September 16, 2021

VIA Electronic Submission to www.regulations.gov

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

**Re: [CMS-1753-P] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals**

Dear Administrator Brooks-LaSure:

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 CY 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (OPPS) Proposed Rule. NAPT is a nonprofit organization made up of world-renowned cancer centers, focused on enhancing the awareness of and access to proton therapy as a clinically sound cancer treatment.[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.

NAPT and the broader radiation oncology community have engaged with the Center for Medicare and Medicaid Innovation (CMMI) on the Radiation Oncology Alternative Payment Model (RO Model) for five years.

See **Appendix A** for our prior comment letter in response to the Specialty Care Models proposed rule. We are disappointed that a number of our concerns regarding the RO Model expressed in meetings with CMMI and in previous comment letters remain unaddressed including:

- ***Inadequacy of the rates for proton therapy*** based on flawed data and a methodology not reflective of the current resource requirements;
- ***Short-term focus of the model (90-day episode) that creates significant disincentives*** for services with a higher upfront investment and longer term value; and
- A model design that ***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.

Our comments on the RO Model proposals in the CY 2022 OPPS Proposed Rule focus on our continued request for exclusion of proton therapy from the RO Model. NAPT requests the following:

- CMS should exclude proton therapy from the RO Model in order to eliminate any financial disincentives to use of an appropriate clinical modality of care and to ensure continued access to this innovative therapy for Medicare beneficiaries battling cancer.
- CMS should maintain flexibility for determining the scope and administration of the proton therapy research exclusion.

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

- CMS should delay implementation of the RO Model to allow reasonable time for participants given the model's complexity coupled with the on-going and continuing challenges of the COVID-19 public health emergency (PHE).

## I. Exclusion of Proton Therapy from RO Model

Consistent with its stance prior to and following the publication of the Specialty Care Model Proposed Rule (CMS-5527-P) in summer 2019, NAPT urges CMS to ***exclude proton therapy*** from the RO model. The Agency should exclude proton therapy as the ***payment rates for the 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.

### A. Inadequate Payment Rates based on Flawed Methodology

For CY 2022, CMS proposes to use three base years (CY 2017 through CY 2019) from which it compiled historical episodes of care for the proposed fifteen different cancer types across the multiple modalities of radiation therapy. Continuing with its previously finalized approach, the Agency narrows the data employed to calculate the national base rates to only those episodes furnished in a hospital outpatient (HOPD) setting. CMS has argued for exclusively using HOPD episodes as "OPPS payments have been more stable over time and have a stronger empirical foundation than those under the PFS". NAPT remains very troubled by this approach as episodes where proton therapy radiation treatment services were furnished represent only 1.0% of the total episodes of care used to establish the base rates.[2]

**Table 1. Total Episodes of Care by Setting (CY 2017 – CY 2019)**

| Setting of Care | Episodes with Protons* | | All Episodes | | Proton Episodes as % of Total |
|---|---|---|---|---|---|
| | Volume | % of Total | Volume | % of Total | |
| Freestanding | 4,743 | 59.1% | 169,143 | 33.6% | 2.8% |
| Outpatient | 3,287 | 40.9% | 333,220 | 66.3% | 1.0% |
| Freestanding & Outpatient | 2 | 0.0% | 348 | 0.1% | 0.6% |
| **Total** | **8,032** | **100.0%** | **502,711** | **100.0%** | **1.6%** |

* Episodes with proton therapy, may include other modalities
Source: RO Episode File (2017 – 2019) (XLS) (Radiation Oncology Model website – file last reviewed 08/26/21)

By restricting the methodology to hospital outpatient-based episodes, nearly 60% (4,743) of the proton therapy episodes would be excluded. Analyzing the episodes of care by cancer type, proton therapy episodes would represent more than 1% of the total episodes of care in only six of the fifteen cancer types; proton therapy episodes would represent less than 0.7% of total for the remaining nine. See **Table 2**.

**Table 2. Total Episodes of Care in the Outpatient Setting by Cancer Type (CY 2017 – CY 2019)**

| Cancer Type | Episodes with Protons* | | All Episodes | | Proton Episodes as % of Total |
|---|---|---|---|---|---|
| | Volume | % of Total | Volume | % of Total | |
| Anal | 56 | 1.7% | 3,458 | 1.0% | 1.6% |
| Bladder | 4 | 0.1% | 4,946 | 1.5% | 0.1% |
| Bone Mets | 18 | 0.5% | 30,077 | 9.0% | 0.1% |
| Brain Mets | 22 | 0.7% | 23,022 | 6.9% | 0.1% |
| Breast | 343 | 10.4% | 75,067 | 22.5% | 0.5% |
| Cervical | 0 | 0.0% | 1,862 | 0.6% | 0.0% |

