

September 16, 2019

VIA Electronic Submission to www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator Verma:

On behalf of the National Association for Proton Therapy (“NAPT”) and the Particle Therapy Co-Operative Group - North America (“PTCOG-NA”), please accept the following comments in response to the Radiation Oncology Alternative Payment Model (“RO Model”) discussed in the above-captioned Proposed Rule. NAPT is a nonprofit organization whose members – both hospital based and freestanding – are world-renowned cancer centers, a number of whom are National Cancer Institute (“NCI”) designated comprehensive cancer centers and National Comprehensive Care Network (“NCCN”) members.¹ NAPT’s mission is to work collaboratively to: (i) educate and raise awareness of the clinical benefits of proton therapy among patients, providers, payers, policymakers, and other stakeholders, (ii) ensure patient choice and access to affordable proton therapy, and (iii) encourage cooperative research and innovation to advance the appropriate and cost-effective utilization of proton therapy for certain cancers. PTCOG-NA is the North American affiliate of an international not-for-profit scientific society of radiation oncologists and medical physicists who are committed to the advancement of science, clinical practice, patient outcomes and cooperative research related to particle therapy, including proton therapy.²

As currently proposed, the RO Model makes such drastic cuts to proton beam therapy reimbursement that the limited access to proton beam therapy could be further restricted, depriving Medicare beneficiaries and other patients access to a clinically appropriate modality. Currently, thirty-two centers (with others under construction or development) rely upon reimbursement models from Medicare, Medicaid and private payers to support their on-going operations. With upwards of a 50% ultimate reduction in reimbursement under the Proposed Rule, if finalized, several proton centers will have to re-assess whether furnishing proton beam therapy is financially viable.

Our concerns about the RO Model as proposed are as follows:

- While **CMS has been afforded at least five (5) years** to construct the proposed RO Model, the impacted community has **only been afforded sixty (60) days to understand the limited dataset and highly complex and often ill-defined features of the proposed methodology and implementation approach for the RO Model**. As such, we respectfully repeat our request to have CMS make more robust datasets available (including, without limitation, ICD-10 data and all

¹ Listing of members can be found on the NAPT website, please visit: <http://www.proton-therapy.org>.

² For more information about PTCOG-NA, please visit: www.ptcog-na.org. For information about the international organization please visit: www.ptcog.web.psi.ch.

relevant regression analyses) and extend the comment period to allow all stakeholders a reasonable amount of time to better comprehend the proposal and provide proper input on the relevant factors to appropriately inform the model goals. Given CMS' denial of our request for more robust datasets and additional time for commentary, we have limited our comments to a limited set of issues we have initially identified in the unreasonable timeframe and reserve our rights to provide additional comments.

- The proposed RO Model **payment rates for proton beam therapy are woefully inadequate**, based on flawed data and methodology, not reflective of current resource requirements and **place beneficiaries at significant risk** of not receiving the optimal treatment modality for their cancer and **exposing them to unnecessary radiation**.
- The proposed RO Model is **an experiment with only a short-term focus (a 90-day episode) and includes significant disincentives** for services with higher upfront investment with longer term value (e.g., proton beam therapy's ability to reduce costly medium and long term complications) to the detriment of both Medicare beneficiaries and the Trust Fund. Empirical evidence demonstrates the clinical benefits of proton beam therapy – (1) its efficacy and precision in targeting and treating tumors AND (2) its ability to reduce costly side effects and future secondary malignancies. The short-term focus of the proposed RO Model and its failure to capture the medium- and long-term benefits and savings from proton beam therapy are a detriment to the Medicare program.
- The RO Model should encourage responsible research, new service lines³, and support innovation, a key initiative of the current Administration.⁴ However, as proposed, **the model discourages the use of innovative technology in current practice and may hinder the use of new innovations** without a pathway for which the technology can be appropriately reimbursed. **Fundamentally, the RO Model significantly jeopardizes our country's role as a world leader in advancing the fight against cancer.**

Given the concerns with the underlying principles shaping the RO Model and the flaws with the proposed payment rate methodology, NAPT requests the following:

- ⇒ **The RO Model is an experiment and should be treated as such.** CMS has not yet released sufficient data to empirically support the RO Model's stated goals. Furthermore, the highly complex proposed incentives and corresponding behavioral changes are remarkably difficult to predict. As such, CMS should treat this "test" as an experiment and, thereby, **make participation voluntary**. As proposed, the "test" is highly likely to have far too many unintended consequences, including creating the incentive to expose beneficiaries to excess radiation, the potential for significant indirect additional costs for the Medicare Trust Fund, and marked competitive imbalance.
- ⇒ **The RO Model should exclude all low volume modalities.** All "low volume" modalities should be excluded from the alternative payment model ("APM") for the initial "test", which should be assessed in total and by cancer site. At this time, **we believe proton beam therapy is a "low volume" service** both in total and for all cancer types as it represents by only 0.7% of episodes in the proposed model dataset.
- ⇒ **The advancement of evidence should be a basis for model exclusion.** While the current body of evidence is robust and supports coverage of proton beam therapy for certain cancers, our community has historically supported and continues to focus on evidence generation to

³ New service lines may or may not include new, emerging, or "low volume" technology, but in all instances are new to a specific practice.

⁴ <https://www.cms.gov/newsroom/press-releases/cms-outlines-comprehensive-strategy-foster-innovation-transformative-medical-technologies>.

continuously advance the body of knowledge. That said, the Center for Medicare & Medicaid Innovation (“CMMI”) should actively encourage on-going research across the healthcare ecosystem and use Medicare evidence development precedent (*i.e.*, the historical local coverage determination (“LCD”) standard for evidence generation. Specifically, the beneficiary exclusion for proton beam therapy should be expanded to include both registries structured in compliance with Agency for Healthcare Research and Quality (“AHRQ”) guidance or clinical trials registered on clinicaltrials.gov). Some Medicare contractors also provide exceptions to providers with a history of evidence development and we suggest CMMI consider this as a basis for exclusion as well.

- ⇒ The RO Model should have tiered base rates rather than a single base rate (per cancer type) and all necessary reductions (or discounts) should be proportionately applied. The model payments should be appropriately adjusted for the resources, clinical complexity and other critical considerations. Once a reasonable target volume threshold is established and there is experience developed in connection with the “test,” then careful and deliberate consideration of the relevant resources should be appropriately accounted for in the eventual payment. Specifically, CMS should develop different base rates based on radiation therapy resource levels and clinical complexity (analogous to the hospital outpatient prospective payment system (“OPPS”) ambulatory payment classification levels). Furthermore, the RO Model disproportionately, and significantly more than any other modality, reduces (or discounts) proton beam therapy payment. Appreciating that the Agency may have a savings target as a result of the Patient Access and Medicare Protection Act (“PAMPA”), we note that proton beam therapy was not protected by PAMPA and should not be included in the corresponding “pay for.” That said, if savings must be achieved and all radiation oncology modalities must “pay for” the protection of a limited set of radiation oncology modalities in 2015, then such savings should be proportionately applied to all modalities.
- ⇒ The efficiency and other adjustments cause disproportionate harm. The proposed efficiency payment adjustment will harm “efficient” practices and result in excessive cuts. CMS should adjust the efficiency factor to avoid penalizing efficient practices, including efficient proton therapy practices, and scale back the professional component and technical component discount factors, which risk patient access to radiation therapy modalities by causing significant financial strain for such a capital intensive specialty.
- ⇒ This RO Model should encourage, not discourage on-going innovation. Innovation in radiation oncology has contributed greatly to increased cure rates and reduced side effects from treatment. Yet, the proposed APM does not adequately account for the next generation of advances in the delivery of radiation oncology. If finalized as proposed, this policy position will push the U.S. further behind in the field of oncology and threaten our status as the world’s leader in cancer care. CMS should consider a new technology determination process that pays fee-schedule rates for a limited time and adopt a rate review mechanism for new service lines and upgrades.
- ⇒ The RO Model should have a measured implementation. Once the specifics of the RO Model are finalized and published in a Final Rule, depending on the currently unknown contours of the final APM, CMS should delay implementation until at least July 1, 2020 to allow RO Model participants and the Medicare contractors adequate time to prepare.

Our comments are discussed in greater detail below.

