### Comprehensive ESRD Care Initiative: Frequently Asked Questions

#### What is the Comprehensive ESRD Care (CEC) Model?

The Comprehensive ESRD Care (CEC) model is an accountable care organization (ACO) model developed under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center) to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care. As the first Accountable Care Organization (ACO) model with a disease specific focus, the model aims to identify ways to improve the coordination and quality of care for Medicare beneficiaries living with ESRD, while reducing Medicare expenditures.

#### What is an ESCO?

An "ESCO" or "ESRD Seamless Care Organization" is an Accountable Care Organization (ACO) composed of providers and suppliers who voluntarily come together to form a legal entity that offers coordinated care to beneficiaries with ESRD through the Comprehensive ESRD Care model. An ESCO is required to have participant owners that include at least one nephrologist or nephrology group practice and at least one dialysis facility.

## When does the Comprehensive ESRD Care (CEC) Model begin? When does it end? How many ESCOs are participating?

The Model started October 1, 2015 with 13 participating ESCOs. The initial agreement period lasts for three years. CMS and ESCOs then have the option of extending this agreement for two additional one-year extensions based on the ESCO's performance. The new solicitation is for ESCOs who will start January 1, 2017 and will participate for two performance years, and then be eligible to have their agreements extended for two additional one-year extensions based on the ESCO's performance.

#### What is the deadline for responding to the second round solicitation for the CEC Model?

The application deadline for the second round CEC Model solicitation is July 15, 2016, 5:00pm EDT. More information about applying is available on the CEC website at <u>https://innovation.cms.gov/initiatives/comprehensive-esrd-care/</u>.

#### What types of providers are eligible to participate in an ESCO?

Medicare-enrolled providers of services and suppliers are eligible to participate in the Comprehensive ESRD Care (CEC) Model. This includes physicians, non-physician practitioners, and other healthcare suppliers that are not: (1) Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers; (2) ambulance suppliers; (3) drug and/or device manufacturers; or (4) excluded or otherwise prohibited from participation in Medicare or Medicaid. Medicare-enrolled providers of services that are

also DMEPOS suppliers, but whose primary taxonomy is as a non-DMEPOS provider, are eligible to participate in the Model.

# Can a Medicare provider participate in both the Shared Savings Program and the Comprehensive ESRD Care (CEC) Model?

The Medicare Shared Savings Program requires that each ACO participant taxpayer identification number (TIN) upon which beneficiary assignment is dependent must be exclusive to one Medicare Shared Savings Program ACO (see the Medicare Shared Savings Program regulations at §425.306(b)). This means that a TIN or CMS Certification Number (CCN) billing Medicare for primary care services (as defined in the Medicare Shared Savings Program regulations at §425.20) must be exclusive to one ACO's certified list of ACO participants. This means that providers billing under the same TIN will not be able to be a participant in both the Shared Savings Program and the CEC Model.

This exclusivity rule applies to the Medicare-enrolled billing TIN that is an ACO participant in the ACO, not to individual practitioners. Individual practitioners are free to participate in multiple ACOs if they bill under several different TINs. Also, the exclusivity rule applies only for Medicare Shared Savings Program operational purposes. In no way does it establish or otherwise imply a lock in of beneficiaries or a limitation of provider practice or referrals.

#### What financial incentives does CMS offer ESCOs to improve care?

The payment arrangements applicable to ESCOs are described in detail in Financial Methodology available on the Comprehensive ESRD Care (CEC) Model website. The CEC Model uses a shared savings and losses model, under which ESCOs will share savings, and in some instances be held accountable for a portion of losses, for the particular ESCO's aligned beneficiaries. To assess savings or losses to Medicare, CMS developed an expenditure "baseline," based on historical Medicare Parts A and B expenditures incurred for beneficiaries who would have been aligned to the ESCO in each of the three years prior to the start of the first performance year for this model.

CMS then trends the baseline forward using national data to develop an expenditure benchmark for the beneficiaries aligned to the ESCO. CMS will calculate savings or losses based on a comparison of the benchmark and the actual Medicare Fee-For-Service (FFS) Part A and B expenditures for the aligned population in a given performance year. The savings will be adjusted based on quality performance.

The Comprehensive ESRD Care (CEC) Model includes two payment arrangements. ESCO participants who qualify for a two-sided payment arrangement are eligible for cost savings and will also be responsible for shared losses, while ESCOs who qualify for the one-sided payment track will be eligible for shared savings – but will not be responsible for losses. ESCOs that contain dialysis facilities from a large dialysis organization (LDO) are required to be in the two-sided track, while ESCOs who do not have an LDO dialysis facility (Non-LDO) have the option of choosing the one-sided or two-sided payment tracks.

#### How are beneficiaries aligned to an ESCO?

ESCOs will not enroll beneficiaries in the model nor will beneficiaries have to sign up for the model. CMS prospectively aligns eligible beneficiaries to ESCOs through a claims-based process. The alignment process identifies the Medicare beneficiaries for whom CMS will hold an ESCO clinically and financially accountable. Beneficiaries will maintain full Medicare benefits, including the freedom to receive services from any Medicare-participating provider at any time.