[2] RO Episode File (2017-2019) (XLS) (https://innovation.cms.gov/innovation-models/radiation-oncology-model)

| Cancer Type | Episodes with Protons* | | All Episodes | | Proton Episodes as % of Total |
|---|---|---|---|---|---|
| | Volume | % of Total | Volume | % of Total | |
| CNS | 191 | 5.8% | 7,320 | 2.2% | 2.6% |
| Colorectal | 41 | 1.2% | 10,432 | 3.1% | 0.4% |
| Head & Neck | 399 | 12.1% | 19,951 | 6.0% | 2.0% |
| Lung | 387 | 11.8% | 71,368 | 21.4% | 0.5% |
| Lymphoma | 44 | 1.3% | 11,759 | 3.5% | 0.4% |
| Pancreatic | 66 | 2.0% | 5,246 | 1.6% | 1.3% |
| Prostate | 1,469 | 44.7% | 52,356 | 15.7% | 2.8% |
| Upper GI | 203 | 6.2% | 9,763 | 2.9% | 2.1% |
| Uterine | 44 | 1.3% | 6,593 | 2.0% | 0.7% |
| **Total** | **3,287** | **100.0%** | **333,220** | **100.0%** | **1.0%** |

* Episodes with proton therapy, may include other modalities
Source: RO Episode File (2017 – 2019) (XLS) (Radiation Oncology Model website – last visited 08/26/21)

As CMS previously acknowledged, there is a higher cost to delivering proton therapy. This cost is due to the significant investment required for proton therapy compared to the other modalities and the higher level of ongoing resources required to provide this treatment safely. ***CMS's continued failure to include a meaningful volume of episodes in the calculations of the base rates has led to payment rates that are not reflective of the cost to provide proton therapy and would lead to significant rate cuts.*** To estimate the impact of these cuts, NAPT worked with its mandated members and using member-specific case mix and historical experience adjustment factors from last year[3], NAPT estimates that RO Model rates were ***on average 36.0% lower*** than the historical payment rates for the top five most common cancer types treated with proton therapy.[4] These rates are woefully inadequate and unsustainable and may force RO Model participants to consider a reduction in services in order to remain financially viable.

### B. Proposed Exclusion of Brachytherapy

In the Proposed Rule, CMS proposes to remove brachytherapy as an included modality in the RO Model. Stakeholders expressed concerns about how the RO Model reimbursed multi-modality episodes, especially in cases of cervical cancer and prostate cancer, where standard clinical practice is concordant treatment with external beam radiation therapy and brachytherapy. In response to these concerns, CMS proposes the modality exclusion, stating the following:

> *CMS seeks to neither incentivize nor disincentivize the use of one modality over another, but rather to encourage providers to choose RT services that are the most clinically appropriate for the beneficiaries under their care.[5] (Emphasis added)*

The Agency further acknowledged the concerns that stakeholders had about the possible unintended consequences with its inclusion on beneficiaries' access to care.

***NAPT strongly agrees that CMS should not be implementing policies in the RO Model that create financial disincentives to use a clinically appropriate modality of care and that excludes beneficiaries' access to care***. We are surprised and disappointed, however, that the Agency fails to apply the same reasoning with respect to proton therapy. As noted above, episodes with proton therapy represent only one percent of episodes compiled to set the national base rates. Thus, these calculated base rates do not reflect the cost of furnishing this modality of care and these rates represent a significant and disproportionate drop in reimbursement for proton therapy centers, without any substantial quality measures strengthening the primary

[3] The historical experience adjustment and case mix factors used were provided to mandated members when the implementation date was originally January 1, 2021.
[4] Most commonly treated cancer types based on findings from the CY 2019 NAPT Annual Survey.
[5] 86 FR42293

motivation for CMS to launch the proposed RO model. The short-term financial gains will result in negative long term health outcomes.

RO Model participants have a financial disincentive to (a) invest in proton therapy, where clinically appropriate, due to its higher upfront investment costs; and (b) treat more clinically complex patients. This could include patients with recurrences after prior radiation therapy retreatment, complex tumor locations, uncommon cancer presentations, and clinical scenarios that can often benefit most from proton and photon therapy.[6] This runs counter to the intended goals of the model and is in direct conflict with its reasoning for excluding brachytherapy from the RO Model. Given their desire to not create financial incentives for or against any clinically appropriate modality of care, ***we urge CMS to exclude proton therapy from the RO Model like they did for brachytherapy. CMS must recognize the concerns from proton therapy stakeholders regarding the unintended consequences on beneficiaries' access to innovative cancer treatment.***

