



12100 Sunset Hills Road, Suite 130, Reston, VA 20190 703-234-4078 fax 703-435-4390

September 16, 2019

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5527-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Administrator Verma:

The American Brachytherapy Society (ABS)¹ is eager to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 18, 2019 *Federal Register* notice regarding the Radiation Oncology (RO) Model proposed rule.

The ABS appreciates that the Centers for Medicare and Medicaid Innovation Center (CMMI) has designed a radiation oncology model that is specific to radiation oncology and includes many brachytherapy services. The ABS is very supportive of CMS' goal of aligning payments to quality and value rather than volume, and the radiation therapy modality of brachytherapy has long been considered a high value therapeutic option within radiation therapy^{2,3,4}. **The ABS is supportive of a modality agnostic payment model but has significant concerns regarding the future viability of brachytherapy within the RO Model.**

Although there is significant rate setting complexity with inclusion of brachytherapy within the RO Model, the ABS recommends keeping brachytherapy within the Model. Removal of brachytherapy out of the Model will not incentivize practices to utilize the most efficacious and cost-effective

¹ Founded in 1978, the American Brachytherapy Society (ABS) is a nonprofit organization that seeks to provide insight and research into the use of brachytherapy in malignant and benign conditions. The mission of the ABS is to benefit patients by providing information directly to the consumer, by promoting the highest possible standards of practice of brachytherapy, and to benefit health care professionals by encouraging improved and continuing education for radiation oncologists and other health care professionals involved in the treatment of cancer. Additionally, the ABS seeks to promote clinical and laboratory research into the frontiers of knowledge of the specialty and to study the socioeconomic aspects of the practice of brachytherapy. The organization consists of approximately 1,500 physicians, medical physicists and other health care providers interested in brachytherapy.

² Thaker, N.G., et al., Defining the value framework for prostate brachytherapy using patient-centered outcome metrics and time-driven activity-based costing. *Brachytherapy*, 2016. 15(3): p. 274-282.

³ Thaker, N.G., et al., Communicating Value in Health Care Using Radar Charts: A Case Study of Prostate Cancer. *J Oncol Pract*, 2016. 12(9): p. 813-20.

⁴ Laviana, A.A., et al., Utilizing time-driven activity-based costing to understand the short- and long-term costs of treating localized, low-risk prostate cancer. *Cancer*, 2016. 122(3): p. 447-55.

treatments for cancer patients and we believe that all modalities of radiation therapy should be included in the Model. However, there are significant challenges in reimbursing combination modality brachytherapy in the current rate setting methodology for the national base rates, and we encourage CMS to consider our recommendations on adjusting the payment mechanism to make payments more fair and equitable and to ensure adequate access of cost-effective life-saving treatments for cancer patients.

There are unintended financial incentives in this Model that will lead to further under-utilization of brachytherapy (a high value modality) and over-utilization of more costly modalities. The ABS remains eager to work with CMS to adapt the model to ensure the fair and predictable payment for brachytherapy; that the RO Model rewards radiation oncologists for improving the value of radiation oncology for patients; and that the incentives are positively aligned with the delivery of high quality, high value cancer care. **As proposed, the ABS is gravely concerned that the RO Model will negatively incentivize the use of brachytherapy as a multi-modal radiation therapy approach and will dis-incentivize the use of radioactive brachytherapy sources.**

Summary of Major ABS Recommendations

The American Brachytherapy Society respectfully requests that CMS consider the following recommendations:

- 1) *The ABS recommends reimbursing brachytherapy either through triggering of a second episodic RO Model bundled payment (second PC and TC payment) or through fee-for-service when brachytherapy is delivered before, during, or after external beam radiation therapy (EBRT) within a 90-day episode (for all brachytherapy episodes). Costs of using brachytherapy as a boost after EBRT (i.e. multi-modality radiation therapy) are not captured well in the RO Model methodology and are statistically underrepresented within the national base rate calculations.*
- 2) *The ABS recommends that a modifier be created to acknowledge episodes where brachytherapy is delivered before, during, or after EBRT to ensure that these episodes allow for a second bundle to be triggered to reimburse the brachytherapy or the brachytherapy to be paid FFS and for the episode to not go to reconciliation. The ABS also encourages CMS to not consider multi-radiation modality cases that are delivered by two physicians (two different NPIs that could be in the same or different TINs) as “duplicate RT services”.*
- 3) *The ABS recommends removal of brachytherapy source codes (A-code, C-codes, Q-code) from the RO Model list of bundled HCPCS and thereby uncouple the payment of brachytherapy sources from the professional fees for brachytherapy delivery*
- 4) *The ABS recommends CMS create clinical business rules to remove the palliative and mis-attributed episodes from each of the disease sites, to blend the MPFS with HOPPS data for the PC calculation, and to recalculate the national base rates based on definitively treated cases alone.*

List of ABS Concerns:

1. **The ABS is concerned that the RO Model as proposed has inadequate reimbursement for combination-radiation modality episodes. 57% of cervical cancer and 3-7% of prostate cancer episodes require combination external beam radiation before, during, or after brachytherapy. The ABS recommends reimbursing brachytherapy that is delivered before, during, or after EBRT through one of two possible solutions (ideally in all cases and definitely when there is a second physician [two different NPIs that could be in the same or different TINs] or a second site of service involved):**
 - a. **Allow brachytherapy to trigger a second RO Model bundle (with a separate PC and TC payment) when delivered before, during, or after EBRT for cervical cancer within a single 90-day episode**
 - b. **Allow brachytherapy to be reimbursed as FFS when delivered before, during, or after EBRT within a single 90-day episode**
2. **Clinical, logistical, and site of service differences exist when providing combination modality radiation therapy (i.e. EBRT followed by brachytherapy). In the proposed RO Model these common clinical scenarios are not recognized and with adoption as written optimal patient care will suffer. Brachytherapy takes additional skill, time and carries additional risk than external beam alone, and the rate setting methodology for the national proposed base rates does not adequately account for the brachytherapy costs. The ABS recommends that when brachytherapy is delivered before, during, or after EBRT (whether the brachy is delivered by the same physician or more commonly by a second physician, in the same site of service or a different site of service), payment for brachytherapy should be through the triggering of a second episodic bundled payment or through FFS.**
3. **When brachytherapy is delivered before, during, or after EBRT, a modifier code could be created to acknowledge the occurrence of these multiple radiation modalities so that the brachytherapy is paid with a second bundle payment or with FFS and that the episode is not labeled a “duplicate RT service” and does not go to reconciliation.**
4. **The ABS respectfully recommends that CMS remove the brachytherapy source codes (including all A-codes, C-codes, and Q-codes) from the list of RO Model bundled HCPCS codes (Table 2 of the proposal).**
5. **The ABS encourages CMS to remove Liver Cancer as a disease site within the RO Model and to remove all brachytherapy source codes (including C2616), given the disproportionate impact of including cases of Yttrium-90 in a Liver Cancer bundle.**
6. **The ABS strongly recommends that when brachytherapy is delivered before, during, or after EBRT (by a second physician) that the brachytherapy surgical codes (57155, 57156, 55920, 58346) in the RO Model should be paid with FFS. The ABS also recommends that these episodes of combination radiation modality should not meet the criteria for inclusion into duplicate RT services that require reconciliation. This is consistent with our recommendation to pay for brachytherapy that occurs before, during, or after EBRT with the triggering of a second bundle payment or through**

FFS.

- 7. When cancer patients require treatment to multiple sites (such as patients with oligometastatic disease), the ABS recommends paying for treatment of the additional sites with FFS.**
- 8. The ABS would recommend the Agency consider paying for new service lines or new indications of radiation therapy as FFS or through the RO Model Episode Bundle, whichever is higher. This is similar to the OCM novel therapies adjustment.**
- 9. The ABS recommends that CMS pay FFS for any new technology identified by a new CPT code or new technology code during the term of the model.**
- 10. The ABS asks that CMS clarify how Medicare administrative contractors will manage PC and TC claims after the 28-day window between the treatment planning code and the treatment delivery code has passed without triggering an episode. Would all subsequent PC and TC claims be paid as FFS? Will the TC claims (either with the RO Model-specific HCPCS code or FFS HCPCS code) and the second PC episode payment claims be denied and then reconciled as per the incomplete episode policy in the proposal? Would all TC claims after the 28 day window be paid under FFS and the initial episode PC payment be the only amount reconciled? The ABS urges CMS to pay all CPT/HCPCS codes that are billed outside of the 28-day window (i.e. an incomplete episode) as FFS.**
- 11. The ABS recommends using a blend of MPFS and HOPPS fee schedules for determining the PC portion of the national base rate.**
- 12. The ABS recommends CMS remove the palliative and mis-attributed episodes from each of the disease sites and recalculate the national base rates based on definitively treated cases alone. CMS should consider using a blend of MPFS and HOPPS fee schedules for the PC national base rate and should consider using the HOPPS APC without the C-APC methodology for the TC national base rate for cervical cancer. As detailed in letters from ASTRO, the C-APC HOPPS methodology undervalues the brachytherapy reimbursement (best illustrated in Cervical Cancer), and a blend with MPFS and/or calculation of reimbursement with HOPPS APC FFS aligns reimbursement with the patient care provided.**
- 13. The ABS is gravely concerned that there are mis-attributions of episodes due to ICD coding and inconsistent definitions around which CPT/HCPCS codes are included in each modality assignment. ABS strongly recommends that CMS consider delay of model implementation until data integrity issues are clarified with practitioners in a transparent manner. ABS recommends that CMS consider creation of clinical business rules to remove palliative and mis-attributed episodes from the national base rate calculation.**
- 14. The ABS strongly recommends that CMS remove the historical experience adjustment (which is disproportionately determined by the Winsorized historical**

payment), zero out the efficiency factor for efficient practices, and make payments more truly site neutral.