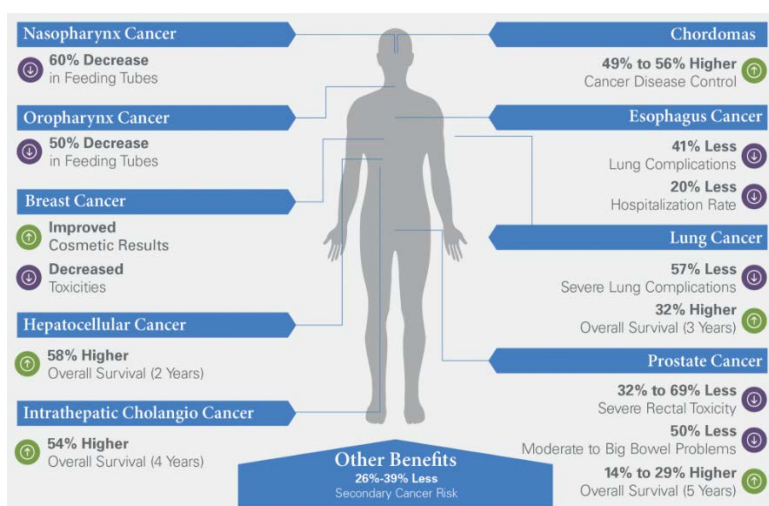
I. High Value of Proton Beam Therapy

In the Proposed Rule, CMS questioned the benefits of proton beam therapy given the higher up-front treatment costs when compared to other, less expensive modalities. In support of its position, CMS cited the 2014 Institute for Clinical Economic Review (“ICER”) report conducted on behalf of the

Washington State Health Care Technology Authority and the June 2018 MedPAC Report to Congress.^{5,6} NAPT strongly disagrees with this characterization of proton beam therapy as a modality with limited benefits vis-à-vis other modalities and believes the evidence demonstrates that proton beam therapy provides significant value to patients with common cancers.

Proton beam therapy has a proven history of improved outcomes over other treatments. It was cleared as a safe and effective treatment by the Food and Drug Administration (“FDA”) thirty-one years ago. A critical clinical benefit of proton beam therapy is the elimination of excess radiation to healthy tissues and organs, minimizing costly side effects and secondary malignancies.

Not only does proton beam therapy minimize the exposure of surrounding healthy tissue to excess radiation, it also reduces the risk of short-term and long-term complications. In addition, proton therapy lowers the risk of secondary malignancies and may reduce the need for future additional tests and procedures over the lifetime of a patient.⁷ As cancer survival rates have increased significantly in the last 20 years, a diagnosis of cancer has become a chronic illness for many cancer patients. It is more important than ever to reduce costly short- and long- term side effects of cancer treatment with care that is the least toxic and harmful to patients.



Clinical Benefits of Proton Beam Therapy⁸

Proton therapy is the standard of care treatment for multiple oncology diagnoses and clinical evidence has demonstrated its value in other common cancers. The NCCN Guidelines for Treatment of Cancer suggests the use of proton beam therapy for **fourteen different sites**.⁹ The clinical evidence on

⁵ Ollendorf, D. A., J. A. Colby, and S. D. Pearson. 2014. Proton beam therapy. Report prepared by the Institute for Clinical and Economic Review for the Health Technology Assessment Program, Washington State Health Care Authority. Olympia, WA: Washington State Health Care Authority. ([Link](#))

⁶ Medicare Payment Advisory Committee. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 10, 2018. ([Link](#))

⁷ Chung CS, Yock TI, Nelson K, et al. Incidence of second malignancies among patients treated with proton versus photon radiation. *Int J Radiat Oncol Biol Phys* 2013 Sep 1;87(1):46-52.

⁸ Credit: MD Anderson Proton Therapy Center. For a robust list of peer-reviewed evidence, please see our model coverage policy. ([Link](#))

⁹ National Comprehensive Cancer Network Guidelines for Treatment of Cancer for the following sites - Bone Cancer (1.2020), CNS Cancers (1.2019), Esophageal / Esophagogastric Junction Cancers (2.2019), Head and Neck Cancers (2.2019), Hepatobiliary Cancers (3.2019), Hodgkin Lymphoma (2.2019), Malignant Pleural Mesothelioma (2.2019), Uveal Melanoma (1.2019), Non-Hodgkin's Lymphoma - B-Cell Lymphomas (4.2019) and T-Cell

proton beam therapy has demonstrated a decrease in complications (e.g., feeding tubes and cardiopulmonary complications), higher disease control, improved overall survival rates, and lower risk of secondary malignancies.

