

Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Comprehensive ESRD Care (CEC) Model

Request for Applications

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I. 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 (SSP), Pioneer Accountable Care Organization (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 of services and 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:

- 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.

II. 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.

III. Scope and General Approach

CMS expects between 10 and 15 unique ESRD seamless care organizations (ESCOs) to participate in this Model with representation from all dialysis provider organizations/facility types and geographic areas. CMS may make more than 15 awards if resources are available and a compelling reason exists to do so.

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, over time, escalate the degree of the ESCO's financial accountability;
- 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,
- Shared learning that is continuous and data-driven.

While CMS is committed to improving care for beneficiaries with ESRD, the Agency reserves the right to decide not to move forward with the CEC Model for any reason, as is true for all models pursued under Section 1115A authority. Similarly, as implementation of the Model ensues, CMS reserves the right to terminate the Model if it is deemed that it is not achieving the goals and aims of the initiative.

IV. Deadline for Applications

Interested applicants must submit a letter of intent (LOI) no later than March 15, 2013. Letters of intent will be used only for planning purposes and will not be binding. An LOI template is provided in *Appendix A* so that applicants can begin preparing their LOI responses. At a later date, CMS will provide information on the electronic portal that will be used to submit LOIs.

CMS will not consider applications from organizations that do not submit a Letter of Intent.

Applications must be submitted electronically no later than 11:59 p.m. EDT May 1, 2013. An application template is provided in *Appendix B* so that applicants can begin preparing their responses. At a later date, CMS will provide information on the electronic portal that will be used to submit applications.

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 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 matching.

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 the finalization of the CEC Model Participation Agreement. ESCO applicants, however, should include at least 50% of their proposed ESCO participants in the LOI and 100% of their proposed ESCO participant owners in the application. ESCO participant owners 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 (owner and non-owner) identified and CMS-vetted.

V. 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;
- 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;
- Reductions in catheter delivered hemodialysis and consequent infections and other complications;
- Increased use of home dialysis modalities as appropriate; and,
- 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 D 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 matched 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 dialysis and related services covered 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; dietitians/nutritionists; health educators; pharmacists; behavioral health specialists; and, community health workers/patient navigators.

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 management¹. 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 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:

¹ The plan must incorporate the ESRD-specific assessment and plan required by the ESRD Facilities Conditions for Coverage at 42 CFR 494.80-90.

- 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 clinical element 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.

Potential strategies that ESCOs might employ to improve patient access to services may include:

- Providing on-site co-location of different providers and/or rounding services by non-dialysis providers at dialysis facilities;
- Assisting beneficiaries in scheduling non-dialysis related medical appointments;
- Assisting beneficiaries in obtaining appropriate transportation services ;
- Providing in-home visits and/or arranging for longer or more frequent dialysis when clinically appropriate; and,
- Ensuring flexible access to dialysis care during normal and extended business hours (e.g. different appointment times, nurse call lines, etc.).

As mentioned above, applicants are strongly encouraged to propose alternative innovative strategies/interventions that would allow them to best address the improved access to services clinical element of this Model.

VI. Eligibility of Medicare and Medicaid Beneficiaries

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 matched to an ESCO 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 “match” eligible beneficiaries through a claims-based process. The beneficiary matching process (described in detail in the *Matching 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 matching 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 matching 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 be receiving dialysis services
- Must reside in the United States and within the market area² of the ESCO and receive at least 50% of his/her annual dialysis services (measured by expenditures) in the ESCO’s geographic area
- Must be aged 18 or above³ Must NOT have already been matched to a Medicare ACO or another Medicare program/demonstration/model involving shared savings at the date of initial matching for the CEC Model (please refer to the *Participation in Other Medicare Programs, Initiatives, Models, or Demonstrations* section below for additional information)
- Must NOT have a functioning transplant
- Must NOT have Medicare as a secondary payer

² Markets are defined as no more than two contiguous Medicare CBSAs 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.

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

An ESCO is required to have a minimum of 500 matched beneficiaries based on a defined look-back period prior to the start of the Model. The ESCO must maintain at least 500 matched beneficiaries throughout the life of the Model to continue with participation. If at any point during the first performance year an ESCO drops below the minimum threshold, the ESCO will be placed on a CAP until the start of the second performance year. This will allow the ESCO the opportunity to add a dialysis facility for purposes of increasing its number of matched beneficiaries. Important to note is that ESCOs are prohibited from adding providers and suppliers (either participant owners or non-owners) during a performance year. The ESCO can still share in savings during the CAP period, but if the ESCO does not meet the minimum threshold by the start of the next performance year, CMS may terminate its CEC Model Participation Agreement.

At the end of each performance year, CMS will retrospectively remove months of experience for beneficiaries who have lost eligibility. For example, a beneficiary who did not receive at least 50% of his/her annual dialysis services (measured by expenditures) in the ESCO's geographic area would be removed from an ESCO's beneficiary match list for financial reconciliation purposes. Another example where beneficiary months would be removed is in the case of transplant. If a prospectively matched beneficiary received a transplant before the start of the performance, the months after transplant would be removed for financial reconciliation purposes.

Matching Process

CMS will match 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 match that beneficiary to the dialysis facility, and by extension the ESCO, for the upcoming performance year. This is in contrast to other approaches used in the Shared Savings Program or the Pioneer ACO Model that generally rely on a plurality of primary care services over an extended period of time.

Given that ESRD beneficiaries are a particularly vulnerable population requiring regular dialysis for survival, CMS also considers the prospective "first touch" matching approach to be a patient-centered strategy that will give ESCOs incentives to better serve and feel accountable for the broad spectrum of their beneficiaries. However, if a beneficiary is matched with an ESCO and receives no dialysis services from that ESCO in the performance year, the beneficiary will not be matched with that ESCO in the subsequent performance year. CMS will remove any beneficiaries from an ESCO's subsequent performance year match list if they received more than 50% of their dialysis services from another facility outside of the geographic area of the ESCO during the current performance year. ESRD beneficiaries tend to be extremely consistent in their use of dialysis facilities. Utilization data show that 95% of ESRD beneficiaries continue seeking services at the same dialysis facility in the subsequent year (assuming the beneficiary does not receive a transplant).

Prospective matching would consist of beneficiaries identified prior to the first performance period, and beneficiaries added as each performance period ensues. Therefore, there will also be both a historical and dynamic pathway for matching. The multiple pathways are listed below:

1. **Prior to the first performance period:** CMS will prospectively match all beneficiaries who meet eligibility requirements by identifying the dialysis facility that billed Medicare for the earliest dialysis during the 9-month period prior to the first performance year.
2. **Prior to the start of the second and third performance periods:** For performance years two and three, we will use a historical matching process under which all beneficiaries that were matched to the ESCO as of the end of the preceding performance year will again be matched to that ESCO, assuming eligibility requirements continue to be met, except that CMS will exclude those beneficiaries who did not receive any dialysis care from the ESCO during the previous performance year or who received more than 50% of their dialysis services from a facility outside the geographic area of the ESCO during the performance year.
3. **During each performance period:** On a quarterly basis, CMS will dynamically add eligible beneficiaries starting dialysis to the prospectively matched 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. A dialysis facility will not be offered the choice to match a newly-eligible beneficiary since matching is the result of actual dialysis utilization. Beneficiaries may also be dynamically excluded for a loss in eligibility (e.g., ceasing dialysis treatment, joining Medicare Advantage, receiving a functioning transplant, etc.).