15. The ABS strongly recommends further validation of the ordinary least squares regression-derived case mix adjustments in both the MPFS and HOPPS settings.
16. The ABS is concerned that the payment adjustment methodology as proposed harms efficient and low cost practices, such as the majority of brachytherapy practitioners. The ABS urges CMS not to penalize Efficient practices through this methodology. The ABS also strongly recommends CMS limit the downside risk for practices; this model provides no safeguard for excessive financial downside.
17. The ABS highly encourages CMS to provide more transparency regarding the RO Participant's predicted vs expected payment calculations, as few participants will have access to individual/practice case mix variable details within their own practice.
18. The ABS recommends applying the payment withholds (incorrect payment, quality, patient experience) to future cash flow rather than withholds of current revenues.
19. The ABS strongly believes that the exclusion of the TC component from the 5% incentive payment within the MPFS is in direct opposition to the MACRA-required Technical Component Payments. We do not believe that inclusion of the 5% incentive payment for the TC through the MPFS (for freestanding centers) would affect the site neutral test of the RO Model.
20. The ABS recommends that CMS decrease the PC and TC discount factors to 3% and allow practices to receive a 5% incentive payment as part of being an Advanced APM for both the PC and TC components of reimbursement. Alternatively, ABS recommends that CMS apply no TC discount if there is no opportunity for a 5% incentive payment. This more fairly balances savings for CMS while still incentivizing high quality, low cost, and equitable care for Medicare patients.
21. The ABS urges CMS to start the model on a voluntary basis with no provider financial risk. A phase in process allows practices to transition to the coding/billing practices needed to succeed in this model and allows time to build infrastructures to collect data.
22. The ABS is concerned about the unfunded mandate to collect quality metric data for all patients (not just those in the RO Model). The ABS strongly recommends data collection on only those patients in the Model.
23. ABS recommends a voluntary phase-in period to collect the quality metric data which assists practices to change operational infrastructures for more robust data reporting. ABS recommends a pay for reporting of quality metric data that is outside of the currently established RO Model proposal. Practices need payment in order to cover the potentially practice high costs required to collect and report on these

quality metrics.

24. The ABS recommends that CMS collaborate with professional societies to identify additional metrics that meaningfully measure quality of cancer care and impact on outcomes (including survival).
25. The ABS recommends that accreditation (such as via the ACR, ACRO, or the ASTRO APEx programs) count for the monitoring requirements, which would reduce the compliance monitoring burden on practices and CMS.
26. ABS also strongly urges CMS to honor its commitment to MIPS practices that have complied with the MIPS program requirements by issuing the MIPS bonus payments in the payment methodology for 2020 and 2021.
27. The ABS is concerned about the short timeline for implementation of the model. The ABS recommends delaying until at least Apr 1, 2020 and more optimally until Jul 1, 2020 with a time period (1-2 years) to initially allow voluntary opt-in prior to a mandatory start. The ABS strongly recommends that CMS revise the mandatory nature of the RO Model and provide an opt-in and opt-out clause for practices that span multiple CBSA's with a single TIN.

Brachytherapy as a unique modality within radiation oncology

Brachytherapy is a unique modality that includes both surgical procedures and radiation therapy delivery within the field of radiation oncology, and requires an unusual skill set to administer. Brachytherapy improves patient survival when used as a boost to external beam radiation therapy.

CMS has proposed to include all modalities of radiation therapy, including included external beam radiotherapy (such as 3-dimensional conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), and proton beam therapy), intraoperative radiotherapy (IORT), image-guided radiation therapy (IGRT), and **brachytherapy**.

Brachytherapy is a unique modality within radiation oncology. It is used in the definitive setting alone as a monotherapy for low to favorable-intermediate risk prostate cancer with high cure rates in the 95% range. It is also used in the post-operative setting for many cancers, such as uterine, cervical, breast, rectal, and other cancers. Brachytherapy is used after external beam radiotherapy (EBRT) as a radiation "boost" treatment for certain cancers, such as cervical, uterine, and prostate cancers. The advantage of brachytherapy is that radiation sources are placed temporarily or permanently into or over the tumor allowing for high dose delivery of radiation while sparing the surrounding normal organs. This contrasts with EBRT where multiple radiation beams traverse through normal tissue to reach the treatment target. Unlike most other modalities of radiation therapy, brachytherapy requires additional skill and effort including performing a surgical procedure to place applicators into/adjacent to the tumor. The applicators allow the radiation source to deliver radiation directly into/adjacent to the tumor, which spares normal tissues. At times the surgical procedure involves other sub-specialized physicians. The

radiation oncologist performing the procedure and the site of service frequently differ between the EBRT and the brachytherapy, as the skill and expertise is not universal. Studies demonstrate outcome improvement when brachytherapy is performed by experienced clinicians.

Brachytherapy is typically used in the definitive setting, where the goal of therapy is curative. The majority of CMS' expenditures for cancer care is in the non-definitive, palliative setting where cancer has already spread to a distant part of the body. If local treatments are given an opportunity to continue to evolve to improve local control, there will ideally be fewer cases of metastatic disease that develop. Even definitive management of cases with oligometastatic disease, where a patient has a limited number of metastases only, has shown improvements in progression free and overall survival. The ABS believes that CMS should create a Model that incentivizes the most optimal and effective care upfront for patients eligible for definitive treatment management, and appropriate rate setting for the most effective modalities, including brachytherapy, will have positive downstream economic savings for CMS.

Brachytherapy has long been considered a high quality and high value radiation therapy modality within radiation oncology and is essential in the treatment of several types of cancers. Clinical

Decreased Utilization of Brachytherapy Boost

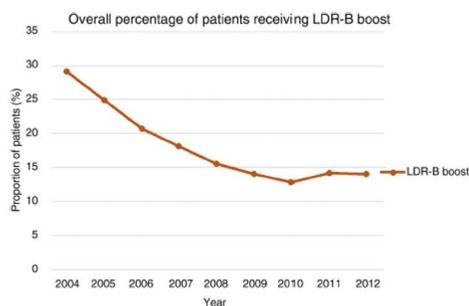


Fig. 1 - Proportion of patients treated with androgen suppression and external-beam radiation with low-dose rate brachytherapy (LDR-B) boost between 2004 and 2012 relative to dose-escalated external beam radiation therapy alone.

S. Johnson et al. Eur Urol 2017

evidence shows that patients have improved survival and less toxicity when brachytherapy is delivered as a “boost” after EBRT for cervical cancer patients^{5,6} when compared to those that have only external therapy. The addition of a brachytherapy “boost” in selected prostate cancer patients demonstrates a low rate of biochemical recurrence^{7,8,9,10}. Recent studies have shown that brachytherapy is one of the lowest cost modalities for prostate cancer, yet delivers comparable outcomes¹¹. However, the use of brachytherapy in the United States has significantly declined

with an associated **decline** in cure and survival in cervical cancer patients.

⁵ Holschneider, C.H., et al., Brachytherapy: A critical component of primary radiation therapy for cervical cancer: From the Society of Gynecologic Oncology (SGO) and the American Brachytherapy Society (ABS). Brachytherapy, 2019. 18(2): p. 123-132.

⁶ Han K IJROBP 2013, Gill IJROBP 2014

⁷ Chin, J., et al., Brachytherapy for Patients With Prostate Cancer: American Society of Clinical Oncology/Cancer Care Ontario Joint Guideline Update. J Clin Oncol, 2017. 35(15): p. 1737-1743.

⁸ ASCENDE-RT trial Hoskin Radiother Oncol 2012

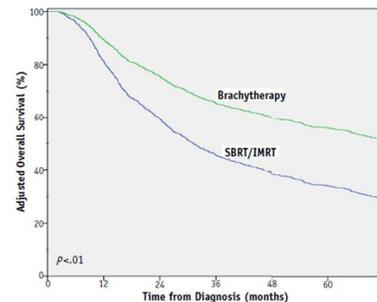
⁹ Sathya et al Radiother Oncol 2005

¹⁰ Kishan JAMA 2018

¹¹ Laviana, A.A., et al., Utilizing time-driven activity-based costing to understand the short- and long-term costs of treating localized, low-risk prostate cancer. Cancer, 2016. 122(3): p. 447-55.

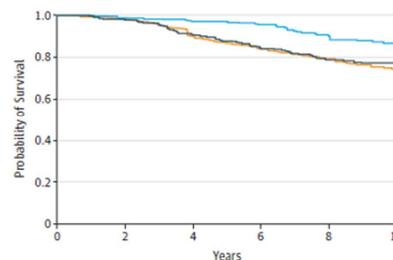
A SEER database analysis of 7,359 patients between 1998 and 2009 reported a **25% reduction in brachytherapy use** resulting in a **13% cause specific survival reduction for cervical cancer**¹². Similarly, the National Cancer Data Base (NCDB) was also analyzed to determine which radiation dose escalation techniques were being utilized from 2004 to 2011 for cervical cancer patients specifically¹³. **Brachytherapy use declined 10%** while more costly and less conformal modalities such as IMRT/SBRT (EBRT techniques) increased by 10%. This decreased utilization in brachytherapy boost and increased utilization in EBRT boost translated into a **significant reduction in median survival (70.9 mos for patients receiving brachytherapy boost vs. 47.1 months for IMRT/SBRT boost)** (Fig. 1¹⁴). The decrease in survival is equivalent to the increase in survival afforded by chemotherapy which means patients are exposed to the side effects, danger and expense of chemotherapy, only to see the benefits erased if brachytherapy is not competently delivered. Similarly, although addition of a brachytherapy boost to EBRT improves overall survival compared with EBRT alone¹⁵ the use of brachytherapy for prostate cancer has also decreased significantly over time¹⁶. **The cause of reduction in brachytherapy use is multi-factorial, but includes declining reimbursements which has led to diminishing expertise among radiation oncologists**¹⁷. Inadequate support for brachytherapy and an inability to keep a viable brachytherapy program open in the current economic environment are directly leading to inferior outcomes for some of the most vulnerable cancer patient populations, including women with cervical cancer. The RO Model as proposed may further dis-incentivize the use of this high value therapy among radiation oncologists.

Brachytherapy Improves Survival for Cervical Cancer – NCDB Study



Gill et al. IJROBP 2014

Brachytherapy Improves Survival for Patients with High Risk Prostate Cancer



Kishan JAMA 2018

¹² Smith GL, Eifel PJ: Trends in the utilization of brachytherapy in cervical cancer in the United States: In regard to Han et al. Int J Radiat Oncol Biol Phys. 2014;88:459-460.

¹³ Gill BS, Lin JF, Krivak TC, et al: National Cancer Data Base analysis of radiation therapy consolidation modality for cervical cancer: The impact of new technological advancements. Int J Radiat Oncol Biol Phys. 2014;90:1083-1090.