The growth of clinical indications for proton beam therapy has been supported by clinical trials and significant evidence development. The evidence development for proton beam therapy has been multi-institutional with many different major academic institutions contributing to the hundreds of published journal articles over the last five years.¹⁰ Some payers, including three Medicare Contractors, have requirements for continued evidence development through clinical trials and/or registries for selected indications. Randomized controlled trials, while an optimal type of trial for certain healthcare services, are often not a feasible option for evidence development in the area of radiation oncology and as such, a significant portion of the evidence is based on prospective clinical trials and retrospective analyses. A study by Poonacha et al. (2011) analyzed the underlying data for NCCN Guidelines and found that “most recommendations in oncology are not based on high-quality evidence or evidence from randomized controlled trials.”¹¹ Only six percent of guidelines were based on high level of evidence (i.e., randomized clinical trials with uniform consensus).

Contrary to what the Agency stated in the Proposed Rule, the clinical value of proton beam therapy is well established. Several highly respected healthcare systems, academic medical centers, community providers and payors known for their stringent evidence requirements have invested in proton beam therapy centers due to its clinical value and benefits to their patients. Many regional and national payers have established broad coverage and coverage with evidence development based on their critical evaluation of the evidence on the short, medium and long-term benefits of proton therapy. In addition to the aforementioned NCCN guidelines, the American Society for Radiation Oncology (“ASTRO”) has established a positive model policy on proton beam therapy. The Washington State Health Care Authority, which had previously relied on the ICER report cited in the Proposed Rule, conducted a re-review of proton beam therapy in 2018 – 2019 “based on newly available evidence” and broadened their list of covered cancer types.¹² Finally, the MedPAC report cited in the Proposed Rule was written with a limited understanding of the clinical attributes of proton beam therapy (See **Exhibit A**). There was no consultation with clinical experts in the field and MedPAC relied on older evidence (4+ years old) and claims data without the necessary context.

NAPT strongly believes that the current and growing evidence base clearly demonstrates the clinical value of proton beam therapy for Medicare and its beneficiaries. ***CMS should not use questions regarding proton beam therapy’s clinical value coupled with its higher upfront investment as the basis for inclusion in the RO Model.***

Lymphomas (2.2019), Non-Small Cell Lung Cancer (6.2019), Prostate Cancer (4.2019), Soft Tissue Sarcoma (3.2019), and Thymomas and Thymic Carcinomas (2.2019). ([Link](#))

¹⁰ Institutions include but not limited to Northwestern Medicine, University of Pennsylvania, Massachusetts General Hospital/Harvard University, MD Anderson, Mayo Clinic, University of Florida, Washington University of St. Louis, University of Maryland, University of Washington Medical Center/Seattle Cancer Care Alliance, Cincinnati Children’s Hospital Medical Center, University Hospitals/Case Western, Proton Collaborative Group, and Loma Linda Medical Center.

¹¹ Poonacha TK, Go RS. Level of scientific evidence underlying recommendations arising from the National Comprehensive Cancer Network clinical practice guidelines. *J Clin Oncol* 2011;29(2): 186-191.

¹² Washington State Health Technology Clinical Committee findings and decision on proton beam therapy re-review. ([Link](#))

II. Jeopardized Access and Beneficiaries at Risk

In setting the national base rates for the RO Model, CMS compiled the historical episodes of care from CY 2015 through CY 2017 for seventeen types of cancer across multiple modalities of radiation therapy services. The Agency narrowed the data employed to calculate the national base rates to those episodes furnished in a hospital outpatient (“HOPD”) setting. In outlining the proposal, CMS argued for using only HOPD episodes as “OPPS payments have been more stable over time and have a stronger empirical foundation than those under the PFS”. CMS also discussed how, when episodes of care involving radiation therapy (“RT”) services were furnished in a freestanding center, the payments were 11% higher than those episodes furnished in a HOPD.