ESCOs will be informed of their historically matched prospective beneficiary population (i.e., the beneficiaries for whom they will be accountable at the start of the first performance period). Additional beneficiaries entering dialysis for the first time will be matched to the ESCO as the performance periods progress. Additionally, quarterly updates will be provided to each ESCO's matched beneficiary list to reflect any changes in eligibility status.

Finalizing Matching

Matching will be retrospectively finalized as part of a reconciliation process after each performance year. CMS will identify the final matched 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 match list for the entire performance period at reconciliation (e.g., if they received the majority of dialysis expenditures in a non-adjacent market) or select beneficiary months may be removed from settlement (e.g., months of and after transplant). Additional adjustments may be made to the match list to discourage facilities from gaming (e.g., the removal of a month where a given dialysis facility intentionally scheduled beneficiaries' first dialysis treatments at the end of a month).

Matching Notification

ESCOs will be required to send letters to their newly matched beneficiary population prior to the start of each performance year informing them of the initiative and their matched status. ESCOs will also be required to send notification letters to newly matched beneficiaries during a given performance year if they are dynamically added to the match list after first receiving dialysis services from the dialysis facility participating in the ESCO.

CMS will provide each ESCO with their list of matched beneficiaries. The ESCO will then be required to send all matched beneficiaries a notification letter..

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 providers⁴;
- Data sharing options; and,
- Contact information for the ESCO and 1-800-Medicare for questions and/or concerns.

Notification letters sent (prior to the start of each performance year) to beneficiaries matched to the ESCO will emulate those used in the Shared Savings Program and the Pioneer ACO Model.

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

VII. 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 small dialysis organizations (SDOs), 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).

Organizations will not be able to submit a single application for multiple facilities located across different markets. Markets are defined as no more than two contiguous Medicare core-based statistical areas (CBSA), 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.

ESCO applicants must include the TINs, CMS Certification Numbers (CCNs) (facilities only), NPIs (organization) 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. Recognizing that the process of forging the relationships necessary to apply to the CEC Model may

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”.

extend into and beyond the application period, the final ESCO participant list (owner and non-owner) must be finalized before the signing of the CEC Model Participation Agreement. However, applicants are required to include at least 50% of their proposed ESCO participants in the LOI and 100% of the proposed ESCO participant owners in the application. The proposed ESCO participant owners submitted in the application will be used to conduct historical beneficiary matching. ESCO participant owners 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 LDOs are prohibited from applying as part of the same ESCO. Second, dialysis facilities owned by LDOs are prohibited from partnering with dialysis facilities owned by non-LDOs—unless non-LDOs in the CBSA would be unable to combine to meet the minimum beneficiary threshold required to participate in the Model. In that case, an LDO would be permitted to partner with one or more non-LDOs to ensure their ability to participate in the Model; the burden will be on the applicant to demonstrate that such circumstances apply. There are no restrictions on non-LDO organizations/facilities from partnering in the submission of a single ESCO application.

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 C*.

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 that are not (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 services that are also DMEPOS suppliers are eligible to participate in the Model, but must meet the additional eligibility requirements set forth in this document.

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 ESCO providers/suppliers prior to the start of each performance year. The ESCO will not be able to add ESCO providers/suppliers during the course of a performance year.

The CEC Model application will request information about the applicants' proposed ESCO participants and ESCO providers/suppliers 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).

Applications will also require applicants to disclose any sanctions, investigations, probations or corrective action plans that the applicant and its proposed ESCO participants and ESCO providers/suppliers are currently undergoing or have undergone in the last three years.

Participation in Other Medicare Programs, Initiatives, Models or Demonstrations

The Affordable Care Act presented created 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 Shared Savings Program, the Pioneer ACO Model, 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 Shared Savings Program will not be eligible for the CEC Model. Individual providers (defined by a TIN/NPI combination) participating in a Pioneer ACO may participate in the CEC Model with the exception of primary care providers.

Where a beneficiary may meet eligibility criteria and be matched 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 matched 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, however, should include at least 50% of their proposed ESCO participants in the LOI and 100% of their proposed ESCO participant owners in the application. ESCO participant owners 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 (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. An ESCO participant, defined as an individual or a group of ESCO providers/suppliers that, together with other ESCO participants, agrees to become accountable for the quality, cost, and overall care of the ESCO beneficiaries and to comply with the terms and conditions of the CEC Model Participation Agreement. 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 and ESCO participant owners include their entire TIN in the Model.

ESCO participants may be ESCO participant owners or ESCO participant non-owners. All dialysis facilities and nephrologists/nephrology group practices must apply to this model as participant owners. ESCO participant owners have an increased level of accountability to CMS in that they must (1) be signatories to the CEC Model Participation Agreement with CMS, (2) have an ownership stake in the ESCO, and (3) assume liability for shared losses ("downside risk"). CMS intends to recoup such shared losses from participant owners and is currently investigating the mechanism by which to do so. One mechanism under consideration is retaining, in whole or in part, Medicare payments otherwise due and owing for any services rendered by the ESCO participant owner, including amounts payable for such services to any entity to which the ESCO participant owner has reassigned Medicare payments. 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 revenue⁵ multiplied by the ESCO's total shared losses. The following example illustrates this requirement⁶:

- An ESCO's total revenue for matched beneficiaries is \$1,000,000, with a single ESCO participant owner contributing \$100,000 to the total revenue. Assuming a target benchmark of \$800,000,

⁵ An ESCO's total revenue is defined as the total of all Medicare Part A and Part B claims paid to all ESCO providers/suppliers for the care of matched ESCO beneficiaries. 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 matched 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.

the ESCO would be responsible for shared losses of \$200,000—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 participant owners:

