POWERS

POWERS PYLES SUTTER & VERVILLE PC

ATTORNEYS AT LAW

MEMORANDUM

To: **Clients and Friends**

From: **Powers, Pyles Sutter & Verville**

Date: **July 31, 2019**

Subject: **Proposed Rule for End-Stage Renal Disease Treatment Choices Model (ETC)**

On July 18, 2019, the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register a Proposed Rule on Specialty Care Models to Improve Quality of Care and Reduce Expenditures. Comments are due by 5:00 p.m. EST on September 16, 2019.

The Proposed Rule outlines two mandatory payment models that are expected to provide higher quality care at a lower cost. Both proposed models aim to "further the agency's goal of increasing the extent to which CMS initiatives pay for value and outcomes, rather than for volume of services alone." One model – the Radiation Oncology (RO Model) – would employ a mandatory model to "test whether prospective episode-based payments to physician group practices (PGPs), [hospital outpatient departments], and freestanding radiation therapy centers for [radiotherapy] episodes of care would reduce Medicare expenditures while preserving or enhancing the quality of care." The second model – the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model – would similarly utilize a mandatory model in which payment adjustments would be used to incentivize higher rates of home dialysis, kidney transplants, and kidney-pancreas transplants. CMS predicts that the ETC Model would result in net savings of $169 million to the Medicare program.

This memorandum is intended to summarize some of the key provisions of the proposed ETC Model as set forth in the Proposed Rule.

Program Overview

The ETC Model is a test model that seeks to shift payments for ESRD patients from volume-based to value-based by adjusting Medicare payments to selected ESRD Facilities and Managing Clinicians[1] based on the rate of home dialysis and kidney or kidney-pancreas transplants among their Medicare patients with ESRD. CMS hopes that it would encourage "the alignment of financial and other incentives for health care providers." The model would also test whether these incentives affect patients' choices among treatment modalities.

The ETC Model would be implemented over a period of six and a half years, running from January 1, 2020 to June 30, 2026. However, CMS has contemplated (and is accepting comments on)

[1] A Managing Clinician is a "Medicare-enrolled physician or non-physician practitioner who furnishes and bills the MCP for managing one or more adult ESRD beneficiaries."

delaying the implementation date by three months, consequently shifting the end date and other key dates three months later as well. The model would involve a large and geographically diverse array of Medicare providers and suppliers to ensure useful, "evidence-based" data under different conditions. The model would employ two payment adjustments, a Home Dialysis Payment Adjustment (HDPA) and a Performance Payment Adjustment (PPA).

Selection of ETC Participants and Beneficiaries

ETC Participants. ETC Participants would be ESRD Facilities and Managing Clinicians randomly selected on a geographic basis. CMS aims to capture half of ESRD adult beneficiaries by randomly selecting half of the Hospital Referral Regions (HRRs) in the fifty states and the District of Columbia, stratified by region.[2] All ESRD Facilities and Managing Clinicians in a selected geographic area must participate in the model. HRRs that are not selected to participate in the model, or "comparison geographic areas," would be used to develop performance benchmarks and evaluate model impact.

Beneficiaries. ESRD Beneficiaries are those "receiving dialysis or other services for end-stage renal disease, up to and including the month in which he or she receives a kidney or kidney-pancreas transplant." Some ESRD Beneficiaries (and pre-emptive transplant beneficiaries) would be excluded from the ETC Model. A beneficiary would be excluded if he or she is not enrolled in Medicare Part B; is enrolled in Medicare Advantage; is less than eighteen years old during a month; is not living in the United States; is in hospice; has dementia; or is receiving dialysis because of an acute kidney injury (AKI). Further, CMS is inviting comment on whether to exclude based on an additional advanced age threshold and for the housing insecure.

Attribution of Beneficiaries

ESRD Beneficiaries would be attributed to ESRD Facilities and Managing Clinicians on a monthly basis. They would only be attributed to one ESRD Facility and one Managing Clinician for that month.

ESRD Facilities. An ESRD Beneficiary would be attributed to an ESRD Facility if he or she received a plurality of dialysis services (excluding those for AKI) from that ESRD Facility during that month. If an equal amount of services were rendered at multiple ESRD Facilities, the beneficiary would be attributed to the ESRD Facility from which he or she first received services that month.

Managing Clinicians. An ESRD Beneficiary would be attributed to a Managing Clinician if that Managing Clinician submits a monthly capitation payment (MCP) claim "with a claim through date in a given month for certain services furnished" to that ESRD Beneficiary. A "pre-emptive transplant beneficiary" would also be attributed to a Managing Clinician "based on the Managing Clinician with whom the beneficiary had the most claims between the start of the MY [model year]

[2] Because of Maryland's Total Cost of Care Model, all HRRs for which at least 20% of the component zip codes are located in Maryland would be included and not subject to randomization.

and the month in which the beneficiary received the transplant" and would remain an attributed beneficiary from the beginning of the model year through the transplant month.