¹⁴ Adapted from Gill et al. Int J Radiat Oncol Biol Phys. 2014;90:1083-1090 and communication from Dr. Sushil Beriwal

¹⁵ Kishan 2018 JAMA

¹⁶ Martin J, Handorf E, Kutikov A, et al. The rise and fall of prostate brachytherapy: Use of brachytherapy for the treatment of localized prostate cancer in the National Cancer Data Base. Cancer. 2014;120:2114–2121.

¹⁷ Petereit DG, Frank SJ, Viswanathan AN, et al. Brachytherapy: where has it gone?. J Clin Oncol. 2015;33(9):980–982. doi:10.1200/JCO.2014.59.8128

THE ABS RECOMMENDS REIMBURSING BRACHYTHERAPY THROUGH TRIGGERING OF A SECOND EPISODIC BUNDLED PAYMENT (SECOND PC AND TC PAYMENT) OR THROUGH FEE-FOR-SERVICE FOR MULTI-RADIATION MODALITY EPISODES INCLUDING BRACHYTHERAPY BOOST (I.E. WHERE BRACHYTHERAPY IS USED BEFORE, DURING, OR AFTER EBRT AND POSSIBLY TWO DIFFERENT PHYSICIANS ARE INVOLVED IN PROVIDING CARE) WITHIN A 90 DAY EPISODE

Cancer treatments can be inherently complex, requiring multiple specialty modalities of treatment (such as surgery, chemotherapy, and radiation therapy). Some cancer treatments may even require multiple forms of radiation therapy and often at different sites of service. The best survival outcomes for patients with cervical cancer is the delivery of EBRT followed by brachytherapy. In addition, data demonstrate that patients with unfavorable intermediate- to high-risk prostate cancer treated with the addition of a brachytherapy boost to EBRT and androgen deprivation therapy have the lowest prostate cancer specific mortality rates and a 50% reduction in biochemical recurrence of their prostate cancer^{18,19}. Thus, combination modality episodes with multi-modality radiation (EBRT and brachytherapy) are an important option for men and women with aggressive cancers, as explicitly stated in the NCCN Guidelines, the ABS consensus guidelines, the ASCO/Cancer Care Ontario Joint Guideline, the AUA/ASTRO/SUO Guideline, among others.

Multi-modality cancer care is not unique even within CMS' existing advanced alternative payment models, such as the Oncology Care Model (OCM). For instance, many cancer patients may require multiple forms of systemic therapy, such as combinations of chemotherapy, molecularly targeted agents/biologics, and immunotherapies. These combinations are necessary and are more effective than when given as single agents. In the OCM, CMS does reimburse for combination systemic therapies and does not unnecessarily pressure the clinician to make a choice of a single modality of therapy where multiple modalities of therapy are considered not only standard but more effective.

Similarly, there are clinical scenarios where multiple modalities of radiation are necessary to achieve optimal patient outcomes. We will detail each of these clinical scenarios below. This use of multiple radiation modalities is especially true when brachytherapy is used in combination with external beam radiation therapy (EBRT) techniques. Similar to using a combination of two different chemotherapies that have two different mechanisms of action, brachytherapy and EBRT both have different mechanisms of action and are not simply substitutable. High dose rate and low dose rate brachytherapy have intrinsically different radiobiological responses on tumor tissues as compared to EBRT, and the most optimal outcomes in some clinical scenarios occur with the combined radiological effects of EBRT and brachytherapy. This is especially true in cervical cancer, high risk uterine cancers, and high risk prostate cancers.

The ABS appreciates CMS' consideration of episodes that could require the involvement of physicians from multiple TINs/CCNs. CMS has calculated that claims data from January 1, 2014 through December 31, 2016 show less than **6% of episodes** had more than one unique TIN or CCN billing for either professional RT services or technical RT services within a single episode.

¹⁸ Morris JW, Tyldesley S, Rodda S, et al. Androgen Suppression Combined with Elective Nodal and Dose Escalated Radiation Therapy (the ASCENDE-RT Trial): An Analysis of Survival Endpoints for a Randomized Trial Comparing a Low-Dose-Rate Brachytherapy Boost to a Dose-Escalated External Beam Boost for High- and Intermediate-risk Prostate Cancer, *Int J Radiat Oncol Biol Phys*. 2017 Jun 1;98(2):275-285.

¹⁹ Kishan AU, Cook RR, Ciezki JP, et al. Radical Prostatectomy, External Beam Radiotherapy, or External Beam Radiotherapy with Brachytherapy Boost and Disease Progression and Mortality in Patients with Gleason Score 9-10 Prostate Cancer, *JAMA* March 6, 2018 Volume 319, Number 9 89

Similarly, our analysis showed that it is uncommon for episodes to have more than one unique TIN or CCN. However, these 6% of cases are highly enriched for multi-radiation modality cases, such as cervical cancer and prostate cancer that undergoes brachytherapy following external beam. Additionally, many additional such cases require multiple physicians that may be in the same TIN. Many professional radiation oncology groups have a limited number of brachytherapy specialists (i.e. radiation oncologists who have skill in brachytherapy). Thus, there are many additional such episodes where the EBRT is delivered by one physician in the group and the brachytherapy is delivered by a second specialized brachytherapy physician who may also be in the same TIN. **Of the 629 episodes treated with combination EBRT and brachy in the RO Episode File for Cervical Cancer, only 17% (108) involved a single physician, while 83% required a second physician (different NPI). This supports ABS' recommendation of paying for the brachytherapy with a second episodic bundle payment or with FFS payment when brachytherapy is delivered before, during, or after EBRT within a single 90 day episode.**

Of the 2,946 episodes of total cervical cancer (FREE and OPD) in the CMS file, **53.5% (1,573) required brachytherapy**. Of the cases of cervical cancer treated in the OPD, **57% required brachytherapy**. This is consistent with most practices that treat cervical cancer. Of the 91,552 episodes of prostate cancer in the CMS file, 8% (7,174) required brachytherapy either as a monotherapy or as a boost. Of these, **only 4% (3,847) required combination EBRT (3D conformal or IMRT) with a brachytherapy boost**.

The **number of episodes of cervical cancer that have 21+ treatment deliveries** (which is what would be expected for a case of multi-radiation combination therapy) is **abnormally low** in the CMS data file (only 9.9%). For many radiation oncology practices, the frequency of EBRT and brachytherapy can range from 40-60%, as combination modality therapy is the standard of treatment for cervical cancer. **The ABS is concerned that there are errors in the claims data which are leading to incorrect attribution of CPT/HCPCS codes to particular modalities and under-representing the true cost of delivering combination modality (EBRT and brachytherapy care).**

The current RO Model does not accurately and adequately account for multi-radiation modality episodes in certain clinical scenarios. Many patients with cervical or prostate cancer may initially undergo EBRT in a freestanding setting, and then receive a brachytherapy boost in the HOPD setting by a separate physician (or less often the same physician). The CMS has stated that the physician who started the EBRT would be the Dual Participant and that the HOPD and physician in the HOPD would not receive a TC payment. This would be unacceptable for the HOPD and would lead to decreased access to vulnerable cancer patients, including those with higher risk cervical and prostate cancer. Please see the list of multi-radiation modality scenarios below:

Common Clinical Scenarios involving Multi-Radiation Modalities, Multiple Physicians, and Multiple Sites of Service

The ABS is concerned that given the significant clinical, logistical, and site of service heterogeneity that is inherent to providing combination modality (i.e. EBRT followed by brachytherapy) radiation therapy, there are several common clinical scenarios that will be challenging within the proposed RO Model.

- 1. *Physician in freestanding facility does the EBRT and then a different physician (second NPI) does the brachy in the HOPD setting***

- a. The ABS requests clarification: If the brachytherapy physician is in a different TIN as the first physician, would the brachytherapy following EBRT be paid FFS? If the brachytherapy for the second physician is in a same TIN as the first physician, would the brachytherapy following EBRT also be paid FFS?
 - b. **ABS recommends that a second episodic bundle payment or FFS payment be made for the brachytherapy when delivered before, during, or after EBRT.**
 - c. **Additionally, the ABS recommends that a modifier code be created to acknowledge the occurrence of these multiple radiation modalities within an episode so that the episode is not labeled a “duplicate RT service” when there is a second participant (TC in this case) and does not go to reconciliation. Such episodes should NOT go to reconciliation, as that would be a burden for both CMS, the involved physicians, and the freestanding center or OPD.**
- 2. *Physician in freestanding facility does the EBRT and then same physician does the brachy in the HOPD setting***
- a. Physician would be a Dual Participant due to the EBRT, and hospital would be a second Technical Participant.
 - b. In the current proposal, the hospital would not get a TC payment. This is problematic for the freestanding physician and the hospital and would require some mechanism for reconciliation with the hospital for technical costs of operating room time. **ABS recommends that a second episodic bundle payment or FFS payment be made for the brachytherapy when delivered before, during, or after EBRT.**
 - c. **Additionally, the ABS recommends that a modifier code be created to acknowledge the occurrence of these multiple radiation modalities within an episode so that the episode is not labeled a “duplicate RT service” when there is a second participant (TC in this case) and does not go to reconciliation. Such episodes should NOT go to reconciliation, as that would be a burden for both CMS, the involved physicians, and the freestanding center or OPD.**
- 3. *Physician in one HOPD or Freestanding center does the EBRT but patient is then sent to a different physician (different NPI with a different TIN) who then does the brachy in a different HOPD or Freestanding center***
- a. Physician who did the EBRT has a different TIN than the physician who did the brachytherapy, and the first HOPD where EBRT was done has a different TIN than the second HOPD. It is ABS' understanding that the first physician who did the EBRT would be the Professional Participant of the episode, the first hospital would be the Technical Participant, or if EBRT was in freestanding center that first physician would be a Dual Participant. **CMS has stated that the second physician would get paid FFS. However, it does not appear that the second hospital or freestanding center would get paid FFS for the TC of delivery of that component of therapy. ABS recommends that the TC for the second hospital/freestanding center also be paid FFS. Additionally, does this protocol apply if physician and both hospitals are in the same CBSA?**
- 4. *Physician in HOPD does the EBRT and a different physician then does the brachy in the same HOPD***
- a. If the physician who did the EBRT, the second physician who did the brachy, and hospital are in the same TIN → First physician who did the EBRT would be Professional Participant, Hospital would be the Technical Participant. What would happen to the second physician who delivered the brachy? Since in the same TIN, that second physician would not be a PC component or FFS?

