law enforcement agency.
- h. The KCE compliance plan must be in compliance with all applicable laws and regulations and be updated periodically to reflect changes in those laws and regulations.
 - I attest that my compliance plan meets the listed criteria. I further certify that the information contained within the compliance plan is true and correct and that the compliance plan is in compliance with all applicable laws and regulations and be updated periodically to reflect changes in those laws and regulations.

Section C – Financial Payment Options, Financial Guarantee

13. Please identify the payment model that the KCE is selecting in this application.

- The CKCC Graduated Option
 - The CKCC Graduated Option: Level 1 (one-sided model risk, i.e., shared savings only; this option will automatically glide to the Level 2 of the Graduated Model in the follow PY. KCE may elect to participate in a model with increased risk.)
 - The CKCC Graduated Option: Level 2 (transition to risk; two-sided risk; this option will automatically glide to the Professional Model in the follow PY. KCE may elect to participate in the Global Model.)
- The CKCC Professional Option (two-sided model risk; 50% symmetrical shared savings/losses)
- The CKCC Global Option (two-sided risk option; 100% shared savings/losses)
 - TCC
 - No TCC

14. Financial Guarantee: For two-sided KCEs (shared savings/losses except those participating in Level 1 of the Graduated Risk Option).

The financial guarantee must be capable of repaying an amount of shared losses equal to at least 7% of total per capita Medicare Parts A and B fee-for-service expenditures for your KCE's aligned beneficiaries based on expenditures used to calculate the benchmark for the applicable agreement performance year, as estimated by CMS.

What type of repayment financial guarantee will you use to repay CMS for any shared losses, or other monies owed to CMS? (Check all that apply):

- Funds placed in escrow
- Surety bonds
- A line of credit the Medicare program can draw upon, as evidenced by a letter of credit

Section D – Care Model Patient Centeredness

15. Please provide a narrative explanation of 1) why the KCE wishes to participate in one of the CKCC Options, 2) the KCE's proposed KCE participants, and 3) how the KCE will achieve the goals of better health and better care for Medicare beneficiaries with CKD, ESRD and transplants? (2 pages).
16. Please provide a narrative description of the KCE's plan for engaging with CKD and ESRD beneficiaries and their caregivers. At a minimum, please address the following (10 pages):
 - a. Managing the progression of CKD
 - b. Modality options and Transition onto dialysis
 - c. Coordination of care with different health care providers and suppliers
 - d. Transplant process and managing post-transplant care
 - e. Health I.T. and data interoperability
 - f. Social determinants of health
 - g. Prescription drug utilization
 - h. Shared decision-making, self-management and self-care skill development
 - i. Managing care for dually eligible beneficiaries

Section E – Attestation and Signature

I have read the contents of this application. By my signature, I certify to the best of my knowledge, information, and belief that the information contained herein is true, correct, and complete, that I am authorized to sign this application on behalf of the KCE, and that I authorize the Centers for Medicare & Medicaid Services (CMS) to verify this information. If I become aware that any information in this application is not true, correct, or complete, I agree to notify CMS of this fact immediately and to provide the correct and/or complete information. This authorization is on behalf of the KCE applicant and the signatory is authorized to sign on behalf of the applicant organization.

Printed Name of Applicant Executive Contact

Date

Signature of Applicant Executive Contact

Date

Comprehensive Kidney Care Contracting (CKCC) Option Application Submission Process

Interested applicants must file an application by no later than January 22, 2020. To file an application, applicants may access an electronic portal via the KCC Option's website at <https://innovation.cms.gov/initiatives/voluntary-kidney-models/>. An application template is provided in Section H so that applicants can begin preparing their responses.

Applicants must create a username and password in order to access the application portal. Applicants will be asked to respond to a series of questions on the description and nature of the entity, primary contact information, legal and organizational structure, and more.

CMS reserves the right to request additional information from applicants in order to assess their applications.

Applicants seeking to withdraw their application must submit an electronic withdrawal request to CMS via the following mailbox: KCF-CKCC-RFA@cms.hhs.gov. The request must be submitted as a PDF on the organization's letterhead and must be signed by an authorized corporate official. It should include: the applicant organization's legal name; the organization's primary point of contact; the full and correct address of the organization; and a description of the nature of the withdrawal. Applicants seeking to withdraw only specific CMS Certification Numbers (CCNs) and/or National Provider Identifier (NPI) numbers from a pending application must follow the same process outlined above. Note that withdrawal of CCNs and/or NPIs from an application will require CMS to reassess the applicant's eligibility in terms of its number of beneficiaries eligible for alignment and in terms of having the minimum required Participants to be in the model.

