September 16, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services

Re: CMS-5527-P. Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures

Dear Administrator Verma:

On behalf of the Premier healthcare alliance serving more than 4,000 U.S. hospitals and health systems and approximately 175,000 other providers and organizations to transform healthcare, we appreciate the opportunity to comment on the Radiation Oncology and End-stage Renal Disease (ESRD) Treatment Choices models. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Premier has the richest industry integrated intelligence platform, which houses quality, safety, operational, supply chain and financial information on approximately 45 percent of patients seen in hospitals across the nation. Combined with this acute care data is ambulatory data that informs providers performance on patients in and out of the hospital. Premier also runs one the largest population health collaboratives in the country, the Population Health Management Collaborative, with more than 500 participating hospitals, in addition to an extensive Bundled Payment Collaborative with more than 200 participating facilities. Our comments primarily reflect the concerns of our hospitals and health systems, along with their employed and aligned independent physicians.

RADIATION ONCOLOGY MODEL

Mandatory Model

CMS states that included radiation therapy (RT) providers and suppliers practicing within selected Core-Based Statistical Areas (CBSAs) will be required to participate in the model. The model will test capitated bundled payments for radiation therapy services for providers and facilities. CMS indicates that a mandatory, broad-based randomly selected sample is necessary to create a robust data set for evaluation of the prospective payment approach. Premier understands the need for CMS to ensure a critical mass and representative participation in the model. However, **Premier opposes mandatory participation in models, as providers should be able to select participation based on their mission, abilities and market realities.**

CMS also indicated that actuarial estimates showed hospital outpatient departments (HOPDs) and freestanding radiation therapy centers (FRTCs) with higher costs would be unlikely to voluntarily participate in the model. CMS indicates that providers would likely fare better under the current payment system than under the model. The payment structure for the RO model relies heavily on payment cuts and withholds and lacks an incentive structure outside of potential qualification for bonuses under the Quality Payment Program. Rather than mandating participation, CMS should attempt to implement changes to reward performance and make the model attractive to potential participants. **Premier recommends that CMS avoid creating models that do not provide meaningful incentives for high-performing participants and primarily serve as a payment reduction.** The model constitutes a significant change in direction from previous alternative payment models (APMs) that provide financial incentives for performance and/or funding for practice transformation. The goal of APMs should be to fundamentally change care delivery and improve population health, rather than seeking opportunities to leverage market dynamics to reduce costs.

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Model Performance Period

CMS proposes to test the RO model for five performance years, January 2020 through December 2024. CMS also notes consideration of an alternate model start date of April 1, 2020 that would create a nine-month performance year (PY) 1 with no impact to subsequent PYs. Given the timing of the proposed rule, CMS will be unable to release a final rule before the fourth quarter of 2019. Further, CMS will not indicate the CBSAs that will be included in the model until the final rule. Accordingly, selected participants will have no time to prepare for the model. Moreover, CMS acknowledges that additional time beyond January 2020 may be necessarily to finalize the model and begin operations.

The RO model will constitute a substantial modification to payment for participants, as well as introduce new needs for financial and quality performance monitoring. Given these operational challenges, **CMS should start the model no sooner than nine months after the publishing of the final rule OR the list of included regions, whichever is later.** Prior Center for Medicare & Medicaid Innovation (CMMI) mandatory models that have been implement, such as the Comprehensive Care for Joint Replacement (CJR) model, have included a listing of included mandatory regions in the proposed rule. This allows public comment on the suitability of the geographies selected and providers to begin planning for potential inclusion in the model. **We encourage CMS to accept public comment on the list of included regions.**

Additionally, to support practice transformation and ensure that providers can act upon data, **CMS should include a performance year 0 (PY0) to allow providers to understand previous performance and operationalize the model**. During a PY0, participants could submit no-pay claims for the episode while continuing normal billing. This approach would allow CMS to address model episode costs discussed below and allow participants to change workflows to align with the model, utilize performance data from CMS to identify areas for transformation, and receive additional education from CMS on model parameters and meeting objectives. A PY0 would provide further benefit by allowing providers and vendors additional time to operationalize data collection and reporting requirements, as discussed below.

