Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation

Comprehensive ESRD Care (CEC) Model

Request for Applications

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II. Background and Introduction

The Centers for Medicare & Medicaid Services (CMS) is committed to achieving better care for individuals, better health for populations, and reduced expenditures for Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries. One potential mechanism for achieving this goal is for CMS to partner with groups of health care providers and suppliers to accept joint responsibility for the cost and quality of care outcomes for a specified group of beneficiaries. CMS is currently pursuing such partnerships through several broad initiatives, including the Medicare Shared Savings Program, the Next Generation Accountable Care Organization (ACO) Model, the Pioneer ACO Model, and other initiatives undertaken by the Center for Medicare & Medicaid Innovation (CMS Innovation Center) within CMS.

Several objectives underlie CMS's overall approach to testing accountable care models, including:

- Promoting changes in the delivery of care from fragmented care to coordinated care systems as part of broader efforts to improve care integration, such as initiatives on medical homes and bundled payments;
- Promoting effective engagement with, and protections for, beneficiaries;
- Protecting the Medicare Trust Funds while finding new ways of delivering care that will decrease expenditures over time;
- Learning what it takes for providers to most effectively deliver better care for individuals, better health for populations, and lower growth in expenditures for the Medicare fee-for-service population; and
- Developing close working partnerships with providers.

The purpose of the Comprehensive ESRD Care (CEC) Model is to improve outcomes for Medicare beneficiaries with end-stage renal disease (ESRD) and reduce total per capita expenditures by creating financial incentives for dialysis facilities, nephrologists, and other Medicare providers or suppliers to collaboratively and comprehensively address the extensive needs of the complex ESRD beneficiary population. Specifically, CMS will test whether financial risk arrangements with guaranteed discounts to the Medicare program will:

- Improve key care processes such as chronic disease management;
- Improve clinical outcomes, such as transplantation rates, mortality rates, and disease complications;
- Improve beneficiary experiences of care, quality of life, and functional status;
- Improve management of care transitions;
- Reduce utilization of key services such as emergency department visits, hospitalizations, and readmissions; and,
- Reduce total Medicare Parts A and B per capita expenditures.

The CEC Model launched on October 1, 2015. This RFA will solicit applications from potential ESCOs that wish to participate in the model starting January 1, 2017. We note that the model design changes included in this document would apply to all ESCOs enrolled in PY 2.

III. 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 health care 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 models that improve coordination, efficiency and quality. Section 1899 of the Social Security Act authorizes CMS to share Medicare savings and losses with accountable care organizations under certain circumstances.

The CEC 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 and Medicaid beneficiaries with ESRD that is based on section 1899 authority. The Model will test whether financial risk arrangements with guaranteed discounts to the Medicare program will improve ESRD beneficiary outcomes and reduce Medicare costs.

IV. Scope and General Approach

The CEC model currently has approximately 16,000 beneficiaries aligned[1] to 13 ESRD Seamless Care Organizations (ESCOs) for Performance Year (PY) 1. The solicitation for PY 2 aims to add at least 7 ESCOs and 6,000 beneficiaries to the model, though more ESCOs could be accepted at CMS discretion.

The goal of the CEC Model is to test a new model of care delivery and payment for the segment of the Medicare fee-for-service (FFS) beneficiary population with ESRD. Core operational elements of the Model are summarized below:

- Respect for Medicare FFS beneficiaries' freedom to continue to seek the services and providers of their choice;
- Selection of a diverse group of ESCOs willing to commit to transformation of their business and care delivery models;
- Payment arrangements that hold ESCOs responsible for the total cost of care for their beneficiaries;
- Standardized quality performance metrics and other parameters across ESCOs to allow for rigorous evaluation;
- Provision of monthly and quarterly data reports to ESCOs for purposes of supporting care improvement;
- Strong beneficiary protections and comprehensive and frequent monitoring;
- Formative and summative evaluation; and,

[1] Note: Alignment is the term used by the CEC Model to describe the process of assigning Medicare beneficiaries to an ESCO through their claims

- Shared learning that is continuous and data-driven.

While CMS is committed to improving care for beneficiaries with ESRD, the Agency may terminate the Model if termination is required under Section 1115A (b) (3).

V. Deadline for Applications

Interested ESCOs including Large Dialysis Organization (LDO) and non-Large Dialysis Organization (non-LDO) applicants must file an application by no later than July 15, 2016. To file an application, applicants may access an electronic portal via the CEC website at https://innovation.cms.gov/initiatives/comprehensive-esrd-care/. An application template is provided in *Appendix A* so that applicants can begin preparing their responses.

To submit an application, applicants must email ESRD-CMMI@cms.hhs.gov with their name, email, and any proposed ESCO applicant name(s) and they will receive a username and password.

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: ESRD-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. 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.

Of important note, and described in the Legal Entity and Contracting Requirements section below, applicants to the CEC Model will not be expected to have their legal entity formed until after application selection and prior to joining the model on January 1, 2017. However, ESCO applicants should include 100% of their proposed ESCO Participants in the application. ESCO Participants will not be able to be added after application submission. Prior to the signing of the CEC Model Participation Agreement, selected applicants must have 100% of their Participants (Participant Owner, Participant Non-Owner, and ESCO Provider/Supplier – the Participant List) identified and CMS-vetted, and the ESCO must certify in the manner prescribed by CMS that its Participant List is true, accurate, and complete. ESCO applicants must also identify in their applications the dialysis organization that directly or indirectly owns all of the ESCO's Participant Owner dialysis facilities (the Company). The Company must sign the ESCO's application to the CEC Model, and it also must be a signatory to the CEC Participation Agreement. CMS will conduct a program integrity screening on all ESCO Participants and the Company and may reject an application or an ESCO participant on the basis of the program integrity screening results.

VI. Description of the CEC Model

A clinical care model for the ESRD beneficiary population should promote patient-centered, high-quality care that seamlessly addresses these beneficiaries' complex clinical needs. The following sub-sections highlight, more specifically, the core clinical elements of the Model. In essence, CMS hypothesizes that comprehensive medical management of, and better care coordination for, ESRD beneficiaries will result in improved outcomes and expenditure savings by producing:

- Fewer unnecessary visits to the emergency department;
- Reduced hospitalizations and avoidable re-hospitalizations;
- Fewer dialysis-related complications, such as infections
- Reduced lengths of stay;
- Reductions in hospital- and treatment-acquired conditions;
- Wider adoption of improved clinical practices resulting in improved beneficiary outcomes and reduced risk of adverse events;
- Additional referrals to transplant centers, with subsequent reductions in morbidity, mortality, and cost, if transplant occurs;
- Patient-centered selection of dialysis access and modality,
- Improved quality of life and functional status among ESRD beneficiaries.

It is important to note that CMS will not prescribe how ESCOs should address the three high-level clinical elements described below. While CMS has listed some potential strategies and/or clinical intervention for addressing the high-level clinical elements, applicants are strongly encouraged to propose alternative innovative strategies/interventions. Applications will be scored and selected based on the ESCO's proposed approach to addressing the high-level clinical elements (see Appendix C for the application selection criteria).

Additionally, CMS does not intend to reimburse ESCOs for non-Medicare covered services. ESCOs are expected to pay for additional services that they believe will help them address the high-level clinical elements outlined below—and ultimately, improve clinical and financial outcomes for their aligned beneficiary population. Any non-Medicare covered interventions employed by the ESCO must comply with all applicable laws and regulations, except as explicitly provided in any waiver that may be granted pursuant to section 1115A(d)(1) specifically for the CEC Model. As a large portion of the ESRD beneficiary population is dually eligible for both Medicare and Medicaid, CMS expects that some of the elements of the model may interact with services provided by Medicaid. Where this occurs, CMS will look for the ESCO's proposed coordination across both programs.

Comprehensive and Coordinated Care Delivery

The care needs of beneficiaries with ESRD are typically complex due to multiple co-morbidities and polypharmacy, requiring care coordination services that many do not routinely receive today. In order to promote seamless and integrated care, a comprehensive care delivery model must emphasize coordination across a full-range of clinical and non-clinical support services, as well as across providers and settings.

This may be best achieved through the establishment of an interdisciplinary care team—led by a nephrologist.

CMS anticipates that an extended team of skilled clinical and non-clinical providers and practitioners would support the care of ESRD patients beyond the ESRD-related services included in the ESRD Prospective Payment System (PPS) bundle. In such a model of appropriate, high quality integrated care, the coordination of a full range of clinical and supportive services may include:

- Primary care and other preventative services;
- Specialty care for co-morbidities or non-renal acute conditions (e.g. podiatry, cardiology, orthopedics, etc.);
- Vascular access;
- Laboratory testing and diagnostic imaging;
- Pharmacy care management;
- Patient/family/caregiver education; and,
- Psychiatric, behavioral therapy and counseling services.

Examples of providers (physicians and non-physician practitioners) that may be appropriately involved in an interdisciplinary team include, but are not limited to: non-nephrology physicians such as general internists, endocrinologists, cardiologists, vascular surgeons, podiatrists, and psychiatrists; nurse practitioners and physician assistants; registered nurses/licensed practical nurses; licensed clinical social workers; nurse case managers; dieticians/nutritionists; health educators; pharmacists; behavioral health specialists; and, community health workers/patient navigators. Excluded providers include (1) Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers, (2) ambulance suppliers, and (3) drug and/or device manufacturers. Of note, Medicare-enrolled providers of non-DMEPOS services that also serve as DMEPOS suppliers are eligible to participate in the Model, provided that they do not participate in their capacity as DMEPOS providers.

Social barriers often contribute to avoidable high costs of care in this vulnerable patient population. In certain circumstances, timely access to, and availability of, non-clinical support services may improve clinical outcomes and reduce unnecessary health care utilization. Such support services may include assistance arranging transportation to and from service providers and assistance coordinating community resources such as housing and nutritional services. As mentioned above, CMS will not provide additional payment for non-covered support services. The expectation is that ESCOs cover any additional services they believe to be important in the furtherance of the Model's clinical goals—in compliance with all applicable laws and regulations, except as explicitly provided in any waiver that may be granted pursuant to section 1115A(d)(1) specifically for the CEC Model.

Finally, CMS anticipates that the CEC Model will promote policies, procedures, and practices by ESCOs to create, execute, and update patient assessments and plans of care—inclusive of clinical needs beyond renal disease care management[2]. CMS expects that comprehensive plans of care should be jointly created and managed by the patient, their caregiver, and the interdisciplinary team working to coordinate the

[2] The plan must incorporate the ESRD-specific assessment and plan required by the ESRD Facilities Conditions for Coverage at 42 CFR 494.80-90.

patient's care. Care plans should ensure that patient needs and preferences for health services and information sharing across providers and sites are met. CMS would expect that comprehensive care plans address the following:

- Comprehensive clinical assessment
- Determination and documentation of patient's goals
- Development and regular updating of care management plans
- Patient's knowledge about conditions, treatments, and medications
- Documentation of patient's preferences
- Medication management
- Process for monitoring clinical progress and follow-up
- Systematic process of care transition planning and follow-up
- Promotion of self-care skills
- Availability of care plan among interdisciplinary team members

As mentioned above, applicants are strongly encouraged to propose alternative innovative strategies/interventions that would allow them to best address the comprehensive and coordinated care delivery clinical element of this Model.