While NAPT appreciates the Agency’s desire to eliminate financial incentives to furnish care in one setting over another and thus is proposing a site neutral based payment, we urge CMS to reconsider its approach of establishing base rates only on hospital outpatient episodes due to its detrimental impact on proton therapy centers. As demonstrated in Table 1 below, **proton beam therapy episodes – defined as episodes with proton beam therapy radiation treatment delivery services furnished – only represent 1.4% of the total episodes** of care used to establish the base rates.¹³

Table 1. Total Episodes of Care by Setting (CY 2015 – CY 2017)

Setting	Episodes: Proton*		Episodes: All Modalities		Proton as % of Total Episodes
	Volume	% of Total	Volume	% of Total	
Freestanding	4,609	64.9%	184,164	35.6%	2.5%
Outpatient	2,489	35.1%	333,291	64.3%	0.7%
Freestanding & Outpatient	3	0.0%	523	0.1%	0.6%
Total	7,101	100.0%	517,988**	100.0%	1.4%

* Episodes with proton therapy, may include other modalities

** Excludes episodes not rendered in freestanding or hospital outpatient (n=10)

By restricting the methodology to hospital outpatient-based episodes, nearly 65% of the proton therapy episodes would be excluded and would represent **less than 1 percent (0.7%) of total episodes** of care in the model.¹⁴ Analyzing the episodes of care by cancer type, proton beam therapy episodes would represent more than 1% of the total episodes of care in only six of the seventeen cancer types; proton beam therapy episodes would represent less than 0.5% of total for the remaining eleven. See Table 2.

Table 2. Total HOPD Episodes of Care by Cancer Type (CY 2015 – CY 2017)

Setting	Episodes: Proton*		Episodes: All Modalities		Proton as % of Total Episodes
	Volume	% of Total	Volume	% of Total	
Anal	45	1.8%	3,159	0.9%	1.4%
Bladder	8	0.3%	4,729	1.4%	0.2%
Bone Mets	13	0.5%	28,294	8.5%	0.0%
Brain Mets	13	0.5%	22,100	6.6%	0.1%
Breast	178	7.2%	74,805	22.4%	0.2%
Cervical	1	0.0%	2,087	0.6%	0.0%
CNS Tumors	122	4.9%	7,315	2.2%	1.7%
Colorectal	43	1.7%	10,989	3.3%	0.4%

¹³ Episodes in the Radiation Oncology Model Episode File released by CMMI, were flagged as proton beam episodes if the value in the field Count_Proton was any value other than “0 services.”

¹⁴ Episodes in the Radiation Oncology Model Episode File released by CMMI, were flagged as hospital outpatient services if the treatment setting was “outpatient”, not “freestanding” or “both.”

Setting	Episodes: Proton*		Episodes: All Modalities		Proton as % of Total Episodes
	Volume	% of Total	Volume	% of Total	
Head & Neck	227	9.1%	19,445	5.8%	1.2%
Kidney	0	0.0%	1,828	0.5%	0.0%
Liver	81	3.3%	4,348	1.3%	1.9%
Lung	342	13.7%	69,865	21.0%	0.5%
Lymphoma	46	1.8%	11,758	3.5%	0.4%
Pancreatic	55	2.2%	5,014	1.5%	1.1%
Prostate	1,131	45.4%	46,990	14.1%	2.4%
Upper GI	149	6.0%	9,807	2.9%	1.5%
Uterine	35	1.4%	10,758	3.2%	0.3%
Total	2,489	100.0%	333,291	100.0%	0.7%

* Episodes with proton therapy, may include other modalities

In the Proposed Rule, CMS discusses the exclusion criteria for participants including hospitals and freestanding centers that furnish radiation therapy services in Maryland, Vermont or U.S. territories. In addition, the RO Model proposes to exclude “low volume” RT services from the RO Model on the basis that the services “are not offered in sufficient amounts for purposes of evaluation.” Furthermore, CMS indicated that only “commonly used” modalities would be included. How does the Agency define “commonly used” and “low volume” thresholds that it is applying in the RO Model? As the data above clearly demonstrates, we strongly believe that proton beam therapy is not “commonly used” for Medicare beneficiaries and is “low volume.”

As CMS acknowledged in the Proposed Rule, there is a higher cost to delivering proton beam therapy. This cost is due to the significant investment required for proton beam therapy compared to the other modalities and the resources required to provide this treatment. CMS’s failure to include a meaningful volume of episodes in the calculations of the base rates led to payment rates that are not reflective of the cost to provide proton beam therapy and, if finalized, would lead to significant rate cuts. As a result, many proton centers would be unable to provide treatment at these woefully inadequate rates. To assess the impact of these cuts, NAPT compared the 2017 episode payments reflected in the data file released by CMS in comparison to the estimated payments under the RO Model for episodes that included only proton beam therapy. See Table 3.