RO Model Episodes

Consideration of Multiple Treatment Sites and Modalities

CMS outlines the 90-day structure of a RT bundle for included modalities in the rule. An episode will be initiated by an initial RT treatment planning service, then followed by at least one technical RO service within 28 days. Providers and facilities would each receive a defined bundled payment based on primary cancer type. CMS does not address situations where an included beneficiary may need to receive radiation therapy at multiple treatment sites for secondary malignancies. For example, an episode may be initiated through treatment for breast cancer, but then a secondary brain metastasis may require radiation therapy. During a Medicare Learning Network call on the proposed rule, CMS indicated there would not be additional payment if there is need for multiple treatment sites or modalities. Failure to provide reimbursement for clinically necessary treatments may create financial incentives to delay care until after a RO bundle has completed. **CMS must adjust the payment structure to account for multiple treatment sites and secondary malignancies.** This can be achieved through clinical risk adjustment or creating add-on payments for multiple treatment sites.

CMS indicates that given the goals and the payment design of the RO model, all treatment modalities should be treated the same. However, given the six-year duration of the model, there is a high likelihood of innovation in treatment and best clinical practices. In the Oncology Care model, CMS has updated payment calculations to compensate for selected cases where changes in best clinical practices have adversely impacted financial performance under the model. **Premier recommends that CMS establish an add-on payment to systemically account for new approved technologies and advances in care.**

Low-volume Procedures

The proposed rule discusses low-volume modalities and exceptions for selected services. **Premier supports CMS's inclusion of certain low-volume excluded modalities, such as brachytherapy surgical procedures that are clinically supported and cost-effective**. The use of brachytherapy is clinically supported for procedures such as

prostate feed implants and may become a preferred practice of care for participants in the model given the relatively lower expense of the procedure.

Pricing Methodology

Payment Discounts and Withholds

CMS proposes a 5 percent discount for the technical component, and a 4 percent discount for the professional component. This discount is followed by the application of withholds for incorrect payment, patient experience of care and quality performance. This corresponds to an 8 percent reduction in initial payment, with the opportunity to earn back four percent on the professional component and 3 percent on the technical component.

Premier acknowledges that at least eight 8 percent of payments subject to discount/withhold are required to meet the Advanced APM nominal risk standard based on revenue. **However, Premier is concerned that this model is simply a payment cut, rather than as an opportunity to create incentives that reward high-value, low-cost care.** A mandatory 8 percent payment reduction paired with additional reporting and administrative burden represents a substantial of revenue for the providers selected to participate. Premier strongly recommends that CMS redesign the structure of the model to incorporate positive payment incentives, rather than a downside-only model.

Most importantly, **CMS should create a graduated glide path to risk for the RO model,** similar to the approach used in the Medicare Shared Savings Program (MSSP) Pathways to Success model. This would allow providers who are not yet prepared to accept the high nominal risk standard to meet the Advanced APM requirements to gain experience in the model before incurring significant financial risk. Providers who are prepared for significant risk could accelerate to a track with the full 8 percent at risk. CMS could also consider other approaches for incenting care changes. For example, CMS could use a smaller payment withhold to create a value-based incentive program for RO. This would allow high performers the opportunity to receive increased payment that can be reinvested into their care processes. **At a minimum, CMS should reduce the required discount factor and increase the withhold amount that can be earned back.** This would allow the model to continue to meet the AAPM criteria while providing more opportunity for participants to reduce their payment cut.

Data for Case-mix Adjustments

Premier supports CMS' proposal to use a three-year period of episodic payments in order to determine predicted payments. However, Premier recommends that CMS utilize more recent data than 2015-2017, pending availability. A delay in the model start date would also permit CMS to utilize more recent data to predict payments. Premier also recommends using more recent data to determine if providers exceed the 60-episode threshold to become eligible for participant-specific payment amount rather than the trended national base rates.

Professional and Technical Billing and Payment

Participants in the model will be required to bill a RO model-specific Healthcare Common Procedure Coding System (HCPCS) code for the model, with a modifier to indicate the initiation and the conclusion of a RO episode. In addition to the RO-specific HCPCS code and modifier claims bill, CMS proposes that RO participants will be required to submit no-pay encounter data. However, CMS does not detail the process for billing and payment. **Operational details are foundational for potential participants to understand how a model will be implemented, the potential cost of implementing mandatory changes and to start planning for changes in clinical and administrative workflows**. The proposed model requirements constitute a significant increase in effort and administrative expense related to model-specific billing requirements. In a subsequent Medicare Learning Network webinar on the proposed rule, CMS indicates there will be a follow-on webinar devoted to billing questions but there has not yet been notice or listing of future educational sessions. Whenever possible, CMS should ensure such details are available when a model is announced. **Premier requests that CMS have detailed billing and coordination information available when models are announced.** The current lack of information supports an additional delay in the implementation of the RO model.

