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September 3, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: File code CMS-5527-P

Dear Ms. Verma:

The Medicare Payment Advisory Commission welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services proposed rule entitled “Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures,” *Federal Register*, vol. 84, no. 138, pp. 34478–34595 (July 18, 2019). We appreciate your staff’s ongoing efforts to develop and test new payment models, particularly given the many competing demands on the agency’s resources.

In this proposed rule, CMS proposes to implement two new mandatory Medicare payment models: the Radiation Oncology Model and the End-Stage Renal Disease (ESRD) Treatment Choices Model. The goal for these proposed models is to preserve or enhance quality of care while reducing program spending through enhanced financial accountability for model participants.

Proposed Radiation Oncology Model

The Radiation Oncology (RO) Model would include prospective payments for certain radiotherapy (RT) services furnished during a 90-day episode for cancer types that meet certain criteria: They are commonly treated with radiation, make up the majority of all incidence of cancer types, and demonstrate pricing stability (i.e., claims data are sufficiently reliable to calculate accurate prices for episodes). Based on these criteria, the model would include 17 types of cancer, including breast, prostate, lung, cervical, liver, and pancreatic cancer. The model would begin on either January 1 or April 1, 2020, and end on December 31, 2024.

CMS proposes to test the RO Model in randomly selected geographic areas. CMS plans to use core based statistical areas (CBSAs) for the geographic areas. To select the CBSAs for the model, CMS would use a stratified sample design in which CBSAs would be divided into five quintiles based on the total number of RO episodes in each CBSA. CMS would randomly select CBSAs for the participant group and the comparison group from each quintile. Participation in the model would be mandatory for all RT providers located in a CBSA that is selected for the participant group.

The model would include three types of provider participants: physician group practices (which include individual physicians), freestanding radiation therapy centers, and hospital outpatient departments (HOPDs). CMS would split episode payments into two components: (1) the professional component (PC), which covers the RT services provided by a physician and (2) the technical component (TC), which covers the cost of equipment, supplies, and staff related to RT services. CMS would create two separate payments because the professional and technical services of an episode are sometimes furnished by separate providers. Physician group practices would furnish the PC of an episode, HOPDs would furnish the TC, and freestanding centers would furnish the TC or both components (freestanding centers that provide both components would be known as dual participants).

CMS would set a separate payment amount for the PC and TC of each cancer type included in the model. The payment amount would include certain RT services (such as treatment planning, treatment delivery, and treatment management) but exclude non-RT services (such as evaluation and management (E&M) services). Therefore, model participants would not be held accountable for the total cost of all care provided to beneficiaries during the 90-day episode. Beneficiaries would be financially liable for 20 percent coinsurance for the bundled payment amounts.

The model would include various RT modalities, such as 3-dimensional conformal radiotherapy, intensity-modulated radiotherapy, stereotactic radiosurgery, and proton beam therapy (PBT). However, CMS is considering excluding PBT from the model when a beneficiary is participating in a federally-funded, multi-institution, randomized control trial for PBT. The rationale for excluding PBT in these cases would be to enable researchers to gather further evidence of PBT's health benefits compared with other modalities.

CMS proposes to determine the episode payment amount for each component (PC and TC) and cancer type using a national base rate, with adjustments for a trend factor and the case mix, historic experience, and geographic location of each model participant (i.e., a physician group practice, HOPD, or freestanding center). CMS plans to create site-neutral base rates for each component and cancer type based on historic average payments for an episode of care in the HOPD setting using data from 2015 through 2017. The base rate would be the same whether the episode is provided in an HOPD or in a freestanding radiation therapy center, which is normally paid under the physician fee schedule (PFS). CMS states that it plans to use HOPD payment rates instead of PFS rates to set the base rates for two reasons: (1) HOPD rates have been more stable over time, and (2) they have a stronger empirical foundation than PFS rates because they are derived from hospital cost report data.

The base rates would be adjusted for:

- a trend factor—the change in payment rates for the services in the episode between the baseline period (2015–2017) and the performance year (e.g., 2020);
- a case-mix adjustment for each model participant to account for factors beyond the participant's control, such as the patient's cancer type, age, sex, mortality, and use of

chemotherapy (CMS would calculate a single case-mix adjustment for each provider participant that would be applied to all of the episodes attributed to that participant.);

- the participant's historical experience, which measures whether a participant's actual spending for RO episodes is higher or lower than expected spending based on their case mix; and
- the participant's geographic location.

The payment amounts would be reduced based on the following adjustments:

- a discount factor of 5 percent for TC episodes and 4 percent for PC episodes to reduce spending for the Medicare program and beneficiaries;
- an incorrect-payment withhold of 2 percent to recoup potential overpayments for duplicate RT services and incomplete episodes during an annual reconciliation process;
- a quality withhold of 2 percent for PC episodes; and
- a patient-experience withhold of 1 percent for TC episodes (by the 3rd performance year).