V. Appendix A: Glossary of Key Definitions

Term	Definition
ACO	Accountable Care Organization - ACOs are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high-quality care to their Medicare patients.
AMCP	Adjusted Monthly Capitation Payment
APM	Alternative Payment Model - As defined in 42 CFR 414.1305, an APM is any of the following: (1) a model under section 1115 of the Social Security Act (Act) (other than a health care innovation award); (2) the shared savings program under section 1899 of the Act; (3) a demonstration under section 1866(C) of the Act; (4) a demonstration required by federal law. APMs can apply to a specific clinical condition, a care episode, or a population.
Advanced APM	An APM that CMS determines meets the criteria set forth in 42 CFR 414.1415.
Beneficiary	A Medicare beneficiary who has been aligned to the KCF practice or KCE according to the alignment methodology detailed above.
BY	Base year - The three years prior to the start of the CKCC Options. BY1, BY2, and BY3 correspond to calendar years 2017, 2018, and 2019, respectively.
CAP	Corrective Action Plan

CBSA	Core-Based Statistical Area - A core-based statistical area is a U.S. geographic area defined by the Office of Management and Budget that consists of one or more counties anchored by an urban center of at least 10,000 people plus adjacent counties that are socioeconomically tied to the urban center by commuting.
CEC	Comprehensive ESRD Care Model - Payment model run by The Innovation Center from 2015-2020 that tests coordinated kidney care for ESRD beneficiaries.
CI	The continuous improvement (CI) component
CKD	Chronic Kidney Disease - Condition characterized by the gradual loss of kidney function over time. May ultimately lead to ESRD.
CMMI	Center for Medicare and Medicaid Innovation - Division of CMS that supports the development and testing of innovative health care payment and service delivery models.
CMS	Centers for Medicare & Medicare Services - Federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare and Medicaid programs and contains the Innovation Center
CPC+	Comprehensive Primary Care Plus Model
Dialysis Facility	An entity that provides outpatient maintenance dialysis services (including Hospital-Based Dialysis Facilities and Home Dialysis training and support services) either as a Medicare-enrolled entity or as an operating division of a Medicare-enrolled entity that is owned in whole or in part by the Company.
DC	CMMI's Direct Contracting Model
ESCO	ESRD Seamless Care Organization – An ACO composed of providers and suppliers who voluntarily come together to form a legal entity that offers coordinated care to beneficiaries with ESRD through the Comprehensive ESRD Care model.
ESRD	End-Stage Renal Disease - Medical condition in which a person's kidneys cease functioning on a permanent basis leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life. Beneficiaries may become entitled to Medicare based on ESRD.
ETC	ESRD Treatment Choices Model, which is currently being proposed through rulemaking
FFS	Fee-for-Service - A method in which doctors and other health care providers are paid for each service performed.
GFR or eGFR	Glomerular Filtration Rate - A test used to check how well the kidneys are working. Specifically, it estimates how much blood passes through the glomeruli each minute. Glomeruli are the tiny filters in the kidneys that filter waste from the blood.
CMS-HCC Model	CMS Hierarchical Condition Category Condition Model – A risk adjustment model used by CMS that is used to calculate risk scores, which are used in adjusting capitated payments made for beneficiaries enrolled in Medicare Advantage (MA) and other plans.
HD	Hemodialysis – A modality of dialysis where a machine and a special filter called an artificial kidney, or a dialyzer, are used to clean the blood through an access in your blood vessels.

Home Dialysis	Peritoneal or hemodialysis performed by an appropriately trained Beneficiary (and/or the Beneficiary’s caregiver) at the home of the Beneficiary.
IME	Indirect Medical Education – A payment adjustment to reflect the higher cost of a teaching hospital versus a non-teaching hospital.
KCE	Kidney Contracting Entity– Entity made up of providers and suppliers coordinating care in the CKCC Options for aligned beneficiaries with CKD or ESRD
KDE	Kidney Disease Education - Medicare covers up to 6 sessions of kidney disease education services if the beneficiary has Stage 4 chronic kidney disease that will usually require dialysis or a kidney transplant.
KTB	Kidney Transplant Bonus
LDO	Large Dialysis Organization; An entity that, as of the Effective Date, owns, directly or indirectly, 35 or more Dialysis Facilities.
MA	Medicare Advantage
Marketing Materials and Activities	Marketing Materials and Activities are defined as general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, Web pages, mailings, social media, or other activities conducted by or on behalf of the KCF practice or KCE, or by KCF or CKCC Participants, or Preferred Providers, when used to educate, solicit, notify, or contact Beneficiaries regarding the KCC Model.
MCP	Medicare Capitation Payment or Monthly Capitation Payments
MIPS	Merit-Based Incentive Payment System - the performance-based incentive program for eligible clinicians paid under the PFS, required by section 1848(q) of the Social Security Act.
MIPS APMs	An APM that meets the following criteria as specified at 42 CFR 414.1370(b): (1) APM Entities participate in the APM under an agreement with CMS or through a law or regulation; (2) The APM is designed such that APM Entities participating in the APM include at least one MIPS eligible clinician on a Participation List; (3) The APM bases payment on cost/utilization and quality measures; and (4) The APM is not either of the following: (i)New APMs. An APM for which the first performance year begins after the first day of the MIPS performance period for the year. (ii)APM in final year of operation for which the APM scoring standard is impracticable. An APM in the final year of operation for which CMS determines, within 60 days after the beginning of the MIPS performance period for the year, that it is impracticable for APM Entity groups to report to MIPS using the APM scoring standard.
MLR	Minimum Loss Rate - The minimum percentage of the Total Performance Year Expenditure Benchmark that the KCE must incur in losses to be liable for Shared Losses.