Beneficiary Coinsurance

CMS proposes that the 20 percent coinsurance amount for radiation oncology services under Medicare FFS continue in the model. CMS notes that, because reimbursement will occur in two installments and will cover multiple RT services, individual coinsurance payments are likely to exceed amounts paid on a per visit basis. For patients without a secondary insurer, CMS recommends that the participant create a payment plan for the beneficiary. However, CMS does not provide guidance or direction on creating a payment plan for beneficiaries. Further, CMS does not include discussion of the model impacts benefit coordination with secondary payers under the model**. Premier encourages CMS to provide enhanced support services and guidance on beneficiary coinsurance and coordination with secondary payers.**

Quality Measures

CMS proposes to adopt four quality measures and collect the CAHPS® Cancer Care Radiation Therapy Survey for the RO Model. The four quality measures would be applicable to providers and operate as pay-for-performance measures starting in PY1. CMS notes that there are no applicable outcome measures for the RO population. **Premier encourages CMS to develop appropriate outcomes measures prior to developing an APM.**

The CAHPs survey would apply to facilities and begin as pay-for-reporting in PYs 1 and 2, before transitioning to pay-for-performance in PY3. CMS believes all the proposed measures would be appropriate for RT services spanning a 90-day episode period, are applicable to a full range of cancer types, and can be used to accurately measure change or improvements in the quality of RT services. Further, CMS plans to wait until PY3 to incorporate the CAHPS survey in order to establish a baseline of performance for measurement. Premier is concerned about the inclusion of the CAHPS survey in the model. CMS should first pilot using the CAHPS survey for this population.

RO Model as an Advanced APM and a MIPS APM

CMS anticipates that the proposed RO Model would meet the criteria necessary for an Advanced APM and a Merit-based Incentive Payment System (MIPS) APM in the Quality Payment Program (QPP). The RO participant, specifically either a Dual participant or a Professional participant, would be the APM Entity, under its proposal. **As noted above in our comments on Pricing Methodology, Premier encourages CMS to redesign the model payment to allow for two-sided risk**. Further, not all participating providers are currently prepared to meet the standards to be classified as an Advanced APM and may not have previous experience in a risk-based model. **Premier recommends that CMS create a graduated glide path to risk for the RO model.**

Reconciliation

CMS states that reconciliation of payments, including paybacks of payment withholds, will occur in August following the performance year. This timeline constitutes a substantial delay for returning payment withholds, especially considering the magnitude of payment reductions in the RO model. **Premier recommends that CMS institute an initial reconciliation to occur immediately after the performance year to minimize interruption to participant finances and potential limitations on patient access to care.** For the RO model, we recommend that CMS provide an initial reconciliation based on claims available at the end of the performance period with a subsequent final reconciliation after claims run out has completed.

Data Sharing

CMS explains in the proposed rule that the agency may require an annual mandatory survey in which CMS will request additional operational information, such as the cost of providing care, frequency of equipment use, EHR vendors and accreditation status. CMS notes that in setting the relative value units (RVUs) for services, the agency relies heavily on voluntary submission of pricing information for supplies and equipment with limited means to validate the accuracy of the submitted information. As a result, it is difficult to establish the cost of expensive capital equipment, such as a linear

accelerator, in order to determine RVUs for physicians' services that use such equipment. CMS also requests the average number of hours that radiation therapy is used per day.

These data elements do not have a direct relation to the model and CMS has not provided sufficient information on the intended use(s) of the data and whether the information will be aggregated and blinded. Two of the data elements proposed, the cost of specific capital equipment purchases and number of hours a radiation machine is used daily, could include potentially proprietary or competitive information that would at a minimum require a review by a participant's counsel to ensure the data can be legally disclosed. Furthermore, CMS proposes to require these additional data collection requirements from providers for which they are 1) already reducing payment and 2) imposing additional administrative costs under the mandatory model, while non-participating providers would not incur these costs**. Premier requests that CMS limit data to information needed to evaluate the model.** CMS should specify the purpose of collecting the proposed data elements, the intended use for the data, whether the data collected will be aggregated and blinded, and evaluate the cost to participants of providing the requested information. Further, CMS should refrain from collecting potentially proprietary information from providers in the model.