After CMS reconciles episode payments for duplicate RT services and incomplete episodes, model participants may receive up to the full 2 percent incorrect-payment withhold or may have to repay additional funds. They would also be able to earn back a portion (up to 100 percent) of their quality and patient experience withholds based on their performance on quality and patient experience measures and reporting of clinical data.

To measure the quality of PC episodes, CMS proposes to adopt four provider-reported process measures: plan of care for pain, screening for depression and follow-up plan, advance care plan, and treatment summary communication (the share of patients who have a treatment summary report in the chart that was communicated to the physician providing continuing care and to the patient within one month of completing treatment). By the 3rd performance year, CMS plans to use a set of patient experience measures based on the Consumer Assessment of Healthcare Providers and Systems[®] Cancer Care Survey for Radiation Therapy to measure the quality of TC episodes.¹ CMS also proposes to require participants to report clinical data such as cancer stage, disease involvement, and treatment intent for five types of cancer to CMS. CMS may use the clinical data to understand the details of care furnished during the episode, support clinical monitoring and evaluation of the model, inform future refinements to the model, and develop new quality measures.

CMS proposes that this model would qualify to be an advanced alternative payment model (A-APM) under the Quality Payment Program, which means that clinicians who participate in the model through an eligible entity and have a sufficient share of revenue coming through the model

¹ CAHPS[®] is a registered trademark of the Agency for Healthcare Research and Quality, a U.S. government agency.

would receive an incentive payment of 5 percent of their fee schedule payments for each year through 2024. CMS states that this model would meet the statutory requirements to be an A-APM: CMS would require model participants to use certified electronic health record technology, would use quality measure performance as a factor in determining payments to participants, and would require participants to bear financial risk for monetary losses of more than a nominal amount because participants would be at risk for the cost of all RT services beyond the episode payment amount.

Comment

The Commission supports the development of alternative approaches to paying for RT services that aim to reduce spending while preserving or improving quality and outcomes. In general, we agree that the proposed RO Model would encourage providers to be more efficient in delivering RT services by holding them accountable for the cost of an episode of care. We encourage CMS to proceed with testing an episode payment model for RT services. However, we have concerns about how CMS would calculate the episode payment rates in this model and how CMS would measure quality. In addition, this model is not consistent with the Commission's principles for A-APMs. Finally, we support CMS's proposal to include PBT in the model.

We have three concerns with how CMS proposes to calculate episode payment rates under this model:

- The use of HOPD payment rates instead of PFS rates to set the base rates would increase payments for freestanding radiation therapy centers and reduce savings for the Medicare program and beneficiaries.
- It is unclear why CMS uses cancer type as a factor in determining the case-mix adjustment for each model participant if there will be separate payment rates for each cancer type.
- The historical-experience adjustment would reward inefficient providers and penalize efficient providers, which would undermine the intent of the model.

CMS proposes to create site-neutral base rates for the TC of each type of cancer by multiplying the volume of each RT service included in the episode by the HOPD payment rate for each service, summed across all RT services in the episode. These base rates would apply whether the TC episode is provided in a HOPD or in a freestanding radiation therapy center, which is normally paid under the PFS. Because HOPD payment rates for the TC of RT services are higher than PFS rates, freestanding centers would receive higher payments under this model than they currently do, even though CMS does not present evidence that current payments for freestanding centers are inadequate. To avoid an unwarranted increase to payment rates for freestanding centers, CMS should pay separate base rates for the TC based on whether it is provided in a HOPD or a freestanding center (the base rate should be based on the payment system in each setting).

CMS proposes to use cancer type as a factor in determining the case-mix adjustment for each provider participant. However, CMS plans to create separate base payment rates for each type of

cancer, which means that the base rates would already account for differences in the cost of RT across different cancer types. Therefore, CMS should either explain why it proposes to include cancer type in the case-mix adjustment, or not make this adjustment.

CMS proposes to use a historical-experience adjustment in which provider participants that are historically *inefficient* (their actual episode spending is higher than expected based on their historic average case mix) would receive *higher* episode payments, while participants whose historical experience is *efficient* (their actual episode spending is lower than expected based on their historic average case mix) would receive *lower* episode payments. Rewarding inefficient providers and penalizing efficient providers would undermine the model's intent, which CMS says is to reduce "program spending through enhanced financial accountability for model participants." Therefore, CMS should not adopt the historical-experience adjustment. Including a case-mix adjustment should be sufficient to adjust the episode payment for factors beyond a provider's control.