Table 3. Comparison of Total 2017 Payments vs. Estimated Payments under RO Model for Proton Episodes

Indication/Modality	2017 Episodes*	Total Payments (2017)	Estimated Payments, RO Model**	Difference	% Difference
Protons: Breast	173	\$ 3,126,422	\$ 1,943,937	(\$ 1,182,485)	-37.8%
Protons: Head/Neck	228	\$ 7,760,947	\$ 4,263,389	(\$ 3,497,558)	-45.1%
Protons: Lung	231	\$ 6,186,306	\$ 2,989,881	(\$ 3,178,424)	-51.5%
Protons: Prostate	1,386	\$ 61,865,723	\$ 30,436,067	(\$ 31,429,656)	-50.8%
Protons: Upper GI	109	\$ 3,138,769	\$ 1,567,587	(\$ 1,571,182)	-50.1%
All protons	2,453	\$ 90,830,305	\$ 45,761,289	(\$ 45,069,016)	-49.6%
All other modalities	172,232	\$ 2,476,506,846	\$ 2,377,795,022	(\$ 98,711,824)	-4.0%

* Episodes in freestanding and hospital outpatient settings

** Estimates by cancer type; estimates represent nationwide implementation of model RO Model and assumes an average combined historical experience, case mix, and efficiency adjustment of 1.0.

The aggregated difference (savings) between the 2017 payments and the estimated RO Model payments is over \$45 million for proton beam therapy when looking across all episodes, nearly a 50%

reduction in payment for proton beam therapy. When limited to 40% of total episodes – comparable to the proposed design of the model, the percent difference between the 2017 payments and the estimated payments using the national base rates remains close to 50%. As the Agency has indicated, the proposed RO Model would place proton beam therapy “down a glide path” to ultimately effectuating nearly a 50% reduction in payment. As proposed, for participants without historical experience, this reduction would be immediate.

In addition to the concerns noted above (regarding low volume of proton beam episodes and restriction of rate-setting analysis to HOPD episodes), NAPT has several serious concerns about the payment rate methodology. First, as discussed above, the payment rates are agnostic to modality and site of service, ignoring the differential resource requirements to furnish clinically appropriate care to Medicare beneficiaries. Also, while the Agency has proposed different rates based on type of cancer, there are no adjustments to or differentiation in payment rates based on stage of cancer, relevant comorbidities and other critical clinical considerations. In addition, as designed, the RO Model is a *de facto* least costly alternative policy.

Second, once the national base rates are established, CMS proposes to apply a number of factors including a historical adjustment and discount factors. As discussed in the Proposed Rule, the historical experience adjustment, calculated based on actual, expected and predicted episode payments at the RO participant level, excluding outliers, could increase or decrease the national base rate. Based on NAPT’s understanding of the historical experience adjustment, some proton beam therapy providers (i.e., those with historical experience) may have an increase in the national base rates based on this adjustment factor, given the historically higher episode costs for proton beam therapy. Discussions with CMS and CMMI have suggested the potential benefits of this adjustment for proton beam therapy participants. While this adjustment, if finalized as proposed, may partially mitigate the effects of the inadequate base rates in year one, the application of the “efficiency factor” will increasingly lessen the benefit of the historical experience adjustment as the efficiency factor changes in years two through five. Ultimately, NAPT believes that this adjustment application is equating to a phase-in of woefully inadequate payment rates over the proposed RO Model period. The initial phase-in, itself, presents enormous challenges and directly jeopardizes access.

Third, starting at the national base rates (with adjustments), CMS proposes to apply additional reductions referred to as discount factors. Specifically, the Agency proposes a four-percent discount for the professional component of an episode and a five-percent discount for the technical component. CMS stated that the discounts “strike an appropriate balance in creating savings for Medicare while not creating substantial financial burden on RO participants with respect to reduction in payment.” NAPT strongly disagrees with this presumption. These cuts represent an additional, meaningful reduction to already inadequate reimbursement rates. Finalization of these discount factors as proposed coupled with the proposed methodology for setting the national base rates would exacerbate the financial risk of this model on proton beam therapy centers.