Evaluation

CMS proposes to evaluate the model by evaluating utilization, expenditures, patient experience of care, design and implementation issues, unintended consequences, and overlaps with other initiatives. Given the extent of payment discount and withholds proposed, **Premier recommends evaluation of the model's impact on participating providers and patient access to care**.

Potential Overlap with Other Models

CMS notes that the RO model may create overlap with other Innovation Center models. CMS does not envision that the episode payments made under the RO Model will need to be adjusted to reflect payments made under CMMI initiatives or the MSSP. CMS states that if such adjustments are necessary, it would propose overlap policies for the RO Model through notice and comment rulemaking. **Premier agrees with CMS' proposed approach of requiring appropriate notice and comment period for changes in overlap policies with other CMMI models**.

CMS indicates in the proposed rule that an amendment to the Bunded Payments for Care Improvement (BPCI) Advanced participation agreement may be necessary to account for RO Model overlap in that model's reconciliation calculations. However, CMS should refrain from mandating changes to legally binding participation agreements without a public comment process. Continuing modifications to participation agreements undermines participants' ability to account for risk in the BPCI Advanced program. **Premier recommends that potential RO model overlap with the BPCI Advanced be addressed through a notice and public comment process,** rather than through a mandatory amendment to BPCI Advanced participant agreements.

Hardship Exemption

CMS is not proposing and does not believe that a hardship exemption for RO participants under the RO Model is necessary, since the model's pricing methodology gives significant weight to historical experience in determining the amounts for participant-specific professional episode payments and participant-specific technical episode payments. However, hardship exemptions for extreme and uncontrollable circumstances have recently been implemented in other APMs, including the MSSP and the Comprehensive Care for Joint Replacement model, as well as the Quality Reporting Program. Natural disasters, such as hurricanes, wildfires, and earthquakes, pose a risk of beneficiary displacement and/or loss of participant operational capacity. **Premier believes a hardship exemption is needed for extreme and uncontrollable circumstances.** When the EUC is triggered, Premier recommends that CMS immediately end and reconcile affected episodes.

END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

Implementation Basics

CMS proposes the End-stage Renal Disease (ESRD) Treatment Choices (ETC) to run five years, January 2020 through December 2026. CMS anticipates that the model will incentivize increased utilization of home dialysis and renal transplantation. CMS also notes consideration of an alternate model start date of April 1, 2020. The alternate start date would not alter the length of any measurement years but would delay the start and end date of each measurement year (MY) by three months. **Premier strongly recommends that CMS delay the ETC model start date to no earlier than April 1, 2020 and preferably until July 1, 2020.** Providers need adequate time to prepare for the model, implementing new care processes and technology to monitor performance in the model. CMS has not yet indicated the Hospital Referral Regions (HRRs) that will be included in the model and does not anticipate releasing a list of included regions until the final rule; this will leave providers in selected time with less than two months to prepare for the start of the model. Further, CMS acknowledges that additional time beyond January 2020 may be necessarily to finalize the model and begin operations. It is imperative that CMS provide full information prior to the start of the model and avoid releasing additional details through subregulatory guidance. **Accordingly, CMS should not start the model until full model details, including implementation guidance, is available.**

Mandatory Model

CMS states that included clinicians and facilities practicing within selected Hospital Referral Regions (HRRs) will be required to participate in the model. CMS indicates that a mandatory, broad-based randomly selected sample is necessary to create a robust data set for evaluation. Premier understands the need for CMS to ensure a critical mass and representative participation in the model. However, **Premier opposes mandatory participation in models, as providers should be able to select participation based on their mission, abilities and market realities.**

If it is necessary to require mandatory participation in a model, Premier recommends first testing the model on a voluntary basis. However, the ETC model does incorporate key elements that Premier believes are necessary if a model is mandated, that is, beginning the mandatory models with an upside-only adjustment prior to the introduction and scaling of two-sided risk.