CMS proposes that model participants would be able to earn back a portion (up to 100 percent) of their 2 percent quality withhold and 1 percent patient experience withhold based on their performance on four process measures and a set of patient experience measures, as well as the reporting of clinical data. The Commission's position is that Medicare quality programs should include a small set of population-based outcome, patient experience, and value measures. CMS did not propose any outcome measures for this model because they "have determined there are currently no outcome measures available or applicable for the RO Model." However, the Oncology Care Model (OCM), in which providers take accountability for a six-month episode of care surrounding chemotherapy treatment for cancer patients, uses three claims-based outcome measures to determine performance-based payments:

- risk-adjusted proportion of patients with all-cause hospital admissions within the six-month episode,
- risk-adjusted proportion of patients with all-cause emergency department (ED) visits or observation stays that did not result in a hospital admission within the six-month episode, and
- proportion of patients that died who were admitted to hospice for three days or more.²

CMS should consider using similar outcome measures for the RO Model, as both the OCM Model and the RO Model focus on cancer treatment. The use of claims-based outcome measures in the RO Model would enable CMS to hold providers accountable for the quality of their care and allow CMS to evaluate whether prospective episode payments for RT services reduce spending without causing negative outcomes. In addition, claims-based outcome measures, such as readmission rates, do not impose a reporting burden on providers and are part of the Merit-based Incentive Payment System.

² Centers for Medicare & Medicaid Services. Oncology Care Model Other Payer Core Measure Set. <https://innovation.cms.gov/Files/x/ocm-otherpayercoremeasure.pdf>.

CMS proposes that the RO Model would qualify to be an A-APM under the Quality Payment Program because it would meet the statutory requirements to be an A-APM. However, the Commission has developed basic principles for A-APMs that go beyond the statutory requirements, and the RO Model does not meet two of these principles:

- clinicians should receive a 5 percent incentive payment only if the eligible entity in which they participate is successful in controlling cost, improving quality, or both; and
- the eligible entity should be at financial risk for total Part A and Part B spending.³

According to the Commission's first principle, incentive payments should not be awarded for simply participating in an APM entity but should be contingent on quality and spending performance. Under CMS's proposal, however, clinicians who participate in the RO Model through an eligible entity and have a sufficient share of revenue coming through the model would receive an incentive payment, whether or not the entity limits costs per episode or improves quality. The motivation for the Commission's second principle is to help move the fee-for-service (FFS) payment system from volume to value, encourage care coordination, and more broadly reform the delivery system. However, under the proposed model, entities are only responsible for spending on certain RT services within a 90-day episode of care. They are not held accountable for spending on other services provided to beneficiaries in the model, such as E&M visits, tests, ED visits, or hospital admissions. Entities would also have an incentive to reduce the cost per episode while increasing the total number of episodes. In addition, there is not a single entity that would be responsible for episode spending because CMS would make separate episode payments for the TC and PC portions of the episode, unless an entity is a dual participant that provides both the TC and PC portions of an episode. Because the RO Model does not meet these two important Commission principles for A-APMs, we assert that this model should not be considered an A-APM.

CMS proposes to include PBT in the model but is considering excluding it when a beneficiary is participating in a federally-funded, multi-institution, randomized control trial for PBT to enable researchers to gather further evidence of PBT's health benefits compared with other modalities. We support including PBT in a radiation oncology model because Medicare's payment rates for PBT are substantially higher than for other types of external beam radiation therapy.⁴ In addition, the use of PBT has expanded in recent years from pediatric and rare adult cancers to include more common types of cancer, such as prostate and lung cancer, despite a lack of evidence that it offers a clinical advantage over alternative treatments for these types of cancer. Therefore, including PBT in the episode payment would create an incentive to use lower-cost, comparable modalities. If CMS decides to exclude PBT from the model when it is part of a research study, CMS should only do so if the study is a federally-funded, multi-institution, randomized control trial. This requirement would help ensure that studies of PBT produce robust information on how it compares

³ Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC. MedPAC.

⁴ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC. MedPAC.

with other modalities. In addition, limiting this exclusion would allow the model to include at least some beneficiaries who receive PBT.

Proposed ESRD Treatment Choices Model

CMS is seeking comments on its proposal to implement a mandatory payment model—the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model—through the Center for Medicare & Medicaid Innovation. The ETC Model, which would begin January 1, 2020, and end June 30, 2026, would test whether financial incentives result in increasing home dialysis use and kidney transplantation among adult ESRD beneficiaries. The model would adjust certain Medicare payments to ESRD facilities and managing clinicians (who receive a monthly capitated payment (MCP) established in the Part B physician fee schedule for outpatient dialysis-related management services) that are required to participate in the model, through upward or downward payment adjustments based on their home dialysis and kidney transplant rates.