Payment Structure

The proposal is to provide for two different adjustments to the payments to ESRD facilities under the ESRD PPS and to Managing Clinicians under the Medicare Physician Fee Schedule. These adjustments are as follows:

1. **Home Dialysis Payment Adjustment (HDPA).** The HDPA is "a positive adjustment on certain home dialysis and home dialysis-related claims during the initial three years of the model." The proposed amount is 3% in CY 2020, 2% in CY 2021, and 1% in CY 2022. The Clinician HDPA would adjust the MCP. The Facility HDPA would adjust the Adjusted ESRD PPS per Treatment Base Rate. Such adjustments would not be made for transplants. As the ETC Model progresses, "[t]he magnitude of the HDPA would decrease as the magnitude of the Performance Payment Adjustment (PPA) (see below) increases, to shift from a process-based incentive approach (the HDPA) to an outcomes-based incentive approach (the PPA)."

2. **Performance Payment Adjustment (PPA).** The PPA is a positive or negative adjustment "on dialysis and dialysis-related Medicare payments, for both home and in-center dialysis, based on ESRD facilities' and Managing Clinicians' rates of kidney and kidney-pancreas transplants and home dialysis among attributed beneficiaries during the applicable MY." Adjustments would be determined using Modality Performance Scores (MPS) – which reflect the home dialysis and transplant rates – and would increase in "magnitude" over the duration of the model. Although both ESRD Facilities and Managing Clinicians can receive negative adjustments, ESRD Facilities' negative adjustments would be of a greater magnitude because of their "larger size and ability to bear downside financial risk relative to individual clinicians."

   The Clinician PPA would be an adjustment to the MCP, while the Facility PPA would be made to the ESRD PPS per Treatment Base Rate. PPAs would be made during Performance Payment Adjustment Periods (PPA Periods) on claims "with claim through dates beginning January 1, 2021, and ending June 30, 2026." The PPA Periods would be six months long with the first PPA beginning July 1, 2021. Each PPA would be based on a lagging data from a prior designated Model Year (MY) (e.g., PPA Period July 1, 2021 would use data from MY January 1, 2020 to December 31, 2020). Depending on the Modality Performance Score (MPS) for a particular MY, the Facility PPA will vary. For example, for the first two PPA Periods the variance would be from a positive 5% to a negative 8% depending on the Facility's MPS. The magnitude of the PPA payment adjustments will increase over time. The Facility PPA in the last two PPA Periods would vary from a positive 10% and to a negative 13%. The Managing Clinician PPA tied to the Managing Clinician's MPS would have the same upside adjustments as the Facility PPA. However, the negative adjustments would be slightly less for the Managing Clinician.

Certain low-volume ESRD Facilities and Managing Clinicians would be exempted from PPAs. ESRD Facilities meeting the low-volume threshold exclusion are those with "fewer than [eleven] attributed beneficiary-years during a given MY from the application of the PPA during the corresponding PPA Period." For Managing Clinicians, "the low-volume threshold would be set at the bottom five percent of ETC Participants[3] who are Managing Clinicians in terms of the number of beneficiary-years for which the Managing Clinician billed the MCP during the MY."

PPA Rate Calculations and Scoring

Rate Calculations. The home dialysis rate would be calculated as "the rate of ESRD Beneficiaries attributed to the ETC Participant who dialyzed at home during the relevant MY." The transplant rate would be calculated as "the rate of ESRD Beneficiaries and, if applicable, pre-emptive transplant beneficiaries attributed to the ETC Participant who received kidney or kidney-pancreas transplant during the MY." Beneficiaries over seventy-five years old in a given month, beneficiaries in skilled nursing facilities (SNFs), and beneficiaries in hospice would all be excluded from the transplant rate calculation. The home dialysis rate and the transplant rate would both be risk adjusted and reliability adjusted.

Scoring. An ETC Participant's MPS would be calculated using a formula that includes the "higher of the achievement score or improvement score for the home dialysis rate and the higher of the achievement score or improvement score for the transplant rate." The formula would be weighted so as to give more weight to an ETC Participant's home dialysis rate score.

ETC Participants would receive achievement scores against benchmarks from "historical rates of home dialysis and transplants in comparison geographic areas." Benchmarks would be based on "12 months of data, beginning 18 months before the start of the MY and ending 6 months before the start of the MY." As the model progresses, CMS aims to "increase achievement benchmarks among ETC Participants above the rates observed in comparison geographic areas."

Improvement scores would be "based on historical rates of home dialysis and transplants by the ETC Participant during the benchmark year" by comparing home dialysis and transplant rates against prior MYs.

Notification. CMS intends to notify ETC Participants "of their attributed beneficiaries, MPSs and corresponding PPAs" at least a month before the PPA Period in which the PPAs would be applied.

Review

Limitations on Review. CMS proposes broad preclusions of review. There would be no review – judicial or administrative – for model selection; participant selection or termination; model change

[3] ETC Participants include ETC Facilities and Managing Clinicians participating in the ETC Model.

or termination; or "the elements, parameters, scope, and duration of such Innovation Center models for testing or dissemination." Other limitations also apply.