As noted above, the national base rates alone as proposed under the RO Model resulted in up to a 50% reduction compared to current reimbursement levels. Given the comparative paucity of these rates, RO Model participants would have a **financial disincentive to use a clinically appropriate modality** with higher upfront investment costs and to treat more clinically complex patients (e.g., patients with retreatment, complex tumor locations, uncommon cancer presentation, and other atypical clinical scenarios). This runs counter to the intended goals of the model, namely, preserving or enhancing the quality of care furnished to such beneficiaries.

The inadequacy of the payment rates puts Medicare beneficiaries at risk to receive excess radiation to healthy tissues. This increase in radiation exposure will lead to short, medium and long-term costly complications not accounted for in the proposed RO Model. It is important to note that the effect is not just on Medicare patients and their quality of life but also on the Medicare Trust Fund through increased costs and hospitalizations associated with complications and secondary malignancies. The risk for secondary malignancies from radiation increases over time. It is vital to ensure that providers reduce the risk of secondary cancers for survivors as patients begin to live longer due to advanced treatments.

NAPT is concerned not only about the impact of the proposed model on Medicare beneficiaries but also on the RO Model participants. Unsustainable payment rates will put centers' viability at risk, both operational centers as well as centers currently under development. According to the annual NAPT survey, in 2018, Medicare is a material payor for the majority of members, representing over 46% in their payor mix. Reducing their payment rates by up to 50% below cost will not be sustainable. Just as important, while this model is focused on Medicare fee-for-service, it has implications for other payors as many private payors often use the Medicare rates as a proxy. To the extent that the proton beam therapy centers cannot have a robust payor mix, it puts centers' viability at risk. That viability impacts not only Medicare beneficiaries but indirectly affects a broader set of patients including pediatric cancer patients who will lose access to a treatment that is now the standard of care.¹⁵

Any model that impacts the viability of a center may have broader geographic implications, particularly in the western United States. Currently, there are only four centers¹⁶ in the western part of the country that can furnish proton beam therapy services to cancer patients. A RO Model that includes proton beam therapy may significantly hinder the development of new centers in that part of the country, continuing to limit access to rural and underserved communities.



III. Implementation of an Experiment

In the Proposed Rule, CMS discusses how the RO Model is an experiment.

We believe that these two proposed models would test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries. (Emphasis Added)

NAPT supports innovative models and a move toward value-based care. While not agreeing with the Agency, we understand conceptually why CMS is proposing to implement a mandatory model given the concerns regarding the lack of participation in a voluntary design. However, given the breadth of concepts that CMS is testing in this Proposed Model (e.g., prospective payments vs. fee-for-service with back-end reconciliation, modality agnostic payments by cancer type, 90-day episodes), the model should be rolled out in a phased and evidence driven manner. **Establishing a mandatory model with estimated 40% of the eligible episodes on Day 1 is not evidence driven.** NAPT also has concerns about the assignment of providers to the model based on random selection of core-based statistical areas. It may potentially create competitive disadvantages for those participating in the model and thus exacerbating the potential financial hardships imposed by the model.

¹⁵ See ASTRO Model Policy on Proton Beam Therapy.

¹⁶ We note that there is a legacy research device in Northern California. However, it does not appear to be providing services to Medicare beneficiaries and may no longer be in use.

As discussed above, the RO Model is an experiment that is seeking to “test” ways to reduce “program expenditures while preserving or enhancing quality of care.” NAPT is concerned that the experiment has several major flaws that will impact the success of the model. As an example, by limiting the data timeframe to three retrospective years of most recent data, CMS was unable to assess the complete actuarial impact of the proposed model on the Medicare Trust Fund. Second, the model focuses only on a 90-day window and limits the services in the bundled payment to only radiation therapy services. With such a narrow definition, this experiment would not capture the medium and long term adverse clinical consequences and additional spending associated with the excess radiation that patients may be exposed to due to the financial disincentives discussed above. “Savings” captured by the proposed RO Model would not reflect true, complete savings from the changes in treatment delivery and would completely disregard the critical medium and longer-term costs and impact to Medicare beneficiaries and the Medicare Trust Fund.