CMS would select participants—ESRD facilities and managing clinicians—for the model according to their location in geographic areas (306 hospital referral regions) that would be randomly selected, stratified by region, so as to account for approximately 50 percent of adult ESRD beneficiaries in all 50 states and the District of Columbia. CMS would apply the following two payment adjustments to the base payment rate of providers (ESRD facilities and managing clinicians) required to participate in the ETC Model:

- The *home dialysis payment adjustment* (HDP) would increase the managing clinician's MCP rate for home dialysis patients and the ESRD facility's base rate for home dialysis treatments under the ESRD prospective payment system (PPS) by 3 percent in 2020, 2 percent in 2021, and 1 percent in 2022.
- The *performance payment adjustment* (PPA) would apply to payments for all dialysis treatments beginning June 30, 2021; could be either positive or negative for a participant but would be net negative across all participants (asymmetric); and would be applied to each participant's base payment rate. The PPA would be determined by comparing each participant's rate of home dialysis and kidney transplant to a benchmark (calculated based on the rates of a control group of home dialysis and kidney transplantation of ESRD facilities and managing clinicians not included in the ETC). For managing clinicians only, the rate of kidney transplant would include both dialysis beneficiaries who receive a transplant as well as beneficiaries with advanced chronic kidney disease (CKD) (and not yet on dialysis) who receive a transplant.

Dialysis facilities and managing clinicians not selected as participants in the ETC would continue to be paid under the ESRD PPS and Part B physician fee schedule, respectively; Medicare would not adjust their payments using the HDP or the PPA.

The PPA proposed by CMS would be based on home dialysis and kidney transplantation rates. CMS proposes to measure the home dialysis rate at the facility and managing clinician level, with

the denominator defined as attributed beneficiary years of total dialysis treatments and the numerator defined as attributed beneficiary years of home dialysis treatments. Beneficiaries would be attributed on a monthly basis to the facility that submitted the most dialysis treatment claims for a beneficiary, and to the managing clinician that submitted the claim for a beneficiary’s monthly dialysis management. CMS proposes to use CMS hierarchical condition category (CMS–HCC) risk scores to account for differences in the propensity to use home dialysis among dialysis beneficiaries. In the first two measurement years, home dialysis rates for facilities and clinicians would be scored from 0 to 2 points in 0.5-point increments based on comparison with a control group where the 30th, 50th, 75th, and 90th percentile values from the control group distribution would define home dialysis rate ranges for each score.⁵

Achievement score scale for home dialysis and transplant rates	Points
Participant rate \geq 90 th percentile rate in comparison group	2
90 th > Participant rate \geq 75 th percentile rate in comparison group	1.5
75 th > Participant rate \geq 50 th percentile rate in comparison group	1.0
50 th > Participant rate \geq 30 th percentile rate in comparison group	0.5
30 th percentile rate in comparison group > Participant rate	0

Note: Proposed scores would be used for measurement years 1 and 2. We interpret Table 13 to be based on mutually exclusive achievement score categories.

Source: CMS proposed rule 2019, Table 13.

CMS proposes to measure the transplant rate at the facility level, with the denominator defined as attributed beneficiary years of total dialysis treatments and the numerator defined as attributed beneficiaries who received a transplant during the measurement year. The transplant rate would also be measured at the managing clinician level but would also include beneficiaries receiving a preemptive (before beginning dialysis) transplant to the numerator and the addition of dialysis treatment years for those beneficiaries to the denominator. The beneficiary attribution and scoring method would be the same as the home dialysis rate measure; however, to account for differences in the likelihood of receiving a transplant, CMS proposes to use the age categories and corresponding risk coefficients based on the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist, a measure that will be included in the ESRD quality improvement program for facilities beginning in payment year 2022.⁶

⁵ CMS proposed that home dialysis scores be weighted double the value of transplant rate scores because participants have less of an influence on transplant rates than home dialysis use.

⁶ CMS defines the percentage of prevalent patients waitlisted (“PPPW”) measure as the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2022-Technical-Specifications-.pdf>). This measure includes patients under the age of 75 and excludes certain patients admitted to a skilled nursing facility or hospice.

CMS would randomly assign the 306 hospital referral regions (HRRs) in the United States into treatment (participating in the ETC Model) and control groups.⁷ CMS believes that random assignment of HRRs to treatment and control group will account for relevant differences in the measurement.

The PPA will have the largest effect on program spending of any ETC Model component. Over the course of the model, CMS estimates that:

- the PPA will reduce Medicare payments to facilities by \$220 million and to managing clinicians by \$8 million; and
- the HDPA will increase Medicare payments to facilities by \$39 million and to managing clinicians by \$4 million.