Targeted Review of MPS. CMS proposes "a policy that would permit ETC Participants to contest errors found in their MPS, but not in the ETC Model home dialysis rate calculation methodology, transplant rate calculation methodology, achievement and improvement benchmarking methodology, or MPS calculation methodology." To request a targeted review, an ETC Participant must submit written notice no more than sixty days after receiving notification of its MPS (or no later than another CMS-specified date). No more than sixty days after receiving the request, CMS would decide whether to conduct a targeted review, either accepting or denying the request or requesting further information that must be supplied within thirty days. If a review is conducted and an error identified, the ETC Participant would be notified within thirty days and the payment would be corrected in the next PPA Period. Any decisions made would be final not reviewable.

Monitoring of ETC Model

CMS would monitor the ETC model to ensure that that it "is implemented safely and appropriately, the quality or experience of care for beneficiaries is not harmed, and adequate patient and program integrity safeguards are in place." It would look for negative consequences of the program, including adverse events. CMS would employ risk adjustment and beneficiary exclusions and review claims data to counteract potential negative incentives to include beneficiaries unsuited for home dialysis. Patient interviews and surveys would also be utilized to identify potential coercion. Two existing ESRD Facility quality measures would be used as part of the monitoring process: the Standardized Mortality Ratio (SMR)[4] and the Standardized Hospitalization Ratio (SHR).[5]

Monitoring includes a number of other activities. For example, ETC Participants and Downstream Participants must participate in CMS requested site visits. At least fifteen days' notice of a site visit would be given when possible, although unannounced site visits may be used "to investigate concerns about the health and safety of beneficiaries or other patients or other program integrity issues." Other monitoring activities include claims, quality measure and medical record audits, documentation requests, interviews with staff and beneficiaries/caregivers and tracking patient complaints and appeals.

Beneficiary Protections

ETC Participants must notify patients that they are participating in the model and must "prominently display informational materials in each of their office or facility locations where beneficiaries receive treatment to notify beneficiaries that the ETC Participant is participating in the ETC model." CMS would supply a template to be used for this purpose.

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[4] The SMR is a "[r]isk-adjusted standardized mortality ratio of the number of observed deaths to the number of expected deaths for patients at the ESRD facility."

[5] The SHR is a "[r]isk-adjusted standardized hospitalization ratio of the number of observed hospitalizations to the number of expected hospitalizations for patients at the ESRD facility."

CMS affirms that "the model would not restrict a beneficiary's freedom to choose an ESRD facility or Managing Clinician, or other provider or supplier" and ensures the provision of "medically necessary services." Patients attributed to ETC Participants cannot opt out, but they maintain the ability to choose where and from whom they receive services. However, this would not restrict ETC Participants from discussing the "benefits of care provided" through that ETC Participant, so long as it otherwise comports with the law and the proposed regulation. CMS also includes provisions to prevent "lemon-dropping"[6] and "cherry-picking"[7] of patients.

Descriptive Model Materials and Activities

CMS would prohibit descriptive model materials and activities[8] that "are materially inaccurate or misleading." CMS may review these materials and activities. Each document must include a disclaimer statement that: "The statements contained in this document do not necessarily reflect the view or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document." Additionally, ETC Participants "must retain copies of all written and electronic descriptive model materials and activities and appropriate records for other descriptive model materials and activities in a manner consistent with" the record retention provision.

Audits and Record Retention

The Proposed Rule states that "[t]he Federal Government…has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model." The Proposed Rule outlines particular documents or evidence to which the government must be granted access. Documents and other evidence must be retained for six years "from the last payment determination…under the Innovation Center or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later."

There would be two exceptions to the six year retention requirement. The first exception would require retention beyond six years given notification of a "special need" to retain the records. The notification must be given a minimum of thirty calendar days prior to "the normal disposition date." The second exception would require extended retention in cases of "termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants." Documents retained as a consequence of ETC Participant fault would be retained for an additional six years "from the date of any resulting final resolution."

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[6] Lemon-dropping is defined as "taking action to avoid treating beneficiaries with chronic conditions…or who are entitled to Medicaid because of disability."

[7] Cherry-picking is defined as "taking any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the model participant's or downstream participant's financial or quality performance."

[8] Descriptive model materials and activities are defined as "general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other materials or activities distributed or conducted by or on behalf of the model participant or its downstream participants when used to educate, notify, or contract beneficiaries regarding the Innovation Center model."

Remedial Action

If an ETC Participant is noncompliant per the provisions of the regulation, CMS may take one or more remedial actions. Remedial actions include, among others: termination of an ETC Participant's agreement with a Downstream Participant relating to the ETC Model; termination of the ETC Participant; and recovery of certain payments made under the model.

Data Rights and Intellectual Property

CMS would protect an ETC Participant's proprietary technology and information, but it would otherwise retain the right to "disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public."

Terminating the Model

CMS may terminate the ETC Model. To do so, it must provide written notice of the reason for termination, along with the effective date of the same. Termination of the ETC Model would not be reviewable through judicial or administrative review.

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If you have any questions, please feel free to contact Jim Jorling at 202-349-4257 or James.Jorling@powerslaw.com, or the Powers attorney with whom you usually work.