- b. ABS recommends that a second episodic bundle payment or FFS payment be made for the brachytherapy when delivered before, during, or after EBRT.**
- 5. Physician in freestanding facility does the EBRT and then the same physician does the brachy in the freestanding center**
 - a. Physician would be a Dual Participant.
 - b. ABS recommends that a second episodic bundle payment or FFS payment be made for the brachytherapy when delivered before, during, or after EBRT.**
- 6. Physician in HOPD does the EBRT and same physician then does the brachy in the same HOPD**
 - a. Both the physician and hospital are in the same TIN → Physician would be Professional Participant, Hospital Technical Participant.
 - b. ABS recommends that a second episodic bundle payment or FFS payment be made for the brachytherapy when delivered before, during, or after EBRT.**

If CMS pays for brachytherapy that follows EBRT within a single 90-day episode as FFS, it would alleviate the inadvertent negative incentives in the proposed payment model and ensure that this patient population continues to receive high-quality care. Overall, this would be a rare occurrence within the field of radiation oncology, as calculated by CMS, and would have a very minimal financial impact on CMS' additional expenditures, especially if brachytherapy remains in the model as monotherapy. The risk of taking advantage of additional FFS for brachytherapy before, during, or after EBRT is quite low, given the low frequency outside of 2-3 major disease sites, that would even require brachytherapy with EBRT. Additionally, performing brachytherapy is very time and staff intensive, and is NOT a therapy can be over-utilized easily.

The ABS also encourages CMS to not consider multi-radiation modality cases delivered by two physicians in two different TINs as “duplicate RT services”. As described above, these episodes that require EBRT by one physician and brachytherapy by a second physician are not duplicating any RT services, but are rather completing a single course of radiation therapy. These cases should not go to reconciliation, as that would significantly delay payment until reconciliation occurs in August of the year following the performance year. **The ABS recommends that a modifier be created to acknowledge episodes where brachytherapy is delivered before, during, or after EBRT to ensure that these episodes are paid by a second bundle or through FFS, and for the episode to not go to reconciliation.**

CMS' methodology, as outlined in the RO Model proposal and within the RO Episode File (2015-2017) Technical Document, appears to define a “brachytherapy” modality episode if there is a brachytherapy delivery code (for instance 77767, 77768, 77770, 77771, 77772, 77778, 77761, 77762, 77763) associated with the treatment delivery codes within an episode. This methodology does not differentiate an episode of care where brachytherapy is delivered as a monotherapy (i.e. the only modality of radiation therapy in an episode) or as a multi-radiation modality (i.e. where brachytherapy is delivered before, during, or after EBRT). Based on the RO Episode File (2015-2017) Technical Document, there is a varying number of services within each brachytherapy episode, which means that the episodes defined as brachytherapy include episodes of brachytherapy as monotherapy and brachytherapy as a combined modality therapy. Within prostate cancer, the most common multi-radiation modality episode would consist of delivery of 20-25 EBRT treatments (with conformal external beam, IMRT, or proton therapy) followed by a brachytherapy boost. Thus, we would expect these multi-radiation modality episodes to be

between 20-40 treatments. There are however some brachy episodes that are above 41+ episodes, which would need auditing as these are clinically atypical. It appears that CMS is including some non brachytherapy delivery codes within the COUNT_BRACHY column.

As stated above, episodes that require multi-radiation modality services are under-represented within the RO Model data and do not statistically impact the RO Model national base rate. Additionally, multi-radiation modal episodes may involve multiple radiation oncologists (one for the EBRT and one for the brachytherapy), the same site of service, or a different site of service. Given the significant expertise required to deliver brachytherapy, many radiation oncologists who perform the initial EBRT may even send the patient to a different institution (with the same CBSA or outside of it) to receive the brachytherapy boost. The ABS is concerned that the RO Model has no financial safeguards in place for complex cases, which will put practices and hospitals at financial risk for delivering clinically appropriate care to their patients and undermine patient access to medically necessary care.

Given the significant variations that exist in how multi-radiation modality care is delivered in clinical practice, it's low frequency of occurrence, and it's low use within the CMS data file, **The ABS recommends reimbursing brachytherapy through either triggering of a second RO Model episodic bundle (second PC and TC payment) or fee-for-service when brachytherapy is delivered before, during, or after external beam radiation therapy (EBRT) within a 90-day episode (regardless of brachytherapy delivery in the same or different TIN/CCN and with the same or a second NPI).**

Excluding brachytherapy radioactive sources from the episode bundle

We appreciate CMS' analysis regarding inclusion of brachytherapy radioactive sources (or radioisotopes). Although the ABS is supportive of CMS' intent to include nearly all aspects of radiation oncology into the RO Model, we believe that inclusion of brachytherapy radioactive sources will create negative incentives to utilize brachytherapy within an episode of care and will ultimately undermine access to high-quality and high-value LDR and HDR brachytherapy treatments. Brachytherapy sources are also considered a medical device and not a surgical and radiation therapy procedure.

Currently, brachytherapy sources are paid individual rates based on the type of radioactive source. Given the inherent differences in the types of sources needed for clinical care (including half-life, energy, dose rate, production in a medical reactor or cyclotron, and costs associated with manufacturing of the sources) the costs of each sources can vary significantly and need to be ordered and made specifically for each patient. CMS has considering bundling of payment of brachytherapy sources under Medicare previously, where there was a proposal to bundle the payment for professional services with brachytherapy sources together under the HOPPS. Congress ultimately created legislation in 2003 under the Medicare Modernization Act of 2003 under the Social Security Act at section 1833(t)(2)(H) that required brachytherapy source coding (C-codes) and brachytherapy source payment rates that are separate from the professional services. Billing for each patient would be based on the differences in isotopes, radioactive intensity, and the number of isotopes that are required for treatment of the individual patient. Given the smaller representation of brachytherapy (as a monotherapy and as a combination modality therapy) within radiation oncology, there are challenges in utilizing a mean episode cost approach for an infrequently utilized modality like brachytherapy, and we are concerned that the currently methodology would not adequately account for the varying cost of the brachytherapy sources.

The ABS respectfully requests that CMS remove the brachytherapy radioactive elements codes (inclusive of all C-codes, i.e. A9527, C1715, C1716, C1717, C1719, C1728, C2616, C2634, C2635, C2636, C2638, C2639, C2640, C2641, C2642, C2643, C2644, C2645, C2698, C2699 and Q3001) from the list of RO Model bundled HCPCS codes (Table 2 of the proposal).

Liver Cancer and Yttrium-90

In addition to the commonly used brachytherapy sources, it appears that C2616 (Yttrium-90) is included in the payment data. Such a source is associated with radiopharmaceutical delivery codes, and CMS has explained that they intend to exclude radiopharmaceuticals from the RO Model. The proposed 2020 Medicare hospital outpatient payment for the Yttrium-90 brachytherapy source alone is \$17,595 while the proposed TC National Base Rate for liver cancer is \$14,650. Yttrium-90 also comprises about 35% of episodes and contributed significantly to the current Liver Cancer national base rate calculation, as seen below:

OPD Liver Cancer Episodes (TC Only) from the CMS RO Episode File

Liver Cancer Modality	Approximate Frequency of Cases	Average TC Reimbursement for cases with modality
Brachytherapy (Y-90 cases)	35%	\$19,644.58
Conformal external beam (3D)	15%	\$8,331.55
IMRT	22%	\$14,517.34
Proton therapy	1.5%	\$27,120.48
SRS/SBRT	26%	\$12,419.00
IORT	0%	\$0.00
TC National Base Rate		\$14,650

Given that C2616 should be removed from the list of codes, recalculation of the national base rate would lead to an inadvertent and disproportionately large decrease in the reimbursement for liver cancer. This would lead to a significant decrease in payment for the remaining external beam modalities, as below:

Liver Cancer Modality	Frequency of Cases	Average TC Reimbursement
Brachytherapy	35%	\$3,018.58
Conformal external beam (3D)	15%	\$8,331.55
IMRT	23%	\$14,517.34
Proton therapy	2%	\$27,120.48
SRS	26%	\$12,419.00
IORT	0%	\$0.00

Possible new TC National Base Rate		~\$9,280 (weighted sum)

The ABS therefore encourages CMS to remove Liver Cancer as a disease site within the RO Model and to remove all brachytherapy source codes (including C2616).

Brachytherapy surgical codes in the RO Model bundled HCPCS codes

The ABS appreciates CMS' goal of including a wide range of CPT/HCPCS codes in the RO Model. The RO Model includes some brachytherapy surgical procedures, including 57155, 57156, 55920, 58346 for gynecological procedures, while excluding others, like 55875. Depending upon the site of service (freestanding vs HOPD), the participating radiation oncologist (who may be the same physician who delivered the EBRT or more commonly a *different* physician who is only delivering the brachytherapy component) or the participation of a sub-specialty surgeon in the procedure (with a -62 modifier if done with the radiation oncologist as a co-surgeon), these brachytherapy surgical codes are used differently from practice to practice. Inclusion of these codes within the RO Model would introduce logistical difficulties in cases of site of service differentials and different physicians assisting in the procedure or involved in the episode of care. There are approximately 4-8% of these codes (including 57155, 57156, 55920, 58346) that are delivered by a Gynecologic Oncologist rather than a Radiation Oncologist.

The ABS would strongly recommend that when brachytherapy is delivered before, during, or after EBRT (by a second physician) that the brachytherapy surgical codes (57155, 57156, 55920, 58346) that are in the RO Model should be paid at FFS. The ABS also recommends that these episodes of combination radiation modality should not meet the criteria for inclusion into duplicate RT services that would require reconciliation (whether or not the two physicians are in the same or a different TIN). This is consistent with our recommendation to pay for brachytherapy that occurs before, during, or after EBRT with the triggering of a second bundle payment (second PC or TC) or through FFS. Given the limited use of brachytherapy within the field of radiation oncology, payment of these codes with FFS would have negligible impact on the national base rates.