Home Dialysis Payment Adjustment

In the first three years of the model, CMS proposes to make a positive payment adjustment on claims submitted by all facility and clinician ETC participants for home dialysis and related services. The applicable adjustment percentage would apply to the 1) clinician monthly capitated payment (MCP); and 2) the facility Adjusted ESRD PPS per Treatment Base Rate. **Premier applauds CMS for incenting care changes with a positive payment adjustment.** The enhanced payment will support clinicians in providing additional beneficiary communication and monitoring required of home dialysis. **Moreover, we firmly believe that any mandatory model should begin as upside-only.**

The positive adjustment under the HDPA would decline annually (3 percent in 2020, 2 percent in 2021, and 1 percent in 2022). The payment bonus will apply only to patients receiving home dialysis. The transition to home dialysis will require extensive practice transformation, along with patient and provider education. **Premier strongly recommends that CMS increase the magnitude and extend the duration of the HDPA bonus to better incent uptake of home dialysis.**

CMS proposes to apply the facility HDPA to the Adjusted ESRD PPS per Treatment Base Rate for services furnished at or through ESRD facilities to a home dialysis beneficiary. While CMS acknowledges and proposes flexibility for the Kidney Disease Education benefit under the model elsewhere in the proposed rule, this education focuses on potential treatment options, the management of comorbidities, and other selected topics; additional patient education and training specific to home dialysis will be necessary. Within the current facility payment for ESRD care, the Training Add-on Payment provides reimbursement to train beneficiaries regarding home or self-administered dialysis. This training payment directly supports the goal of promoting home dialysis and could be enhanced to advance the goals of the ETC model. **Premier recommends that CMS base the facility HDPA to both the Training Add On payment in addition to the Adjusted ESRD PPS per Treatment Base Rate.**

CMS proposes to apply the clinician HDPA to the amount otherwise paid under Part B for MCP claims when claim lines for ESRD beneficiaries age 18 or older who receive home-dialysis services during the entire month of the claim (CPT codes 90965 or 90966). CMS considered applying the HDPA to all claims billed by the managing clinician to an ESRD beneficiary (not just to dialysis management services) before deciding on the proposed approach. **Premier concurs that the clinician adjustment should be based on the dialysis management amount rather than all services provided by a managing clinician to an ESRD beneficiary**. Expanding the adjustment to all services could introduce unintended incentives to increase utilization.

Application of HDPA When Medicare is the Secondary Payer

CMS proposes to apply the HDPA when Medicare is the secondary payer for a beneficiary. CMS proposes application of the HDPA for these claims to encourage the selection of home dialysis during the initial transition period onto treatment. **Premier supports CMS's proposal to continue to apply the HDPA adjustment apply when Medicare is the secondary payer.**

Performance Payment Adjustment

CMS proposes the Performance Payment Adjustment (PPA) to adjust payment based on home dialysis and transplant rates. Performance measurement to determine PPA adjustments would begin with the model's inception but the adjustments would not be applied until July 2021 (year 2). The PPA would apply to both: 1) the MCP; and 2) the Adjusted ESRD PPS per Treatment Base Rate. As proposed, the PPA may be positive or negative with the magnitude of the adjustment would increasing over the duration of the ETC model.

Performance Measurement

CMS proposes to separately assess the home dialysis and transplant rates for each ETC participant's attributed population for each 12-month measurement year using Medicare claims and administrative data plus data from the Scientific Registry of Transplant Recipients.

Home Dialysis Rate

The facility and clinician home dialysis rate assesses the proportion of home dialysis treatment beneficiary years by total dialysis treatment beneficiary years. Premier is concerned that the home dialysis rate does not incorporate important variations that are likely to impact performance under the model. Home dialysis, while appropriate and preferable for many beneficiaries, is not clinically appropriate to initiate for all patients. Further, some beneficiaries may begin home dialysis then revert to facility-based dialysis for health or safety reasons. Other beneficiaries may decline receiving dialysis at home either before or after receiving home dialysis training. In these cases, facility-based treatment is the appropriate site of care due to health status or patient preference. **Premier urges that CMS modify the proposed home dialysis rates by including appropriate adjustments when patients are unsuitable for home dialysis.**

Transplant rate

The facility transplant rate assesses the total number of attributed beneficiaries receiving a transplant anytime during the MY by the total dialysis treatment beneficiary years. The clinician transplant rate assesses the total number of attributed beneficiaries receiving a transplant anytime during the MY and the number of attributed pre-emptive transplant beneficiaries by the total dialysis treatment beneficiary years and total number of attributed beneficiary years for preemptive transplant beneficiaries.