IV. Importance of Evidence Development

While the current body of evidence is robust and supports coverage of the therapy for certain cancers, our community is committed to continued evaluation of the short, medium and long-term benefits of this modality through evidence development. As discussed above, evidence development has been multi-institutional and has led to hundreds of published journal articles over the last five years – disproportionately more evidence than for any other radiation oncology modality during that timeframe. In addition, as of August 2019, our community is actively participating in 32 clinical trials and 6 observational studies.

In the Proposed Rule, CMS sought feedback on allowing the exclusion of a RO Model participant who is “enrolled in a federally-funded, multi-institution, randomized control clinical trial for proton beam therapy so that further clinical evidence assessing its health benefit comparable to other modalities can be gathered.” While NAPT appreciates this concept, we believe that it is incredibly narrow in scope; currently, no existing clinical trials would meet this criterion. We strongly urge CMS to broaden the beneficiary exclusion to all clinical trials (not just federally funded randomized controlled trials) and data registries for continued evidence development. Some Medicare contractors also provide exceptions to providers with a history of evidence development and we suggest CMMI consider this as a basis for exclusion as well.

NAPT is also concerned more broadly that the proposed RO Model does not give a pathway for participants using new and innovative technologies to receive adequate reimbursement. Radiation oncology is a continuously evolving specialty where new advances have enabled physicians to more effectively map the cancer and/or effectively deliver clinically appropriate treatment while minimizing exposure to surrounding tissues. The absence of a pathway through which new technology can either receive additional payment or be excluded from the RO Model until a certain utilization level is reached will stifle the adoption of innovative and potentially life-saving technologies. This failure to provide a pathway for innovative technology also runs counter to the Administration’s stated goals of encouraging innovation and improving patient access.

Innovation is the fuel that powers the engine of progress and creativity. That is why the Trump Administration is taking action in every possible way to promote, enhance, and foster innovation within the healthcare system. We are committed to removing government barriers and modernizing regulations around new technologies to ensure safe and effective treatments are readily accessible to beneficiaries without delaying patient care. (Administrator Verma, May 2019)

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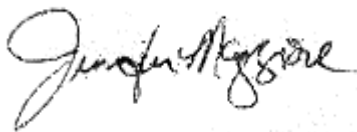
NAPT has identified several grave concerns that should be considered as part of the final rule adoption. In particular, we believe that the rule has incorrectly identified proton therapy as a “low value” treatment option, rather than a high value treatment option, given proton beam therapy’s efficacy and precision in targeting and treating tumors and its ability to reduce costly side effects and future secondary malignancies. Second, the APM’s drastic proposed reduction in payments coupled with additional discounts and withholds may place many proton therapy centers at financial risk given their tight operating margins and may ultimately result in further limiting access to proton therapy in the United States, despite the proven effectiveness of the treatment.

Given these concerns, the NAPT requests the following:

- ⇒ CMS should make participation in the RO Model voluntary.
- ⇒ CMS should establish a low volume threshold, below which modalities, including proton beam therapy, are excluded.
- ⇒ CMS should expand its exclusion proposal for proton beam therapy beneficiaries by using the Medicare evidence development precedent (*i.e.*, both registries structured in compliance with AHRQ guidance and clinical trials registered on clinicaltrials.gov).
- ⇒ Given the differences in resource requirements and clinical complexities, CMS should establish tiered base rates rather than a single base rate (per cancer type) regardless of modality of care and any necessary reductions in payments or discounts should be applied proportionately.
- ⇒ CMS should adjust the efficiency factor to avoid penalizing efficient practices, including efficient proton therapy practices, and the discount factors should be reduced in order to minimize further financial strain on proton beam therapy centers.
- ⇒ CMS should have a pathway through which new service lines and innovation, including new radiation oncology technology, is clearly incentivized.
- ⇒ Once finalized, and largely depending on the currently unknown contours of the final APM, CMS should delay implementation until at least July 1, 2020 to allow reasonable time for Medicare contractors and the providers in the selected core-based statistical areas to prepare for the new approach.

We appreciate your consideration of our feedback on the Proposed Rule for the RO Model. Should you have any questions, please do not hesitate to contact me at jmaggiore@proton-therapy.org.

Respectfully submitted,



Jennifer Maggiore
Executive Director, NAPT



Dr. Eugen Hug
Chairman, PTCOG-NA



Exhibit A.

NAPT 2018 Response Letter to MedPAC on Characterization of Proton Beam Therapy as Potentially Low-Value Service