Overall, there is net negative effect from the PPA and HDPA adjustments; Medicare spending to dialysis facilities and managing clinicians in the mandatory ETC Model will be reduced by \$185 million over the 6.5-year model.

Comment

The Commission applauds the agency's commitment to increasing use of kidney transplantation and home dialysis among ESRD beneficiaries. Kidney transplantation is widely regarded as a better ESRD treatment option than dialysis in terms of patients' clinical and quality-of-life outcomes. Compared with in-center dialysis, home-based dialysis offers ESRD patients greater autonomy, fewer transportation challenges, improved quality of life, and enhanced satisfaction.

However, we have significant methodological concerns such that we believe CMS should not implement the proposed ETC Model. We believe the proposed measurement of home dialysis and kidney transplantation rates in the PPA adjustment lack sufficient validity to serve as the basis for the payment incentives. For both the home dialysis and transplant measures, we have specific concerns about the reliability of the measurement; the comparison-to-control-group benchmarks and scoring method; the risk-adjustment method; and, in certain instances, the alignment of incentives for participants.

The Commission believes that CMS should instead implement an approach similar to CMMI's Comprehensive End-Stage Renal Disease Care (CEC) Model that could: (1) provide a holistic approach to the care of beneficiaries with CKD, who often have multiple comorbidities in addition to kidney disease; and (2) hold both dialysis facilities and managing clinicians jointly accountable for the outcomes (quality, utilization, and financial) of beneficiaries with CKD, including rates of home dialysis and transplantation. Kidney transplant centers, a key participant in the transplant process, should also be considered to participate in such a model.

⁷ Hospital referral regions were developed by the Dartmouth Atlas project. Because of Maryland's unique payment structure, CMS proposes to assign most HRRs that include Maryland to the treatment group.

Concerns with home dialysis measurement

- Home dialysis rates are not uniform geographically, and we are concerned that random assignment of HRRs would not generate equal distributions of home dialysis rates among the participants in each group. In this proposed rule, CMS has not explained whether it would check that the distributions of home dialysis rates in treatment and control HRRs are equivalent after randomization, nor has it described a remedy if it discovered nonequivalent home dialysis distributions in the treatment and control groups.
- The ETC Model may provide mid-sized and large dialysis providers conflicting incentives that undermine the goal of increasing the national home dialysis rate. Mid-sized and large dialysis organizations will likely operate facilities that will be assigned to the treatment group in some HRRs and the control group in other HRRs. The design of the model (i.e., the set of financial incentives) would potentially put these providers in the awkward position of maintaining a status quo level of effort in control HRRs while exerting additional effort to increase home dialysis rates in treatment HRRs. The diverging incentives of treatment and control HRRs could affect organizational decisions such as the opening or closing facilities, the location of home dialysis programs, and a myriad of other decisions about the allocation of organizational resources. Furthermore, the model's incentives may unintentionally result in these organizations waiting until the model terminates to implement best practices organization-wide. Although CMS states its intent to increase treatment group benchmarks in each year, the model incentives do not guarantee that the status quo will be maintained in the control HRRs. CMS does not address the possibility that home dialysis rates may decrease in control HRRs if resources are shifted by dialysis organizations to treatment HRRs. Such a decline in home dialysis rates in the control group would affect the benchmark rates for scoring and could result in CMS rewarding participants in treatment HRRs for maintaining the status quo. These concerns also apply to transplant rate measurement.
- CMS's proposed scoring method does not reflect the distribution of home dialysis rates at facilities. CMS did not provide information about the distribution of home dialysis rates across facilities, but our analysis of 2017 cost reports submitted to CMS by freestanding dialysis facilities shows that roughly 50 percent of freestanding facilities furnished any home dialysis treatments. CMS's proposal to score facilities based on home dialysis rates at the 30th, 50th, 75th and 90th percentile is not operational as there would be no differentiation among the lower three groups (scoring 0, 0.5, or 1 point) because the 30th and 50th percentile rates would be both 0 percent. Furthermore, CMS should publish information about the distribution of home dialysis rates across facilities and, consistent with the Commissions principles for measuring quality in the Medicare program, establish pre-determined targets for scoring measures.⁸

⁸ Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

- Given that home dialysis is used by approximately 11 percent of dialysis patients, some organizations strategically centralize their home dialysis program in one facility in a region to allow the nursing staff and the arrangement of the facility to specialize in the skills and knowledge that are unique to the training and management of home dialysis. Our analysis of 2017 freestanding cost reports showed that about 6 percent of freestanding facilities (approximately 400 facilities) furnished only home treatments and did not furnish any in-center treatments.