Enhanced Patient-Centered Care and Improved Communication

Patient-centered care is a central feature of the CEC Model. CMS anticipates that patient and caregiver engagement and shared-decision making that accounts for the patient's goals and preferences will be critical to the success of the Model. CMS expects providers to engage patients and their caregivers often and provide them with education/information that enables timely, informed decision making about various care options—especially renal transplantation and choices about the setting and modality of dialysis, such as the option for home dialysis or peritoneal dialysis.

Providing opportunities for developing self-management and self-care skills will also enable patients and their caregivers to be more involved in their care, improving overall outcomes. Patients who participate in individual and group educational sessions will increase knowledge about their disease and overall health. Fostering linkages with community-based partners will provide access and assistance to patients in need of support to overcome barriers such as lack of housing, social supports, and risky health behaviors.

Finally, CMS envisions that this Model will enhance communication across providers, facilities, patients, and their caregivers through the dynamic electronic exchange of key clinical and other health-related information. ESCOs will need to establish an effective mechanism that allows for open communication of key care management processes among patients, their caregivers, and the interdisciplinary ESCO participant team—to allow timely identification and management of care management issues. CMS expects that enhanced communication through HIT will allow for:

- Reliable exchange of key clinical information
- Ongoing monitoring of clinical parameters

- Development of registry capacity
- Systematic proactive reminders
- Continuous quality improvement
- Population-based care management

As mentioned above, applicants are strongly encouraged to propose alternative innovative strategies/interventions that would allow them to best address the enhanced patient-centered care and improved communication that are key clinical elements of this Model.

Improved Access to Services

Often, patients with ESRD experience a multitude of clinical and social challenges that are barriers to receiving appropriate, comprehensive care. These challenges (e.g. lack of transportation, lack of caregiver support, etc.) may prevent full beneficiary engagement in care, resulting in poor health and quality of life outcomes. Beneficiaries and their caregivers report that they are often unable to access their care providers when they need them. Furthermore, stakeholders report that in-center dialysis facility hours often do not reflect patient preferences and negatively affect quality of life (e.g., mid-day appointments interrupt employment). Thus, the CEC Model also prioritizes timely and flexible access to services and members of the care team.

The CEC Model is also patient-centered in its promotion of customized dialysis care—meaning the flexibility to offer more or less dialysis as appropriate given a beneficiary's clinical needs. There is clinical evidence that more dialysis, at least in some patients, may decrease complications such as fluid overload and electrolyte imbalances.

VII. Alignment of Medicare Beneficiaries in the Model

ESCOs will not enroll beneficiaries in the Model, nor will beneficiaries be permitted to seek out a participating ESCO to enroll in. Beneficiaries will be aligned to an ESCO by CMS if they meet the eligibility requirements outlined below and receive dialysis services from a dialysis facility participating in an ESCO.

The CMS 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 ESRD for whom CMS will hold an ESCO clinically and financially accountable.

It is important to note that the prospective beneficiary alignment approach will be used to assess ESCO quality and financial performance. It will not inhibit beneficiary choice of provider—and does not include any restrictions on, or changes to, Medicare FFS benefits. Medicare FFS beneficiaries will continue to maintain freedom of choice of provider under this Model.

Beneficiary Eligibility

To be eligible for alignment to an ESCO, beneficiaries must meet the following criteria:

- Must be enrolled in Medicare parts A and B

- Must NOT be enrolled in a Medicare Advantage plan, cost plan, or other non-Medicare Advantage Medicare managed care plan
- Must have had a qualifying first touch dialysis visit at a participating dialysis facility, discussed in further detail below
- Must reside in the United States
- Must be aged 18 or above[3]
- Must NOT be aligned to another existing Medicare shared savings initiative unless otherwise determined by CMS(please refer to the *Participation in Other Medicare Programs, Initiatives, Models, or Demonstrations* section below for additional information)
- Must NOT have had a kidney transplant in the last year
- Must NOT have Medicare as a secondary payer

An ESCO is required to have a minimum of 350 aligned beneficiaries based on a defined look-back period prior to the start of the Model. The ESCO must maintain at least 350 aligned beneficiaries throughout the life of the Model to continue with participation. If at any point during a performance year an ESCO drops below the minimum threshold, the ESCO will be placed on a Corrective Action Plan (CAP) until the minimum threshold is met. The ESCO can still share in savings during the CAP period, but if the ESCO does not meet the minimum threshold as of the date specified in the CAP, CMS may terminate its CEC Model Participation Agreement. In addition, if CMS determines during financial reconciliation that the ESCO's final aligned population includes fewer than 350 ESCO Beneficiaries for a performance year, CMS may specify a higher MSR, MLR, or both for that year. Non-LDO ESCOs with fewer than 350 at the start of a performance year will have their beneficiaries grouped in an Aggregation Pool. If a non-LDO ESCO fails to satisfy the 350 minimum ESCO Beneficiary requirement at any time, then CMS may request a CAP from the ESCO. CMS in its sole discretion may allow a non-LDO ESCO that has fewer than 350 ESCO Beneficiaries to participate in the CEC model if there is no Aggregation Pool that includes 350 ESCO Beneficiaries. In these circumstances, the ESCO will be subject to a CAP and may be subject to an MSR of more than 4.75%.

Important to note is that ESCOs are prohibited from adding Participants during a performance year. The ESCO is able to add Participants at the start of each performance year.

At the end of each performance year, CMS will retrospectively remove months of experience from financial calculations for beneficiaries who were not eligible during specific months. For example, if an aligned beneficiary received a transplant during the performance year, the month of transplant and the months after transplant would be removed for financial reconciliation purposes.

In some cases, CMS will remove an aligned beneficiary from financial reconciliation for the entire performance year. For example, a beneficiary who did not receive at least 50% of his/her annual dialysis services (measured by expenditures) in the ESCO's market after their first month of alignment in the ESCO's market would be removed from an ESCO's beneficiary alignment list for financial reconciliation purposes for the entire performance year.

[3] Pediatric beneficiaries (age 17 and under) are excluded from alignment due to different needs of this small population (<1% of total ESRD beneficiaries).

Aggregation for non-LDO ESCOs

CMS's review of claims patterns suggests that many potential non-LDO ESCOs may have difficulty meeting the 350 aligned beneficiary minimum on their own. In addition, a number of potential non-LDO applicants have indicated that the high minimum savings rate is a deterrent to participation. Therefore, for purposes of satisfying the aligned beneficiary minimum and for financial benchmarking and distribution of shared savings, we will offer each non-LDO applicant an opportunity to aggregate the beneficiaries it serves with those served by other non-LDO applicants. Non-LDO ESCOs may elect to group its aligned beneficiaries in an "aggregation pool" with other non-LDO ESCO aligned beneficiaries if that ESCO also elects to group their beneficiaries in an aggregation pool. Non-LDO ESCOs with fewer than 350 beneficiaries in their ESCO are required to be included in an aggregation pool, while non-LDO ESCOs with more than 350 beneficiaries in their ESCO will have the option of joining an aggregation pool. Individual ESCO applicants in a given aggregation pool will remain independent legal entities and will be treated as such for purposes of meeting all other program requirements such as governance or ownership structure. The aggregation option will be open to non-LDO ESCOs in the one-sided and two-sided tracks but the aggregation pool for each payment track will be separated.

CMS will take into account the applicant's preferences for aggregation partners when making final decisions regarding the composition of an aggregation pool, while also considering other factors including the location and size of specific applicants, but will make the ultimate decision about the number and composition of aggregation pools for Non-LDOs.

If, during the life of the model, an ESCO is terminated for any reason (voluntary or not) and thereby affects the ability of an aggregated pool to collectively meet the minimum threshold, CMS may disqualify and terminate the participation of remaining ESCOs in the pool unless those ESCOs can add sufficient clinical partners to meet the minimum threshold.

CMS may add additional requirements as it further develops the Model design, evaluates applications for participation in the Model, and finalizes the CEC Model Participation Agreement for all Participants.

Alignment Process

CMS will align beneficiaries to an ESCO based on dialysis utilization using a "first touch" approach—meaning that a beneficiary's first visit to a given dialysis facility during a particular period will prospectively align that beneficiary to the dialysis facility, and by extension the ESCO, for the upcoming performance year. This is in contrast to the approach used in other ACO programs that rely on a plurality of primary care services over an extended period of time during a prior year.

Given that ESRD beneficiaries are a particularly vulnerable population requiring regular dialysis for survival, CMS also considers the prospective "first touch" alignment approach to be a patient-centered approach that will give ESCOs incentives to better serve and feel accountable for the broad spectrum of their beneficiaries. However, if a beneficiary is aligned to an ESCO and receives no dialysis services from that ESCO during a performance year, the beneficiary will not be aligned to that ESCO in the subsequent performance year and they will be removed from the alignment list for that year for financial and quality purposes during the alignment reconciliation process.

CMS will also remove any beneficiaries from an ESCO's performance year alignment list and from subsequent lists if, after the conclusion of a performance year, it is calculated that the beneficiary received

more than 50% of their dialysis services from facilities outside of the geographic market of the ESCO for that performance year after they had their first touch for that performance year.

Prospective alignment would consist of identifying beneficiaries prior to the first performance year for a particular ESCO, and also adding beneficiaries as each performance year ensues. Therefore, there will be both a historical and dynamic pathway for alignment. The multiple pathways are listed below:

1. **Prior to the first performance period**: CMS will prospectively align all beneficiaries who meet eligibility requirements by identifying the dialysis facility that billed Medicare for the earliest dialysis starting on the January 1st before the ESCO started in the model up until alignment is performed for the first performance year.
2. **During each performance period**: On a monthly basis, CMS will add eligible beneficiaries starting dialysis to the aligned population for an ESCO. This will occur when a beneficiary first receives dialysis services from the dialysis facility participating in the ESCO and the beneficiary's first claim is submitted for dialysis services via form 72x. Alignment of new beneficiaries is the result of actual dialysis utilization, so it does not involve any action or election on the part of the ESCO or dialysis facility other than routine provision of services.
3. **For performance periods after the first performance period:** For performance periods after an ESCO's first performance year, we will use a historical claims review process under which all beneficiaries that were aligned to the ESCO as of the end of the preceding performance year will again be aligned to that ESCO, assuming eligibility requirements continue to be met. Beneficiaries aligned in the preceding year who have been excluded during the annual reconciliation process for having received a transplant, for having received no dialysis care from an ESCO dialysis facility during the previous performance year, or for having received more than 50% of their dialysis services from a facility outside the geographic area of the ESCO during the performance year, will not be automatically realigned in a subsequent year.