This metric is inappropriate because neither participating clinicians nor facilities can directly affect the transplant rate, which is based on a wide variety of factors outside their control, including organ availability and viability for transplant, patient comorbidities and patient choice. Managing Clinicians and facilities are able to refer a beneficiary to a transplant specialist, but they cannot ensure that the beneficiary or patient receives a transplant or is added to the transplant list. CMS could explore use of alternative measures, including those already included in the ESRD QIP program for facilities, such as Percent of Prevalent Patients Waitlisted or Report for the Standardized First Kidney Transplant Waitlist Ratio for

Incident Dialysis Patients, and test to ensure applicability for clinician measurement. **Premier recommends that CMS remove the transplant rate from PPA calculations and instead consider the percent of patients referred waitlisted or other similar measures to more accurately capture participants' efforts to promote transplantation.**

Risk Adjustment

CMS proposes to use the CMS-HCC (Hierarchical Condition Category) ESRD Dialysis Model to risk adjust the home dialysis rates for both clinicians and facilities. The most recent final risk score available for the beneficiary at the time of rate calculation would be used. Premier supports CMS' use of HCC scores as a starting point for risk adjustment in the ETC model. However, home dialysis requires sufficient community support and housing stability to ensure continuity in care. To appropriately adjust for risk, **Premier recommends that CMS include variables to account for high-risk, high-need populations, including but not limited to: 1) the percentage of dually eligible individuals as a proxy for socioeconomic status and 2) home and community-based support for dialysis.**

Benchmarking and MPS Scoring

The ETC model will constitute a substantial change to the provision of care, requiring practice transformation. The model will also necessitate extensive beneficiary and provider education efforts around the benefits of home dialysis care. CMS acknowledges significant challenges that will need to be overcome through ongoing education, including the need for home care partner support, business practices, and health literacy. To support practice transformation, allow for sufficient time for providers to understand performance under a mandatory model before the introduction of downside risk and permit time for CMS-led provider and beneficiary education, **Premier recommends that the PPA not be applied until at least the 3rd calendar year of the model.**

CMS will assess performance under the model through achievement and improvement scores. For achievement scoring, CMS proposes to compare ETC model participants' home dialysis and transplant rates against benchmarks for the nonparticipant facilities and clinicians. For improvement scoring, CMS proposes to compare home dialysis and transplant rates of ETC model clinician and facility participants against the participant's prior year benchmarks. Participants will receive the higher of the achievement score or improvement score for the home dialysis rate and the transplant rate, which will be combined to produce the ETC Participant's Modality Performance Score (MPS). This design provides the ability for providers to succeed through high performance or through year-over-year improvement. **Premier supports CMS's approach of awarding the higher of the achievement rate score or the improvement score.** While Premier supports more heavily weighting the home dialysis measure, as noted above, we do not support inclusion of the transplant measure. An MPS that incorporated a home dialysis rate and percentage of patients waitlisted could equally weight both measures.

CMS states it intends to increase achievement benchmarks for ETC Participants above the rates observed in comparison geographic areas in future measurement years. CMS is considering that an ETC Participant would have to have a combined home dialysis rate and transplant rate equivalent to 80 percent of attributed beneficiaries dialyzing at home and/or having received a transplant in MY 9 and 10 in order to receive the maximum achievement score. While an aggressive goal for home dialysis and transplant rates is laudable, tying the model benchmark to this goal may set unrealistic expectations for the ETC model and introduce inappropriate incentives for home dialysis when it is not clinically appropriate. CMS' analysis of other countries home dialysis rates indicate that only Hong Kong has exceeded a 70 percent home dialysis rate, with New Zealand and Guatemala the only two countries that exceeded a 40 percent home dialysis rate. None of the countries or regions examined have met the 80 percent goal that CMS outlines as a potential goal within five years of introducing the ETC model. The experience of other countries may not be generalized to the US, as they have substantially different healthcare payment systems, population and demographics, restrictions on patient choice, and length of time that home dialysis has been established as the preferred dialysis delivery site. **Premier recommends CMS base achievement and improvement scores for both the home dialysis and transplant rates on participant and cohort experience when calculating the Modality Performance Score, rather than on an arbitrary benchmark**.

Final PPA Determination

CMS proposes a schedule for clinician and facility PPA adjustments that increases the amount of potential payment bonus and penalty each year. CMS proposes asymmetric risk, with larger maximum penalties than potential bonuses. The maximum bonus for both facilities and clinicians increases from 5 percent to 10 percent. The maximum penalty increases from -6 to -11 percent for clinicians and -8 percent to -13 percent for facilities.