MSR	Minimum Savings Rate - The minimum percentage of the Total Performance Year Expenditure Benchmark that the KCE must achieve in savings to be eligible to receive Shared Savings.
KCF	CMS Kidney Care First
NGACO Model	Next Generation ACO Model – This Innovation Center Model is an initiative for ACOs that are experienced in coordinating care for populations of patients, allowing them to share in greater risk and reward than the Shared Savings Program.
NLDAC	The National Living Donor Assistance Center - A federally funded program to assist agreeable, eligible donors with reimbursement of travel and subsistence expenses toward living organ donation.
Non-LDO	Non-Large Dialysis Organization; An entity that, as of the Effective Date, owns, directly or indirectly, no more than 35 Dialysis Facilities.
NQF	The National Quality Forum - A United States-based non-profit membership organization that promotes patient protections and healthcare quality through measurement and public reporting.
OACT	Office of the Actuary
OPO	Organ Procurement Organization - A non-profit organization that is responsible for the evaluation and procurement of deceased-donor organs for organ transplantation.
Participation Agreement	Participation Agreement refers to the agreements that will outline the requirements and conditions of participation in the KCC Models.
PBA	Performance Based Adjustment
PBPM	Per Beneficiary Per Month
PBPY	Per Beneficiary Per Year - A measurement of expenditures calculated by dividing expenditures by Beneficiary- Years. This differs from a per capita basis, which is expressed in per beneficiary terms.
PCF	CMMI's Primary Care First Model
PD	Peritoneal Dialysis – A modality of dialysis where the blood is cleaned through the lining of your abdomen via a catheter.
PHQ	The Patient Health Questionnaire – a tool used to screen for mental health.
PY	Performance year - The 12-month period beginning on January 1 of each year during the term of the Participation Agreement.
Quality Gateway	A set of measures that includes and indicates appropriate clinical care and engagement for the patient population, that are directly and indirectly related to the beneficiary's kidney disease, and that are applicable to both late stage CKD patients and ESRD patients.
QCP	CKD Quarterly Capitation Payment
QPP	The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) amended the Social Security Act to create the Quality Payment Program. There are 2 ways clinicians can participate in the Quality Payment Program: the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models. The Quality Payment Program transforms the Medicare physician payment system from one focused on volume to one focused on value through an incentive program that rewards the delivery of high-quality patient care through two avenues: Advanced Alternative Payment Models (Advanced APMs) and the Merit-based Incentive Payment System (MIPS).
RFA	Request for Application

Risk Adjustment	The process of adjusting for diagnoses and demographic factors that are expected to affect Medicare Part A and Part B expenditures.
Shared Savings	The amount owed to the KCE by CMS due to KCE Total Revenue below the ESCO's Total Performance Year Expenditure Benchmark for the applicable Performance Year as determined by CMS. This number represents the final amount paid to the KCE.
Shared Savings Program	The Medicare Shared Savings Program – Medicare program that aims to encourage coordination and cooperation among providers and suppliers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in expenditures.
SNF	Skilled Nursing Facility
TCC	Total Care Capitation