ESCOs will be informed of their historically aligned prospective beneficiary population (i.e., the beneficiaries for whom they will be accountable at the start of the first performance period). Additional beneficiaries who have an eligible first touch dialysis visit at an ESCO dialysis facility will be aligned to the ESCO as the performance periods progress and CMS will notify ESCOs of additional aligned beneficiaries through monthly alignment reports.

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 ESCO, including each beneficiary's months of service within the performance period, as incurred through the end of the performance year and allowing for a minimum of three months claims run-out. In certain cases, a beneficiary may be removed from the ESCO alignment list for the entire performance period at reconciliation (e.g., if they received the majority of dialysis expenditures in a non-adjacent market or did not visit an ESCO dialysis facility during the year) or select beneficiary months may be removed from settlement (e.g., months of and after transplant or months following a beneficiary's death).

Alignment Notification

ESCOs will be required to send letters to their newly aligned beneficiary population informing them of the initiative and their alignment to the model within 30 days of receiving their alignment list

All notification letters will include CMS approved language with the following elements:

- A short description of the initiative;
- An explanation that the beneficiary retains full Medicare FFS benefits and the freedom to choose his or her providers[4];
- Contact information for the ESCO and 1-800-Medicare for questions and/or concerns.

CMS may provide a template to be used for these notification letters.

Notifications specific to data sharing are described in more detail in the *Data Sharing* section below.

VIII. Applicant Eligibility and Participation Requirements

Applicant Eligibility
Together, the following providers are eligible to form an ESCO that may apply to participate in the Model:

- Medicare Certified dialysis facilities, including facilities owned by large dialysis organizations (LDOs), facilities owned by non-Large dialysis organizations (non-LDOs), hospital-based facilities, and independently-owned dialysis facilities;
- Nephrologists and/or nephrology practices; and
- Other Medicare enrolled providers and suppliers (described in more detail below).

ESCOs must be located within a single market. Markets are defined as no more than three Medicare core-based statistical areas (CBSA) that are contiguous or connected by rural areas, with permissible inclusion of contiguous rural counties that are not included in a Medicare CBSA. The only exception to this requirement would be in the case of rural-based applicants not included in any Medicare CBSA. For rural applicants not included in any Medicare CBSA, the market area of the ESCO will be defined based on a geographic unit no larger than a state. This rule will apply to all ESCOs in the Model in PY 2.

ESCO applicants must include the TINs, CMS Certification Numbers (CCNs) (facilities only), and NPIs (individual or organizational) for their proposed ESCO Participants. Where appropriate, ESCO applicants must also include the NPIs (individual or organizational) for all of their proposed ESCO Providers/Suppliers. ESCO applicants must also identify in their applications the dialysis organization that directly or indirectly owns all of the ESCO's Participant Owner dialysis facilities (the Company). The final ESCO Participant List (Participant Owners and Participant Non-Owners and ESCO Providers/Suppliers) must be finalized before the start of the Performance Period. **Applicants must include 100% of the proposed ESCO Participants in the application.** The proposed ESCO Participant

[4] 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".

Owner dialysis facilities submitted in the application will be used to conduct historical beneficiary alignment. **ESCO Participants will not be able to be added after application submission.**

While various combinations of eligible providers and suppliers are permissible, CMS has established several application-related safeguards against further consolidation of the dialysis market. First, dialysis facilities owned by different Companies are prohibited from applying as part of the same ESCO. This necessarily means that dialysis facilities owned by LDOs are prohibited from partnering with dialysis facilities owned by non-LDOs or other LDOs. Dialysis Facilities in non-LDO ESCOs also must only be owned by a single company.

In addition to these safeguards, normal anti-trust rules will apply and ESCO applicants should consider the potential impact of those requirements when structuring their organizations. In particular, approval of an applicant to participate in the CEC Model does not constitute a determination by the Federal Trade Commission and Department of Justice that an ESCO is clinically or financially integrated. Of important note, all ESCO organizational and provider/supplier arrangements must fall within the confines of the legal entity and contracting requirements described in detail below.

Definitions for terms used in this section, and subsequent sections, can be found in the glossary provided in *Appendix B*.

To ensure beneficiary freedom of choice ESCO Participants must not be prohibited from referring their Medicare beneficiaries to any dialysis facility or other Medicare enrolled provider or supplier. In addition, ESCOs may not prohibit ESCO Participants (including all ESCO Participant Owners, Participant Non-Owners, and Providers/Suppliers) from contracting with entities that are not Participants (Non-Participants).

Because beneficiaries are aligned to a given ESCO based on their care relationship with the participating dialysis facility, dialysis facilities participating in the CEC Model are prohibited from participating in multiple ESCOs. This prohibition does not affect the dialysis facility's ability to contract with Providers/Suppliers and payers that are Non-Participants.

Eligible Providers/Suppliers

Medicare-enrolled providers of services and suppliers are eligible to participate in the CEC Model. This includes physicians, non-physician practitioners, and other health care suppliers except for those that are: (1) Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers, (2) ambulance suppliers, and (3) drug and/or device manufacturers. Of note, Medicare-enrolled providers of non-DMEPOS services that also serve as DMEPOS suppliers are eligible to participate in the Model, provided that they do not participate in their capacity as DMEPOS providers.

CMS reserves the right to (1) prohibit additional categories of providers/suppliers from participating in the Model where CMS determines that the participation of such categories of providers/suppliers in the Model would pose an elevated program integrity risk to the Medicare program, and (2) not select otherwise qualified applicants on the basis of information found during a program integrity review.

CMS will require the ESCO applicant to provide a list of all the proposed Participants as a part of the application for CMS vetting and review. This list must also include all owners of any joint venture entities that will be Participants in the model. The ESCO will not be able to add any ESCO Participants

during the course of a performance year, but will have an opportunity to request CMS consider additional individuals and entities as potential Participants before the start of each performance year of the model.

The CEC Model application will request information about the applicants' proposed ESCO Participants so that the CMS Innovation Center can conduct Medicare provider/supplier vetting. This will involve collecting the following for each proposed ESCO participant and ESCO provider/supplier:

- Full name and address (including zip code);
- CCN (facilities only);
- Tax Identification Number (TIN); and,
- NPI (individual or organizational).

Applicants are required to disclose any sanctions, investigations, probations or corrective action plans that the applicant its proposed ESCO Participants, and its owners or managers are currently undergoing or have undergone in the last five years.

Participation in Other Medicare Programs, Initiatives, Models or Demonstrations

The Affordable Care Act presented many opportunities for reforming the delivery and financing of health care. The interventions supported through this Model must complement and support other health reform efforts, while still maintaining sufficient independence to isolate the effects of this initiative. CMS is not seeking to fund interventions that compete or interfere with existing demonstrations, models, initiatives or programs. However, CMS may fund complementary demonstrations, models, initiatives and programs to further test innovative care models under section 1115A of the Social Security Act authority. To the extent that multiple new models are viable options for the same providers and/or beneficiaries, CMS will take appropriate steps to minimize beneficiary overlap and prohibit duplicate payments for savings generated based on the same beneficiary.

The most substantial provider and beneficiary overlaps may arise between this Model and the Medicare Shared Savings Program, the Pioneer and Next Generation ACO Models, the Financial Alignment Demonstration, and the Comprehensive Primary Care (CPC) Initiative.

Provider eligibility for participation will adhere to existing policies in other CMS initiatives. Specifically, a TIN already participating in or applying to the Medicare Shared Savings Program will not be eligible for the CEC Model. Providers (defined by a TIN/NPI combination) participating in a Pioneer or Next Generation ACO may participate in the CEC Model with the exception of primary care providers.

Where a beneficiary may meet eligibility criteria and be aligned to more than one initiative, the agency applies a hierarchical set of rules to determine which initiative will include that beneficiary. Medicare beneficiaries will not be aligned to more than one shared savings program.

Legal Entity and Contracting Requirements

Applicants to the CEC Model will not be expected to have the ESCO legal entity formed until after application selection and prior to the execution of the CEC Model Participation Agreement. ESCO applicants should include 100% of their proposed Participant Owners, Participant Non-Owners, and ESCO Providers/Suppliers in the application. ESCO Participants will not be able to be added after application submission. *Prior to starting in the model, selected applicants must have 100% of their Participants (owner and non-owner) identified and CMS-vetted.*

Each ESCO must have a TIN and be a separate and unique legal entity that is recognized and authorized to conduct business under applicable state law. The ESCO may be an existing legal entity if it conforms to all of the requirements set forth in the RFA. To be eligible for Model participation, the ESCO must be capable of:

- Receiving and distributing shared savings payments;
- Repaying shared losses, if applicable; and,
- Establishing reporting mechanisms and ensuring ESCO participant compliance with program requirements, including but not limited to quality performance standards.

Each ESCO must be a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law; identified by a TIN; and formed by ESCO Participant Owners. Each ESCO Participant must have a Medicare-enrolled TIN through which its participating ESCO providers/ suppliers bill. Important to note is that not all of the providers/suppliers that bill under the ESCO participant's TIN are required to participate in the Model as ESCO Providers/Suppliers. However, for program integrity reasons, CMS will give strong preference to applications where the ESCO Participants include all NPIs that bill under that TIN in the Model.

An ESCO Participant may be a Participant Owner, a Participant Non-Owner, or an ESCO Providers/Supplier. All dialysis facilities and nephrologists/nephrology group practices must apply to this model as Participant Owners, except that a nephrologist who bills through the TIN of a nephrology group practice that is a Participant Owner has the option of either participating as a Participant Owner or participating as an ESCO Provider/Supplier. ESCO Participant Owners have an increased level of accountability to CMS in that they must (1) have agreed to participate in the CEC model pursuant to a written agreement with the ESCO, (2) have a direct ownership or investment interest in the ESCO, and (3) assume liability for shared losses ("downside risk") for ESCOs that are participating in a two-sided model. Participant Owners must assume downside risk at a level that is equivalent to a minimum of 50% of their portion of the ESCO's total expenditures[5] multiplied by the ESCO's total shared losses. The following example illustrates this requirement[6]:

- An ESCO's total expenditures for aligned beneficiaries are $1,000,000, with a single ESCO Participant Owner contributing $100,000 to the total expenditures. Assuming a target benchmark of $800,000, the ESCO would be responsible for shared losses of $200,000*0.5—with the single ESCO Participant Owner responsible for paying back at least $10,000 of the losses [.5 * (100,000/1,000,000)*(200,000) = $10,000].

Subject to the requirements detailed below, each ESCO must have at least one of each of the following included as Participant Owners:

- A dialysis facility; and

[5] An ESCO's total revenue is defined as the total of all Medicare Part A and Part B claims paid to all providers or suppliers for the items and services furnished to all ESCO beneficiaries in a given Performance Year. A participant's portion of the total revenue is calculated by the total of all Medicare Part A and Part B claims paid to the participant's TIN for aligned ESCO beneficiaries divided by the ESCO's total revenue.

[6] In circumstances where an ESCO Participant Owner is defined by a partial TIN only the claims of the participating ESCO Providers/Suppliers under the TIN will be used to calculate the minimum shared loss contribution.

- A nephrologist and/or nephrology practice.

