October 2, 2020

CMS Finalizes New Payment Model for End Stage Renal Disease (ESRD) and Issues Updates on Fraud and Abuse Waivers for Comprehensive Kidney Care Contracting (CKCC) Options of the Kidney Care Choices (KCC) Model

On September 18, the Centers for Medicare & Medicaid Services (CMS) finalized the End-Stage Renal Disease Treatment Choices (ETC) Model, addressing quality of care and Medicare expenditures for patients with chronic kidney disease (CKD).[1] The mandatory ETC Model will be implemented on January 1, 2021 and is estimated to impact approximately 30% of kidney care providers.[2] CMS also recently released a notice of waiver of certain fraud and abuse laws applicable to providers selected to participate in the Comprehensive Kidney Care Contracting (CKCC) Options of the Kidney Care Choices (KCC) Model, which is being tested by the Center for Medicare and Medicaid Innovation (CMMI). The KCC program provides an alternative payment model for nephrology care for patients with late-stage CKD (Stages 4 or 5) and ESRD, and is designed to delay the onset of dialysis and incentivize kidney transplantation.

This Alert addresses both updates in turn below.

ESRD Treatment Choices (ETC) Model

CMS first solicited comments on the ETC Model through a proposed rule on July 18, 2019. The structure of the ETC Model, as now finalized by CMS, is largely similar to the 2019 proposal. (Ropes & Gray analyzed this proposed program in a previous Alert.) The ETC Model will implement payment adjustments to incentivize participating ESRD facilities and clinicians caring for beneficiaries with ESRD ("Managing Clinicians") to support greater use of home dialysis and kidney transplantation. It will assess whether such payment adjustments improve the utilization of home dialysis and transplants and reduce Medicare expenditures.

The ETC Model includes two payment adjustments:

1. **Home Dialysis Payment Adjustment (HDPA)** – CMS will make positive adjustments to certain payments to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on certain home dialysis claims and to the Monthly Capitation Payments (MCP) to participating Managing Clinicians on home dialysis-related claims.[3] The adjustments will apply from January 1, 2021 until December 31, 2023.[4]

2. **Performance Payment Adjustment (PPA)** – CMS will make positive or negative adjustments on dialysis and dialysis-related Medicare payments, both at home and in-center, based on ESRD facilities' and Managing Clinicians' rates of home dialysis and transplants.[5] These adjustments will apply to claims beginning January 1, 2021 through June 30, 2027.[6]

Participation will be required for Managing Clinicians and ESRD facilities in randomly selected geographic areas, which will be posted on the ETC Model website.[7] CMS has said that Managing Clinicians and ESRD facilities will be selected from all 50 states and the District of Columbia in order to compose approximately 30% of all such facilities and providers nationwide.

For those ESRD facilities and Managing Clinicians located in the selected geographic areas, participation in the new ETC Model will be mandatory. The HDPA will provide a positive adjustment during the initial three years on home dialysis and related claims. Thus, participants that have already invested in and established robust home dialysis programs may see the greatest benefit if required to participate. Additionally, large dialysis organizations may experience greater revenue increases during this initial period as a reflection of the larger volume of patients served, but the PPA will adjust upward or downward the per-treatment payment for dialysis based on home dialysis and transplant rates, and CMS will phase in greater positive and negative adjustments over the period.[8]

Payment adjustments will be counted as expenditures under the Medicare Shared Savings Program and other initiatives.[9] CMS will waive certain Medicare program requirements for the ESRD PPS, ESRD Quality Incentive Program, Medicare Physician Fee Schedule and Medicare Kidney Disease Education (KDE) benefit to the extent necessary to make the payment adjustments and to provide additional access to educational tools "to ensure beneficiaries select their preferred kidney replacement modality" in testing the ETC Model.[10] The final rule made certain technical modifications to the way the program was proposed, including clarifications of calculation measures and attributed ESRD beneficiaries.

Fraud and Abuse Waiver for CKCC Kidney Care Choices Model

Separately, CMS released the "Notice of Waiver of Certain Fraud and Abuse Laws in Connection With the Comprehensive Kidney Care Contracting Options of the Kidney Care Choices Model." The waiver, which is applicable to entities already selected to participate in the CKCC Option of the KCC program, covers certain contractual and payment arrangements between and among program participants (called KCE Participants or Preferred Providers) and the Kidney Contracting Entity (KCE), which is the central entity through which program participation is facilitated, during the so-called "Implementation Period," the initial ramp-up period for KCEs from October 15, 2020[11] through March 31, 2021. Following the Implementation Period, the first "Performance Period" begins on April 1, 2021, at which point KCEs will begin undertaking financial risk.

Through the CKCC Options of the KCC Model, CMMI established an alternative payment model to incentivize better management of kidney disease. The KCC Model utilizes financial incentives such as risk-sharing arrangements and financial bonuses associated with successful kidney transplants to encourage health care providers who treat patients with CKD 4 and 5 or ESRD, such as nephrologists, kidney transplant providers, and dialysis providers, to be responsible for aligned beneficiaries' kidney care. Under the program, these providers form a KCE, which functions as a network to coordinate patient care and align the participating providers. Although KCEs do not undertake any financial risk during the Implementation Period, KCEs select one of three risk-sharing options (CKCC Graduated, Professional, or Global) that will go into effect during the Performance Period.