Adoption of new service lines and new indications of radiation therapy

The RO Model as proposed disincentivizes the adoption of new service lines or a new indication for radiation therapy that a RO Model participant does not yet provide. The adoption of a new service line by a radiation oncology participant is dependent on the technical skill available within a practice, the predicted volume of such a service, and its value for patients. Some examples of this within brachytherapy include the future adoption of MRI-guided brachytherapy or a definitive treatment approach for an oligometastatic cancer patient. Starting a new technologically oriented service line requires high fixed start-up costs. The cost of delivering care with a new service line may be higher than the practice's historical costs, given the cost of the equipment and need for special technically skilled physicians and staff. In the current RO Model, adoption of a new brachytherapy service line that is more costly than the average episode payment to the participant places the participant at financial risk of not being able to cover the costs of the new service line. Since the participant's specific PC and TC payment rate for each disease site is primarily (90%) driven by its historical costs (see Payment Adjustment Methodology Concerns), adoption of a new service line that delivers high quality and high value care for patients would be disincentivized.

The proposal utilizes a trend factor to adjust the 2017 national base rates. This trend factor is specific to each disease site and allows for updates in payments to reflect current trends in the OPSS and PFS rates for RT services. The trend factor calculations would update the national base rates using the most recently available claims data of those non-participating providers (i.e. those outside of the RO Model) and suppliers and the volume at which they billed for RT services as well as their corresponding payment rates. Theoretically, this would help to adjust the national base rates to ensure that payments within the RO Model reflect the changes in treatment patterns and payment rates that have occurred outside of the model. However, there is a delay between any increase in episode cost outside of the model and an increase in the trend factor. Additionally, there is a delay between higher practice episode costs being adequately incorporated into the new historical practice episode rate, which is used to calculate the historical experience adjustment.

The ABS believes that the trend factor does not adequately or expeditiously update the episode payments for practitioners within the RO Model. Similarly, CMS has acknowledged this within the OCM, where there is a novel therapies adjustment. Conceptually, the novel therapies adjustment in the OCM is intended to account for a practice's or pool's use of newly approved oncology drugs that may not be reflected in the trend factor. If a practice's/pool's new oncology drug expenditures as a percentage of its total episode expenditures is higher than that for episodes outside of OCM, then an adjustment will be made based on 80% of the difference between the practice's/pool's proportion and the non-OCM proportion. *The novel therapies adjustment will never lower the benchmark; it can only increase the benchmark.* Even the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) makes an allowance for new/advanced drugs using a transitional drug add-on payment adjustment.

Given the high fixed cost to start clinical treatments with a new technology, a lack of adjustment for such higher cost care would need to be born by the radiation oncology practice for an extended period of time before the trend factor may adjust the episode payment upwards. **The ABS would recommend the Agency consider paying for new service lines as FFS or through the RO Model Episode Bundle, whichever is higher.** This should be done for a period of 2-3 years until the cost of this new service line is incorporated into the practice's payment rate. A modifier could be created to acknowledge episodes where a new service line is being used. The adjustment for a new service line would never lower the benchmark payment to the practice, but would only increase it.

Stifling innovative technology

Radiation oncology is a rapidly evolving field, and brachytherapy as a modality within radiation oncology continues to experience significant innovations. Innovative technologies may improve patient outcomes, reduce side effects, improve quality of life, and enhance value of cancer care. The ABS is concerned that the RO Model as proposed may stifle innovation in radiation oncology. The use of new technology frequently requires a very high capital investment in technology and clinical/technical labor. New technology may initially receive a Category III CPT code, and after adequate clinical information on clinical efficacy, safety or applicability to clinical practice is obtained, the new technology may be transitioned to a Category I CPT code. Another avenue for new technology uptake could include the use of existing CPT/HCPCS codes, but with a different combination or more units than historically used. In both situations, use of new technology can increase the cost of care delivery within an episode. CPT codes that are not within the RO Model Bundled HCPCS would be paid separately from the bundled payment, but CPT codes which are

bundled in the RO Model but are used in more frequency or differently than historically done would add cost to the participant without any upward adjustment of the episode payment.

The ABS recommends that CMS pay FFS for any new technology identified by a new CPT code or new technology code during the term of the model.

Treatment of Multiple Sites

The ABS appreciates CMS' inclusion of a large number disease types (17 different disease types) within the RO Model. Within the field of radiation oncology, there is currently an evolution in treatment paradigms for the treatment of patients with cancer that has spread to limited sites (known as oligometastatic disease)^{20,21}. For patients who meet these criteria, they are candidates for treatment to multiple sites, including the primary tumor and a limited number of metastatic sites. Given that many primary tumor sites are included in this Model and 2 major sites of metastatic disease (bone and brain) are also included in the Model, we foresee that there will be significant clinical growth of utilization of multiple radiation therapy modalities to treat multiple sites (either concurrently or sequentially). This is a trend that will continue to grow, and we are concerned that the Model as proposed will actually dis-incentivize care that would be of the highest quality for the patient. Although brachytherapy is not commonly utilized at this time for the treatment of oligometastatic patients, we anticipate that there may be future growth and need of brachytherapy services for these patients. **The ABS is concerned that the costs of patients who require treatment to multiple sites is not accurate in the RO Model proposed national base rates. We would recommend CMS consider paying for treatment of a second site with FFS.** If only 1 episode could be triggered for a patient that could require treatment to 3 or 4 sites of disease, this would place the Participant at a significant downside financial risk for delivering the optimal and highest quality treatment to the patient. Without making such an adjustment to the Model, CMS could risk incentivizing low quality care that ultimately leads to worsened outcomes for patients.

Episode length

CMS is proposing a 90-day episode that is triggered when there is a treatment planning service (77261-77263) furnished by a Professional/Dual participant and when there is at least one radiation treatment delivery service furnished by a Technical/Dual participant within a 28 day window. The ABS is supportive of the 90-day episode window and a 28-day window between the treatment planning code and the first treatment delivery service. Based on feedback from ABS members there are clinical cases where the treatment delivery service would be delivered outside of the 28-day window. For instance, many cases of multi-radiation modality cases (such as EBRT followed by brachytherapy) may also require coordination with another specialty (who is delivering concurrent systemic therapy such as anti-hormonal therapy) and coordination of timing of the systemic therapy. In such cases however RO participants may need to furnish the treatment

²⁰ Palma et al. Stereotactic ablative radiotherapy versus standard of care palliative treatment in patients with oligometastatic cancers (SABR-COMET): a randomised, phase 2, open-label trial. *The Lancet*. Vol 393, Issue 10185, 18–24 May 2019, Pages 2051-2058

²¹ Gomez et al. Local Consolidative Therapy Vs. Maintenance Therapy or Observation for Patients With Oligometastatic Non–Small-Cell Lung Cancer: Long-Term Results of a Multi-Institutional, Phase II, Randomized Study. *Journal of Clinical Oncology* 2019 37:18, 1558-1565.

planning service closer to the date of treatment delivery to ensure that care is initiated within the 28-day window.

However, clinical circumstances will still arise where the treatment delivery code will be furnished outside of the 28-day window from treatment planning code, triggering an incomplete episode. **The ABS asks if CMS could clarify how Medicare administrative contractors will manage PC and TC claims after the 28-day window has passed. Would all subsequent PC and TC claims be paid as FFS? Will the TC claims (either with the RO Model-specific HCPCS code or FFS HCPCS code) and the second PC episode payment claims be denied and then reconciled as per the incomplete episode policy in the proposal? Would all TC claims after the 28 day window be paid under FFS and the initial episode PC payment be the only amount reconciled at a later date?** If practices would need to wait until the reconciliation period (1 year after the PY) and true-up period (approximately 2 years after the PY), this would create a significant cash flow delay for RO Participants. **The ABS urges CMS to consider paying all CPT/HCPCS codes that are billed outside of the 28-day window (i.e. an incomplete episode) as FFS.**

Flawed C-APC Methodology, Data integrity issues within the CMS Dataset and utilizing a blend of MPFS and HOPPS APC FFS Fee Schedule for payment calculations for Cervical Cancer

In the RO Model proposal, CMS is proposing to utilize the HOPPS fee schedule for setting the national base rates. The HOPPS payments for some brachytherapy procedures, such as brachytherapy for cervical cancer (57155), utilizes the C-APC methodology. The ABS recognizes CMS' commitment to the C-APC methodology, and we support methodology that simplifies the payment system. However, we have previously voiced our concerns over the methodology of the C-APC payment calculation²² and its inadvertent decrease in payment for life-saving cervical brachytherapy given the monthly (as opposed to daily) billing that is standard for hospitals. ***The ABS recommends using a blend of MPFS and HOPPS fee schedules for determining the PC portion of the national base rate. The C-APC HOPPS methodology inadvertently has decreased the reimbursement for brachytherapy procedures such as those for Cervical Cancer, and a blend with MPFS and/or calculation of reimbursement with HOPPS APC FFS would better align reimbursement with the patient care provided.***

CMS' comprehensive APC (C-APC) methodology is a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. The C-APC pays for all items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service. Payments for these services are packaged into the payment for the primary service (J1). This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

As discussed in the introduction above, the best outcomes for patients with Cervical Cancer is the combination of EBRT followed by brachytherapy (i.e. multi-radiation modality care). In the US, the most commonly used regimens for treatment of Cervical Cancer include 25-30 fractions of external beam radiation therapy (which could include 3D conformal radiation therapy or IMRT) with concurrent cisplatin-based chemotherapy, followed by 5 fractions of brachytherapy boost. All

²² Re: Comprehensive Ambulatory Payment Classification Methodology. March 11, 2019. ASTRO Letter to CMS.

of this care is ideally completed with 56 days from the start of treatment ²³ and would fit within a 90-day episode of care as proposed in the RO Model.

Given that there are 5 brachytherapy procedures (5 x 57155) that are delivered typically twice a week over the course of 2.5 weeks, hospitals that perform these procedure will typically bill once each month. However, payment would only be made based on the services on the claim, which may include a clustering of all 5 x 57155 brachytherapy procedures. Given that payment is via the C-APC methodology, the ultimate payment would only be 1 x the C-APC payment for APC 5415 (due to complexity adjustment) plus the reimbursement of the 5 x brachytherapy sources (C1717). **This payment methodology has inadvertently significantly decreased the reimbursement for the services provided to Cervical Cancer patients, and has threatened access to life-saving care, as radiation oncology practitioners are no longer able to provide these services in many areas.** In the table below, please see a comparison of the reimbursement of 25 fractions of IMRT followed by 5 fractions of brachytherapy for Cervical Cancer in the freestanding setting, in the HOPPS C-APC setting, and based on the theoretical reimbursement if solely based on HOPPS APC FFS without C-APC methodology.