Other Medicare enrolled providers and suppliers (except DMEPOS suppliers, ambulance suppliers and drug/device manufacturers) are able to join the ESCO as Participant Owners, but are not mandatory Participants required for eligibility.

ESCO Participant Non-Owners cannot take an ownership stake in the ESCO. They must, however, have a contractual relationship with the ESCO that requires them to comply with the terms and conditions of the CEC Model Participation Agreement. ESCO Participant Non-Owners and Providers/Suppliers are not required to assume downside risk, but are not prohibited from doing so.

The ESCO may also contract with other community-based organizations (e.g., care management organization, quality improvement organization, etc.) that are not ESCO Participants (e.g., because they do not have a Medicare-enrolled TIN and/or have not contracted with the ESCO to be bound by the CEC Model Participation Agreement). These organizations are not considered ESCO Participants, but the ESCO may want to form informal relationships with these organizations.

CMS will share in savings and losses with the ESCO. All Participant Owners in an ESCO with two-sided risk must take on the risk of shared losses. Only ESCO Participants and the Company will be permitted to receive any distribution of shared savings.

While all eligible ESCO Participants can receive a portion of shared savings, where ESCOs participate in the two-sided risk model, only Participant Owners are required to take on down-side risk. The minimum amount of risk that each Participant Owner must assume is a function of the owner's respective contribution to the ESCO's total Medicare FFS revenue for the aligned beneficiary population. The ESCO's distribution of shared savings or losses must comply with all applicable laws and regulations, except as explicitly provided in any written waiver that may be issued pursuant to section 1115A(d)(1) specifically for the CEC Model. ESCO Participant Non-Owners may contract with the ESCO to take on down-side risk, but there is no requirement to do so. The ESCO, ESCO Participants, and the Company may not indemnify an ESCO Participant against the payment of or liability for shared losses, or waive, finance, or guarantee the payment of shared losses.

As mentioned above, the ESCO and the Company must be signatories to the CEC Model Participation Agreement between CMS and the ESCO. ESCO Participant Owners, Participant Non-Owners and ESCO Providers/Suppliers must execute a contract with the ESCO that requires them to comply with the applicable terms of the CEC Model Participation Agreement. Thus, Participant Owners, Participant Non-Owners, and ESCO Providers/Suppliers will all be required to comply with the terms of the CEC Model Participation Agreement.

Table 1 summarizes the key design features of the ESCO legal structure.

Table 1. Key Design Features of the ESCO Legal Structure

	Composition	Signatory on Participation Agreement	Assume Down-Side Risk (2-sided risk Only)	Able to Share in Savings
ESCO	Legal entity	X	X	X
ESCO Participant Owners	Mandatory ESCO Participant Owners include: • At least one dialysis facility; • At least one nephrologist/nephrology practice; and, Optional ESCO Participant Owners include: • Other Medicare providers or suppliers (other than a dialysis facility, nephrologist/nephrology practice, DMEPOS, ambulance supplier, or drug/device manufacturer)		X	X
Company	A single corporate entity that owns all Participant Owner dialysis facilities (directly or indirectly)			X
ESCO Participant Non-Owners	ESCO Participant Non-Owners may include: • Other Medicare providers or suppliers (other than a dialysis facility, DMEPOS, ambulance supplier, or drug/device manufacturer).		X (not required, but allowed)	X
ESCO Providers/ Suppliers	ESCO Providers/Suppliers may include: • Other Medicare providers or suppliers			X

Governance Structure Requirements

CMS does not expect applicants to the CEC Model to have their complete and final governance structure formed until after they have been selected. Applicants must include a proposed governance membership and structure in their application. However, the governance structure must be fully formed and must comply with all the CEC Model's governance structure requirements prior to the signing of the CEC Model Participation Agreement.

The ESCO governing body must meet the following requirements:

- The ESCO must be a legal entity separate from any of its Participants, the Company, or any entity owned directly or indirectly, in whole or in part, by the Company, and shall maintain an identifiable governing body that has a transparent governing process and responsibility for oversight and direction of the ESCO in its activities under this Agreement.

- The governing body of the ESCO must not be the same as the governing body of any entity that is a Participant, the corporate parent of a Participant, the subsidiary of a Participant, the Company, or any entity owned directly or indirectly, in whole or in part by the Company.
- The governing body must include at least one individual who will represent and advocate for the interests of Medicare beneficiaries. This individual will either be a Medicare beneficiary who is diagnosed with ESRD or an Independent Consumer Advocate. In cases where such representation on the governing body is prohibited by State law, the ESCO, with CMS approval, will provide for an alternative mechanism to ensure that its policies and procedures reflect consumer and patient perspectives.
- The governing body may not include a Prohibited Participant, or an owner or an employee of a Prohibited Participant, defined as an individual or entity that is: (1) a Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier; (2) an ambulance supplier; (3) a drug or device manufacturer; or (4) excluded or otherwise prohibited from participation in the Medicare or Medicaid programs.. Of note, Medicare-enrolled providers of non-DMEPOS services that also serve as DMEPOS suppliers are eligible to participate in the Model, provided that they do not participate in their capacity as DMEPOS providers.
- The ESCO must ensure that Participants have at least 75% control of the ESCO's governing body.
- With respect to the voting interests of ESCO shareholders, members, or similarly situated individuals or entities, the ESCO must ensure that --
    - No single Participant controls more than 50%;
    - The Participants on the governing body that are Dialysis Facilities do not individually or cumulatively control more than 50%; and
    - The Company and any entities owned directly or indirectly, in whole or in part by the Company do not individually or cumulatively control more than 50%.
- The ESCO must provide each member of the governing body with a copy of the CEC Participation Agreement.
- The governing body members must have a fiduciary duty, including the duty of loyalty, to the ESCO and not to any of its Participants, the Company, an entity owned directly or indirectly, in whole or in part by the Company, or a Prohibited Participant. The governing body members must act consistently with that fiduciary duty in performing their responsibilities as governing body members.
- The ESCO must have a conflict of interest policy that applies to members of the governing body, requires governing body members to disclose all relevant financial interests or other potential conflicts of interest, identifies processes for determining whether a conflict of interest exists and addressing any conflicts of interest, and sets forth remedial actions to be taken against governing body members who fail to comply with the policy.
- The ESCO shall maintain governing body records, including minutes of meetings and records of votes.

IX. Other Key Operational Elements of the CEC Model

Legal Waivers

Under section 1115A(d)(1) of Title XI of the Social Security Act (SSA), as added by section 3021 of the Patient Protection and Affordable Care Act, 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). Notwithstanding any other provision of this RFA, individuals and entities participating in the CEC Model must comply with all applicable laws and regulations, except as explicitly provided in any waiver that may be granted pursuant to section 1115A(d)(1) specifically for the CEC Model. Any such waiver will apply solely to the CEC Model and could differ in scope or design from waivers granted for other programs or models.

With respect to certain fraud and abuse provisions in sections 1128A, 1128B and 1877 of the SSA, the Secretary has issued waivers pursuant to §1115A(d)(1) for the CEC Model. The current waivers for the CEC Model are available at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html and on the OIG website. Such waivers may be revised or revoked at any time. We note that the fraud and abuse law waivers for the CEC Model apply only to certain arrangements that comply with the criteria set forth in the applicable waiver. Parties should consult with legal counsel as necessary to ensure that arrangements for which they seek waiver protection meet all of the conditions of an applicable waiver. No new or revised waivers of fraud and abuse authorities are being issued in this RFA.

Approval of an applicant to participate in the CEC Model 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 ESCO or any of its Participants 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 Participation Agreement or any other provision of law. The CEC Model Participation Agreement shall not be construed to bind any Government agency except CMS and binds CMS only to the extent provided herein.

For guidance related to financial or clinical integration, please refer to the Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care (Statements 8 and 9), available at http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf

Monitoring and Oversight

CMS has prescribed CEC Model participant requirements aimed at protecting beneficiaries and preventing program integrity issues from arising (e.g., eligibility criteria, legal entity and contracting requirements, and governance body requirements). For example, no one participant in the ESCO may have more than 50% representation on the governing body. The purpose of this requirement is to prevent one participant from having excessive decision making authority. Another pertinent example is that

ESCOs will be required to include an independent Medicare ESRD beneficiary representative and non-affiliated consumer advocate actively on their governing body.

In addition to these requirements, designate a compliance officer who is not legal counsel to the ESCO or to the Company, who is not in a direct reporting relationship to legal counsel to the ESCO or the Company, and who reports directly to the ESCO's governing body. The compliance officer may, but is not required to, serve as the compliance officer of one or more Participants in the ESCO. The compliance officer may not serve as the compliance officer of the Company.. ESCOs will be required to include at least the following in their compliance plans:

- A quality assurance strategy that, at the very least, includes a peer review process to investigate cases of potentially suboptimal care;
- Descriptions of the remedial processes that apply when Participants fail to comply with the CEC Model Participation Agreement, Medicare regulations, and/or internal procedures and performance standards including correction action plans (CAPs) and circumstances for expulsion; and,
- Descriptions of antitrust compliance efforts, including appropriate firewalls or other safeguards against improper exchanges of prices or other competitively sensitive information among competing Participants that could facilitate collusion and reduce competition in the provision of services outside the CEC Model.

ESCOs are prohibited from restricting beneficiary access to necessary care. CMS will routinely analyze data on service utilization and investigate aberrant utilization patterns. Program integrity domains that CMS will focus on during the course of this Model include, but are not limited to: provider recruitment; beneficiary experience and infringement on choice; under-utilization, over-utilization and/or cost-shifting to either the Medicaid or commercial populations; and compliance with the CEC Model Participation Agreement.

The CMS Innovation Center will employ a range of methods to monitor and assess ESCO performance (including the performance of its Participant Owners, Participant Non-Owners, and Providers/Suppliers) including, but not limited to:

- Analysis of specific financial and quality performance data reported by the ESCO;
- Analysis of beneficiary and provider complaints including, but not limited to, those submitted through 1-800 Medicare, the ESRD Networks, and internal processes established and supported by the ESCO;
- Audits (including, but not limited to, claims data mining, medical chart review, beneficiary survey data, coding audits, on-site compliance reviews, and review of financial transactions involving the ESCO and/or ESCO Participants.

When program monitoring efforts reveal potential non-compliance, CMS will address noncompliance with Model requirements by employing a variety of remedial actions, based on the level and type of issue identified. For example, CMS may:

- Impose a Corrective Action Plans (CAP);
- Terminate the ESCO or require the ESCO to terminate an ESCO Participant

- Make a referral to the Secretary for consideration under Sec. 1881(c)(3) [42 U.S.C. 1395rr][7]; and,
- Prohibit the ESCO's distribution of shared savings or to a Participant or the Company;
- Prohibit the ESCO's distribution of performance-based payments to physicians;
- Unilaterally amend the ESCO's participation agreement with CMS to make inapplicable any or all waivers of existing law made pursuant to section 1115A(d)(1) of the Act

The Participation Agreement does not limit or restrict Office of the Inspector General's (OIG) authority to audit, evaluate, investigate, or inspect an ESCO, its ESCO Participants, ESCO providers/ suppliers, and other individuals or entities performing functions or services related to the ESCO.

CMS may add additional program integrity safeguards and requirements to the program as it further develops the Model design, evaluates applications for participation in the Model, and finalizes the CEC Model Participation Agreement.

Quality Performance

To ensure that ESCOs meet the specified goals of patient-centeredness, high standards of clinical care, care coordination across care settings, and positive patient outcomes, the CEC model requires the assessment of claims-based and clinical quality measures, as well as information from administration of the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems *(*ICH CAHPS) and the Kidney Disease Quality of Life (KDQOL) surveys. .

The reporting of quality measures is a key mechanism for CMS to verify clinical improvements, assess patient health outcomes and appropriate coordination of care, and ensure continued quality of care for the beneficiaries.

In consultation with national ESRD experts, including patient advocates and nephrologists, CMS developed the set of CEC Model quality measures, applying the following priorities:

- Appropriate to the health issues of dialysis patients;
- Effective for quality of care monitoring and program oversight;
- Inclusive of process and outcome measures that will enable a robust evaluation of patient, provider and delivery system outcomes;
- Conducive to use across clinical methods, modalities, and care settings;
- Effective for incentivizing better care, better health, and lower costs across Medicare Part A, Part B, Part D and Medicaid programs.
- Include measures of appropriate medication utilization;
- Straightforward to operationalize and measure; and,

[7] Where the Secretary determines, on the basis of the data contained in the network's annual report and such other relevant data as may be available to her, that a facility or provider has consistently failed to cooperate with network plans and goals or to follow the recommendations of the medical review board, she may terminate or withhold certification of such facility or provider (for purposes of payment for services furnished to individuals with end stage renal disease) until she determines that such provider or facility is making reasonable and appropriate efforts to cooperate with the network's plans and goals.

- Inclusive of other CMS ESRD quality initiative data.

Specification of the quality measure set and scoring principles will be reviewed annually and be subject to revision each performance year.

Table 2 includes the quality measures for the first performance period, through the end of PY 1. For this period, CMS will assess ESCO performance on a pay-for-reporting basis for all quality measures. CMS plans to employ a pay-for-performance methodology for all clinical, claims-based, and survey measures for subsequent performance years, beginning in PY 2, for currently participating ESCOs. For new ESCOs that start in PY 2, their first year of pay-for-performance for quality will be PY 3. On an annual basis, an ESCO's performance on each of these measures would be used to determine an overall quality score, which will be factored into the calculation of shared savings payment or a shared loss payment. An ESCO must achieve a minimum threshold quality score in order to be eligible for shared savings. This overall score will consider both an ESCO's performance on a particular measure against national benchmarks and improvement compared to its performance in the previous year. ESCOs will receive the higher of these two scoring scenarios, designed to encourage both quality improvement and attainment of high quality care. Accordingly, CMS will determine benchmarks for each of the quality measures, reflecting national performance percentiles, to be used for performance scoring. The ESCO's results from their first participating performance year where they are being assessed through a pay-for-reporting methodology will be used as baseline performance for calculating improvement scoring in their next performance year when they are being assessed through a pay-for-performance methodology. In addition, CMS requires that for the ESCO to be eligible for shared savings that its aggregate score determined from the performance of participating dialysis facilities for the CMS ESRD Quality Incentive Program (QIP) equal or exceed the QIP minimum Total Performance Score.

Table 2: Quality Measures for the CEC Model.

Measure Title	NQF #	Measure Steward	CEC Data Source
Domain: Patient Safety			
ESCO Standardized Mortality Ratio	0369	CMS	Claims and CMS administrative data
Documentation of Current Medications in the Medical Record	Adapted 0419[8]	CMS	Hybrid[9]
Bloodstream Infection in Hemodialysis Outpatients	1460	CDC	QIP results[10]
Falls: Screening, Risk Assessment and Plan of Care to Prevent Future Falls	Adapted 0101	NCQA	Hybrid
Domain: Person- and Caregiver-Centered Experience and Outcomes			
Kidney Disease Quality of Life (KDQOL) Survey	N/A	RAND	Survey
Advance Care Plan	Adapted 0326	NCQA	Hybrid
ICH-CAHPS: Nephrologists' Communication and Caring	0258	AHRQ	QIP results
ICH-CAHPS: Quality of Dialysis Center Care and Operations	0258	AHRQ	QIP results
ICH-CAHPS: Providing Information to Patients	0258	AHRQ	QIP results
ICH-CAHPS: Rating of Kidney Doctors	0258	AHRQ	QIP results
ICH-CAHPS: Rating of Dialysis Center Staff	0258	AHRQ	QIP results
ICH-CAHPS: Rating of Dialysis Center	0258	AHRQ	QIP results
Domain: Communication and Care Coordination			
ESCO Standardized Hospitalization Ratio for Admissions	1463	CMS	Claims and CMS administrative data
ESCO Standardized Readmission Ratio	2496	CMS	Claims and CMS administrative data
Medication Reconciliation Post Discharge	Adapted 0554	NCQA	Hybrid
Domain: Clinical Quality of Care			
Diabetes Care: Eye Exam	0055	NCQA	Hybrid
Diabetes Care: Foot Exam	0056	NCQA	Hybrid
Hemodialysis Adequacy: Minimum Delivered Hemodialysis Dose	0249	CMS	QIP results
Proportion of Patients with Hypercalcemia	1454	CMS	QIP results
Peritoneal Dialysis Adequacy: Delivered Dose of Peritoneal Dialysis Above Minimum	0318	CMS	QIP results
Hemodialysis Vascular Access: Maximizing Placement of Arterial Venous Fistula	0257	CMS	QIP results
Hemodialysis Vascular Access: Minimizing Use of Catheters as Chronic Dialysis Access	0256	CMS	QIP results
Domain: Population Health			
Influenza Immunization for the ESRD Population	Adapted 0226	KCQA	Hybrid
Pneumonia Vaccination Status	Adapted 0043	NCQA	Hybrid
Screening for Clinical Depression and Follow-Up Plan	Adapted 0418	CMS	Hybrid
Tobacco Use: Screening and Cessation Intervention	Adapted 0028	AMA PCPI	Hybrid

[8] An Adapted measure is a measure with changes to the specifications for the NQF-endorsed version of the measure, such as expanded age ranges (e.g., 18 and older instead of 65 and older) or alternate data sources for the measure. Measures with an age stratification (e.g., 18 and older instead of all ages) are not considered adaptations from the NQF endorsed measures.

[9] Hybrid measures use claims and medical record data. The ESCO is responsible for reporting on the portion of the measure that requires use of medical record data.

[10] The ESRD QIP generates measure results from Medicare claims, the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb), and the National Healthcare Safety Network (NHSN).

Data Sharing

Under appropriate data use agreements and upon the ESCO's request, CMS plans to share several types of Medicare data with ESCOs to support care improvement efforts, consistent with all relevant laws and regulations pertaining to beneficiary privacy, including pertinent documentation of contractual relationships.

ESCOs are required to notify aligned beneficiaries in writing that CMS will share their data with the ESCO. (See *Alignment Notification* section for additional information on the expected content of the notification).

Aligned beneficiaries will have the option to opt out of data sharing by calling 1-800 MEDICARE at any point during the performance year. CMS will only share data with the ESCO for aligned beneficiaries who have not opted out of data sharing.

CMS plans to share the following data files and reports with ESCOs on a regular basis:

1. At the start of the first performance year – Detailed, standard (not customized), historical (three years) claims data on aligned beneficiaries who have not opted out of data sharing. During each performance year, CMS will also provide historical claims data as additional beneficiaries are aligned to the ESCO. Claims data associated with diagnoses that are related to substance abuse will not be shared.
2. On a monthly basis – Standard beneficiary-level claims feeds, which will include beneficiary identifiers, and services delivered by providers inside and outside of the ESCO. Claims files will include Medicare Part A, Part B, and Part D data as well as demographic information on the aligned beneficiaries who have not opted out of data sharing.
3. On a monthly basis – Total Part A and B expenditures and claims lag reports with no claims run-out
4. On a quarterly basis – Total Part A and B expenditures with a three month claims run-out
5. On an annual basis – Financial reconciliation reports, including the ESCO's performance on quality and patient experience metrics.

Evaluation

All ESCOs will be required to participate in CMS's formative and summative evaluations—aimed at assessing the impact of the Model on the goals of better health, better health care, and lower Medicare per capita costs for aligned beneficiaries. CMS will conduct rigorous quantitative analysis of both quality performance and monitoring measures in order to answer a number of research questions outlined below. The evaluation will also include qualitative analyses in order to capture and compare qualitative differences between the CEC Model and other ACO initiatives that include ESRD beneficiaries. The evaluation will also assess Model participant/provider/beneficiary perceptions, barriers to change, key areas of participant focus, and changes in practice culture.

X. Payment

Expenditure Baseline and Benchmark Calculations

CMS will calculate a *cross-sectional* expenditure baseline from the Medicare Parts A and B FFS expenditures for beneficiaries who would have been aligned to the ESCOs in each of the three full years prior to the start of the Model's first performance year. Similar to the methodology in the Pioneer ACO Model, this approach would generate comparable benchmark expenditures for the population served by the ESCOs during the three years immediately preceding the agreement period. Comparability through risk adjustment and trending between per capita expenditures in the baseline and performance year periods helps ensure a more accurate measurement of savings in performance periods. For ESCOs deemed eligible (and that choose) to extend their performance into the optional performance years 4 and 5 (which may be the third or fourth years in the model for ESCOs entering in PY2), baseline expenditures will not be rebased using actual performance data from performance years 1-3.

Baseline expenditures will include all Part A and B (including dialysis) expenditures in 2012, 2013, or 2014 (base year 1, 2 or 3, respectively) for the ESCOs starting in Model PY 1 and Model PY 2. The majority of dialysis facilities elected to be paid completely through the ESRD Prospective Payment System bundle in 2011, as opposed to participating in the transition—hence, the vast majority of 2012 claims are post-bundle. No special adjustment will be made for base year dialysis expenditures not paid under the PPS bundle, as the comparable ESRD national average growth percentage already includes the national average mix of pre- and post- bundle dialysis expenditures. Any further change in the dialysis bundle composition will be implicitly accounted for because performance year settlement will employ retrospectively-calculated national average growth amounts for updating the benchmark.

The weighted average per capita expenditures for aligned beneficiaries in the first two base years (BY1 (2012) and BY2 (2013)) will be adjusted to be comparable to the most recent base year (BY3 (2014)) in the following ways:

1. Trending by the national average growth percentage in comparable ESRD Medicare FFS per capita expenditures;
2. Risk adjusting for the difference in the average prospective HCC risk score relative to the aligned population in BY3; and,
3. Removing adjustments to the ESRD PPS bundled base rate and replacing the adjusted rate with the base rate.

The adjusted and trended per capita expenditures for BY1 and BY2 will be averaged with the per-capita expenditure for BY3, resulting in a single per-capita historical benchmark expenditure amount for each eligibility subgroup. The historical benchmark will then be updated to create each performance year benchmark, as described in the following section.

For each performance year, the historical expenditure baseline will be risk-adjusted, trended, price-adjusted, and bundle-adjusted (as described above) to form an updated benchmark reflecting the performance year to compare with the ESCO's actual performance year (PY) average per capita expenditure amount —potentially generating shared savings, or shared losses, if applicable.

The CEC Model will use a risk adjustment methodology similar to that used in the Medicare Shared Savings Program. (Note: the prior section describes full HCC adjustment that will be used for combining

the three base years' expenditures). A full adjustment will be made for differences in the average prospective HCC score for beneficiaries newly-aligned in the performance year compared to the average prospective HCC score for beneficiaries newly aligned in BY3. The remaining continuously aligned beneficiaries, those assigned both for the performance year and the immediate prior year, and those assigned both in BY3 and the immediate prior year (BY2), are adjusted for demographic changes only. The only exception would be in the case where the average prospective HCC score comparison would result in a lower adjustment than that given by the demographic adjustment, in which case the prospective HCC score adjustment will be used.

Trending will follow a blended method. The risk-adjusted benchmark will be increased by a blend of the national average *percentage* growth rate in comparable ESRD Medicare per-capita expenditures and the *absolute dollar equivalent* of that growth rate (50% each).

For the base and performance periods, CMS will calculate expenditures on a per capita (i.e. per-beneficiary-per-year) basis. If a beneficiary has fewer than 12 months of services in a given base or performance year, the individual per capita expenditure amount will be weighted by the number of months in the year that they were aligned to the ESCO. If a beneficiary dies during the base year or any of the performance years, all costs incurred during the measurement period will be counted in the expenditure calculations.

Expenditures will include all Medicare Part A and B expenditures, including the ESRD PPS payments, or payments under Medicare Parts A and B for years prior to full phase-in of the bundle. Of note, expenditures related to the preparation or execution of kidney transplant (e.g., organ acquisition costs) will be excluded, along with add-ons for DSH and Inpatient Medical Expenditures and Uncompensated Care.

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

1. Evaluation of the recipient and donor
2. Blood and tissue typing of the recipient and donor
3. Organ acquisition
4. Execution of the transplant itself
5. Services following the transplant.

Per capita benchmark expenditures will be separately calculated, trended and compared to actual performance year expenditures for each of the distinct eligibility categories listed below:

1. Aged dual eligible
2. Aged non-dual eligible
3. Disabled dual eligible
4. Disabled non-dual eligible
5. ESRD only (i.e. not otherwise aged or disabled)

This stratification is designed to account for known differences in the absolute level and typical growth rates of expenditures for each subgroup of beneficiaries. However, if a stratification category contains fewer than a minimum defined number of beneficiaries[11] in the base and/or performance periods, then it will be collapsed within the other eligibility categories in order to provide a more credible shared-savings measurement.

For each Non-LDO aggregation pool, CMS will calculate an aggregate historical baseline, performance year benchmarks, and performance year expenditures, weighting to account for the distribution of aligned beneficiaries across aggregation pool partners. CMS will also calculate each of these expenditure values for the individual ESCOs within each aggregation pool, for monitoring purposes and to support ESCOs in their care improvement work.

CMS will allow for separate aggregation pools for Non-LDOs, one or more for Non-LDO ESCOs participating in the 2-sided track starting in PY 2 and one or more for Non-LDO ESCOs who are participating in the 1-sided payment track. The number of the pools will be at CMS discretion. There will be a single MSR/MLR for the 2-sided non-LDO pool(s) that will be selected collectively by the non-LDO ESCOs participating in the pool. The MSR for the 1-sided non-LDO pool will be set based on the actuarial formula described in Table 3 below.

CMS will compare the resulting aggregate performance expenditures for a given pool to its aggregate updated benchmarks to determine a single overall savings percentage for the aggregated pool using the applicable MSR as outlined in Table 3 below. For each Non-LDO Aggregation pool, CMS will distribute aggregate savings to individual ESCOs based on its number of aligned beneficiaries and will adjust those savings based on the quality score for each ESCO.

Payment Arrangements

All applicants with LDO ownership will be in the two-sided payment track. Applicants with non-LDO ownership have the option of choosing to be in the one-sided payment track or the two-sided payment track. The purpose of including different payment models is to acknowledge that LDOs have greater experience in risk-based arrangements and ensure that CMS is able to test this Model across multiple provider types. A summary of the payment arrangements can be found in Table 3.

[11] The minimum number of beneficiaries for a beneficiary eligibility stratification category will be determined as part of finalization of the detailed model specifications that are to be drafted prior to the Model start date.

Table 3. Key Design Features of the Various ESCO Payment Arrangements

Design Feature	LDO Financial Model	Non-LDO Financial Model I	Non-LDO Financial Model II
Risk Structure	**2-sided**	**1-sided**	**2-sided**
Minimum savings/loss rate (MSR/MLR)	**+/-1% threshold for first-dollar shared savings or losses (option for higher threshold of up to +/-2% if desired)**	**4.75% MSR for first-dollar shared savings at 350 beneficiaries, decreasing to 4% at 500 beneficiaries, decreasing to 2% as number of beneficiaries increase to 2,000**	**+/-1% threshold for first-dollar shared savings or losses (option for higher threshold of up to +/-2% if desired)**
Guaranteed Discount	**Guaranteed discount applied only to non-dialysis FFS Part A and B per capita benchmark.** **Model PY 2 (2017): 1%** **Model PY 3 (2018): 2%** **Model PY4+(2019-): 3%**	**None**	**None**
Shared Savings / Shared Loss Percentages	**After locking in guaranteed discounts, 75%**	**50%**	**75%**
Caps on Shared Savings/Shared Losses	**10% Model PY 2 (2017)** **15% Model PY 3+ (2018-)**	**5%**	**10% Model PY 2 (2017)** **15% Model PY 3+ (2018-)**
Rebasing	**No rebasing**	**No rebasing**	**No rebasing**

When the MSR/MLR threshold is passed, the ESCO will share savings or losses on the full difference between the benchmark and the actual expenditures up to the cap amounts described below. LDO ESCO benchmarks will be reduced to take into account required guaranteed discounts that escalate over the performance years, as described below.

Under sharing for non-LDO ESCOs in the one-sided model, an ESCO or an aggregation pool meeting MSR requirements will receive up to 50% of savings subject to a maximum of 5% of total expenditures (expressed as a percentage of the aggregate updated benchmark). Savings will then be distributed in an aggregation pool based on number of beneficiaries in each ESCO in the pool and adjusted for quality.

Under sharing for non-LDO ESCOs in the two-sided model, an ESCO or an aggregation pool meeting MSR/MLR requirements will receive up to 75% of savings, or owe 75% of losses, subject to a maximum of 10% savings or losses on total included expenditures for the ESCO's or the aggregation pool's aligned

beneficiaries (maximum rises to 15% in PY 3). Savings or losses will then be distributed in an aggregation pool based on the number of beneficiaries in each ESCO in the pool and adjusted for quality.

Under sharing for LDO ESCOs, an ESCO meeting MSR requirements will receive up to 75% of savings, or owe 75% of losses, subject to a maximum of 10% savings or losses on total included expenditures for the ESCO's aligned beneficiaries (maximum rises to 15% in PY 3). LDO ESCOs will have benchmarks reduced to reflect a discount applied only to all non-dialysis Fee-for-Service Medicare Part A and Part B costs (PY 2: 1.0%, PY 3: 2.0%, PY 4+: 3.0%). The discounts will be applied equally across all LDO ESCOs each performance year, regardless of whether the ESCO started in Model PY 1 or Model PY 2. Savings or losses will then be measured relative to the resulting discounted benchmark.

For all ESCOs that enter agreements to continue participation in the model for years 4 and 5, the benchmark would not be rebased using actual expenditure data from PY1-PY3.

The discount required from LDO ESCOs recognizes the advantages such organizations have that would allow them to make rapid progress in making significant improvements in efficiency of care that they agree to be available for their ESRD patients. Notwithstanding the more aggressive nature of this approach, which is designed to generate larger real savings for CMS, the greater sharing percentages (up to 75%) and higher maximum savings percentage (up to 15%) represent notable upside for LDO ESCOs if they can create material and sustained savings on total cost of care for their beneficiaries.

CMS aims to encourage ESCO participation by avoiding arrangements that put them at excessive financial risk. Therefore, CMS will provide ESCOs with the option of truncating an assigned beneficiary's total annual Medicare Parts A and B FFS per capita expenditures, for each benchmark and performance year, to minimize variation from catastrophically large claims. An individual beneficiary's truncation point for expenditures within a given benchmark or performance year will be set at the 99th percentile for non-ESRD beneficiaries plus the difference between the average cost for ESRD beneficiaries and non-ESRD beneficiaries (roughly lies between the 90th and 95th percentile for ESRD beneficiaries).To ensure appropriate comparability, national average expenditures used to trend benchmarks and create updated targets will symmetrically account for large claim truncation as will be applied to the ESCO's population as described above.

If an ESCO does not elect this option, the ESCO must maintain aggregate stop loss protection for the ESCO that at a minimum provides an actuarially equivalent level of coverage to the option of having claims truncated.

Providers will continue to receive payment through existing Medicare FFS mechanisms. However, CMS is looking at adding new payment mechanisms in a future performance year, some of which may be similar to the infrastructure payments available under the Next Generation ACO Model and the population based payments used in both the Pioneer and Next Generation ACO Models. These payment mechanisms would give ESCOs more control over claims payments for aligned beneficiaries.

XI. Information Resources for Beneficiaries and Providers

The primary resource for beneficiaries with questions about the Model will be 1-800 MEDICARE (although ESCOs will be required to establish processes to answer beneficiary queries as well). CMS has developed scripts for customer service representatives (CSRs) that will answer anticipated questions related to the CEC Model. This Model will leverage existing linkages between 1-800 MEDICARE and

the ESRD Networks—to ensure there are no gaps or inconsistencies with existing beneficiary complaint and inquiry processes. CMS will closely track 1-800 MEDICARE call volumes and script triggers to identify patterns of incoming calls.

CMS has established an email inbox for all provider and public inquiries related to the CEC Model at ESRD-CMMI@cms.hhs.gov.

XII. Application Scoring and Selection

Applicants will be scored based on six key domains: patient-centeredness; organizational structure, leadership and management, financial plan/experience, care coordination capabilities, and care for vulnerable populations. These domains and associated point scores are detailed in Appendix C, Applicant Selection Criteria and Associated Points. CMS will evaluate an application in accordance with the criteria listed in Appendix C. Applications will be evaluated to assess whether the ESCO can provide a credible plan for collaboration between Participants. In addition, applicants should demonstrate that its organizational structure promotes the goals of the model by including a diverse set of providers that will demonstrate a commitment to high quality coordinated care to beneficiaries.

CMS will consider applications from organizations that meet all the eligibility requirements described previously who submit a completed application to CMS by the established deadline of July 15, 2016... CMS will screen applications to determine application completeness and eligibility, including whether the organization meets the minimum eligibility requirements outlined in the Section VII, *Applicant Eligibility* above. If the operational timeline allows, CMS may give applicants the opportunity to make corrections and or clarifications to incomplete or ineligible applications.

Final selection will be based on the strength of the application and select other factors, including the diversity of geographic areas, organizational provider types, applicant commitment to lowering Medicaid and Part D costs, and model design features represented, as well as the results of a program integrity risk assessment and an examination of the potential market effects.

Complete and eligible applications will be scored based on the criteria listed in Appendix C. CMS will select Participants based on their application scores and other select factors (e.g., results of program integrity review, potential market effects, etc.) to ensure balanced participation from provider types. CMS reserves the right to conduct pre-selection reviews of applicants during the application process for the purpose of understanding expenditure patterns of applicant organizations and their Participants. CMS may choose to interview applicants.

XIII. Duration of Agreement

Agreements for ESCOs joining the model in PY2 will have an initial term consisting of two performance periods with an option to extend the agreement for two additional 12-month performance periods. CMS expects the first performance period to begin in January 2017 for all new Participants.

Additional performance periods may be offered subject in part to ESCOs meeting program integrity requirements along with financial and quality performance targets. CMS may choose not to offer the additional performance period if the ESCO does not generate savings and/or meet performance standards or other program requirements during the first two performance periods (any data available from the third performance period would also be considered). Additionally, CMS may terminate the agreement at any

point due to non-compliance with the CEC Model Participation Agreement and/or performance related issues.

XIV. Learning and Diffusion Resources

The CMS Innovation Center is working with national healthcare experts to develop resources and activities to support the CEC Model and its primary aims. The CMS Innovation Center will support ESCOs 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 CMS Innovation Center initiatives. The CMS Innovation Center will test various approaches to group learning and exchange, helping program Participants effectively share their experiences, track their progress, and rapidly adopt new ways of achieving improvements in quality, efficiency and population health for Medicare, Medicaid and CHIP beneficiaries.

In order to fulfill the terms and conditions of the Model, all selected ESCOs are expected 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 CMS Innovation Center.

XV. Public Reporting

The CEC Model emphasizes transparency and public accountability. At a minimum, ESCOs will be required to publicly report information regarding their organizational structure and Participants. At a minimum, CMS will publicly report the quality performance scores of participating ESCOs, including beneficiary experience outcomes. Specific public reporting requirements will be clearly outlined in the CEC Model Participation Agreement.

XVI. Termination

CMS reserves the right to terminate an ESCO's CEC Model Participation Agreement at any point during the Model for reasons associated with poor performance, non-compliance with the terms and conditions of the CEC Model Participation Agreement, or if otherwise specified in the Participation Agreement or required by section 1115A(b)(3)(B) of the Social Security Act. Specific reasons and procedures for termination will be clearly outlined in the CEC Model Participation Agreement.

Appendix A: Application Template

Important to note before outlining the requirements listed below is that applicants to the CEC Model will not be expected to have their legal entity formed until after application selection and prior to the finalization of the CEC Model Participation Agreement. ESCO applicants should include 100% of their proposed Participant Owners, Participant Non-Owners, and ESCO Providers/Suppliers in the application. ESCO Participants cannot be added after application submission. Prior to the signing of the CEC Model Participation Agreement, selected applicants must have 100% of their Participants identified and CMS-vetted.

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

Section A – Applicant ESCO Information and Eligibility Requirements

1. Applicant ESCO Name
    A. Applicant ESCO Name:
    B. Company
2. Primary Contact at Applicant ESCO
    First Name:
    Last Name:
    Title/Position:
    Phone:
    Phone Ext.:
    Email:
3. Applicant ESCO Primary Contact Address
    Street Address Line 1:
    Street Address Line 2:
    City:
    State:
    Zip Code (5 digits):
    Zip Code (4 digits):

4. Applicant ESCO Executive Contact (CEO, Executive Director, etc.)

   First Name:

   Last Name:

   Phone:

   Phone Ext.:

   Email:

5. Applicant Company Contact

   First Name:

   Last Name:

   Phone:

   Phone Ext.:

   Email:

6. Was this application completed by an individual outside of the ESCO Organization (e.g. external consultant, attorney, etc.)?

   Yes/No

   If Yes,

   First Name:

   Last Name:

   Organization/Company:

   Phone:

   Phone Ext.:

   Email:

7. Are any of the Applicant ESCO's dialysis facilities currently participating in a Medicare shared savings initiative?

   If **YES**, please check all initiative(s) that apply:

   - None
   - Care Management for High-cost Beneficiaries Demonstration
   - Comprehensive Primary Care Initiative
   - Independence at Home Medical Practice Demonstration
   - Medicare Health Care Quality Demonstration Programs (including Indiana Health Information Exchange and North Carolina Community Care Network)
   - Multi-payer Advanced Primary Care Practice Demonstration with a shared savings arrangement
   - Physician Group Practice Transition Demonstration
   - Pioneer ACO Model

- Next Generation ACO Model
- Medicare Shared Savings Program
- Other (please specify):

8. Are any of the Applicant ESCO's proposed ESCO Participants, other than dialysis facilities, currently participating in a Medicare shared savings initiative?

   If **YES**, please check all initiative(s) that apply:

   - None
   - Care Management for High-cost Beneficiaries Demonstration
   - Comprehensive Primary Care Initiative
   - Independence at Home Medical Practice Demonstration
   - Medicare Health Care Quality Demonstration Programs (including Indiana Health Information Exchange and North Carolina Community Care Network)
   - Multi-payer Advanced Primary Care Practice Demonstration with a shared savings arrangement
   - Physician Group Practice Transition Demonstration
   - Pioneer ACO Model
   - Next Generation ACO Model
   - Medicare Shared Savings Program
   - Other (please specify):

9. Is the Applicant ESCO, or any of the proposed ESCO Participants, currently participating in, applied to participate in, or intend to apply to the Bundled Payment for Care Improvements Model?

   If **YES**, please check all Model(s) that apply:

   - None
   - Model 1
   - Model 2
   - Model 3
   - Model 4

10. Is the Applicant ESCO a recognized legal entity in the state in which it is located? (Yes/No)

    If **YES**, please attach a certificate of incorporation or other documentation that the Applicant ESCO is recognized as a legal entity by the state in which it is located.

    If **NO**, please confirm that the Applicant ESCO has begun the process of establishing a legal entity and estimate how long the process is expected to take.

11. What is planned tax status of the Applicant ESCO? (for-profit/not-for-profit)

12. Please submit the agreement(s) planned for use between the Applicant ESCO and its proposed Participants. The agreement(s) must include the following:

    A. An explicit requirement that the proposed ESCO participant will comply with the requirements and conditions of the CEC Model Participation Agreement and will require its Providers/Suppliers to comply with applicable terms of same;

B. An explicit requirement that ESCO Participants retain their ability to (1) refer their Medicare beneficiaries to any dialysis facility or other Medicare enrolled provider or supplier to ensure beneficiary freedom of choice, and (2) contract with other payers independently or through other entities other than the ESCO.

C. How the shared savings opportunity or other financial reward arrangements will encourage proposed ESCO Participants to adhere to the quality assurance and improvement program, as well as evidence-based clinical guidelines.

13. Please complete the following table with information about all of the Applicant ESCO's proposed ESCO Participants. Please refer to the Request For Applications Appendix B for definitions of Participant Owners, Participant Non-Owners, and Providers/Suppliers. Proposed ESCO Participants will also be required to provide contact information for their proposed participants. This will be each ESCO Applicant's only opportunity to include Participants for their ESCO.

Participant Name (Legal Organization or Practice Name associated with TIN)	Proposed Participant Status (i.e., Participant Owner or Participant Non-Owner or ESCO Provider/Supplier)	Address	Medicare Provider/Supplier Type	Medicare-Enrolled Participant Tax Identification Number	CMS Certification Number (CCN), if applicable	Organizational National Provider Identifier (NPI) if applicable
John Smith Nephrology						

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

14. Please provide a proposed organizational chart for the Applicant ESCO. It should depict the legal structure, the proposed composition of the ESCO (i.e., all of the ESCO Participants), and any relevant committees (2 pages).

15. Please provide a narrative description of any past collaboration among the proposed ESCO Participants, including previous experience working together, and any current discussions between or among ESCO Participants about future acquisitions of, or collaborations with, one or more other ESCO Participants. Also, include a description of how the proposed ESCO Participants will work together in the future to achieve the goals of this Model, including details such as decision-making processes and resources necessary to achieve goals of the Model (2 pages).

16. Please complete the table below with information specific to the Applicant ESCO'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 role.

Name	ESCO Leadership Team Position/Role	Responsibilities

17. Please provide a narrative explanation of why the Applicant ESCO wishes to participate in the CEC Model and how participation in the Model will help CMS, and the Applicant ESCO's proposed Participants, achieve the goals of better health and better care for Medicare beneficiaries with ESRD (2 pages).

18. Please complete the table below with information specific to the Applicant ESCO's proposed governing body:

Name	Position in the ESCO's Governing Body	ESCO Participant Being Represented (if applicable)	ESCO Participant Status (e.g., Owner Non-owner)	Voting Power (% of total)

19. Please describe how the governing body will ensure that the interests of beneficiaries and providers will be represented adequately. Specifically, explain the following:

    A. Role of the independent Medicare beneficiary representative and the trained and/or experienced non-affiliated, independent consumer advocate that will participate in the governing body;

    B. Rationale behind the proposed or existing makeup of the governing body and voting power distribution.

20. Please submit the compliance plan intended for use by the Applicant ESCO. The compliance plan must identify a compliance officer, who must not be legal counsel to the ESCO or the Company, must not be in a direct reporting relationship to legal counsel for the ESCO or the Company, and must report directly to the ESCO's governing body, and include 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 corrective action plan (CAP) issued by CMS and a description of the participant termination circumstances;

    C. The remedial processes that apply when Participants fail to comply with the CEC Model Participation Agreement, Medicare regulations, and/or internal procedures and performance standards including correction action plans (CAPs) and circumstances for expulsion; 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 Participants that could facilitate collusion and reduce competition in the provision of services outside the ESCO; and how the ESCO plans to reassure CMS that it will not use its market leverage to raise its commercial reimbursements rates at levels significantly disproportionate to growth in Medicare reimbursement rates.

Section C – Patient Centeredness

21. Please provide a narrative description of the Applicant ESCO's plan for engaging with beneficiaries and their caregivers. At a minimum, please address the following:

    A. Shared decision-making

    B. Care transitions

    C. Beneficiary education about dialysis care and renal transplant options

22. Please describe the existing or planned mechanisms that the Applicant ESCO will use to conduct beneficiary outreach.

23. Please describe the Applicant ESCO's existing or planned approach for evaluating beneficiary satisfaction in addition to CMS required beneficiary experience surveys and how the ESCO intends to use such information to improve its care management and coordination processes.

Section D – Clinical Care Model: Implementation Plan, Care Coordination, and Care for Vulnerable Populations

24. Please describe the Applicant ESCO's plan to achieve better health, better healthcare, and lower costs through integrated and coordinated care interventions. Please address the following in your narrative:

A. The Applicant ESCO's use of interdisciplinary care teams to coordinate care for patients with multiple chronic conditions;

B. The Applicant ESCO's methods and processes to coordinate care throughout an episode of care and during care transitions, such as discharge from a hospital or transfer of care from a dialysis facility to primary care providers and/or specialists (both inside and outside the ESCO);

C. The Applicant ESCO's use of health information technology;

D. The Applicant ESCO's strategies for improving beneficiary access to care;

E. The Applicant ESCO's development and use of population health management tools;

F. Please describe the Applicant ESCO's plan to incorporate medication management into its care coordination approach; and,

G. Additional specific care interventions and tools.

25. Please describe the Applicant ESCO's plan to incorporate mental/behavioral health and social services into the comprehensive care management of ESRD beneficiaries. Please describe the Applicant ESCO's previous experience and/or plans to work with State Medicaid Agencies to coordinate benefits of Medicare-Medicaid Enrollees (dual eligibles).

26. Please upload a letter of support from the State Medicaid Agency (optional)

27. Please describe the Applicant ESCO's existing or planned ability to provide timely performance feedback to ESCO providers

28. Please describe the experience of the proposed ESCO Participants reporting on established clinical and patient satisfaction quality measures. Please be specific about the measure set and purpose for collection.

29. Please provide the anticipated percentage of eligible professionals in the Applicant ESCO that will have attested to Electronic Health Record Meaningful Use Criteria by December 31, 2015 ___

30. What percentage of the Applicant ESCO's total revenues, in the last fiscal year, were derived from the below sources? Applicants may approximate this by summing the revenues for all of the proposed ESCO Participants.

    - Medicare Fee-For-Service
    - Medicare Advantage
    - Commercial Insurance
    - Medicaid
    - Self-pay
    - Other:

31. Please complete the below table with any certification and accreditation information specific to the Applicant ESCO's proposed Participants.

ESCO Participant	ESCO Provider/Supplier or department receiving Certification/Accreditation, if applicable	Accrediting Body	Certification/Accreditation (including date)

32. Please complete the below table with information specific to any sanctions, investigations, probations, or corrective action plans that the applicant and its proposed ESCO Participants, ESCO Providers/Suppliers, Company, and its owners or managers. Please provide information from the previous five year period.

ESCO Participant	ESCO Provider/Supplier or department at issue, if applicable	Federal or State Agency or Accrediting Body (e.g., DOJ, OIG, The Joint Commission, State Survey Agencies.	Description of Infraction (including date)	Resolution Status (including date)

Section E – Financial Experience and Plan

33. Please identify the payment arrangement that the Applicant ESCO is selecting in this application
    - LDO Track (2-sided)
    - Non-LDO Track (1-sided)
    - Non-LDO Track (2-sided)
34. Please explain how the Applicant ESCO will provide high quality care to its beneficiaries while better managing prescription drug expenditures, including Part D expenditures. Please include any plans the ESCO has to partner with Part D Plans while preserving beneficiary choice of Part D plans.
35. Please explain how the ESCO intends to work toward Medicaid cost containment for the Medicare-Medicaid Enrollee (dual eligible) beneficiary population aligned to the ESCO.
36. Please attach a narrative description of, and justification for how, any shared savings and losses will be distributed. The Applicant ESCO should describe how savings/losses will be distributed among the proposed ESCO Participants. In the case of savings, please explain what percentage of funds will be provided directly to Participants and what percentage would be used toward infrastructure and care redesign investments. The Applicant ESCO should indicate how the distribution plan supports better health, better health care, and lower costs.

Section F – Attestation and Signature

I have read the contents of this application. By my signature, I certify that the information contained herein is true, correct, and complete, and 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 both the company and the ESCO applicant.

_____ _____

Signature of Applicant ESCO Executive Contact Date

_____ _____

Signature of Applicant Company Contact Date

Appendix B: Glossary of Key Definitions

The definitions provided in this glossary may evolve as the CEC Model Participation Agreement is developed and finalized.

COMPANY: The dialysis organization that directly or indirectly owns all of the Participant Owner dialysis facilities

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.

ESRD SEAMLESS CARE ORGANIZATION (ESCO): An ESCO is a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law; identified by a TIN; and formed by ESCO Participant Owners, who must include the following: (1) at least one dialysis facility; (2) at least one nephrologist and/or a nephrology practice. The ESCO and its Participants, including Participant Owners, Participant Non-Owners, and ESCO Providers/Suppliers, agree to participate in the CEC pursuant to a written agreement with the ESCO.

ESCO BENEFICIARY: A Medicare beneficiary who has been aligned to the ESCO based on CMS-defined eligibility criteria.

ESCO PARTICIPANT: An individual or entity that is a Participant Owner, a Participant Non-Owner, or an ESCO Provider/Supplier.

ESCO PARTICIPANT LIST: The list of the Participants that are approved by CMS for participation in the CEC model, as updated from time to time in accordance with the CEC Participation Agreement.

ESCO PARTICIPANT NON – OWNER: An individual or entity that (1) is a Medicare-enrolled provider or supplier identified by a TIN and either a NPI or a CCN; (2) does not have any direct or indirect ownership or investment interest in the ESCO; (3) has agreed to participate in the CEC pursuant to a written agreement with the ESCO; (4) may, but is not required to, receive Shared Savings Payments; (5) may, but is not required to, be liable for a portion of Shared Losses Payments ; and (6) is included on the ESCO Participant List.

ESCO PARTICIPANT OWNER: An individual or entity that (1) is a Medicare-enrolled provider or supplier identified by a TIN and either a NPI or a CCN; (2) has a direct ownership or investment interest in the ESCO; (3) has agreed to participate in the CEC pursuant to a written agreement with the ESCO; (4) may, but is not required to, receive Shared Savings Payments; (5) is liable for Shared Losses Payments; and (6) is included on the ESCO Participant List

ESCO PROVIDER/SUPPLIER: An individual or entity that (1) is a Medicare-enrolled provider or supplier identified by an NPI or CCN; (2) bills for items and services furnished to Medicare beneficiaries under a Medicare billing number assigned to the TIN of a Participant Owner or Participant Non-Owner; (3) has agreed to participate in the CEC pursuant to a written agreement with the ESCO; (4) may, but is not required, to

receive Shared Savings Payments; (5) may, but is not required to, be liable for Shared Losses Payments; and (6) is included on the ESCO Participant List.

ESCO TOTAL REVENUE: The total Medicare Part A and Part B claims paid to all providers or suppliers for the items and services furnished to all ESCO Beneficiaries in a given performance year.

ESRD: End-Stage Renal Disease

HOME DIALYSIS: Peritoneal or hemodialysis performed by an appropriately trained ESCO Beneficiary (and/or the ESCO Beneficiary's caregiver) at the home of the ESCO Beneficiary.

HOSPITAL-BASED DIALYSIS FACILITY: A Dialysis Facility that CMS has determined is hospital based in accordance with 42 CFR 413.174(c).

LARGE DIALYSIS ORGANIZATION (LDO): An LDO is an organization that owns, directly or indirectly, 200 or more dialysis facilities. This definition follows the United States Renal Disease Survey (USRDS) definition and will be amended in the event of any future changes made by that organization.

MEDICARE BENEFICIARY: An individual who is entitled to benefits under Part A of Title XVIII of the Act and/or enrolled under Part B of Title XVIII of the Act.

NON-LARGE DIALYSIS ORGANIZATION (Non-LDO): An entity that is not owned directly or indirectly, in whole or in part by an LDO and, as of the effective date of the CEC Participation Agreement, either wholly owns at least one but fewer than 200 Dialysis Facilities, or jointly owns at least one but fewer than 200 Dialysis Facilities with another entity that is not owned directly or indirectly, in whole or in part by an LDO. This definition follows the United States Renal Disease Survey (USRDS) definition and will be amended in the event of any future changes made by that organization.

PERFORMANCE YEAR EXPENDITURE BENCHMARK: The ESCO's expected Medicare Part A and Part B expenditures for ESCO Beneficiaries in an Eligibility Category during the applicable Performance Year, as determined by CMS according to the parameters set forth in Appendix B.

PROHIBITED PARTICIPANT: An individual or entity that is: (1) a Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier; (2) an ambulance supplier; (3) a drug or device manufacturer; or (4) excluded or otherwise prohibited from participation in the Medicare or Medicaid programs.

SHARED LOSSES: The amount owed to CMS by the ESCO due to ESCO Total Revenue in excess of the ESCO's Total Performance Year Expenditure Benchmark for the applicable Performance Year as determined by CMS.

SHARED SAVINGS: The amount owed to the ESCO by CMS due to ESCO Total Revenue below the ESCO's Total Performance Year Expenditure Benchmark for the applicable Performance Year as determined by CMS.

TOTAL PERFORMANCE YEAR EXPENDITURE BENCHMARK: The expected, combined Medicare Part A and Part B expenditures for ESCO Beneficiaries in all eligibility categories during the applicable performance year, as determined by CMS.

Appendix C. Applicant Selection Criteria and Associated Points

Selection Domain	Applicant Selection Criteria To earn the full amount of points in each domain, the applicant must:	Points
Patient Centeredness	- 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.	25
Organizational Structure	- 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.	10

Selection Domain	Applicant Selection Criteria To earn the full amount of points in each domain, the applicant must:	Points
Leadership & Management	- 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. - Demonstrate an executive and governing body level commitment to the three-part aim - 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 three-part aim. - 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. - 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.	20

Selection Domain	Applicant Selection Criteria To earn the full amount of points in each domain, the applicant must:	Points
Financial Plan/Experience	- Have a shared savings/losses distribution plan that demonstrates a strong commitment to the three part aims of better health, better care, and lower costs. - Present a credible plan for achieving savings under the model. - Provide credible plan for Medicaid cost containment of the dual eligible beneficiary population aligned to the ESCO. - Provide credible plan for reducing Part D expenditures while preserving beneficiary choice of Part D plans.	5

Care Coordination Capabilities and Implementation Plan	- Present a strong, credible, coordinated and feasible plan to realize the three part aims of better health, better care, and lower costs. - 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 Demonstrate ability to coordinate care across full continuum of 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. - Provide credible plan to coordinate benefits of dually eligible beneficiaries aligned to the ESCO with Medicaid State Agencies. - 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	25

Selection Domain	Applicant Selection Criteria To earn the full amount of points in each domain, the applicant must:	Points
Care for Vulnerable Populations	- Include a diverse group of practitioners, and care settings to meet the needs of complex populations - 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 - Include letter of support from the State Medicaid Agency and demonstrate a knowledge of state Medicaid policies, including cost-sharing - Demonstrate clear understanding of unique needs of beneficiaries with multiple chronic conditions and includes care coordination approach that addresses those needs - Provide a care coordination plan that incorporates mental/behavioral health and social services as appropriate	15
Total Points		100