VI. Appendix B. Applicant Selection Criteria and Scoring

Selection Domain	Applicant Selection Criteria To earn full points in each domain, the applicant must:	KCE Score	KCF Score
Care Model Patient Centeredness	<ul style="list-style-type: none"> - Demonstrate the ability to engage beneficiaries and their caregivers in shared decision making, taking into account patient preferences and choice. - Have a feasible plan to establish mechanisms to conduct patient outreach and education on the benefits of care coordination, renal transplantation, and care settings. - Demonstrate the ability to effectively involve beneficiaries in care transitions to improve the continuity and quality of care across settings, e.g., medication lists; care plans co-developed with the patient and embedded in the EHR; case manager follow up. - Demonstrate the ability to engage and activate beneficiaries at home (through such modes as home visits or tele-monitoring) to improve self-management. - Have mechanisms to evaluate patient satisfaction with the access and quality of their care, including choice of providers, and choice in care settings. - Have a plan that establishes an effective mechanism that allows for open communication of key care management processes among patients, their caregivers, and the interdisciplinary participant team. 	25	35
Organizational Structure and Leadership & Management,	<p>Organizational Structure (5)</p> <ul style="list-style-type: none"> - Demonstrate a history of collaboration between participating providers/provider organizations and/or credible plan for how the participants will work together in the model. - Have an organizational structure that promotes patient centered care and the goals of the model. In addition to meeting the minimum eligibility requirements for provider/supplier participation, the applicant organization is made up of a diverse set of provider/suppliers that demonstrates a clear commitment to providing high quality, coordinated care to beneficiaries. - Have a compliance plan that identifies a compliance officer, quality assurance strategy, internal process for addressing corrective action plan, remedial process, and antitrust compliance plan. <p>Leadership and Management (5)</p> <ul style="list-style-type: none"> - Have identified, or demonstrate plans to identify, executives and lead staff throughout the organization with responsibility for clinical, financial, management, HIT, and quality improvement functions. 	10	10

	<ul style="list-style-type: none"> - Demonstrate experienced, strong project leadership and a project management structure and design that will enable accountability for a patient population. Alternatively, the applicant provides a clear and detailed plan for establishing project leadership and management structure that meets this criterion. 		
Governance Structure (CKCC Only)	<ul style="list-style-type: none"> - Have a governance structure that is clearly defined and demonstrates commitment to providing high quality care to beneficiaries consistent with the three-part aim of better health, better care, and lower costs. - Have a multi-stakeholder governing body comprised of well qualified individuals, including an independent ESRD Medicare beneficiary representative and a trained and/or experienced non-affiliated, independent consumer advocate, that adequately and collectively represent the interests of beneficiaries and providers. If the applicant has not yet formed a new legal entity, the applicant must have a feasible and clearly defined plan, including timeline, for the formation of a multi-stakeholder governing body as described above. - Provide a clear and detailed plan for governance structure to identify, report, and remediate suspected fraud and abuse. - Demonstrate an effective governance structure plan including a governing body and/or organizational mechanisms to make decisions, distribute payment, and obtain resources necessary to achieve the goals of the model. 	10	N/A
Care Coordination Capabilities and Implementation Plan	<ul style="list-style-type: none"> - Present a strong, credible, coordinated and feasible plan to realize the goals of the model. - Demonstrate existing capacity or plans to expand capacity to coordinate care through an interdisciplinary team structure that includes practitioners with the necessary areas of expertise and appropriate staffing to meet the needs of complex patients. - Provide clear and detailed plan for a majority of eligible professionals in the organization to meet EHR meaningful use criteria and requirements. - Have population-based management tools and functions or concrete plans to develop and invest in such tools and functions, e.g. registry/ability to aggregate and analyze clinical data. - Have the ability, or credible plans to develop the ability, to electronically exchange patient records across participating providers and other providers in the community to ensure continuity of care. - Have ability to, or credible plan to gain ability to, share performance feedback on a timely basis with participating providers. 	40	40

	<ul style="list-style-type: none"> - Demonstrate ability to coordinate care across full continuum of CKD care to improve the physical health, mental/behavioral health, and functional status of beneficiaries. - Provide credible plan for incorporating medication management into care coordination approach. - Demonstrate a history of collaboration among major stakeholders in the community being served including incorporation of relevant social services in care plans and management. - Demonstrate compelling plan to succeed in the areas of quality improvement and care coordination. - Demonstrate performance under prior or current outcomes-based contracts that includes: (1) financial accountability; (2) evaluation of patient experiences of care; and (3) substantial quality performance incentives. - Provide a care coordination plan that incorporates mental/behavioral health and social services as appropriate. 		
Care for Vulnerable Populations	<ul style="list-style-type: none"> - Include a diverse group of practitioners, and care settings to meet the needs of CKD and ESRD patients. - Include safety net providers that care for indigent populations. - Include practitioners, technology, and other resources that enable access to quality care for populations in rural areas. - Provide care to a large percentage of Medicare-Medicaid Enrollees. - Demonstrate clear understanding of unique needs of beneficiaries with CKD and ESRD that includes a care coordination approach that addresses those needs. 	15	15
Total Points		100	100