Higher negative risk percentages are proposed for facilities as CMS believes facilities are capable of greater risk-bearing than small clinician groups. CMS further states that larger negative adjustments than positive adjustments are necessary to create stronger financial incentives. However, CMS does not provide justification for these proposals. **Premier recommends that CMS create symmetric two-sided risk in the model and align risk amounts for facilities and clinicians.** A symmetric risk pool would still create strong financial incentives for providers to perform well in the model. Additionally, the increased downside risk for facilities serves only to financially penalize one group of providers at a higher magnitude. **Premier continues to encourage CMS to design models that create a level and competitive playing field, allowing all providers to succeed and avoiding market distortions**

CMS proposes to apply the PPA when Medicare is the secondary payer for a beneficiary. CMS proposes application of the PPA for these claims to encourage the selection of home dialysis during the initial transition period onto treatment. Application of the PPA as a secondary payer presents additional challenges since it creates two-sided risk. The primary payer in certain cases may maintain care guidelines or other restrictions that do not align with the goals of the ETC model. These factors reside out of a participating providers' ability to control and may negatively impact reimbursement. **Premier requests that CMS refrain from applying the PPA adjustment when Medicare is the secondary payer.** However, we also encourage CMS to work with other payers to align incentives to achieve the goals of the ETC model.

PPA Low-volume Exclusions

CMS proposes to define a low-volume facility as one having less than 11 attributed beneficiary-years, or less than 132 attributed beneficiary-months, during a given MY; a facility meeting this criterion would be exempt from the PPA during the PPA period corresponding to the low-volume MY. CMS also proposes to set a low-volume threshold for application of the clinician PPA at the bottom 5 percent of ETC clinicians, using the number of beneficiary-years for which the clinician billed the MCP during the MY. For facilities, the 11 attributed beneficiary-year threshold may create situations where providers low-volume classification is not consistent across MYs . **Accordingly, the low-volume threshold for clinician (bottom 5% of providers, based on volume) also be applied to facilities.** This will increase stability in the program year-over-year, in comparison to the proposed 11 beneficiary year threshold, and align model policies across providers.

Overlap of ETC with Other CMS Initiatives

CMS notes that the ETC model will have overlaps with multiple other CMS initiatives. CMS explains that any increase or decrease in program expenditures due to the ETC model would be counted as expenditures under the Medicare Shared Savings Program and other CMS total cost of care initiatives. However, CMS does not specify whether any increases in expenditures due to the ETC program would be subtracted from expenditures in other total cost of care models. **Expenditures attributed for ETC be excluded from total cost of care models, including MSSP, Next Generation ACO and the Comprehensive ESRD Care model.** The increased payment in the ETC model is not accounted for in the benchmarks of the total cost of care models. Thus, participants in total cost of care models may be penalized (for their inability to reduce costs below a benchmark) for meeting the goals of the ETC model.

CMS further states that since the Comprehensive ESRD Care model test will be complete at the end of 2020, overlap with the ETC should be minimal. However, the positive PPA adjustment may increase payments for participants in the model during the overlap period. The limited duration of the overlap does not mitigate the need to account for the overlapping impact of the ETC model. The prior recommendation to exclude ETC expenditures from total cost of care models would address this concern. However, ***at a minimum, CMS should select regions for ETC that do not currently include a Comprehensive ESRD Care model participant to avoid overlapping impacts.***

Additional Comment (Hardship Exemption)

CMS does not address whether the ETC model will provide a hardship exemption for participants in the model. While beneficiaries are attributed to dialysis providers on a monthly basis, a natural disaster could impact existing dialysis care patterns. For example, Hurricane Florence closed more than 40 dialysis clinics across three states in 2018. While many of these facilities reopened quickly, a number of clinics remained closed due to flooding and road closures. Such disasters can also cause loss of home, medical equipment, and cause displacement that may limit beneficiaries' ability to administer home dialysis. **Premier recommends that CMS incorporate an extreme and uncontrollable circumstances policy that would alleviate the potential for negative PPA payment adjustments for affected providers.**

CONCLUSION

The Premier healthcare alliance supports CMS' efforts to transform healthcare care delivery and appreciates the opportunity to share feedback on the proposed design of the RO and ETC models. If you have any questions regarding these comments or need more information, please contact Aisha Pittman, vice president of policy at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance