

September 16, 2019

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***RE: Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures***

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) specialty care models proposed rule, and specifically on the radiation oncology (RO) model.

As described in the proposed rule, the RO model would test whether prospective, bundled payments for 90-day radiotherapy (RT) episodes of care would reduce Medicare spending while preserving or improving the quality of care for Medicare beneficiaries. The model would be mandatory for physician group practices (PGPs), hospital outpatient departments (HOPDs) and freestanding radiation therapy centers that deliver RT services for 17 types of cancer in certain areas of the country. Participants would be required to report certain quality, patient experience and clinical data to CMS over the course of the model.

Our members support moving toward the provision of more accountable, streamlined care and are redesigning delivery systems to increase value and better serve patients. In fact, many of our members have already adopted an evidence-based approach to hypofractionated RT and have seen positive results for patients from this approach. As such, the AHA supports CMS's development of models that could help further these efforts to transform cancer care delivery.



However, the hospitals and health systems that would be required to participate in this model are of many different sizes and types and are at different points in the process of transitioning to value-based care. They should not be required to participate in such a complicated program, which includes 17 different types of cancer, if they do not believe it will benefit the patients they serve. Moreover, other providers that may have the systems in place to excel under this new model could be excluded based on geographic location. **As such, we urge CMS to make the model voluntary for all providers.**

In addition, our members have indicated that it would take approximately a year simply to operationalize changes necessary to comply with the coding and billing requirements of this model. The proposed Jan. 1, 2020 and April 1, 2020 start dates do not provide adequate time to undertake this work and put in place the care processes and procedures necessary to achieve success in the program. **Therefore, we urge CMS to delay the start date of a voluntary model past April 1, 2020 until at least 12 months after the final rule for this model is published.** Doing so would help provide participants sufficient time to operationalize the model's parameters and be in a much better position to achieve success.

**We also urge CMS to balance the risk versus reward equation much more appropriately.** The AHA recognizes that, in crafting the proposed regulation, CMS attempted to achieve a balance between offering incentives for providers who achieve success and fulfilling CMS's obligation to protect taxpayers and the Medicare Trust Fund. **However, as proposed, the balance would be significantly misaligned and put the achievement of savings well out of reach for many providers. Specifically, the rule would require providers to take on 100% risk immediately upon starting in the model, without any stop-loss protections or adjustment for actual versus historical case mix.** It would use historically efficient hospital outpatient departments to set base rates, but also would implement a higher discount and more withholds on top of these efficient rates than any other model the agency has set forth. **This places too much risk and burden on providers with little opportunity for reward in the form of shared savings, especially in light of the significant investments required. A more appropriate balance is needed.** For example, CMS should:

- Make the model's payment retrospective rather than prospective, which would allow CMS to reconcile providers' historical and actual case mix and avoid inappropriate levels of under- or overpayments that would put providers and patient care at risk;
- Replace its historical experience and efficiency adjustments with an adjustment that blends participants' historical performance and national and regional average performance, as has been done in other models;
- Lower the discount amount, especially for the technical component (TC) payment, to 2.5% – 2.75%, including the patient experience withhold;
- Incorporate a stop-loss provision into the model, set at 10% in the first year and increasing by 2.5% each year thereafter;

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- Develop approaches to ensure that appropriate payments are made when providers introduce new service lines or technologies that were not included in their historical data; and
- Ensure that appropriate payments are made for patients treated with multiple RT modalities or with multiple cancer types.

Our detailed comments are attached. If you have any questions, please feel free to contact me or have a member of your team contact Shira Hollander, senior associate director of payment policy, at (202) 626-2329 or [shollander@aha.org](mailto:shollander@aha.org).

Sincerely,

/s/

Thomas P. Nickels  
Executive Vice President  
Government Relations and Public Policy

## AMERICAN HOSPITAL ASSOCIATION (AHA) DETAILED COMMENTS

### MODEL PARTICIPATION

CMS proposes to would require all RT providers and suppliers furnishing RT services within randomly selected Core Based Statistical Areas (CBSAs) to participate, subject to limited exceptions. CMS would publish the list of the CBSAs it selects in the final rule, and it expects the model to cover approximately 40% of RO episodes of care for Medicare beneficiaries nationwide.

Mandatory Participation. **We are concerned with CMS's proposal to make participation in this model mandatory. As a matter of course, hospitals and health systems should not be forced to bear the expense of participation in complicated programs if they do not believe they will benefit patients. Instead, CMS should make the model voluntary for all providers.** And this model is, indeed, complicated. It includes 17 different cancer types – a scope that is far too large to require provider participation. In contrast, the Comprehensive Care for Joint Replacement (CJR) model, CMS's only other mandatory model, includes just two DRGs. Making the RO model mandatory also would force providers to invest in expensive technologies and change care practice without time for evidence-based learning, setting many participants up for failure.

In addition, hospitals and health systems are at many different points along the transition to value. To succeed in the RO model, hospitals and health systems would have to make significant changes to the care processes and policies they have built around current regulatory payment structures. They will need to build upon their current infrastructure for health information technology, patient and family education, treatment planning, and care management. This is no small task; it will require significant investments of time, effort and finances. Doing so for 17 different types of cancer could be impossible for some.

Participating Providers. CMS would exclude from the model providers that furnish RT only in Maryland, Vermont or U.S. territories, is participating or eligible to participate in the Pennsylvania Rural Health Model, or is classified as an ambulatory surgery center, critical access hospital or PPS-exempt cancer hospital. **We support these exclusions.**

Low-volume Providers. For HOPDs or freestanding RT centers providing fewer than 60 attributed episodes during the 2015-2017 period, CMS proposes to assign these participants episode payment amounts equal to the trended national base rates in the first performance year. This would continue in the second performance year should the participant not achieve the 60-episode threshold, but a case-mix adjustment would be

applied to the national base rate. CMS would reevaluate the situation in the third performance year if the participant continues to have fewer than 60 episodes.

**The AHA appreciates CMS's recognition that providers that deliver a low volume of RT would lack the infrastructure and support to achieve efficiencies. However, we urge CMS to fully exclude these providers from the model, rather than just making adjustments to their episode payments.** Our analysis found that there is considerable variation in episode spending relative to payment amounts for providers that perform a very low volume of RT. This analysis suggests that episode pricing for these providers would be highly random and, therefore, very difficult to manage. Excluding TC providers (HOPDs and freestanding centers) that have fewer than 60 attributed episodes of RT during the 2015-2017 baseline period would remove only 11,957 of the 517,978 baseline episodes, or barely more than 2%. This includes 104 providers that delivered just a single episode of RT during the baseline period. Excluding these and other low-volume providers would have a minimal impact on the RO model demonstration, but prevent these providers from being inappropriately penalized.

## **MODEL START DATE**

In the proposed rule, CMS seeks feedback on whether it should launch the RO model on its proposed date of Jan. 1, 2020 or delay the launch of the model until April 1, 2020. **The AHA strongly urges CMS to delay the start date of the model past April 1, 2020 until at least 12 months after the final rule for this model is published. Doing so would help provide participants sufficient time to operationalize the model's parameters and be in a much better position to achieve success.** Hospitals and health systems want and need time to adequately prepare so that they can be successful throughout the program by, for example, analyzing CMS data regarding their current rates of radiation per fraction to identify areas for performance improvement. They have indicated that it would take approximately a year just to operationalize changes necessary to comply with the model's coding and billing requirements. Therefore, Jan. 1, 2020 and April 1, 2020 start dates do not provide adequate time for hospitals to undertake this work and to put in place the care processes and procedures necessary to achieve success in the program. This is especially true given that hospitals and health systems will not know if they are required to participate in the model until the publication of the final rule.

Indeed, CMS has afforded much more lead time in other models, including the Oncology Care Model (OCM), another model focused on cancer care. Letters of intent in that model were due in the spring of 2015 and the model launched more than a full year later, in July 2016. If CMS needed a year to stand up the OCM model, it should afford providers that would be required to participate in this model – who lack the data and other resources that the agency has – a comparably significant amount of time to prepare for participation.

## EPISODE CONSTRUCTION

CMS proposes to include in the model 90-day episodes of RT that begin with an initial treatment planning service, which is followed, within 28 days, by a treatment delivery service. Providers included in the model would use newly created HCPCS codes and “start of an episode” (SOE) and “end of an episode” (EOE) modifiers to signify the beginning and end of treatment. CMS also proposes that a subsequent episode may not be triggered for the same patient until at least 28 days after the previous episode has ended. During this “clean period,” participants would bill Medicare fee-for-service (FFS) for any medically necessary RT services.

The AHA appreciates CMS’s description of the technicalities of how an episode would be triggered and concluded, as well as public release of the RO episode file on which it based episode construction. However, in our analysis of the rule and the file, several important questions have arisen, which are discussed below. We urge the agency to answer these questions with additional materials published during the comment period and in the final rule, helping providers’ ability to fully understand, analyze and respond to the model.

Episode Initiation. It is unclear how technical participants will know when a professional participant starts an episode for one of their patients. Specifically, if a patient arrives at an HOPD for RT treatment, it is not clear how the treating professional and facility will know whether an episode has begun for that patient. We are concerned that without this knowledge, there could be several unnecessary incomplete episodes. We are also concerned that if CMS leaves this up to the participants, it could greatly increase the administrative burden of the model. **Thus, we recommend CMS include in the model a methodology by which it would notify technical participants of the start of an episode.**

Episode Conclusion. We are also unclear from the rule and the discussion on CMS’s Aug. 21, 2019 RO model listening session on several details regarding end-of-episode billing. Specifically, we request CMS clarify whether the clean period always begins on what would be the 91<sup>st</sup> day of an episode, regardless of when CMS receives an EOE modifier, or whether it begins the day after an EOE modifier is billed. If it is the former, we are concerned that providers would have to wait a significant amount of time between when they end an episode and when they receive the second half of the payment for that episode. This would exacerbate the cash flow issues described above that are created by the proposed discounts that are part of the model’s episode prices. **We therefore urge the agency to tie the second half of the episode payment to its receipt of an EOE modifier, not to the completion of a 90-day period.**

Identification of Cancer Type. We are unable to determine how CMS determined the cancer type for each episode when constructing the model’s baseline episodes. We

request that CMS clarify whether it based the cancer type on the diagnosis code on the treatment planning claim that initiated the episode, the diagnosis code on the first treatment delivery service claim following the planning service, or on some other indicator.

Assignment of Professional Component (PC) and Technical Component (TC) Services. Lastly, in Table 2 in the rule, CMS lists all of the HCPCS codes included in the model. However, the agency does not explain how it assigns PC and TC component services and corresponding PC and TC standardized payments for each HCPCS code. We request that CMS clarify the process it uses to categorize claims and payments for each HCPCS code into PC services and TC services

## **TIMING OF EPISODE PAYMENT**

CMS proposes to make the RO model a prospective payment model with payments divided in half, one half coming at the start of an episode and the other half at its completion. **We are concerned about the proposed prospective payment, especially because of the case mix methodology such a method entails.** Specifically, as described above, CMS proposes to apply a case-mix adjustment to the trended national base rates to account for factors included patients' age, sex, cancer type, history of major procedures and/or chemotherapy and mortality. While we appreciate CMS's attempt to adjust for factors outside of participants' control, we do not think it is appropriate to calculate the expected case-mix adjustment for each performance year (PY) using episode data from several years prior. In the rule, CMS explains that it would use data from 2015 through 2017 to calculate the expected case-mix adjustment for the first PY of the model, which would begin at some point in 2020. For the second PY, CMS would use data from 2016 through 2018, for the third PY it would use data from 2017 through 2019, and so forth. This means that there will be a lag of three to five years in between the baseline years used to calculate the case-mix adjustment and the performance period.

**Setting prospective rates based on such outdated data could substantially penalize participants whose actual case mix varies from the baseline data.** This is especially problematic for the use of mortality rate as a case mix variable. We conducted analysis on all of the proposed case mix variables and found that death during an episode and the timing of when a patient died has the largest impact on a provider's case-mix adjustment. For example, if a beneficiary dies in the first 30 days of an episode, the TC payment for that episode would be nearly \$6,000 less than if the patient had survived. However, mortality is quite volatile from year to year, especially for lower volume providers. Thus, a provider with a high mortality rate during the baseline period would receive a low case-mix adjustment and thus a lower payment rate during the performance period. If that provider had relatively few deaths during the performance period, this methodology would result in a substantial underpayment. This

is completely inappropriate and not only greatly reduces participants' ability to budget for their participation in the model, but also potentially threatens their financial solvency.

**Therefore, we urge CMS to alter the model's payment methodology to be retrospective so that it can adjust for providers' actual case mix in a given year, as observed from claims data.** CMS could do so by implementing the methodology it uses in the Bundled Payments for Care Improvement (BPCI) Advanced model. In that model, providers receive upfront target prices, but are paid FFS until a reconciliation period. Alternatively, CMS could use an approach similar to the one it uses in the OCM, in which providers receive an upfront enhanced services payment and a semi-annual, retrospective, performance-based payment that includes an adjustment for actual episode expenditures. Such an approach enables the agency to better target episode payments to the delivery of RT and implement a stop-loss methodology, as described above.

## **EPISODE PRICING METHODOLOGY**

To calculate the payment for each episode included in the model, CMS proposes to use an 8-step process. Through this process, CMS would compute participant-specific payment amounts for the PC and TC portions of the model payment. **In general, we request that CMS provide more detail on its proposed pricing methodology.** As described below, the brevity of this section leaves us with many questions about how prices would be set and updated in the RO model.

National Base Rates. To set the national base rates for the model's episode payments, CMS proposes to calculate the historical average PC and TC costs for each cancer type included in the model, resulting in 34 different base rates. CMS would base these calculations on claims from RT episodes that occurred from 2015 through 2017, were attributed to an HOPD, and in which the majority of technical services were provided in an HOPD. Thus, the base rates for all model episodes, regardless of site of service, would be predicated on the outpatient prospective payment system (OPPS), due to CMS's belief that OPPS payments have been more stable over time than physician fee schedule (PFS) payments.

In the rule, CMS explains that despite providing more RT episodes nationally from 2015 through 2017, HOPDs furnished a lower volume of services within such episodes than did freestanding radiation oncology centers. In light of these facts, CMS chose to use the more efficient site of service – HOPDs – on which to build the national base rate. **By doing so, CMS has built significant savings into the model from the outset. The agency should recognize this choice when making policy decisions regarding the expected level of additional savings by participants.** Yet, as described below, CMS's proposed adjustments to the national base rates, as well as the proposed discounts and withholds, exceed those in any other alternative payment model. When these aggressive adjustments are combined with the already built-in savings, they may

render inefficient providers unable to reasonably achieve savings and force efficient providers to look for savings where none exist. Such an approach could reduce patient access to RT by causing significant financial issues for such a capital intensive specialty.

In addition, CMS must ensure that the RO model payment rates do not take away resources that providers need to test the assumptions behind the model. Doing so could cause participants to be at risk of closure, creating significant issues for treatment compliance and patient access. Indeed, it is not clear from the evidence base that each of the 17 different cancer types should be treated with hypofractionation. In addition, to test whether hypofractionation would lower costs and improve quality for RT patients, many providers would need to upgrade their technology and machinery to provide lower and more precise fractions of RT. This would be an extremely costly change, especially for technical participants that deliver the capital-intensive portions of RT. **Therefore, at the outset, we urge CMS to publish the science behind its belief that hypofractionation would be appropriate for such a large range of cancer types.**

Trend Factor. CMS explains in the rule that it would use the PFS and OPFS rates for RT to establish the trend factor, which would trend forward the national base rates. However, it is unclear from this proposal exactly which fee schedules CMS would use to trend forward which rates. We would expect the agency to use the PFS to trend forward the PC rates, but it could use either OPFS or a combination of PFS and OPFS to trend forward the TC rates. Specifically, for the TC trend factor, CMS could use only HOPD volumes and corresponding OPFS payments to be consistent with how it proposes to set the national base rates, or it could use a mix of HOPD and freestanding volumes and corresponding OPFS and PFS payments. We request that CMS clarify how it would calculate the PC and TC trend factors so that participants can better assess the financial impact of this model.

Case-mix Adjustment. CMS describes in the rule its proposal to make a case-mix adjustment to the trended national base rates to account for specific differences in patient characteristics that are beyond a provider's control. However, CMS does not provide sufficient detail on the regression models it used to construct the case-mix adjustments or on how the components in the case mix methodology were developed. As such, we are unable to meaningfully comment on this adjustment. We urge CMS to issue more information as soon as possible and consider using a more straightforward model to account for the case-mix adjustment.

Historical Experience Adjustment and Efficiency Factor. CMS also proposes to apply an efficiency factor based on the historical experience of providers included in the model. The efficiency factor would determine the weight at which a participant's historical experience adjustment is applied to the trended national base rates. As written in the proposed rule, participants with a historical experience adjustment equal to or less than 0.0 would be categorized as historically efficient compared to the payments predicted

under the FFS payment system for an episode of care. These participants would receive an efficiency factor of 0.90 that would remain fixed over the model performance period. Participants with historical experience adjustments greater than zero would be categorized as historically inefficient and would receive a declining efficiency factor (from 0.9 in the first performance year (PY) to 0.7 in the fifth) to reduce the impact of historical practice patterns on payment over the course of the model.

**We strongly urge CMS to eliminate its proposed historical experience and efficiency factor adjustments.** As proposed in the rule, the methodology creates a nonsensical and inappropriate result. Specifically, it increases baseline payment amounts for inefficient providers, but decreases payment amounts for efficient providers. This result is demonstrated in Table 1 below, which provides an example of the efficiency factor portion of the episode pricing methodology.

**Table 1: Efficiency Factor Analysis Assuming Positive Factors**

	<b>Efficient Provider</b>	<b>Inefficient Provider</b>
Subtotal	\$3,389.40	\$3,389.40
Case-mix Adjustment	0.04	0.04
Historical Experience Adjuster	-0.1	0.13
PY 1 Efficiency Factor	0.9	0.9
Combined Adjustments	0.95	1.16
<b>Payment Amount</b>	<b>\$3,219.93</b>	<b>\$3,921.54</b>

In verbal communication, CMS, at one point suggested that the efficiency factors are in fact supposed to be -0.9 for both efficient and inefficient providers in the first performance year of the model. If that were true, it would reward efficient practices in the first year of the model by increasing their baseline rate. However, it would also increase payments to inefficient practices over the course of the model, as demonstrated in Table 2 below. This means that the pressure on historically inefficient providers to lower their costs would ease over the course of the model. This again is a nonsensical result. CMS has since confirmed that the efficiency factors are intended to be +0.9, but this demonstrates that the efficiency factor is not a sound policy adjustment in any form.

**Table 2: Efficiency Factor Analysis Assuming Negative Factors**

	<b>Efficient Practice (all years)</b>	<b>Inefficient Practice (PY1)</b>	<b>Inefficient Practice (PY2)</b>	<b>Inefficient Practice (PY3)</b>
Subtotal	\$3,389.40	\$3,389.40	\$3,389.40	\$3,389.40
Case-mix Adjustment	0.04	0.04	0.04	0.04
Historical Experience Adjuster	-0.1	0.13	0.13	0.13
Efficiency Factor	-0.9	-0.9	-0.85	-0.80

Combined Adjustments	1.13	0.92	0.93	0.94
<b>Payment Amount</b>	<b>\$3,830.02</b>	<b>\$3,128.42</b>	<b>\$3,150.45</b>	<b>\$3,172.48</b>

**Instead, we urge CMS to use a blend of participants' historical performance and national and regional average performance to adjust the national base rates.**

Specifically, we urge the agency to phase in use the higher of national or regional historical episode payments in calculating the portion of the payment that is not based on participants' own past performance. This approach is simple to understand, consistent with adjustments in other models and represents sound policy in that it would help ensure that appropriate incentives are provided to RO model participants in both high- and low-cost areas. CMS should begin with primarily participant-specific pricing and transition to completely regional or national pricing over the course of the model so as to avoid penalizing participants that generate savings by having their success make future savings more difficult to achieve. However, to be clear, no matter the adjustments CMS makes, programs that are designed to achieve savings for the Medicare program year after year will see diminishing returns over time. Efficient providers will first begin to encounter such limited opportunities for additional gains in efficiency, but eventually, the agency will no longer be able to continue decreasing payments for any providers without putting quality of care at risk. Specifically, as with any emerging payment model, CMS must carefully monitor the model for unintended impacts on quality and access of services. The measures in the proposed for the model provide a window into aspects of the model's impact on quality, but CMS's evaluation of the model also should assess the "bigger picture" of the model's impact on quality and cost.

Discounts and Withholds. After calculating the national base rates for the PC and TC payment amounts, trending those amounts forward and applying case mix, historical, and efficiency adjustments, CMS would apply several discounts and withholds to the payment rates. Specifically, CMS proposes to apply a 4% discount factor to the PC payment and a 5% discount factor to the TC payment. **We are deeply concerned about the amount and application of these discount amounts and the unlevel playing field they create both within the model and between participants and those excluded from the model. They are the largest discounts we have seen CMS set forth in any bundled payment model and are particularly inappropriate given that the agency proposes to:**

- **Build in so much savings at the outset (as discussed above);**
- **Require down-side risk beginning immediately in PY 1; and**
- **Make the model mandatory for providers.**

Through these discounts, Medicare guarantees itself a savings of 4% on the PC payment and 5% on the TC payment, forcing participants to completely shoulder any losses that result if they do not achieve these substantial savings. Taking together the 5% discount and the proposed withholds, CMS actually guarantees itself more than \$41

million in annual savings from TC providers alone. The level of the discount amounts also creates unnecessary competition between those required to participate in the model and those exempted from it, which could produce misaligned incentives that do not benefit patient care.

Additionally, we are puzzled as to why the TC discount factor is higher than the PC discount factor – something which CMS does not discuss in the rule. It is quite concerning to us given that hospital TC providers have little ability to impact the treatment plan/episode cost and make all of the capital investments for RT, yet, at the same time, cannot earn a 5% advanced APM bonus under the Quality Payment Program (QPP) through participation in this model, unlike PC providers.

**Therefore, we strongly urge CMS to lower the discount amounts, especially for the TC payment. We recommend a discount amount of 2.5% – 2.75%, as is used in the OCM for practices that have taken on two-sided risk (depending upon which risk arrangement option they select).** Aligning the discount factors between the two models in this way would further CMS's goal of enabling medical oncologists and radiation oncologists to work collaboratively in a value-based payment environment. It also better recognizes that, in setting the discount amounts, participants are 100% at risk for any costs that exceed their payments.

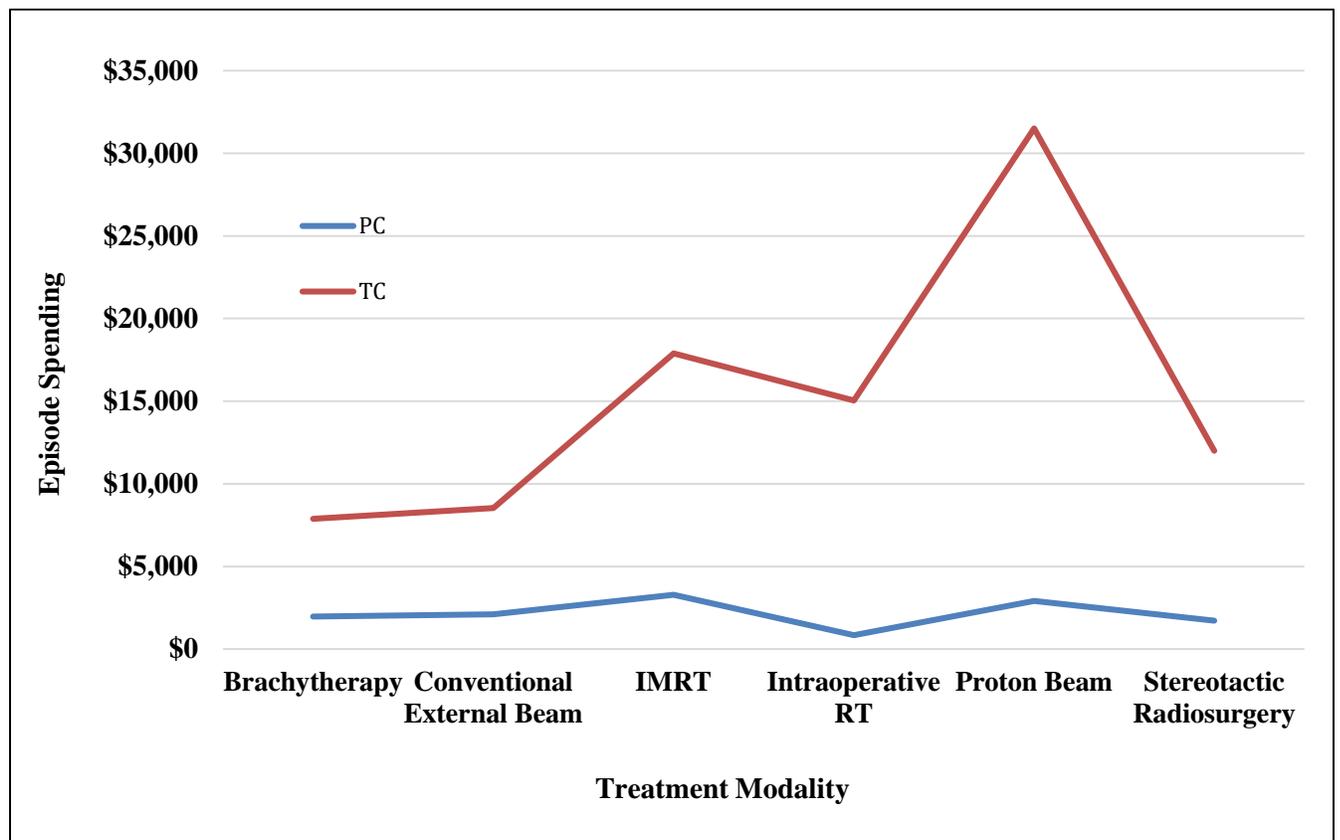
In addition, we urge CMS to *include* in our recommended TC discount the 1% withhold for patient experience, which would keep the discount in line with other models. As proposed, CMS would withhold 1% of the TC payment beginning in PY 3 to account for patient experience in the model. Participants that bill the TC of an episode would be able to earn back up to the full 1% based on their results from the CAHPS Cancer Care Survey. If the 1% patient experience withhold were included into our recommended 2.5% – 2.75% discount, participants that bill the TC would have the opportunity to earn back approximately 36% – 40% of the combined discount and withhold (1/2.75; 1/2.5). Thus, this approach would still incentivize participants to focus on ensuring they provide the best possible experiences for their patients without putting them at inappropriate financial risk.

**Risk Adjustment. We urge CMS to incorporate a risk-adjustment methodology into the RO model.** As proposed, CMS would not make risk adjustments in the program beyond the case-mix adjustment step of the pricing methodology. However, this methodology fails to account for the variation in the cost of providing different modalities of RT within each of the 17 different cancer types included in the model. **The lack of a robust risk adjustment methodology penalizes certain providers based solely on the treatment modality of their patients.**

In our detailed analyses of episode spending, we found large variation based on cancer type and modality of treatment. The disproportionately high spending required to use certain modalities for treatment of certain cancer types supports the need for a risk

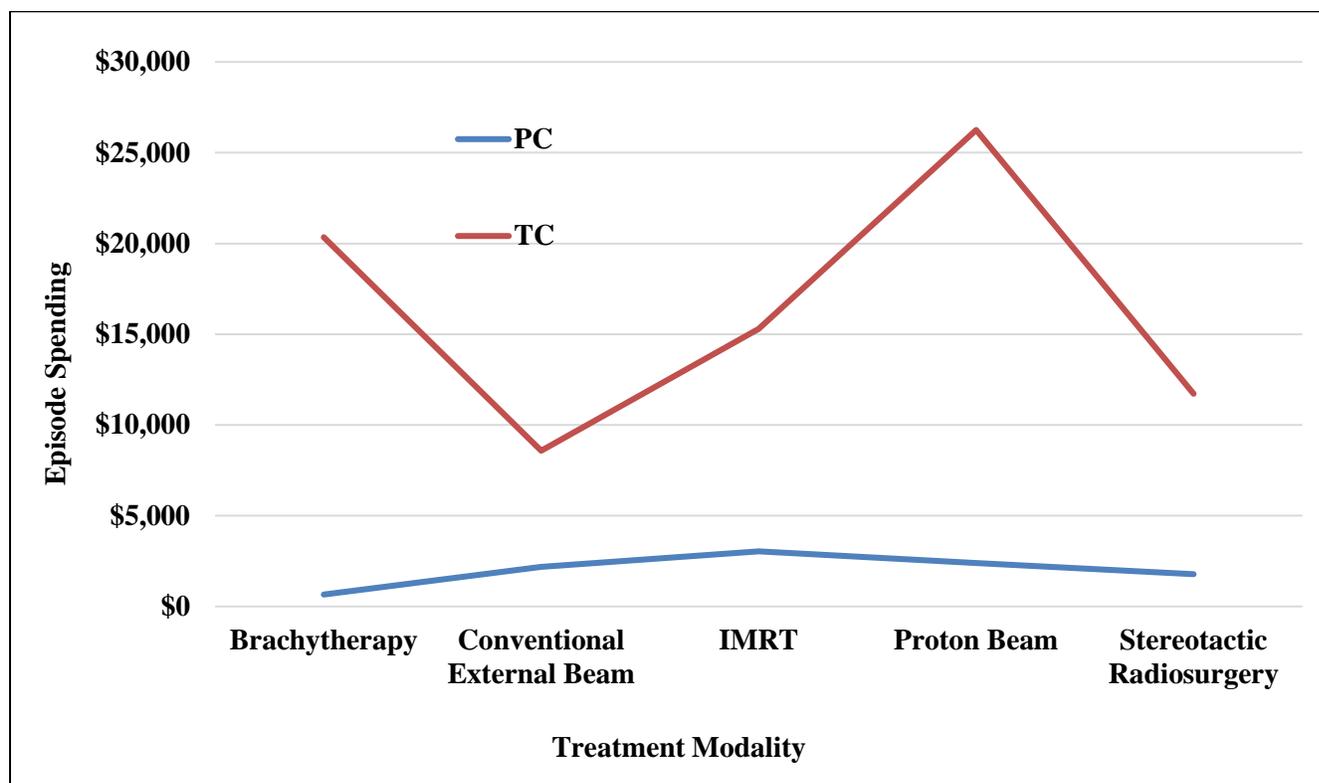
adjustment methodology in the RO model. For example, as shown in Figure 1 below, episode spending for head and neck cancer varies significantly depending on the modality of treatment. TC spending for proton beam therapy episodes is the highest, almost 300% higher than for brachytherapy episodes, which have the lowest spending. TC spending for intensity-modulated radiation therapy (IMRT) episodes is the next highest, 127% higher than for brachytherapy. .

**Figure 1: Head and Neck Cancer Episode Spending, by Treatment Modality**



Spending for other cancer types varies by modality as well, but not with the same pattern. For example, colorectal cancer episodes treated with proton beam therapy have the highest TC spending, but conventional external beam, has the lowest, with a 206% difference (see Figure 2). TC spending for brachytherapy episodes is the next highest, 137% higher than for conventional external beam.

**Figure 2: Colorectal Episode Spending, by Treatment Modality**



Without sufficient risk adjustment, these findings suggest the RO model could considerably discourage the use of certain modalities, particularly proton beam therapy, to treat certain cancers. This could greatly jeopardize access to these types of treatment for the patients that need them. We do wish to point out that while CMS cites reports purporting that proton beam therapy is over lower value when compared to other forms of RT, this blanket statement is not applicable to all disease sites. This type of therapy can serve as an effective, evidence-based treatment for specific clinical indications, such as ocular tumors and chordomas.

Stop-loss Limits. As proposed, participants in the RO model would be 100% at risk for any and all expenditures they incur that exceed their payments. **This degree of risk is inappropriate for a mandatory model.** Many radiation oncologists and providers of RT would be taking on risk for the first time in this model and they will need time and guidance to do so. Requiring them and others that are all at different points in the transition to value-based care to take on 100% risk for 17 different types of cancer sets them up to fail. **Instead, we urge CMS to incorporate a stop-loss provision into the model to mitigate this extremely high degree of risk.**

CMS should implement such a policy regardless of whether it moves to a retrospective payment method as we have recommended. If it maintains the prospective nature of this model, it could implement a stop-loss provision using the encounter data it proposes to require participants to submit. As described in the rule, CMS would require RO participants to submit encounter data (no-pay) claims for all RT services identified on the list of HCPCS codes included in the model that appear in Table 2 of the rule. CMS proposes to use this data for evaluation and model monitoring. But CMS could also use this data to determine what participants would have been paid absent the model. The agency could then determine the difference between a participant's actual payments and what it would have been paid if the same services had been billed FFS. It would then cap the difference to protect participants from catastrophic losses that result from the model. We recommend beginning with a 10% cap in PY 1 and raising the cap 2.5% per year over the course of the model.

Accounting for New Service Lines and New Technologies. CMS does not include in the rule any detail about how it would account for providers' delivery of new RT service lines and use of new technologies to provide this therapy. **Given the continuous evolution of RT technology, it is essential that CMS develop an approach to paying for new service lines and innovations in advance of launching the model.**

*New Service Lines.* In response to changing patient needs and technological advances, certain practices are likely to begin new service lines during the course of the model. New service lines are not new technology, but rather services new to a specific practice, such as beginning to deliver brachytherapy. However, the model's episode pricing methodology is based on a provider's historical payments, which would not include new service lines. This has the potential to dis-incentivize the adoption of new, potentially beneficial service lines. **Therefore, we urge CMS to develop a modification to the payment methodology that would recognize new service lines. The agency could phase in such a modification until a practice generates enough data to incorporate the new service line into its historical data set for future payment rates.**

*New Technology and Innovation.* Radiation therapy has been utilized to deliver life-saving cancer treatments for more than 100 years. Advances in technology, particularly over the last quarter century, have allowed radiation oncologists to more precisely map the location of cancer, delivering higher, more effective doses of radiation that limit the exposure to normal tissue. For example, some of our members are experimenting with the use of Adaptive Radiation Treatment with MRI-Guided Linear Accelerator (MRI-LINAC), an RT technology that offers superior high-definition image quality, far more personalization of RT than is currently available, and the ability to adapt radiation treatment plans based on the movement of patients' tumors and organs. The initial capital cost of the MRI-LINAC is expected to be approximately \$12 million, which would cover only the machine itself and not maintenance and upkeep. CMS should seek to encourage the adoption of such advanced technologies by a wide range of providers to

maximize the potential contribution of RT to patients' health. However, as proposed, the RO model does not include any approach to recognizing new technology such as the MRI-LINAC, which could jeopardize future innovation, limiting the treatment potential of this important therapy. **Because this model is a five-year demonstration, we strongly recommend CMS simply exclude new technologies and clinical trials from the model. If CMS is unwilling to do so, we recommend the agency at least develop a carve-out or separate payment methodology to account for the costs associated with new and emerging technologies.** CMS could look to other models such as OCM and the end stage renal disease (ESRD) PPS, which both make allowances for new and advanced drugs, for approaches to accounting for new RT technology.

## **EXTREME AND UNCONTROLLABLE CIRCUMSTANCES**

CMS explains in the rule that it is not proposing a hardship exemption for the RO model because the model's pricing methodology gives significant weight to historical experience in determining the participant-specific payment amounts. This may be true, but would still leave providers in the midst of an emergency vulnerable to high spending and without resources to meet data reporting and other programmatic requirements during the course of the performance year in which the emergency occurs. In addition, natural and other disasters could greatly impact hospital and health system operations and providers' ability to deliver the RT their patients need. **Thus, we recommend CMS provide for exemptions for participants facing public health emergencies or natural disasters, such as the recent wild fires and hurricanes, to ensure that they are not unfairly penalized due to these circumstances.**

## **CHANGES IN A PATIENT'S COURSE OF RT TREATMENT**

In the provision of RT, a patient's course of treatment may change over the length of that episode. As described below, we request that CMS account for these situations in the payment methodology.

Multi-modality Care. Patients undergoing RT – especially those that are diagnosed with a metastatic form of cancer – could require retreatments or boost treatments during an episode of care. For example, if a patient is treated with one RT modality, he or she may then require a boost with a second modality, resulting in two treatment plans and two courses of treatment in a single episode. In fact, multi-modality treatment is the standard of care for certain cancers, such as combination therapy for gynecological cancer. Similarly, patients with metastatic disease such as brain and bone metastases may require multiple retreatments within a short time period, such as 30 days. We found that almost 7% of episodes included more than one modality, and were much more costly than episodes with only one modality. For example, patients with bone metastases that were treated with two or more modalities had spending that was 96% higher for the PC and 146% higher for the TC than patients treated with one modality.

As another example, patients with cervical cancer that were treated with two or more modalities had spending that was 116% higher for the PC and 104% higher for the TC than patients treated with one modality. Further, cervical cancer episodes with two or more modalities accounted for 55% of all cervical cancer episodes. It is not clear from the rule how or whether CMS would give special consideration to these types of episodes. And, this could be further complicated if the different modalities of treatment are provided by two or more different TC providers. **To avoid jeopardizing access to this type of care for patients who require it, we recommend that CMS fully account for multi-modality care in the payment methodology. If the agency is unable to do so, it should exclude them from the model.**

Accounting for Multiple Disease Sites. In listing the 17 cancer types that it proposes to include in the model, CMS does not indicate how it would account for patients that present with more than one of these cancer types or those that present with an initial diagnosis of one cancer type and are later diagnosed with a second. While the agency has maintained that these are rare situations, our analysis revealed that patients were diagnosed with more than one cancer type in more than 11% of episodes used to calculate the national base rates. **An incidence rate this high of multi-disease claims requires specific consideration.**

In individual communications and on its Aug. 21, 2019 RO model listening session, CMS indicated that for patients with multiple diagnoses, providers included in the model should select the cancer type with the higher reimbursement rate because the providers would not receive separate payment for the other cancer type(s). If this is truly the approach CMS plans to take, we are concerned it would undercompensate providers that treat patients with multiple diagnoses that may require multiple modalities of treatment. This is especially important for patients with brain or bone metastases, or breast, lung or prostate cancer, as patients with one cancer type often also have another of these cancer types. Indeed, our analysis demonstrates that for certain cancer types, spending for episodes with multiple cancer types reported far exceeds spending on episodes with a single cancer type reported. For example, patients with uterine cancer as well as other cancer types had spending that was 36% higher for the PC and 37% higher for the TC than patients with uterine cancer only. As another example, patients with brain metastases as well as other cancer types had spending that was 23% higher for the PC and 16% higher for the TC than patients with brain metastases only.

This situation is further complicated by the fact that patients with multiple diagnoses could require treatment by different PC and TC providers at different locations. We also are concerned about the complexities of clinical data reporting that could arise for providers treating patients with multiple cancer types. CMS also has not addressed the situation in which patients that have or develop one cancer type included in the model are also or subsequently diagnosed with a cancer type that is excluded from the model.

**Given the many complexities that providers who care for patients with multiple cancer diagnoses could face, we recommend fully accounting for multi-disease episodes in the payment methodology. If CMS is unable to do so, it should exclude them from the model.**

## **QUALITY, CLINICAL DATA AND PATIENT EXPERIENCE REPORTING REQUIREMENTS**

Quality Reporting. In order to calculate PC participants' aggregate quality score (AQS), CMS proposes to require participants to report four process measures and additional clinical information that is not available in claims or captured in the four quality measures. The four quality measures on which CMS would require reporting include: Oncology: Medical and Radiation – Plan of Care for Pain; Preventive Care and Screening: Screening for Depression and Follow-up Plan; Advance Care Plan; and Treatment Summary Communication – Radiation Oncology. The first three measures are endorsed by the National Quality Forum (NQF) and are currently in use in the Oncology Care Model and the Merit-based Incentive Payment System (MIPS). The fourth, Treatment Summary Communication, is neither NQF-endorsed nor used in any other CMS program. **We encourage CMS to use only measures endorsed by the NQF, and suggest observing reporting of this measure in a “dry run” before using it in the AQS calculation.**

**We further encourage CMS to consider calculating the AQS using pay-for-reporting on all four quality measures for the first year of the model before transitioning to a performance-based calculation.** Given the lack of clarity regarding the benchmarks that CMS would use for quality reporting, this would allow the agency more time to clarify quality requirements and participants sufficient time to become familiar with them. In addition, as with other CMS programs, we recommend that the agency provide confidential feedback reports with performance information to participants to give them the opportunity to review and correct their quality data before it is used in payment determinations or public reporting.

Clinical Data Reporting. **Regarding the requirement to report basic clinical information that is not available in claims or captured in the four quality measures, we are extremely concerned about the massive burden this requirement would create.** CMS proposes to require providers to report data items such as cancer stage, disease involvement, treatment intent and treatment plan, although CMS has not determined the exact elements and standards for reporting. These requirements will be burdensome without much benefit to patients. Providers already incorporate much of this information in their care; abstracting it from a chart and reporting it in a separate portal – as CMS proposes to require – would add a significant amount of administrative work to already busy staff schedules. This burden would be compounded by CMS's proposal to require providers to report this data for all patients regardless of payer and by the numerous issues with the use of secure portals in other CMS programs. Experience has demonstrated that these portals (1) are frequently

unreliable and logistically challenging; (2) contain limits on who can log into them; (3) crash due to the volume of data inputted; and (4) make feedback reports difficult to download. Moreover, CMS has not provided the precise information fields it would require in connection with the clinical data reporting, making it impossible for providers to plan or determine whether those data elements are already in use in their electronic health records (EHRs). Finally, many professional participants do not have adequate staff to perform this abstraction.

**These and other concerns about the proposed clinical data reporting requirements, combined with the fact that CMS provides no indication of how it would use this data, underscores the need to abandon this proposal.** This is especially true given that for some participants, the cost burden of this reporting would be so high that it would be more cost effective for them to not comply with these requirements than to do so for the very small portion of the quality withhold that doing so would allow them to earn back.

Patient Experience Reporting. Beginning in PY 3, CMS would apply a 1% percent withhold to the TC payment amount, which participants would be able to earn back based on performance on patient experience measures informed by performance on the CAHPS Cancer Care Radiation Therapy (CCR) survey. Like the other surveys in the CAHPS family, the CAHPS CCR poses numerous logistical challenges. Specifically, the survey is very long and often not distributed to patients until several weeks after their encounter, which reduces response rates. In addition, the survey is administered only via mail and phone. **To that end, we encourage CMS to investigate electronic modes of survey administration and to account for these and other difficulties with the survey.**

## **IMPACT OF RO MODEL ON OTHER MEDICARE PAYMENT SYSTEMS**

As CMS continues to develop alternatives to traditional Medicare payment systems, we request that CMS clarify how this particular model would impact the budget neutrality requirements under the OPPS and PFS. This should be specifically described in the final rule.

We also request clarification as to how providers would bill Medicare FFS for those HCPCS and CPT codes not included in the model but which are on the same claim as the RO services included in the model. In addition, how should providers bill for non-model services which, if not for the model, would be bundled under the existing OPPS RO Comprehensive ambulatory payment classification (C-APC)? The AHA recommends that providers be permitted to bill separately under the OPPS for these other non-model HCPCS and CPT codes.