CMS aligns beneficiaries to an ESCO based on dialysis utilization using a "first touch" approach meaning that an eligible beneficiary's first visit to a Comprehensive ESRD Care (CEC) Model participant dialysis facility prospectively aligns that beneficiary to the dialysis facility, and by extension the ESCO, for the performance year, unless the beneficiary loses eligibility (e.g., ceases dialysis treatment, joins Medicare Advantage, receives a functioning transplant, etc.).

### How will beneficiaries be affected by the Comprehensive ESRD Care (CEC) Model? How many beneficiaries are expected to be affected by the CEC Model?

Many beneficiaries with ESRD have multiple comorbidities. The Comprehensive ESRD Care (CEC) Model encourages dialysis facilities, nephrologists, and other providers to coordinate and manage the complete spectrum of care for their ESRD beneficiaries. ESCOs are designed to alleviate this burden for beneficiaries, while improving the partnership between beneficiaries and providers in making health care decisions. The goal is for Medicare beneficiaries to have better control over their health care, and for their dialysis providers to provide better care. There are currently approximately 17,000 beneficiaries aligned to ESCOs in the CEC Model and CMS plans to add at least 7,000 more beneficiaries with a second solicitation.

#### Can beneficiaries opt out of having their data shared with providers taking part in the CEC Model?

ESCOs are required to notify aligned beneficiaries in writing that CMS will share their data with the ESCO unless the beneficiary opts out of data sharing. Beneficiaries aligned to the CEC Model will have the option to opt out of data sharing by calling 1-800 MEDICARE. CMS will only share data with the ESCO for aligned beneficiaries who have not opted out of data sharing.

#### What steps is CMS taking to prevent fraud, waste, and abuse?

The Comprehensive ESRD Care (CEC) Model includes numerous safeguards aimed at protecting beneficiaries and ensuring program integrity, including prohibitions on requiring referrals only to ESCO participants and conditioning participation on referrals for services provided to beneficiaries who are not assigned to the ESCO. CMS will work closely to monitor compliance with program requirements. In addition, CMS will employ routine analysis of Medicare data on service utilization and investigate aberrant utilization patterns.

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 termination of the ESCO from the model. These remediation responses do not limit or restrict the Office of the Inspector General's (OIG) authority to audit, evaluate, investigate, or inspect an ESCO and its ESCO participants.

# What fraud and abuse waivers will CMS be providing to ESCOs participating in the Comprehensive ESRD Care (CEC) Model?

With respect to certain fraud and abuse provisions in sections 1128A, 1128B and 1877 of the SSA, the Secretary has issued waivers pursuant to §1115A(d)(1) for the CEC Model. The current waivers for the CEC Model are available at <a href="https://www.cms.gov/Medicare/Fraud-and-">https://www.cms.gov/Medicare/Fraud-and-</a>

<u>Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html</u> and on the OIG website. Such waivers may be revised or revoked at any time. We note that the fraud and abuse law waivers for the CEC Model apply only to certain arrangements that comply with the criteria set forth in the applicable waiver. Parties should consult with legal counsel as necessary to ensure that arrangements for which they seek waiver protection meet all of the conditions of an applicable waiver.

# How did CMS select the ESCOs currently participating in the Comprehensive ESRD Care (CEC) Model?

CMS conducted a competitive application process to select the participants in the CEC Model. CMS released a Request for Applications (RFA) in April 2014 that detailed selection criteria. Applicants were required to submit both a Letter of Intent and an application. Applications were reviewed by a panel of experts from the Department of Health and Human Services as well as from external organizations, with expertise in the areas of ESRD, ACOs, care improvement and coordination, and care of vulnerable populations. These panels assessed the applications based on the criteria detailed in the RFA. Based on these criteria, CMS chose selected ESCOs for participation in the model.

#### Why is the CEC Model conducting another solicitation?

This solicitation aims to add more ESCOs and improve our ability to detect whether the model has saved money for Medicare and improved the quality of care beneficiaries receive. The model currently has 13 ESCOs, including 12 LDOs and one non-LDO. This solicitation aims to add at least seven ESCOs, including at least four non-LDOs, but would add more if there is additional interest in the marketplace. CMS expects new ESCOs will form given the more advanced state of coordinated care and incentives under the Medicare Access and CHIP Re-Authorization Act (MACRA) Quality Payment Program (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Quality-Payment-Program.html) for practitioners to participate in models like CEC.

#### What is the set of quality measures that will be used for assessing ESCO quality performance?

CMS will require the assessment of claims-based and clinical quality measures as well as the administration of surveys as outlined in the RFA for assessing ESCO quality performance. A set of quality measures that CMS is using for the Comprehensive ESRD Care (CEC) Model quality measures was made available for public review and comments. For more information on the quality measure set, please visit http://innovation.cms.gov/initiatives/comprehensive-ESRD-care/.