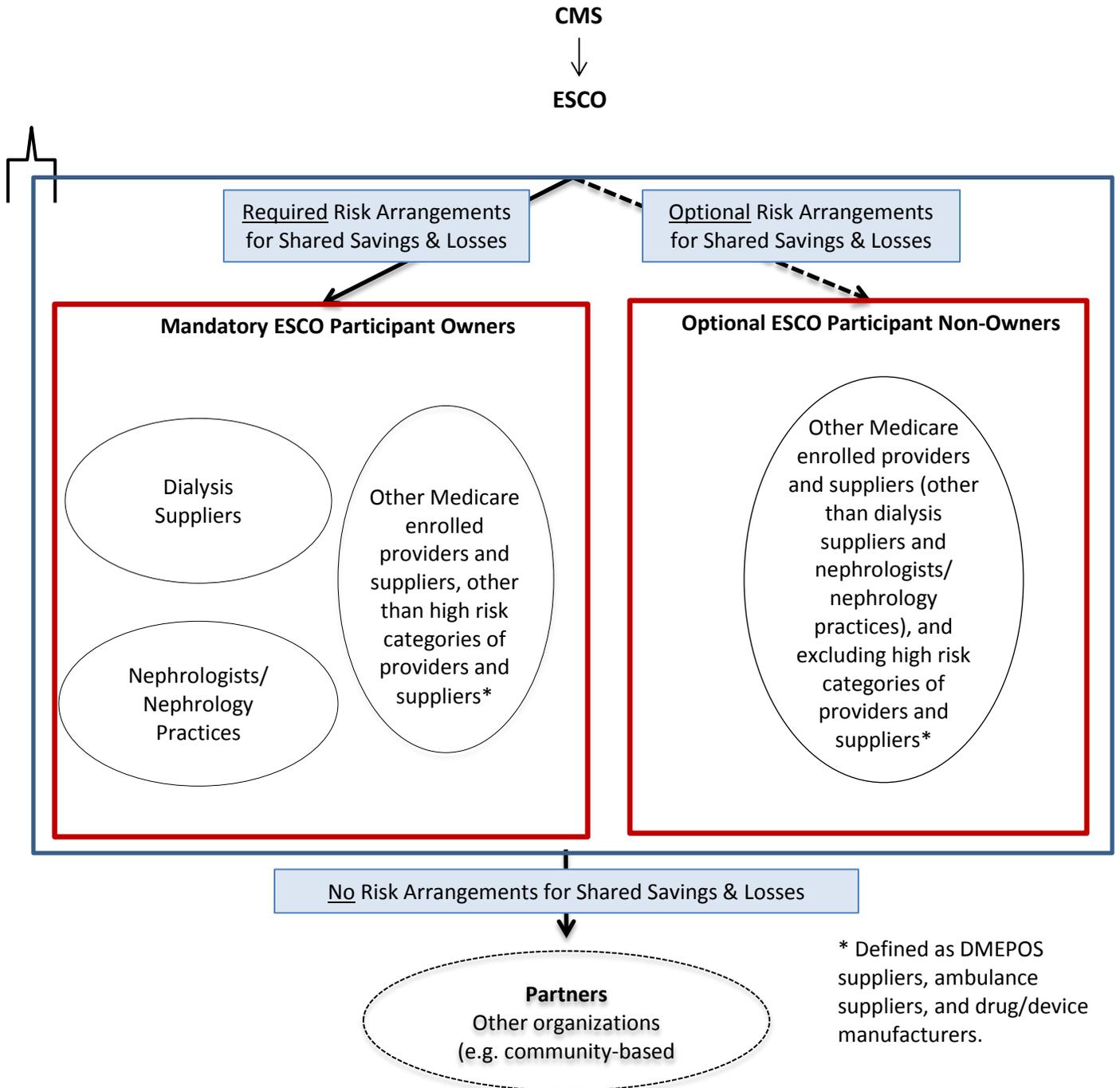
- A dialysis facility;
- A nephrologist or nephrology practice that is not employed by the dialysis facility; and,
- Other Medicare enrolled provider of service or supplier (other than DMEPOS suppliers, ambulance suppliers, and drug/device manufacturers).

ESCO participant non-owners do not have to sign the CEC Model Participant Agreement or 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 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 (herein referred to as ESCO partners) are not considered ESCO participants, but will likely be necessary to the ESCO as it works to address the clinical elements outlined above.

Figure 1 illustrates the compositional structure of the ESCO, depicting the mandatory participant owners of the ESCO and the contractual arrangements between the ESCO and other participant non-owners in the ESCO, as well as ESCO partners.

Figure 1. ESCO Compositional Structure



CMS will share in savings and losses with the ESCO. All participant owners in the ESCO are eligible to receive shared savings payments, but they must also take on risk for the total cost of care for the matched beneficiary population in any performance period in which the ESCO assumes financial risk. Only ESCO participants (owner and non-owner) will be permitted to receive any distribution of shared savings—partners of the ESCO will not be able to receive any distribution of the shared savings.

While all eligible ESCO participants can receive a portion of shared savings, only ESCO 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 matched beneficiary population. Other than a minimum percentage risk, CMS will not dictate how the ESCO distributes shared savings or losses; however, the ESCO’s distribution of shared savings or losses 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. ESCO participant non-owners may contract with the ESCO to take on down-side risk, but there is no requirement to do so. Neither the ESCO nor any ESCO participant may indemnify, finance, or guarantee the losses of another ESCO participant.

As mentioned above, all participant owners in the ESCO must be signatories on the CEC Model Participation Agreement between CMS and the ESCO. ESCO participant non-owners 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 and participant non-owners will both be required to comply with 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	Able to Share in Savings
ESCO	Legal entity	X	X	X
ESCO Participant Owners	Mandatory ESCO participant owners include: <ul style="list-style-type: none"> At least one dialysis facility; At least one nephrologist/nephrology practice; and, At least one other Medicare provider or supplier (other than DMEPOS, ambulance supplier, or drug/device manufacturer). 	X	X	X
ESCO Participant Non-Owners	ESCO participant non-owners may include: <ul style="list-style-type: none"> Other Medicare providers or suppliers (other than a dialysis facility, nephrologist/nephrology practice, DMEPOS, ambulance supplier, or drug/device manufacturer). 		X (not required, but allowed)	X
ESCO Partners	ESCO partners may include: <ul style="list-style-type: none"> Community-based organizations 			

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 and participant non-owners) from contracting with other payers independently or through other entities outside of the ESCO.

Because beneficiaries are matched 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 outside of the ESCO.

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.

An ESCO must maintain an identifiable governing body. The governing body may be a board of directors, board of managers or any other governing body that provides a mechanism for shared governance and decision making.

The ESCO governing body must have:

- Authority to execute the functions of the ESCO including defining the processes to promote evidence-based medicine and patient engagement, reporting on quality and cost measures and coordination of care, and the appointment and removal of an executive officer.
- Authority for final decision-making for the ESCO.
- A conflict of interest policy that applies to members of the governing body, requires disclosure of all relevant financial interests and other conflicts of interest, identifies processes for resolution of conflicts of interest, and sets forth remedial processes for non-compliance.
- A transparent governing process to ensure CMS ability to monitor and audit as appropriate.

The composition of the ESCO governing body must be structured as follows:

- Decision-making must be provider-driven, as evidenced by ESCO participants (owners and non-owners) having at least 75% control of the ESCO's governing body.
- No one participant in the ESCO can represent more than 50% of the membership on the governing body.
- Members must place their fiduciary duty to the ESCO before the interests of any ESCO participant or ESCO provider/supplier or other individual or entity and act consistent with that fiduciary duty.

- The governing body must ensure representation of patient interests through inclusion of an independent ESRD Medicare beneficiary representative and a trained and/or experienced non-affiliated, independent consumer advocate on the governing body⁷.

VIII. 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). With respect to certain provisions in sections 1128A, 1128B and 1877 of the SSA, the Secretary will consider issuing waivers that are consistent with this standard in separately issued documentation. 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.

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/bc/healthcare/industryguide/policy/index.htm>.

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

⁷ An independent or non-affiliated consumer advocate is defined as an individual that does not have a formal relationship with the dialysis facility/facilities or any other participant in the CEC Model.

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, each ESCO must designate a compliance officer—who is not legal counsel to the ESCO and who reports directly to the ESCO’s governing body—to ensure that providers are complying with the Model’s participation requirements. The compliance officers must create and maintain a documented compliance plan and escalate provider non-compliance issues to the governing body for action. 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 ESCO.

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 population; 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 owner and non-owner participants) 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 employ a variety of different response tactics based on the level and type of issue identified, including:

- Corrective Action Plans (CAPs);
- Termination of an ESCO;

- Require the ESCO to terminate an ESCO participating entity or an individual provider/supplier;
- Recoupment of monies (supported via the traditional CMS program integrity recoupment processes) from signatories (i.e., ESCO participant owners) of the CEC Model Participation Agreement;
- Referral to the Secretary for consideration under Sec. 1881(c)(3) [42 U.S.C. 1395rr]⁸; and,
- Referral to law enforcement.

These remediation responses do 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, including ESCO partners.

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, this Model will require the assessment of claims-based and clinical quality measures, as well as the annual administration of the In-Center *Hemodialysis* Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) and the Kidney Disease Quality of Life (KDQOL) surveys. Of note, the ICH CAHPS will be collected as part of the QIP starting in 2014—the intent is to leverage the CAHPS data collected as part of the QIP⁹ for use in this Model.

The reporting of quality measures will be one key mechanism CMS will use to verify clinical improvements, assess patient health outcomes and appropriate coordination of care, and ensure continued quality of care for the beneficiaries. The ESCO’s quality score will be used to assess overall performance and will be factored into the calculation of shared savings and shared losses. ESCOs will be required to meet a minimum threshold score in order to be eligible for shared savings. The specific minimum threshold score and quality scoring methodology are currently being determined. CMS will leverage scoring methodology examples employed by the Medicare Shared Savings Program and the Pioneer ACO Model. CMS will provide ESCO applicants/selected participants with more information regarding quality scoring before they have to commit to the CEC Model Participation Agreement.

⁸ 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.

⁹ Please note dialysis facilities will continue to be subject to the QIP, including payment reductions based on quality performance (when applicable), under the CEC Model.

In consultation with national ESRD experts, including patient advocates and nephrologists, CMS will apply the following priorities in selecting CEC Model quality measures:

- 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,
- Inclusive of other CMS ESRD quality initiative data.

CMS is considering a broad array of process and outcome measures to help assess the effect of the CEC Model in delivering high-quality health care to ESRD patients. In an attempt to ensure that CMS’ ESRD-related quality measurement and improvement efforts are aligned, CMS is working to leverage existing processes and systems in this Model—including the ESRD Quality Incentive Program (QIP), ESRD Networks, the ESRD Clinical Performance Measures project, Fistula First, and CROWNWeb.

Table 2 summarizes the quality measures domains, sample measures, and potential data sources. CMS intends to utilize existing quality measures from current ESRD-related programs, where appropriate, and define additional measures that will address the non-dialysis care central to the design of this Model. The final quality measure set will be used in the shared savings/loss calculations on an annual basis, but more regularly assessed for monitoring purposes.

In year one, CMS plans to assess ESCO performance on a pay-for-reporting basis for all quality measures that require the submission of clinical data (dialysis-related and non-dialysis related) and/or survey data. Claims-based measures that are being used in other CMS ESRD programs will be used to assess ESCO performance on a pay-for-performance basis.

The primary rationale for employing a pay-for-reporting methodology for select measures is that dialysis facilities are not yet experienced in reporting clinical and survey data. In subsequent performance years, CMS will employ a pay-for-performance methodology for all clinical, claims-based, and survey measures.

Table 2. Quality Measure Domains, Example Measures and Potential Data Sources

Domain	Example Measures	Potential Data Source
Preventative Health	Influenza Immunization Pneumococcal Vaccination Screening for Fall Risk	Claims, Chart Review (if needed)

	Depression Screening	
Chronic Disease Management	Dialysis-Related Infection Incidence of Inpatient Admissions for Significant Bleeding Appropriate Referral to Transplant Center Evaluation of Medication Therapy Management (MTM) Services	Claims, Chart Review (if needed)
Care Coordination/Patient Safety	30-Day Readmission Emergency Department Visit Without Hospitalization Medication Reconciliation After Inpatient Facility Discharge Outpatient Medication reconciliation	Claims, Chart Review (if needed)
Patient/Caregiver Experience	Rating of Kidney Doctor Rating of Dialysis Center Staff Satisfaction with Kidney Care Received	ICH CAHPS Survey (collected as part of the QIP)
Patient Quality of Life	Feel Washed Out or Drained Ability to Work Full- or Part-Time Difficulty Doing Things Involving Concentration and Thinking	KDQOL Survey

Quality measures for this Model will be reported through a combination of CMS claims, survey data (i.e., ICH CAHPS and KDQOL)—followed by chart review, if needed. For the claims-based measures, ESCOs do not need to be involved in the data collection effort. Instead, CMS will obtain the necessary Medicare data to calculate the measure. ESCOs will be required to obtain certified vendors to administer the required beneficiary surveys and ensure the submission of data during a specified period of time for the performance year. The vendors must not be affiliated with the ESCO.

As noted above, CMS is working to define the exact quality measures and benchmarks that will be used to determine the ESCO's shared savings or shared losses. CMS plans to provide an initial list of quality measures to interested parties during the application period. CMS will determine the benchmark and calculate the performance rate for each quality measure and each aggregate quality domain for all ESCOs. CMS will also calculate an overall quality score for each ESCO, which is an aggregation of all measures across all domains.

ESCOs will need to meet a minimum threshold level of the benchmark set for each measure. ESCOs may earn both quality points, and EHR measure quality points, on a sliding scale, for purposes of meeting the minimum attainment level on those measures where the sliding scale applies. ESCOs that do not meet the minimum attainment level for a given measure will get zero points for that particular measure. ESCOs will also need to meet a minimum attainment level for each quality measure domain. The

minimum attainment level for each individual measure and each aggregate measure domain will be determined by CMS and will be dependent upon the final set of selected quality measures.

The establishment of an attainment level for each measure and each domain will provide the ESCO with an opportunity to meet quality performance goals and be eligible for shared savings. For example, if an ESCO fails to meet the minimum attainment level for one measure within a given domain, but performs well on the other measures in the domain, it may still be able to meet the minimum attainment level for that domain—and therefore be eligible for shared savings. If, on the other hand, the ESCO fails to meet the minimum attainment level for all measures within a given domain, the ESCO will not be eligible to share in any savings generated.

Each domain will be weighted equally when calculating the overall quality score of the ESCO. Equal weighting of the domains will allow for balancing of multiple measures within any given domain and prevent a single measure from having a greater impact on the overall quality score. As mentioned above, CMS will calculate one overall domain score for both the ICH CAPHS and KDQOL surveys to assess performance.

Quality performance will be reviewed annually and updated as necessary for each performance year within the agreement period. CMS plans to use a quarterly assessment of expenditure performance based on continuous collection of quality data—adjustment will be made for measures where data is only available annually.

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.

Prior to CMS sharing any beneficiary level data with ESCOs, ESCOs are required to notify matched beneficiaries in writing that CMS will share their data with the ESCO unless the beneficiary opts out of data sharing (see *Matching Notification* section for additional information on the expected content of the notification). ESCOs are required to give matched beneficiaries a set period of time after receipt of the notification letter to opt out of data sharing. CMS will only send data to the ESCOs after the initial opt out period has concluded.

Matched beneficiaries will have the option to opt out of data sharing by calling 1-800 MEDICARE or by completing a data sharing opt out form, made available by the ESCO, at any point during the performance year. CMS will only share data with the ESCO for matched beneficiaries who have not opted out of data sharing. The ESCO must also notify CMS within a set period of time to be determined by CMS as to which beneficiaries are no longer actively receiving care from any providers in the ESCO. CMS will not share data with the ESCO on those beneficiaries.

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 (one year) claims data on matched beneficiaries who have not opted out of data sharing. During

each performance year, CMS will also provide historical claims data as additional beneficiaries are matched to the ESCO.

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 matched beneficiaries who have not opted out of data sharing.
3. On a monthly basis – Total Part A and B expenditures and claims lag reports.
4. On an annual basis – Financial reconciliation reports, including the ESCO’s performance on quality and patient experience metrics.

At any time, beneficiaries may opt out of having their identifiable data shared with the ESCO.

At the beginning of each performance period, or on a quarterly basis if beneficiaries are dynamically added to the matched beneficiary population, beneficiaries will receive written notification from ESCOs regarding data sharing. If CMS or the ESCO does not receive notice within a set number of days that the beneficiary wishes to opt-out of data sharing, then the ESCO may request that CMS begin to release that beneficiary’s data (including their historical claims data) in a secure manner to approved users at the ESCO.

Beneficiaries may thereafter opt out of data sharing at any point during the life of the Model. ESCOs must make available to beneficiaries, upon their request, an explanation of which ESCO providers will have access to the beneficiary’s data. Beneficiaries may opt-out of data sharing via the ESCO or 1-800-Medicare. In the former case, the ESCO will be responsible for submitting information in a timely manner (within 30 days) to CMS on beneficiaries who have opted out of data sharing.

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 matched 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, as well as assess Model participant/provider/beneficiary perceptions, barriers to change, areas of particular enthusiasm and practice culture.

IX. Payment

Expenditure Baseline and Benchmark Calculations

CMS will calculate a *cross-sectional* expenditure baseline¹⁰ from the Medicare Parts A and B FFS expenditures for beneficiaries who would have been matched to the ESCOs in each of the three years prior to the start of the Model's first performance year. Similar to that in the Shared Savings Program, this methodology would generate comparable benchmark expenditures for the population served by the ESCOs during the three years immediately preceding the agreement period. Comparability between per capita expenditures in the baseline and performance year periods helps ensure a more accurate measurement of savings in performance periods.

Baseline expenditures will include all Part A and B (including dialysis) expenditures in 2010, 2011, or 2012 (base year 1, 2 or 3, respectively). The majority of dialysis facilities adopted the PPS bundle in 2011—hence, the vast majority of 2011 and 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 (where the update also adjusts for potential differences in price updates for the ESCO compared to the national average price updates, for example if the hospital wage index were to rise 5% in the ESCO market but only 2% at the national average).

The weighted average per capita expenditures for matched beneficiaries in the first two base years (BY1 (2010) and BY2 (2011)) will be adjusted to be comparable to the most recent base year (BY3 (2012)) in the following ways:

1. Trending by the national average growth percentage in comparable ESRD Medicare FFS per capita expenditures;
2. Adjusting for geographic differences in price updates applicable to ESRD Seamless Care Organization-attributed expenditures relative to the national average price updates;
3. Risk adjusting for the difference in the average prospective HCC risk score relative to the matched population in BY3; and,
4. Incorporating material changes in certain factors affecting the average dialysis bundle reimbursement amount.

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.

¹⁰ The expenditure baseline is a measure of the expenditures incurred for the aligned population during the baseline period which is three years prior to start of the first performance year for this Model. The expenditure benchmark is the CMS projection of what should be the Part A and Part B expenditures for an aligned population during a performance year.

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 Shared Savings Program. (Note: the prior section describes full HCC adjustment that will be used for combining the three base years' expenditures, which is also similar to the approach in SSP). A full adjustment will be made for differences in the average prospective HCC score for beneficiaries newly-matched in the performance year compared to the average prospective HCC score for beneficiaries newly matched in BY3. The remaining continuously matched 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).

Price adjustment¹¹ will be performed in the same manner for the baseline and benchmark. The average price change for the ESCO's performance year expenditures relative to BY3 will be compared to the national average price change over the same period. Additionally, an appropriate adjustment will be made to the risk-adjusted and trended benchmark so that it reflects the average prices specific to the ESCO's attributed expenditures in the performance year. This adjustment ensures that shared savings and shared losses would not result from heterogeneous price updates in the ESCO's market relative to the national average price updates used to trend the historical benchmark.

Finally, CMS may make adjustments for material changes between the performance year and BY3 for certain factors affecting the ESCO's average dialysis bundle reimbursement amount per beneficiary per treatment. Such factors may include:

- Material changes (net of the national average change) in the Area Wage Index applicable to the ESCO's expenditures;
- Material changes in the frequency of matched beneficiary months for which beneficiaries had fewer than the expected frequency of maintenance dialysis due to the cessation of treatment (for example, where dialysis ends mid-month immediately preceding transplant)¹²;

¹¹ "Price adjustment" means adjusting for differences in price updates applicable to a specific ESCO relative to the national average price update.

¹² If a beneficiary has less dialysis treatment in a given year (e.g., because of a transplant) then the dialysis-related costs incurred in a given year would be annualized across the year and the overall PBPY expenditures for that beneficiary would be less in a given year. In essence, because the expenditures are less there is a greater opportunity for the ESCO to earn shared savings.

- Adjustment to remove the effect on the calculation of savings/losses of any reduction imposed by the ESRD Quality Incentive Program taking effect in 2012; and
- Change in the mix of co-morbid conditions that directly impact the bundle amount for an individual facility based on that facility's case mix.

Base year and performance year expenditure calculations will exclude months where a beneficiary no longer receives Medicare-reimbursed dialysis.

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 matched 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 bundle, or equivalent services within Medicare Part 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. In all expenditure calculations, expenditures for catastrophic claimants will be truncated at a large claim limit that will vary depending on the ESCO size and selected risk level.

Per capita benchmark expenditures will be separately calculated, trended and compared to actual performance year expenditures for each of the distinct stratification 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 beneficiaries¹³ 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.

Payment Arrangements

The payment arrangements included in the CEC Model are directly tied to the organizational size of the applicant—namely, whether or not the applicant ESCO includes an LDO facility. The purpose of including

¹³ 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.

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. The payment arrangements are non-negotiable.

All applicants that include an LDO facility will be in the LDO two-sided payment track. Applicants that include only non-LDO facilities (i.e., a combination of SDO facilities, hospital-based, and/or independent facilities) may choose from either of the two non-LDO payment tracks. CMS may consider allowing a non-LDO applicant to participate in the LDO two-sided track if the non-LDO demonstrates competency across the selection/scoring domains outlined in the *Application Process and Selection Criteria* section. A summary of the payment arrangements can be found in Table 3.

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

Design Feature	LDO ESCO 2-Sided Risk Throughout	Non-LDO ESCO 2-Sided Risk from Start	Non-LDO ESCO 2-Sided Risk Phase-In
Risk Structure	2-sided	2-sided	1-sided (2-sided in Y3)
Minimum savings rate (MSR) ¹⁴	+/-1% threshold for first-dollar shared savings or losses (option for higher threshold if desired)	+/-1% threshold for first-dollar shared savings or losses (option for higher threshold if desired)	4% MSR for first-dollar shared savings at 500 beneficiaries, decreasing to 2% as number of beneficiaries increase to 2,000 (1% under 2-sided risk in year 3+)
Guaranteed Discount	Year 1: 1% Year 2: 2% Year 3+: 3%	Year 1: none Year 2: none Year 3+: 1%	None
Shared Savings / Shared Loss Percentages	After locking in guaranteed discounts, sharing up to 70% of first-dollar savings/losses in year 1, 75% in years 2+	Year 1: Up to 60% first-dollar share/loss Year 2: Up to 70% share/loss Year3+: Same as LDO Y1 (lock in 1% discount and share up to 70% on either side)	50% in years 1-2 60% in year 3+

¹⁴ In years 4 and 5 ESCOs can elect a higher MSR. However, the MSR threshold will be capped at 2%, which is consistent with Track 2 of the Medicare Shared Savings Program.

Design Feature	LDO ESCO 2-Sided Risk Throughout	Non-LDO ESCO 2-Sided Risk from Start	Non-LDO ESCO 2-Sided Risk Phase-In
Caps on Shared Savings/Shared Losses	10% years 1&2 15% years 3+	10% for all years	5% in years 1&2 10% under 2-sided risk in years 3+
Rebasing	Rebase for Years 4 and 5 on data from PY1-PY3, including net shared savings dollars as baseline expenditures	Rebase for Years 4 and 5 on data from PY1-PY3, including net shared savings dollars as baseline expenditures	Rebase for Years 4 and 5 on data from PY1-PY3, including net shared savings dollars as baseline expenditures

When the MSR 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 1-sided sharing for non-LDO ESCOs in performance years 1 and 2, an ESCO meeting MSR requirements will receive up to 50% of savings subject to a maximum of 5% savings on total expenditures (expressed as a percentage of the aggregate updated benchmark). Under 2-sided sharing for risk phase-in non-LDO ESCOs in year 3, an ESCO meeting MSR requirements will receive up to 60% of savings, or owe 60% of losses, depending on quality scores, subject to a maximum of 10% savings or losses on total included expenditures for the ESCO's matched beneficiaries.

Under 2-sided sharing for non-LDO ESCOs, an ESCO meeting MSR requirements will receive up to 60% (70% in years 2+) of savings, or owe 60% (70% in years 2+) of losses, subject to a maximum of 10% savings or losses on total included expenditures for the ESCO's matched beneficiaries. In year 3, the non-LDO ESCO will have benchmarks reduced to reflect a discount applied to Medicare Part A and Part B costs including maintenance dialysis expenditures of 1%. Savings or losses will then be measured relative to the resulting discounted benchmark. Potential resulting savings or losses would be shared at up to 70% in year 3, depending on quality scores, with maximum savings/losses of 10% in year 3.

Under 2-sided sharing for LDO ESCOs, an ESCO meeting MSR requirements will receive up to 70% (75% in years 2+) of savings, or owe 70% (75% in years 2+) of losses, subject to a maximum of 10% savings or losses on total included expenditures for the ESCO's matched beneficiaries (maximum rises to 15% in year 3). LDO ESCOs will have benchmarks reduced to reflect a discount applied for all Medicare Part A and Part B costs including maintenance dialysis expenditures in years 1 through 3 (1.0%, 2.0%, and 3.0% respectively). Savings or losses will then be measured relative to the resulting discounted benchmark. Potential resulting savings or losses would be shared at up to 70% in year 1 and 75% in years 2 and 3, depending on quality scores, with maximum savings/losses of 10% in years 1 and 2 and 15% in year 3.

For ESCOs that enter agreements to continue participation in the Model for years 4 and 5, the benchmark would be rebased using actual expenditure data from PY1-PY3 including net shared savings dollars baseline expenditures.

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 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 truncate 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 a lower amount for non-LDO ESCOs to further protect them from the effects of catastrophic claims compared to the higher cap proposed for LDO ESCOs. Proposed caps would be calculated as follows:

- **For non-LDO ESCOs:** truncate annualized expenditures at the same cap amount defined for the Shared Savings Program ESRD beneficiaries, which equals 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)
- **For LDO ESCOs:** truncate at the 99th percentile of national Medicare fee-for-service expenditures (for the ESRD population)

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.

X. 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 will develop scripts for customer service representatives (CSRs) that will answer anticipated questions related to the CEC Model. Questions that CSRs cannot answer will be triaged to the CMS Regional Offices, mirroring the system developed for the Shared Savings Program and Pioneer ACO 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 will also create an email inbox for all provider and public inquiries related to the CEC Model.

XI. Application Scoring and Selection

Applicants will be scored based on six key domains including: patient-centeredness; organizational structure, leadership and management, financial plan/experience, care coordination capabilities, and care for vulnerable populations. 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. CMS will accept applications from any organization that meets all of the eligibility requirements described previously.

CMS will only consider applications from organizations that have submitted a letter of intent by the deadline (March 15, 2013). CMS will screen applications to determine completeness and eligibility, including whether the organization meets the minimum eligibility requirements outlined in the *Applicant Eligibility* section above. If the operational timeline allows, CMS will give applicants the opportunity to make corrections and or clarifications to incomplete or ineligible applications.

Each complete and eligible application will be reviewed by a panel of experts that may include individuals from the Department of Health and Human Services (DHHS) as well as other organizations, with expertise in the areas of provider payment policy, care improvement and coordination, ESRD, and care of vulnerable populations. Reviewed applications will be scored based on the criteria listed in Appendix D. CMS will normalize scores across review panels. 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.

XII. Length of Agreement

Agreements will have an initial term consisting of three 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 the fourth quarter of 2013. CMS intends to treat the first performance period in this Model like that of the first performance period in the Shared Savings Program. In effect, the first performance year becomes a 15-month performance period followed by 2 (or up to 4, if extended) additional calendar performance years.

Two additional performance periods may be offered subject in part to the ESCO meeting financial and quality performance targets. CMS may choose not to offer the additional two performance periods 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 agreement and/or performance related issues.

XIII. 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.

XIV. 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.

XV. Termination

CMS reserves the right to terminate the 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 required under 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: Letter of Intent Template



CMS will safeguard the information provided to us in accordance with the Privacy Act of 1974, as amended (5 U.S.C. Section 552a). For more information, please see the CMS Privacy Policy at https://www.cms.gov/AboutWebsite/02_Privacy-Policy.asp

Questions about the Letter of Intent (LOI) for the Comprehensive ESRD Care (CEC) initiative should be directed to ESRD-CMMI@cms.hhs.gov

[Instructions](#)

[FAQs](#)

[Contact Us](#)

The Centers for Medicare and Medicaid Services (CMS) recently released a request for applications for the Comprehensive End-Stage Renal Disease Care (CEC) Initiative. Made possible by the Affordable Care Act, this CMS Innovation Center Initiative will help dialysis facilities, nephrologists, and other Medicare providers and suppliers to deliver higher quality, better coordinated, and more patient-centered care to Medicare beneficiaries with end-stage renal disease. By completing and submitting this Letter of Intent, you are informing the CMS Innovation Center of your interest in the CEC Initiative and reserving the right to formally apply to the Initiative when the application period begins.

If you wish to preview your LOI prior to submission, you may do so using the print or print preview function in your browser. You will also have the opportunity to print your LOI after submission.

DO NOT use your browser's "back page" function or navigate away from this page while completing your LOI. Doing so will cause you to lose information that you have entered into your LOI. If you navigate away from this page, all information that you entered will be lost.

1. Applicant ESCO Name

ESCO Organization Name:

Doing Business As (if applicable):

2. Applicant ESCO Primary Contact

First Name :

Last Name:

Position/Title:

Phone:

Phone Ext:

Email:

3. Applicant ESCO Primary Contact Address

Street:

City:

State:

5 digit ZIP:

4. Please identify the market area where the Applicant ESCO plans to operate (i.e., location of the Applicant ESCO’s proposed participants):

As stated in the CEC RFA, please note that a market is defined as no larger than two contiguous Medicare core-based statistical areas (CBSAs), 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.

[DEFINE MARKET AREAS](#)

Add Market Area Location

[View CBSA Codes](#)

Action	State	County	ZIP
ADD	--None-- ▼	N/A ▼	<input type="text"/>

[Return to main form](#)

5. Please identify the Applicant ESCO's proposed participants in the table below.

As stated in the CEC RFA, if possible, you should include at least 50% of your proposed ESCO participants in response to this question. Of note, this table has multiple fields that may not be seen on your current LOI screen. You may view all of the fields, as well as all of the information you provide for each proposed participant, by clicking "View" in the "Action" column. You may also delete or edit the information that you have provided by selecting "Del" or "Edit" under the "Action" column.

[ADD PARTICIPANTS](#)

Provide all Participant Information below:

Name:

Proposed Status:

Full Address (Street Address, City, State, Zip):

Medicare Provider/Supplier Type:

Tax Id# (TIN):

CCN (if applicable):

Organizational or Individual National Provider Identifier (NPI):

[Save](#) [Save & Add Another](#) [Cancel](#)

6. Medicaid Fee-For-Service Beneficiaries:

Please estimate the total number of Medicare fee-for-service beneficiaries served in a given month in 2012 by all of the dialysis facilities listed in the table above.

Please take the following actions when you are ready to submit your LOI to CMS. You will not be able to make any changes to your LOI after you click the "Upload Signature Certification Page & Submit LOI" button.

Please download, complete, and then upload the Signature Certification Page per the instructions provided below

Please click on the link entitled "Signature Certification Page" to download the document. Then do the following:

- Print the Signature Certification page, fill in the requested information, and sign the document;
- Scan and save the executed Signature Certification Page;
- Proceed to select the "Upload Signature Certification Page & Submit LOI" button to upload the executed Signature Certification Page to the LOI.

You will then need to select your saved document.

- When complete, select "Submit LOI". This will complete the LOI submission process.

Signature Certification Page

* required

Appendix B: 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, however, should include at least 50% of their proposed ESCO participants in the LOI and 100% of their proposed ESCO participant owners in the application. ESCO participant owners 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 (owner and non-owner) 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 Letter of Intent (LOI) Identification Number
 - A. Identification Number:
2. Applicant ESCO Name
 - A. Applicant ESCO Name:
 - B. Applicant ESCO Name reported on the LOI:
 - C. Doing Business As (Optional):
3. Primary Contact at Applicant ESCO
 - First Name:
 - Last Name:
 - Title/Position:
 - Phone:
 - Phone Ext.:
 - Email:
4. Applicant ESCO Primary Contact Address
 - Street Address Line 1:
 - Street Address Line 2:
 - City:
 - State:
 - Zip Code (5 digits):
 - Zip Code (4 digits):
5. Applicant ESCO Executive Contact (CEO, Executive Director, etc.)

First Name:

Last Name:

Phone:

Phone Ext.:

Email:

6. Was this application completed by an individual outside of the ESCO Organization (eg. 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
- 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
 - 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 that the Applicant ESCO has begun the process of establishing a legal entity and estimate how long is the process 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 outside of 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 identify the market area where the Applicant ESCO plans to operate (i.e., location of the Applicant ESCO's proposed participants):

State :

County (or Counties):

Zip code:

Medicare CBSA(s):

14. Please complete the following table with information about all of the Applicant ESCO's proposed ESCO participants. All participant owners must be included. Please refer to the Request For Applications for definitions of Participants, Participant Non-Owners, Participant Owners, and Provider/Supplier. In the table below, list only ESCO Participants. Individual participating Providers/Suppliers that bill under the Participant TIN and therefore makeup the ESCO participant should not be listed in this table.

Participant Name (Legal Organization or Practice Name associated with TIN)	Proposed Participant Status (i.e., Owner or Non-Owner)	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						

15. Please complete the following table for each proposed ESCO participant, listing all of the participating providers and suppliers that bill under the ESCO participant TIN. *Please note, that applicants should only list those providers/suppliers that plan to participate in the ESCO. This may include all providers/suppliers billing under a TIN or only a subset.*

Participant Name: _____ John Smith Nephrology _____

Individual? (Y/N)	Individual or organization	Provider/Supplier Address Line	Medicare Provider/Supplier Type	CMS Certification Number	Individual or Organizational National

	name			(CCN), if applicable	Provider Identifier (NPI)

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

16. 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).
17. 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).
18. 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

19. 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).
20. Please complete the table below with information specific to the Applicant ESCO's proposed governing body:

Name	Position in the	ESCO Participant	ESCO Participant	Voting Power

	ESCO's Governing Body	Being Represented (if applicable)	Status (e.g., Owner Non-owner)	(% of total)

21. 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.

22. Please submit the compliance plan intended for use by the Applicant ESCO. The compliance plan must identify a compliance officer 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

23. 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
24. Please describe the existing or planned mechanisms that the Applicant ESCO will use to conduct beneficiary outreach.
25. 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

26. 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.
27. Please describe the Applicant ESCO's plan to incorporate mental/behavioral health and social services into the comprehensive care management of ESRD beneficiaries.
28. 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).
 - A. Please upload a letter of support from the State Medicaid Agency (optional)
29. Please describe the Applicant ESCO's existing or planned ability to provide timely performance feedback to ESCO providers
30. 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.
31. 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, 2013. ____

32. 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:

33. 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)

34. Please complete the below table with information specific to any investigations of, and sanctions, penalties, or corrective action plans imposed against, the Applicant ESCO's proposed ESCO participants and ESCO providers/suppliers. Please provide information from the previous three 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

35. Please identify the payment arrangement that the Applicant ESCO is selecting in this application.

36. 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.

37. Please explain how the ESCO intends to work toward Medicaid cost containment for the Medicare-Medicaid Enrollee (dual eligible) beneficiary population matched to the ESCO.
38. 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.

Signature of Applicant ESCO Executive Contact

Date

Appendix C: Glossary of Key Definitions

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

DIALYSIS FACILITY: An entity that provides outpatient maintenance dialysis services. This could also include home dialysis training and support services. A hospital-based dialysis facility that provides outpatient dialysis services is also included in this definition.

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/nephrology group practice not employed by the dialysis facility; and (3) and at least one other eligible Medicare-enrolled provider or supplier including physicians and non-physician practitioners, but excluding DMEPOS suppliers, ambulance suppliers, and drug/device manufacturers. The ESCO and its participants including participant owners and participant non-owners agree to become accountable for the quality, cost and overall care of ESCO beneficiaries and to comply with the terms and conditions of the CEC Model Participation Agreement.

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

ESCO PARTICIPANT: An individual ESCO provider/supplier or a group of multiple ESCO providers/suppliers all billing under the same Medicare enrolled TIN that, together with other ESCO participants, agrees to become accountable for the quality, cost, and overall care of the ESCO beneficiaries and to comply with the terms and conditions of the CEC Model Participation Agreement. ESCO participants may be ESCO participant owners or ESCO participant non-owners.

ESCO PARTICIPANT NON-OWNER: An individual ESCO provider/supplier or a group of multiple ESCO providers/suppliers all billing under the same Medicare-enrolled TIN that does not have an ownership stake in the ESCO, but has a contractual relationship with the ESCO that requires the individual or group to comply with the terms and conditions of the CEC Model Participation Agreement.

ESCO PARTICIPANT OWNER: An individual ESCO provider/supplier or a group of multiple ESCO providers/suppliers all billing under the same Medicare-enrolled TIN that (1) has an ownership stake in the ESCO, (2) is a signatory to the CEC Model Participation Agreement, and (3) assumes a minimum portion of the liability for shared losses (“downside risk”) as specified by CMS and agrees that CMS may recover such shared losses. In addition, all dialysis facilities and nephrologists/nephrology group practices participating in the ESCO must be participant owners.

ESCO PARTNER: Individuals or entities that have contracted with the ESCO or ESCO participants, but are not ESCO participants. ESCO partners are not eligible to be ESCO participants 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.

ESCO PROVIDER/SUPPLIER: An individual or entity that (1) is a Medicare-enrolled provider or supplier other than a DMEPOS supplier; (2) is identified by an NPI or CCN; and, (3) bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to a TIN of an ESCO participant, in accordance with applicable Medicare regulations. All ESCO providers/suppliers must be included on the ESCO's TIN/NPI list submitted to CMS on an annual basis and must be required by the ESCO Participant to comply with applicable terms and conditions of the CEC Model Participation Agreement.

ESRD: End-Stage Renal Disease

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

HOSPITAL-BASED DIALYSIS FACILITY: A hospital-based dialysis facility is an integral and subordinate part of a hospital, operated with other departments of the hospital under common licensure, governance, and professional supervision, with full integration of all hospital and facility services.

LARGE DIALYSIS ORGANIZATION (LDO): LDO is an organization that owns greater than 200 dialysis facilities.

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): A non-LDO is an organization and/or dialysis facility that is not owned by an LDO. For the purposes of this Model, a non-LDO includes all dialysis facilities owned by small dialysis organizations (SDOs), independently-owned facilities, and hospital-based facilities.

SHARED LOSSES: Any monetary amount owed to CMS by the ESCO according to the payment arrangement due to spending in excess of the ESCO's Medicare expenditure benchmark for the applicable performance year, or portion thereof, if this amount exceeds the applicable minimum loss rate.

SHARED SAVINGS: A "shared savings" arrangement rewards an ESCO with a specified percentage of total savings achieved once a minimum savings rate is achieved. The reward is a function of the maintenance or improvement of beneficiary quality of care outcomes and a reduction in total Medicare Parts A and B health care spending.

SMALL DIALYSIS ORGANIZATION (SDO): An SDO is defined as an organization that owns fewer than 200 dialysis facilities.

Appendix D. Applicant Selection Criteria and Associated Points

Selection Domain	<p style="text-align: center;">Applicant Selection Criteria</p> <p style="text-align: center;">To earn the full amount of points in each domain, the applicant must:</p>	Points
Patient Centeredness	<ul style="list-style-type: none"> - Demonstrate the ability to engage beneficiaries and their caregivers in shared decision making, taking into account patient preferences and choice. - Have a feasible plan to establish mechanisms to conduct patient outreach and education on the benefits of care coordination, renal transplantation, and care settings. - Demonstrate the ability to effectively involve beneficiaries in care transitions to improve the continuity and quality of care across settings, e.g., medication lists; care plans co-developed with the patient and embedded in the EHR; case manager follow up - Demonstrate the ability to engage and activate beneficiaries at home (through such modes as home visits or tele-monitoring) to improve self-management - Have mechanisms to evaluate patient satisfaction with the access and quality of their care, including choice of providers, and choice in care settings. 	25
Organizational Structure	<ul style="list-style-type: none"> - Demonstrate a history of collaboration between participating providers/provider organizations and/or credible plan for how the participants will work together in the model - Have an organizational structure that promotes patient centered care and the goals of the model. In addition to meeting the minimum eligibility requirements for provider/supplier participation, the applicant organization is made up of a diverse set of provider/suppliers that demonstrates a clear commitment to providing high quality, coordinated care to beneficiaries. 	10
Leadership & Management	<ul style="list-style-type: none"> - Have a governance structure that is clearly defined and demonstrates commitment to providing high quality care to beneficiaries consistent with the three-part aim of better health, better care, and lower costs. 	20

	<ul style="list-style-type: none"> - 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. 	
<p style="text-align: center;">Financial Plan/Experience</p>	<ul style="list-style-type: none"> - 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 matched to the ESCO. 	5

	<ul style="list-style-type: none"> - Provide credible plan for reducing Part D expenditures while preserving beneficiary choice of Part D plans. 	
<p>Care Coordination Capabilities and Implementation Plan</p>	<ul style="list-style-type: none"> - 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 matched 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 	<p>25</p>

<p>Care for Vulnerable Populations</p>	<ul style="list-style-type: none"> - Include a diverse group of practitioner, 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 	<p>15</p>
<p>Total Points</p>		<p>100</p>