The table below shows the 2020 Proposed Reimbursement for Cervical Cancer when treated with either 3D conformal radiation or IMRT x 25 fractions followed by a standard 5 fraction brachytherapy course with 3D planning in the Freestanding (MPFS) setting, HOPPS C-APC methodology (with hospital billing once monthly), HOPPS APC FFS (without C-APC methodology), and the RO Model Proposed National Base Rates. The MPFS is used for the PC and the HOPPS is used to the TC.

	2020 Proposed Reimbursement of: <i>25 EBRT fractions + 5 fractions of brachytherapy</i>	
Site of Service	Professional Component	Technical Component
Freestanding (MPFS)	3D: \$7,512 IMRT: \$8,180	
HOPPS C-APC Methodology	3D: \$7,512 IMRT: \$8,180	3D: \$14,146 IMRT: \$22,176
HOPPS APC FFS Methodology (without C-APC)	3D: \$7,512 IMRT: \$8,180	3D: \$19,281 IMRT: \$34,559

²³ Petereit MD, Daniel G., et al. (1995) The Adverse Effect of Treatment Prolongation in Cervical Carcinoma. International Journal of Radiation Oncology Biology Physics, Volume 32, No. 5, 1995, 1301-1307.

RO Model Proposed National Base Rates (2017 rates)	\$3,779	\$16,955
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Given that combination modality of EBRT (either 3D or IMRT) with brachytherapy boost is the most common modality for cervical cancer treatment, the table above shows that the National Base Rate significantly under-compensates both the Professional and Technical components of care delivery. **The PC in the FFS (MPFS or HOPPS) is in the \$7,152-8,180 range but the National Base Rate is only paying \$3,779.** This is a significant decline (~50%) in reimbursement. **The TC payment is also well below the IMRT episodes and the 3D episodes if the flawed methodology of the C-APC were removed and HOPPS APC FFS rules were applied.**

Given the significant discrepancy in reimbursements for cervical cancer, the ABS recommends that CMS consider one of two possible solutions:

- 1. Allow brachytherapy to trigger a second RO Model bundle (with a separate PC and TC) when delivered before, during, or after EBRT for within a single 90 day episode**
- 2. Allow brachytherapy to be reimbursed as FFS when delivered before, during, or after EBRT within a single 90 day episode**

These solutions will allow fair payment for complex multi-radiation modality care for the most vulnerable cancer patients.

Furthermore, based on review of the RO Episode File (Technical Documents), it appears that CMS may have used the average expense per level of service multiplied by the % of the total to approximate bundle price. **This is a flawed methodology for Cervical Cancer that has a ~57% utilization of multi-radiation modalities (namely EBRT followed by brachytherapy).**

Additionally, there appear to be a large number of mis-attributed episodes to Cervical Cancer in the CMS dataset.

Cervical Cancer					
Modality	1-10	11-20	21-30	31-40	41+
Brachy	527 (18%)	573 (19%)	456 (15%)	14 (0%)	3 (0%)
2D/3DCRT	416 (14%)	178 (6%)	870 (30%)	50 (2%)	2 (0%)
IMRT	183 (6%)	178 (6%)	1057 (36%)	179 (6%)	7 (0%)
IORT	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Protons	0 (0%)	1 (0%)	0 (0%)	0 (0%)	0 (0%)
SRS	63 (2%)	1 (0%)	0 (0%)	0 (0%)	0 (0%)

There are approximately 63 (2%) of episodes that include SRS, which is likely due to the episode treating a metastatic site rather than being treatment of a primary cervical cancer, since SRS is a single fraction of radiation to the brain.

Similarly, the bare minimum clinical number of IMRT or 3D conformal radiation treatments for definitive management of cervical cancer is in the 20-30 range typically followed by

brachytherapy. However, in the CMS dataset there are 45 episodes where there are ≤ 20 services of 2D/3D conformal radiation and 30 episodes where there are ≤ 20 services of IMRT within a combined EBRT and brachytherapy episode. These episodes are inconsistent with clinical medicine and could be only partially captured episodes, incorrectly captured delivery codes, or mis-attributed episodes. There are also many cases of 1-10 delivery episodes with EBRT, which likely represents palliative episodes.

The ABS recommends CMS remove the palliative and mis-attributed episodes from each of the disease sites and recalculate the national base rates based on definitively treated cases alone. CMS should consider using a blend of MPFS and HOPPS fee schedules for the PC for determining the PC national base rate and should consider using the HOPPS APC without the C-APC methodology for the TC national base rate for cervical cancer. The C-APC HOPPS methodology inadvertently has decreased the reimbursement for brachytherapy procedures such as those for Cervical Cancer, and a blend with MPFS and/or calculation of reimbursement with HOPPS APC FFS would better align reimbursement with the patient care provided.

Concern about data integrity in the claims data

The ABS appreciates CMS' utilization of a large number of claims data from a large sample of the US to calculate historical episode reimbursements and set the national base rates. Upon further analysis of the data that has kindly been provided in the RO Episode File (2015-2017) (XLS) and internal data analysis from members of the ABS, **the ABS is concerned that there are flaws in the methodology used in attributing episodes and the costs of episodes to each disease site.**

- Although the historical practice episode costs were Winsorized, it does not appear that the provider data were Winsorized for outliers
- There were nearly 14% of OPS cases that lived through 90 days, but had technical charges that were less than \$5,000, which would be consist with an incomplete episode. It appears that these costs may have been incorporated into the payment calculation.
- There are many episodes where brachytherapy episodes have 11-20, 31-40 or 41+ treatment delivery counts, which is not realistic clinically (See table below). The highest number of brachytherapy treatment deliveries should be 10 (for breast cancer) and is otherwise between 1-6 for the majority of other disease sites. Brachytherapy treatment delivery codes of 11 or more is highly suspicious for data integrity issues. It is possible that the COUNT_BRACHY is including treatment delivery codes for other modalities of care as well (for instance, inclusion of EBRT such as CEB, IMRT, IORT, Proton, or SRS). However, there are also episodes where there are 1-10 or 11-20 Brachy counts and 11-20 or 21-30 IMRT/CEB counts, thereby signifying inconsistency in which codes were used in COUNT_BRACHY. The code set used for each code count are not provided in the technical documentation by CMS (Data Dictionary)²⁴.

²⁴ Technical Documents. <https://innovation.cms.gov/initiatives/radiation-oncology-model/>

- There are approximately 478 episodes (where the patient lived through 90 days) where there were \$0 for the professional or technical charges. **It is unclear how this data would be included in the analysis. Did CMS use these episodes to calculate the National Base Rates or the regression model for the Case Mix adjustment?**
- CMS has included a column in the RO Episode File (2015-2017) called COUNT_SRS. In the Data Dictionary technical document, CMS states that COUNT_SRS counts the number of RT delivery services for “stereotactic radiosurgery” (SRS). This term “stereotactic radiosurgery” is defined by the use of CPT 77371 or 77372 for stereotactic radiosurgery treatment delivery. However, CMS does not state if other codes (such as for stereotactic body radiation therapy 77373) were also included in their analysis. SRS as defined in the CPT should only technically be a single treatment delivery and directed at an intracranial brain lesion. We should not expect to see that code used for non-brain and non CNS lesions therefore. However, upon review of the RO Episode File (2015-2017) file, the following table shows that there are a varying number of patients in non-brain mets and non-CNS sites that have SRS episodes attributed to them. It is therefore likely that CMS is also including SBRT into the SRS count. SRS is typically used for brain metastases, and SBRT is typically used for early primary lung cancers or metastatic disease to various locations in the body (such as spine, bone, adrenal gland, lungs, lymph nodes, among other sites).
- In addition to misattribution of the SRS episodes, there are also episodes of brachytherapy, SRS, and 1-10 3D EBRT that occur in clinically unlikely episodes. CMS should apply clinical business rules to ensure that these episodes are removed from the calculations of the national base rates, and winsorized rates for the predicted/expected payments within the case mix adjustment and the historical experience adjustment. Please see the table below which presents the number of clinically unlikely episodes per disease site.

Disease Site	Number of OPD Episodes per Disease Sites in CMS RO Episode File that contain clinically unlikely episodes
Anal Cancer	SRS: 19 episodes Brachy: 4 episodes CEB 1-10 services: 136 episodes IMRT 1-10 services: 63 episodes
Bladder Cancer	SRS: 100 episodes Brachy: 6 episodes CEB 1-10 services: 604 episodes IMRT 1-10 services: 234 episodes

Bone Metastases	Brachy: 14 episodes
Brain Metastases	Brachy: 9 episodes
Breast Cancer	SRS: 287 episodes CEB 1-10 services: 2,416 episodes
Cervical Cancer	SRS: 19 episodes CEB 1-10 services: 126 episodes IMRT 1-10 services: 45 episodes
CNS Tumor	SRS: likely mis-attribution of brain metastases vs primary CNS neoplasms which would require more detailed claim level audits Brachy: 1 episode CEB 1-10 services: 179 episodes IMRT 1-10 services: 253 episodes (lower likelihood of definitive treatment in 10 fractions of IMRT)
Colorectal Cancer	SRS: 264 episodes Brachy: 72 episodes CEB 1-10 services: 769 episodes
Head and Neck	SRS: 274 episodes Brachy: 20 episodes CEB 1-10 services: 528 episodes IMRT 1-10 services: 442 episodes
Kidney Cancer	SRS: 635 episodes Brachy: 9 episodes CEB 1-10 services: 280 episodes IMRT 1-10 services: 30 episodes
Liver Cancer	CEB 1-10 services: 165 episodes

Lung Cancer	<p>SRS: 14,013 episodes (some proportion of these may be intracranial SRS rather than SBRT)</p> <p>Brachy: 61 episodes</p> <p>CEB 1-10 services: 6,002 episodes</p> <p>IMRT 1-10 services: 782 episodes (smaller proportion of cases are expected to be definitive in the 1-10 IMRT services range)</p>
Pancreatic Cancer	<p>Brachy: 8 episodes</p> <p>CEB 1-10 services: 203 episodes</p> <p>IMRT 1-10 services: 97 episodes</p>
Prostate Cancer	<p>CEB 1-10 services: 2,228 episodes (these are likely bone metastases)</p> <p>IMRT 1-10 services: 226 episodes (these may be bone metastases as well, less likely to represent definitive management)</p>
Upper GI Cancer	<p>SRS: 102 episodes</p> <p>Brachy: 31 episodes</p> <p>CEB 1-10 services: 705 episodes</p> <p>IMRT 1-10 services: 230 episodes</p>
Uterine Cancer	<p>SRS: 82 episodes</p> <p>CEB 1-10 services: 361 episodes</p> <p>IMRT 1-10 services: 92 episodes</p>

- Furthermore, there are numerous cases per disease site where the entire non-metastatic episode consists of 1-10 fractions of EBRT (3D conformal or IMRT), which is likely a palliative case but misattributed due to CMS' ICD attribution rules. Even treatment courses of 11-20 fractions long have a high probability of being mis-attributed palliative episodes.
- As an extension of the point discussed above, based upon the histogram distribution of the costs per episode per disease site, there are a large number of low cost episodes that appear to be mis-attributed to a primary disease site but that should have instead been attributed to a palliative care site (such as metastasis) or should not have been included in the calculation of the disease site base rate. Although this is evident from the frequency of some modalities seen within each disease site and the low cost of many episodes, we cannot verify why these episodes were misattributed because only the high level data was released. There is a high likelihood of ICD9 or ICD10 coding errors (which are frequent in

clinical practice) and CPT/HCPCS coding errors (which are also frequent and estimated to be up to 20% in some cases due to hospital and staff coding errors).

- Another possible source undermining data integrity is in the ICD9 and ICD10 diagnosis coding. CMS has not provided details on how a diagnosis is being assigned given that the data provided is only high level. There are many ways to assign the episode to a disease site – one could use the ICD diagnoses on the claim for the treatment planning service (77261-77263) or could use the ICD codes used for treatment delivery. There is an error rate regarding the correct assignment of ICD diagnoses and the correct order (primary or secondary) they are placed. For instance, a metastatic breast cancer patient may have a primary ICD code for breast cancer and a secondary ICD code for the metastatic site. It is unclear if CMS took both the primary and secondary codes into account or only looked at the primary. **Did CMS only utilize the primary disease site or look at both? Was there an algorithm that would first search for the metastatic brain or breast ICD codes first in either the primary or secondary positions before assigning the primary disease site?**

The ABS is gravely concerned that there are mis-attributions of episodes due to ICD coding and inconsistent definitions around which CPT/HCPCS codes are included in each modality assignment. ABS strongly recommends that CMS delay model implementation until data integrity issues are clarified with practitioners in a transparent manner. ABS recommends that CMS create clinical business rules to remove palliative and mis-attributed episodes from the national base rate calculation.

Payment Adjustment Methodology Concerns

The ABS supports CMS' intent to make the episode payments fair, equitable and transparent, and we hope to work with the Agency on the Payment Methodology. Unfortunately, most radiation oncology practices are unable to ascertain the degree of impact that the payment adjustment methodologies will have on their practice, as we do not have access to information regarding the degree of case mix adjustments, a range of historical experience adjustments, or the impact of the CMS methodology on predicted vs expected episode payments. The ABS is also very concerned that the payment adjustment methodology as currently proposed will harm practices that are already efficient and low cost, such as the majority of brachytherapy practitioners. **The ABS strongly urges CMS to lessen the impact of the historical experience adjustment, zero out the efficiency factor for efficient practices, and make payments more truly site neutral.** Please see below regarding points specific to the Efficiency Factor and the Combined Adjustments and Historical Experience Adjustment:

Combined adjustments and Historical Experience Adjustment

The ABS is concerned that the proposed mechanism for calculating the combined adjustments has too much emphasis on historical experience (i.e. a historical practice cost). Given that a practice's historical experience is calculated from 2015-2017 (with a large emphasis on the 2017 values), this methodology has already taken site of service differentials into account (i.e. MPFS vs HOPPS in those historical look backs). Thus, the historical payments to a practice are NOT

site neutral. Any adjustments of the national base rate based on a practice's historical payment would therefore be taking a site neutral payment and shifting it towards being non-neutral.

In the following sets of calculations, as proposed by CMS in the RO Model proposal, the combined adjustments is based on the historical experience adjustment, efficiency factor and case mix adjustment. We could simplify that calculation as below:

Combined Adjustments

$$= (\text{Historical Experience Adjustment} * \text{Efficiency Factor}) + \text{Case Mix Adjustment} + 1.0$$

$$CA = \left(\frac{\text{Winsorized Historical Payment} - \text{Predicted}}{\text{Expected}} * EF \right) + \frac{\text{Predicted} - \text{Expected}}{\text{Expected}} + 1.0$$

$$CA = \left(\frac{\text{Winsorized Historical Payment} - \text{Predicted}}{\text{Expected}} * 0.9 \right) + \frac{\text{Predicted} - \text{Expected}}{\text{Expected}} + 1.0$$

$$CA = \left(\frac{0.9 * \text{Winsorized Historical Payment} - 0.9 * \text{Predicted}}{\text{Expected}} \right) + \frac{\text{Predicted} - \text{Expected}}{\text{Expected}} + 1.0$$

$$CA = \left(\frac{0.9 * \text{Winsorized Historical Payment} - 0.9 * \text{Predicted} + \text{Predicted} - \text{Expected}}{\text{Expected}} \right) + 1.0$$

$$CA = \left(\frac{0.9 * \text{Winsorized Historical Payment} + 0.1 * \text{Predicted} - \text{Expected}}{\text{Expected}} \right) + 1.0$$

$$CA = \left(\frac{0.9 * \text{Winsorized Historical Payment} + 0.1 * \text{Predicted} - \text{Expected}}{\text{Expected}} \right) + \frac{\text{Expected}}{\text{Expected}}$$

$$CA = \left(\frac{0.9 * \text{Winsorized Historical Payment} + 0.1 * \text{Predicted} - \text{Expected} + \text{Expected}}{\text{Expected}} \right)$$

$$\text{Combined Adjustments} = \left(\frac{0.9 * \text{Winsorized Historical Payment} + 0.1 * \text{Predicted}}{\text{Expected}} \right)$$

Therefore, the combined adjustments are massively driven by the historical payment to each practice. Given that the majority of brachytherapy practitioners are already low cost, high quality, and high value providers (given the relatively lower reimbursements for brachytherapy vs other modalities of radiation therapy), **the ABS is concerned that CMS' large emphasis on adjusting the payment DOWNWARDS for practices that were already efficient to begin with will harm practices that are already low cost and high quality, and will reward those practices that are already high cost.** Although both efficient and inefficient practices will end up being forced to take a discount in this model (and the inefficient practice will take a slightly higher discount),

the overall revenue to inefficient practices will still be higher than that to efficient practices. The ABS recognized CMS' goals of making payments stable, fair, and equitable, but based on this analysis of the combined adjustments, CMS' methodology will inadvertently create a hardship for low cost practices and will reward high cost practices.

The ABS strongly recommends NO historical experience adjustment and further validation of the case mix adjustment coefficients in both the MPFS and HOPPS settings.

Efficient vs Inefficient Practices

The ABS appreciates CMS' focus on defining an efficient vs an inefficient practice. Efficient practices have a Winsorized historical payment that is less than the predicted payment (which is essentially the expected payment for the episodes attributed to the RO Participant adjusted by the case mix regression model derived coefficients). Inefficient practices have a Winsorized historical payment greater than the predicted payment. CMS has stated that their analysis of the MPFS shows 11% greater cost for freestanding compared to OPD, which they felt could be attributed to higher number of fractions in the freestanding vs OPD settings. However, the ABS is concerned that there are systemic errors in CMS' methodology for payment calculations (as detailed in this comment letter). The ABS believes that there may be significant errors and under-calculation of the OPD reimbursement for each disease site. This under-calculation of OPD episode reimbursements likely makes the freestanding MPFS-based calculation appear to be more expensive, but this may be an artifact of CMS' methodology using the HOPPS data only. OPDs may bill less regularly than freestanding centers, which unfortunately decreases payment in the C-APC methodology to the OPD. The ABS is concerned that there are artificially low payments in the HOPPS-only calculations (namely the coding errors and billing infrequency in the OPD setting), CMS may mis-attribute otherwise "efficient" practices into the Inefficient practice bucket. **The ABS strongly recommends CMS use a blend of MPFS and HOPPS for calculating at least the PC component of the episode reimbursement and to clarify the methodology for assigning a practice into an Efficient vs Inefficient group.**

Efficiency Factor

Given the differences in historical episode costs between the efficient (i.e. low cost) and inefficient (i.e. high cost) practices, the CMS has introduced an efficiency factor. The ABS appreciates CMS' consideration of trying to make the payments more equitable between efficient and inefficient practices while balancing the revenues of the historically high cost practices. However, the ABS is gravely concerned that the methodology that CMS has used with the Efficiency Factor falls short of its intention to balance payments between the efficient and inefficient practices over the 5 year Model. We have analyzed the impact of the efficiency factor over the 5 year period of the model. As a summary, please see the table below. The Efficient practice has a NEGATIVE historical experience adjustment given the inputs for historical cost, predicted and expected payments. When applying the 0.9 efficiency factor, this actually serves to PENALIZE efficient practices. The combined adjustment for an Efficient practice is 0.95 which is a 5% decrease in payment from the national base rate.

On the other hand, for an inefficient practice, the high weighting of the historical experience adjuster actually significantly **INCREASES** payment for an Inefficient practice **ABOVE** that of the national base rate. Applying a 0.9 efficiency factor in Year 1 only slightly decreases this to where an **Inefficient practice** is still paid 16% more than the national base rate and 21.8% **MORE** than an Efficient practice. The Efficiency Factor decreases for Inefficient practices over the 5 year Model, but not enough to close the gap between an Inefficient and Efficient practice.

Efficiency Factor Analysis	Efficient Practice	Inefficient Practice Year 1	Inefficient Practice Year 2	Inefficient Practice Year 3	Inefficient Practice Year 4	Inefficient Practice Year 5
Subtotal	\$ 3,389.40	\$ 3,389.40	\$ 3,389.40	\$ 3,389.40	\$ 3,389.40	\$ 3,389.40
Case Mix Adjustment	0.04	0.04	0.04	0.04	0.04	0.04
Historical Experience Adjuster	-0.1	0.13	0.13	0.13	0.13	0.13
PY1 Efficiency Factor	0.9	0.9	0.85	0.8	0.75	0.7
Combined Adjustments	0.95	1.16	1.15	1.14	1.14	1.13
Subtotal	\$ 3,219.93	\$ 3,921.54	\$ 3,899.50	\$ 3,877.47	\$ 3,855.44	\$ 3,833.41
		21.8%	21.1%	20.4%	19.7%	19.1%

The ABS strongly recommends that CMS remove the historical experience adjustment (which is disproportionately determined by the Winsorized historical payment), zero out the efficiency factor for efficient practices, and make payments more truly site neutral. The ABS strongly recommends further validation of the ordinary least squares regression-derived case mix adjustments in both the MPFS and HOPPS settings.

The ABS is concerned that the payment adjustment methodology as currently proposed will harm practices that are already efficient and low cost, such as the majority of brachytherapy practitioners. The ABS would urge CMS not to penalize Efficient practices inadvertently through this methodology. The ABS would also strongly recommend CMS limit the downside risk for practices as in this current model there is no safeguard for excessive financial downside.

Expected vs Predicted Payments

CMS has proposed a methodology for the calculation of a predicted payment (which incorporates the regression model generated coefficients to predict payments under the FFS payment system for an episode of care as a function of the characteristics of the RO participant’s beneficiary population). The proposal also discusses the calculation of an expected payment, which uses the Winsorized episode payment made for each cancer type in the national beneficiary profile without accounting for the case mix adjustment. However, CMS has not provided any details on the range of predicted and expected payments for an RO participant, or examples of how it would be calculated for a practice. These inputs could significantly impact a RO participant’s payment adjustments. **The ABS highly encourages CMS to provide more transparency for what the predicted vs expected payment calculations would be like for the RO participants, as not all participants have access to case mix variable details within their own practice.**

Withholds and Discounts

The ABS appreciates CMS' transparency with regards to the proposed discounts and withholds. Most brachytherapy practitioners have seen declining treatment volumes and declining reimbursement over the past decade, and further upfront withholds and discounts would significantly decrease cash flow for practices that have already seen dwindling reimbursements. In the current proposal, the annual reconciliation period would occur in August of the year following the PY, and the true-up would happen 1 year later. Thus, there could be approximately 20 months between the PY and the true-up process, which we believe would cause a significant financial hardship for practices. **The ABS would recommend consideration of applying the payment withholds (incorrect payment, quality, patient experience) to future cash flow rather than withholds of current revenues.** Otherwise, practices would not be able to recoup those dollars for approximately 20 months post the performance year or would be in a position where additional dollars would need to be paid to CMS for episodes of care delivered nearly 2 years prior.

More importantly, the ABS is gravely concerned about the 5% TC discount and 4% PC discount. While the ABS understands that CMS will utilize the 4% PC and 5% TC discounts for generating savings for CMS in this Model, both of these discounts will significantly harm the financial stability of many smaller to mid-sized brachytherapy and radiation oncology practices. Although there is an opportunity to possibly receive a 5% incentive payment as part of an Advanced APM, CMS is proposing a Medicare Waiver that would not allow the 5% incentive payment to apply to the TC component. Thus, practices would not have any opportunity through delivering high quality or low cost care to receive back any portion of the 5% TC discount. Thus, CMS' proposal is a losing proposition for all practices – it would not incentivize high quality or low cost and would ultimately be a mechanism to cut reimbursement for practices.

The ABS strongly believes that the exclusion of the TC component from the 5% incentive payment within the MPFS is in direct opposition to the MACRA-required Technical Component Payments. We do not believe that inclusion of the 5% incentive payment for the TC through the MPFS would affect the site neutral test of the RO Model.

The ABS recommends that CMS consider decreasing the PC and TC discount factors to 3% and to allow practices to receive a 5% incentive payment as part of being an Advanced APM for both the PC and TC components of reimbursement. Alternatively, ABS recommends no TC discount if there is no opportunity for a 5% incentive payment. This would more fairly balance savings for CMS while still incentivizing high quality, low cost, and equitable care for Medicare patients.

Mandatory participation

The ABS is concerned about the mandatory participation that is required from a large number of practices from the first year. There are significant shortcomings of this current Model which will potentially perversely incentivize higher cost practices and harm lower cost practices. There are also major reservations with regards the ability of this RO Model proposal to ensure continued high quality of care in radiation oncology, as there is potential significant stifling of innovation in this Model. As proposed there is a high likelihood that patient care with radiation therapy will ultimately suffer innovation and growth during the Model period. **The ABS would urge CMS to start the model on a voluntary basis with no financial risk for providers. This phase in process would allow practices to transition to the coding/billing practices needed to succeed in this model and to allow time to build infrastructures to collect data.**

Other models from the CMS have been voluntary in nature and have allowed practices to observe if the model construct actually does allow for the delivery of high quality low cost care. This was seen in the Bundled Payments for Care Improvement Model where a large number of participants ultimately withdrew participation. There is also an opt-out option for the Oncology Care Model (OCM) when there is no clear path forward and excessive downside financial risk to a provider that could put provider's out of business. The ABS is also concerned about the operational challenges for multi-site health systems (including freestanding and hospital-based practices) that operate under a single TIN but within multiple CBSAs. **The ABS strongly recommends that CMS revise the mandatory nature of the RO Model, allow for phase in, provide an opt-in and opt-out option for practices that span multiple CBSA's but with a single TIN, and make payments more equitable.**

Timeline

The ABS is concerned about the short timeline for implementation of the model. Starting the Model on Jan 1, 2020 and even Apr 1, 2020 would be a hardship for practices, as there would be insufficient time to re-tool billing/coding systems and operations, to build specific clinical infrastructure required for the quality metrics and reporting requirements, among other mandatory aspects of the Model. Delaying until at least Apr 1, 2020 and more optimally until even Jul 1, 2020 with a time period (1-2 years) to initially allow voluntary opt-in prior to a mandatory start.

Quality Metrics and Compliance

The ABS appreciates CMS' focus on utilizing quality measures to help in measuring the quality of radiation oncology cared delivered within the RO Model. CMS has included several measures, but has not included benchmarks for several of these measures. CMS could consider using the MIPS benchmarks, which would make quality metric reporting more in line with other programs.

However, the ABS is concerned about the unfunded mandate to collect data for all patients (not just those in the RO Model). This is an unfunded mandate that will be highly burdensome for all practices, but especially smaller and mid-sized practices who have limited financial flexibility to add unfunded infrastructure to their daily operations. ABS is also concerned that such a mandate could violate the privacy of healthcare data for patients not in the RO model. **The ABS strongly recommends data collection on only those patients in the Model.**

Collection of these quality metric data are unfunded in the RO Model proposal. However, other programs from the CMS, such as the OCM, has included a MEOS payment that would be generally applied to practice transformation, including collecting the quality data. The ABS recognizes that the CMS has not included a MEOS payment for assistance in practice transformation, but **the ABS would recommend consideration of a pay for reporting of this quality metric data that is outside of the currently establish RO Model proposal to cover the potentially high costs to practices to adopt the infrastructure (staff and through the electronic medical record) required to collect and report on these quality metrics. A voluntary phase-in period to collect the quality metric data would also help practices change their operational infrastructures to eventually allow for robust reporting of this data.**

In addition to the proposed quality measures (Oncology: Medical and Radiation - Plan of Care for Pain -NQF41 #0383; CMS Quality ID #144; Preventive Care and Screening: Screening for

Depression and Follow-Up Plan -NQF #0418; CMS Quality ID #134; Advance Care Plan -NQF #0326; CMS Quality ID #047; Treatment Summary Communication – Radiation Oncology; CAHPS Cancer Care Survey; Clinical Data Elements), **the ABS recommends that CMS collaborate with professional societies to identify additional metrics that meaningfully measure quality of cancer care and impact on outcomes (including survival).** For instance, the American College of Surgeons Commission on Cancer (CoC) has specified quality measures that are specific to various types of cancers²⁵. As an example, the CoC measures for Cervical Cancer (below²⁶) are highly relevant to the delivery of high-quality radiation therapy:

Measure	Measure Abbreviation	Measure Type
Use of brachytherapy in patients treated with primary radiation with curative intent in any stage of cervical cancer	CBRRT	Surveillance
Radiation therapy completed within 60 days of initiation of radiation among women diagnosed with any stage of cervical cancer	CERRT	Surveillance
Chemotherapy administered to cervical cancer patients who received radiation for stages IB2-IV cancer (Group 1) or with positive pelvic nodes, positive surgical margin, and/or positive parametrium (Group 2)	CERCT	Surveillance

The ABS also appreciate CMS’ focus on monitoring for compliance. There will be limited time for practices to prepare for the start of the RO Model and for CEHRT to become updated to successfully capture the requirements of this Model. Many of the monitoring requirements are already assessed for within accreditation programs. **The ABS would recommend that accreditation (such as via the ACR, ACRO, or the ASTRO APEX programs) count for the monitoring requirements, which would reduce the burden on practices and CMS for monitoring for compliance.** For practices that are not currently accredited, CMS could perhaps allow a phase-in period where non-accredited practices. **ABS also strongly urges CMS to honor its commitment to MIPS practices that have complied with the MIPS program requirements by issuing the MIPS bonus payments in the payment methodology for 2020 and 2021.**

²⁵ <https://www.facs.org/quality-programs/cancer/ncdb/qualitymeasures>

²⁶ <https://www.facs.org/-/media/files/quality-programs/cancer/ncdb/measure-specs-cervix.ashx?la=en>

We hope that CMS will take these issues under careful consideration as they will have a great impact on the provider's ability to offer important cancer treatments to Medicare beneficiaries in 2020 and future years. The ABS is always available to collaborate with CMS, and we hope that CMS will strongly consider the recommendations of the radiation oncology community when finalizing this deeply impactful RO Model. Should CMS staff have questions or require additional information please contact me at (703) 234-4085.

Sincerely,

Peter F. Orio III, D.O., M.S.
Chairman of the Board
American Brachytherapy Society

Nikhil G. Thaker, MD
Chair of Socioeconomics Committee
American Brachytherapy Society