Notably, the waiver that CMS released applies only during the KCC Model's Implementation Period, and applies exclusively to arrangements that are "reasonably related to the performance of KCE Activities." "KCE Activities" are defined under the template participating provider agreements between CMS and KCEs to include activities related to the KCE's core functions, such as "planning for and promoting accountability for the quality, cost, and overall care for a population of KCE Beneficiaries, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty under [the agreement with CMS]." Some notable examples include providing direct patient care in a manner that reduces costs and improves quality and coordinating care, including through telehealth, remote patient monitoring and other enabling technologies.

Under the waiver, the Secretary of HHS waived Stark Law and Anti-Kickback Statute provisions[12] with respect to eligible start-up arrangements during the Implementation Period in preparation for participation in the Performance Period between the KCE and one or more KCE Participants or Preferred Providers or both, provided that all of the following conditions, as summarized below, are met:

- The KCE has entered into an Implementation Period participation agreement with CMS (Implementation Period Participation Agreement).
- All parties enter into the arrangement with the good faith intent to participate in the Performance Period that begins immediately after the expiration of the Implementation Period Participation Agreement.

- In establishing the terms of the arrangement, no party shall give or receive remuneration in return for, or to induce the referral of, items or services furnished to Federal health care program beneficiaries who are not aligned to the KCE.

- For arrangements involving the exchange of information technology used predominantly to create, maintain, transmit, or receive electronic health records, such information technology must be interoperable, as defined in the Implementation Period Participation Agreement.

- The KCE's governing body has authorized the arrangement and made a bona fide determination that the arrangement is reasonably related to KCE Activities.

- The arrangement and its authorization by the governing body are contemporaneously documented and retained for at least 10 years following completion of the arrangement and promptly made available to the Secretary upon request. The documentation must meet specific requirements outlined further in the waiver.

- A description of the arrangement is publicly disclosed and maintained on a public-facing website belonging to the KCE no later than 60 days after the effective date of the arrangement, through the earlier of the expiration or termination date of the Implementation Period Participation Agreement.

- The Implementation Period Participation Agreement does not provide that this waiver is inapplicable.

The waiver goes into effect on the start date of the Implementation Period and ends upon (i) termination of the agreement by CMS, (ii) expiration of the Implementation Period, in the event that the KCE participates in the subsequent Performance Period, or (iii) 90 days after the expiration of the Implementation Period, if the KCE does not enter into the subsequent Performance Period.

At this time, CMS has not released, and has not committed to publish, any fraud and abuse waivers applicable to the Performance Period, when financial accountability commences. Despite this lack of guidance, KCEs must submit to CMS a final list of KCE Participants and Preferred Providers that are expected to participate during the Performance Period no later than October 6, 2020.[13] The uncertainty related to what waivers will apply during the Performance Period impacts the financial arrangements that many KCEs are currently considering. Without clear guidance on the fraud and abuse waiver during the Performance Period, KCEs may have to take a wait-and-see approach to finalizing these financial arrangements. In 2019, CMS proposed safe harbors and exceptions for value-based payment arrangements generally (the "VBP Waivers") that would replace more limited exceptions, including CMMI program-specific waivers that have been issued (see our Alert here). Although CMS has reserved itself the opportunity to announce waivers applicable only to the Performance Period if it deems them necessary, if CMS finalizes the VBP Waivers prior to the start of the Performance Period, it is possible CMS will decline to issue additional program-specific waivers, and KCEs will have to conform their financial arrangements to the final VBP Waivers.

* * *

If you have any questions, please contact your usual Ropes & Gray advisor.

1. Centers for Medicare and Medicaid Services, Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures, 85 Fed. Reg. 61114.
2. Centers for Medicare and Medicaid Services, "CMS Announces Transformative New Model of Care for Medicare Beneficiaries with Chronic Kidney Disease," Press Release (Sep. 18, 2020).
3. *Supra* note 1 at 61117.
4. *Id*.
5. *Id*.
6. *Id*.
7. Centers for Medicare and Medicaid Services, "End-Stage Renal Disease Treatment Choices (ETC) Model," Fact Sheet (Sep. 18, 2020).
8. *Supra* note 1 at 61327-61329.
9. *Id*. at 61117.
10. *Id*. at 61118.
11. On September 30, 2020, CMS notified entities selected to participate in the KCC Model that the effective date of the Implementation Period would be delayed from October 1, 2020 until October 15, 2020.
12. 42 U.S.C. 1320a–7b(b)(1) and (2); 42 U.S.C. 1395(a).
13. On September 30, 2020, CMS notified entities selected to participate in the KCC Model that the deadline for submitting the list of participating providers had been pushed from September 30, 2020 to October 6, 2020.