Measuring the home dialysis rate at the facility level does not align with this approach to providing home dialysis through centralized facilities. In the ETC Model, not only would home dialysis-only facilities have a home dialysis rate of 100 percent, but other local facilities operated by the same organization are likely to have a 0 percent home dialysis rate, as patients interested in home dialysis are referred to the home dialysis-only facility in the region. It is likely that the centralization strategy also exists in a less distinct form in other regions, where organizations may not have a home dialysis-only facility, but limit the facilities in a region that offer home dialysis as part of a specialization strategy.

- CMS-HCC risk scores are not highly correlated with the propensity to use home dialysis among beneficiaries and should not be used to risk adjust the home dialysis measure. Risk scores are a standardized unit of expected spending that use demographic characteristics and diagnoses from the prior year to estimate expected Medicare spending the next year. Although total Medicare spending is sometimes used as a proxy for relative health status, risk scores are not a good proxy for propensity to use home dialysis as they do not correlate with many of the factors identified in literature as indicative of increased home dialysis use.⁹ Risk-score coefficients are not calibrated based on propensity to use home dialysis; they are calibrated for Medicare spending. For example, a beneficiary with a risk score of 2.0 is expected to have spending twice that of a beneficiary with risk score of 1.0, but the beneficiary with 2.0 risk score is not expected to be half as likely to use home dialysis (assuming an inverse relationship between risk score and home dialysis propensity) compared with the beneficiary with a risk score of 1.0. Furthermore, CMS notes that the appropriate risk scores for application in the measurement year would not be available and proposes to apply risk scores estimated for use in the prior year instead. Using prior year risk scores further diminishes any relationship between the risk scores and propensity to use home dialysis.
- CMS has not explicitly addressed the effect of the current shortage of peritoneal dialysis solutions on measuring home dialysis rates. According to the Food and Drug Administration, peritoneal dialysis solutions are currently in shortage. The supply shortage resulted from the product's leading manufacturer experiencing increased PD demand and

⁹ Factors affecting use of home dialysis include: clinical factors (e.g., patients' other health problems and prior nephrology care) and nonclinical factors (e.g., patients' social circumstances, nephrologist's training and preference, dialysis facility's staff experience). In addition, since 2014, manufacturers have not produced enough dialysate, the solution used in peritoneal dialysis, to meet demand, which has limited recent growth in the use of peritoneal dialysis (http://medpac.gov/docs/default-source/reports/mar18_medpac_ch6_sec.pdf?sfvrsn=0).

limited manufacturing capacity.¹⁰ Because of the shortage, beginning in August 2014, the manufacturer gave each dialysis provider an allocation for how many new patients could be started on peritoneal dialysis based on the provider's history of growth during the first six months of 2014.¹¹ The shortage might affect a given facility's use of home dialysis.¹² Although the agency states that it "*would be examining the extent of any unintended consequences, including...fluctuations in machine and supplies markets...*", it does not explicitly address how it would determine whether the shortage is affecting a given provider's use of home dialysis and the potential effect of such a shortage on the stability of home dialysis rates. For example, the model might create an incentive to divert supplies in shortage to the treatment HRRs.

- We are concerned that the ETC does not formally measure beneficiary experience. According to CMS, it considered including the in-center hemodialysis CAHPS survey to monitor beneficiary perceptions of changes in quality of care as a result of the ETC Model but did not do so because this survey does not include home dialysis beneficiaries. The agency states that in its monitoring activities, it may include interviews with beneficiaries and their caregivers. Given the ETC Model's potential effect on beneficiaries' care, we urge CMS to implement a more formal approach to assess beneficiaries' experiences, such as developing a home dialysis CAHPS instrument. (The agency is using CAHPS instruments to measure beneficiary experience in the proposed radiation model.) Assessing patient experience is a key component in the Commission's principles for measuring quality.¹³ These concerns also apply to monitoring the experience of beneficiaries undergoing a transplant.

Concerns with transplant rate measurement

- Measuring the transplant rate at the facility level is not likely to produce reliable estimates and may not allow for an operational scoring method for the ETC. CMS did not provide any information about the distribution of facility-level transplant rates, but we are skeptical that the measure is sensitive to a facility's effort to increase transplant rates. CMS should provide transplant rates by facility (and managing clinician), including numerator and denominator values. Our analyses show that about 10,100 transplants were provided to Medicare beneficiaries in 2017. Dividing these transplants across 7,097 eligible dialysis facilities shows an average transplant rate of less than 1.5 transplants per facility. Given that Medicare dialysis patients are somewhat concentrated in larger facilities (about 64 percent of dialysis treatments were provided

¹⁰ Baxter. 2014. Letter from Richard Marritt, Region Head and General Manager, US and Canada. July 28.

¹¹ Seaborg, E. 2015. Peritoneal dialysis fluid shortage disrupted growth of popular therapy. *Kidney News*, March.

¹² Beginning in 2014, this shortage may have affected the growth in home dialysis among Medicare beneficiaries. Between 2014 and 2017, the total number of home dialysis beneficiaries increased by 3 percent per year; by contrast, between 2012 and 2014, the total number of home dialysis beneficiaries increased by 7 percent per year.

¹³ Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

in the largest 40 percent of facilities),¹⁴ we think most facilities would have 0 or 1 transplants among their attributed population. Given the lack of variation in the numerator, we note that (1) a single transplant carries significant weight on the transplant rate for any facility, yet the likelihood of transplantation is affected by a multitude of factors outside of a facility's control,¹⁵ and (2) differences in the transplant rate would mostly be driven by the denominator (i.e., the ETC would estimate 1 transplant out of 20 attributed patients [$1/20 = 0.05$] to be twice as good as 1 transplant out of 40 attributed patients [$1/40 = 0.025$]). Because of these factors, we do not believe facility transplant rates provide a robust basis for evaluating a facility's efforts to increase the number of transplants. The transplant rate calculated for individual facilities would capture mostly noise rather than signal.

- Similarly, measuring the transplant rate at the managing clinician level is also not likely to produce robust estimates. For managing clinicians, more transplants would be attributed to participants, as the ETC Model would attribute both transplants for Medicare beneficiaries (10,100 in 2017) and preemptive transplants (i.e., transplants that occur before the beneficiary requires dialysis) to managing clinicians. However, with about 20,000 kidney transplants provided in the U.S. in 2016 (not all of which would be attributed to managing clinicians participating in the model) and 7,283 eligible managing clinicians, the distribution of transplants per managing clinician would be similar to the facility-level measure.

CMS should use a broader approach to care for beneficiaries with advanced CKD

Overall, the Commission believes that the ETC Model, while laudable in its goal of increasing home dialysis use and kidney transplantation among ESRD beneficiaries, is too narrowly focused and does not promote holistic care for the multiple chronic and acute conditions that ESRD beneficiaries face. The Commission believes that CMS should implement a broader approach under a shared savings program, which would hold both dialysis facilities and managing clinicians jointly accountable for all the care furnished to their patients with advanced CKD. We have previously said that a shared savings program for dialysis facilities and managing clinicians, if structured properly, could present an opportunity to transform the FFS delivery system, improve care management and coordination, and reward providers who are doing their part to control costs and improve quality. By contrast, the narrow scope of the proposed ETC Model—focusing on increasing only home dialysis use and kidney transplantation—does not address some of the undesirable incentives inherent in FFS payment (such as the lack of collaboration among health care providers to coordinate a patient's care.)

¹⁴ Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

¹⁵ Factors that affect access to kidney transplantation besides donation rates include the clinical allocation process; patient's health literacy, clinical characteristics, and preferences; the availability of education for patients; clinical referral for transplant evaluation at a transplant center; and transplant center policies.

A broader approach under a shared savings program that would hold both dialysis facilities and managing clinicians accountable for all the care furnished to their patients with advanced CKD could incentivize home dialysis use and kidney transplantation by:

- holding providers accountable for the service utilization, financial, and quality outcomes of beneficiaries following kidney transplantation;
- holding providers accountable for the service utilization, financial, and quality outcomes of beneficiaries with advanced chronic kidney disease (e.g., CKD stage 3B and CKD stage 4); and/or
- paying a bonus (e.g., through shared Medicare savings) for beneficiaries who are successfully maintained on home dialysis and kidney transplant.

The results of the CMMI's CEC Model should inform CMS's efforts to improve care of ESRD beneficiaries. Under the CEC Model, ESRD Seamless Care Organizations—which are accountable care organization-like entities specific to the dialysis population that consist of at least one dialysis facility and one nephrologist—are held accountable for the clinical and financial (Part A and Part B) outcomes of prospectively matched dialysis beneficiaries. The CEC Model does not include beneficiaries with advanced CKD and beneficiaries who received a kidney transplant.

The first performance year (2015–2016) of the CEC Model showed promising results, with lower total spending and improvements in utilization and quality of care. For example, the CEC Model significantly reduced total Part A and Part B spending, rates of hospitalization and office visits, and ESRD complications (e.g., volume depletion, hyperpotassemia, fluid overload, heart failure, and pulmonary edema).¹⁶ During the first performance year, the CEC Model did not significantly change (increase or decrease) rates of home dialysis or kidney transplantation. CMS has not yet released the performance results of the CEC Model for performance years two (2017) and three (2018). The Commission has long supported two-sided risk ACOs with prospective assignment, such as the CEC, because they provide stronger incentives for providers, protect the Medicare trust funds, and make it possible to provide regulatory relief—and thus allow for more innovative care delivery models.

Under a broader model, CMS should consider including transplant centers, a key Medicare provider not included in the ETC. While ESRD facilities and managing clinicians together are responsible for educating beneficiaries about their renal management choices and referring beneficiaries for transplantation, transplant centers are responsible for determining which patients are placed on the kidney wait list and which organs are transplanted.¹⁷ In the proposed rule, CMS

¹⁶ Marrufo, G., B. Negrusa, D. Ullman, et al. 2017. *Comprehensive End-Stage Renal Disease Care (CEC) Model: Performance Year 1 annual evaluation report*. Report prepared by the Lewin Group for the Centers for Medicare & Medicaid Services. Baltimore, MD: CMS.

¹⁷ Regarding the role of transplant centers, UNOS states that: “Each transplant program makes its own decision about whether to accept someone for a transplant. The transplant team at each program has its own standards for accepting candidates. Each team may view the same facts and information different ways and make different decisions about listing a person for a transplant.” See <https://unos.org/transplant/frequently-asked-questions/>.

acknowledges that, compared to improvements in home dialysis use, ETC participants may have more difficulty in improving rates of kidney transplantation due to the limited supply of organs and the number of other providers and suppliers that are part of the transplant process but are not included as participants in the ETC Model. A broader model that includes organ transplant hospitals would better align incentives to promote increased rates of transplantation, reduce rates of organ discard, promote living donation, and promote preemptive transplantation.¹⁸

CMS has also released two other kidney models—the Kidney Care First (KCF) Model and Comprehensive Kidney Care Contracting (CKCC) Models—that are broader than the ETC Model in that they include beneficiaries with advanced CKD and beneficiaries who have received a kidney transplant, as well as dialysis beneficiaries (similar to the Commission’s approach suggested above). Unlike the ETC, both models are voluntary. The KCF Model (with one-sided payment risk) requires the participation of nephrologists or nephrology practices while the CKCC Models (with either one-sided or two-sided payment risk) require that nephrologists or nephrology practices and transplant providers participate. Notably, the potential effectiveness of these models is limited by not requiring the participation of dialysis facilities, who are, together with managing clinicians, partners in caring for all ESRD beneficiaries on dialysis and (for some dialysis facilities) beneficiaries with advanced CKD.

Finally, CMS could consider implementing a nationwide quality improvement initiative, a complementary strategy that would focus on increasing rates of home dialysis and kidney transplantation by prioritizing proactive education nationwide among all Medicare beneficiaries with advanced CKD and kidney providers. Such an initiative has the potential to improve care among FFS beneficiaries as well as those enrolled in Medicare Advantage. In 2004, the agency implemented “Fistula First,” a quality improvement project conducted by all 18 ESRD networks that collaborated with major stakeholders, including dialysis providers, primary care physicians, nephrologists, vascular access surgeons, interventional radiologists/nephrologists, professional societies, and patient advocacy groups, to promote the use of arteriovenous fistulas in all suitable hemodialysis patients.¹⁹ This initiative has contributed to the increasing use of AV fistulas in hemodialysis patients between 2004 and 2017.²⁰

In summary, we find that although the ETC Model’s goals of improving rates of kidney transplantation and home dialysis are commendable, CMS should instead implement a broader approach using the ESCO as a model that would hold both dialysis facilities and managing clinicians accountable for all care furnished to beneficiaries with advanced CKD.

¹⁸ Hippen, B. E., and F. W. Maddux. 2018. Integrating kidney transplantation into value-based care for people with renal failure. *American Journal of Transplantation* 18, no. 1: 43–52.

¹⁹ In its announcement of the quality initiative, the agency said that “Fistula First” aims at having fistulas placed in at least half of new dialysis patients with a long-range goal of maintaining fistulas in 40 percent of eligible patients who remain on dialysis (<https://www.cms.gov/newsroom/press-releases/cms-launches-fistula-first-initiative-improve-care-and-quality-life-hemodialysis-patients>). Over time, the quality initiative has focused to reducing use of central venous catheters—“Fistula First Cather Last.”

²⁰ United States Renal Data System, National Institute of Diabetes and Digestive and Kidney Diseases. 2018. *USRDS 2018 annual data report*. Bethesda, MD: NIDDK.

Seema Verma
Administrator
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MedPAC appreciates the opportunity to comment on this proposed rule. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, MedPAC's Executive Director at (202) 220-3700.

Sincerely,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." The signature is written in a cursive, flowing style.

Francis J. Crosson, M.D.
Chairman