## II. Delay of Implementation Date

In the Proposed Rule, the Centers for Medicare and Medicaid Services (CMS) proposes to set an implementation date of January 1, 2022 – the earliest date permitted under the Consolidation and Appropriations Act of 2021. Congress had included language in the CAA due to stakeholder's repeated concerns about implementing this model during a pandemic and due to on-going concerns regarding the RO Model methodology. We are incredibly disappointed that the Agency has decided to proceed with the earliest implementation date permitted. For the past eighteen months and continuing today, healthcare providers have faced unprecedented and ongoing challenges due to the COVID-19 pandemic (including, but not limited to, increased costs and staff shortages). Many RO Model participants across the country, particularly in states like Florida and Louisiana, are facing a new surge in COVID-19 cases due to the Delta variant and are recovering from devastating storms such as Hurricane Ida.[7]

In 2021, the volume of radiation oncology patients has remained constant, but managing the complexity of cancer care and navigating patients through this pandemic has created additional burdens for centers and increased their costs significantly. At the same time, RO Model participants are having to prepare for the January 1 implementation without having access to critical data needed to assess the financial implications of this model (e.g., case mix adjustment, historical experience, trend factors) until after the publication of the OPPS Final Rule, a mere two months prior to the effective date. In addition, RO Model participants are only now learning additional details on the expected billing processes as well as quality and clinical data element requirements, which may require significant practice changes in order to ensure compliance. It is wholly unrealistic to expect impacted practices and facilities to be ready to participate in the RO Model in four months during a continuing PHE. ***Given the challenges in adapting to this new model coupled with the on-going operational and financial challenges due to the COVID-19 pandemic, we urge CMS to delay the effective date of the RO Model.***

## III. Extreme and Uncontrollable Circumstance

In the Proposed Rule, CMS proposes to adopt an Extreme and Uncontrollable Circumstance (EUC) policy for the RO Model. The Agency is proposing to define an EUC as a "circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to delivery care in accordance with the RO Model's requirements and affects the entire region or locale."[8] Under the proposed policy, if the Agency declares an EUC for a geographic region, then it may take the following actions:

1) Amend or delay the model performance period in cases of a nationwide EUC;

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[6] According to the RO Episode File (2017 – 2019), 6.2% of the proton episodes also had IMRT; for SBS, SBRT, and CEB, it was less than 1% of episodes. (Source: https://innovation.cms.gov/innovation-models/radiation-oncology-model)

[7] Members in hardest hit areas report unprecedented number of patients overwhelming the hospitals and this is supported by latest statistics from the CDC (e.g., HHS region 4 (which includes Florida) reports the highest new admissions per 100,000 population in the last 10 months (7.28 on August 21st versus 6.13 on January 9th). https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html (Last visited August 26, 2021)

[8] 86 FR 42311

2) Eliminate or delay certain reporting requirements for RO participants, make certain requirements optional, and/or extend the timeline for reporting data to CMS; and
3) Amend the RO Model's pricing methodology by adjusting the quality withhold or trend factor adjustments if certain criteria apply to the EUC.

In a national, regional, or local event, CMS proposes to only apply the EUC policy if the magnitude of the event calls for the use of special authority to help providers respond to the emergency and continue providing care.

Rather than using a "bright-line test" to assess each EUC, CMS proposes to tailor the modifications based on the circumstances and the "geographic area" impacted. Specifically, the Agency proposes to consider the following factors:

- Whether the RO participants are furnishing services within a geographic area considered to be within an "emergency area" during an "emergency period" as defined in section 1135(g) of the Social Security Act.
- Whether the geographic area within a county, parish, U.S. territory, or tribal government designated under the Stafford Act served as a condition precedent for the Secretary's exercise of the 1135 waiver authority, or the National Emergencies Act.
- Whether a state of emergency has been declared in the relevant geographic area.

NAPT supports the establishment of an EUC policy for the RO Model. Our members are in unprecedented times as they have spent the last 18 months battling the impact of the COVID-19 PHE on their ability to provide care to their patients. Preparing for the RO Model in just over five months is incredibly challenging in a normal year and much more challenging during this PHE, especially given that many RO Model participants across the country (particularly in states like Florida and Texas) are facing a surge in COVID-19 cases due to the Delta variant. As noted above, members in hardest hit areas report unprecedented number of patients overwhelming the hospitals.

Appreciating the EUC policy proposal, NAPT encourages the Agency to maintain ample flexibility regarding how the Agency will define a "geographic region or geographic area" and "state of emergency" declaration under this proposal in order to address, for example, participant level COVID-19 infection trends, hospitalizations and staffing shortages irrespective of the status of a state or geographic region, as a whole. Furthermore, we ask CMS to strongly consider whether the current COVID-19 PHE meets the criteria for a delay in the implementation date of the RO Model. Again, our members and the broader radiation oncology community are deeply concerned about implementing the RO Model in the midst of one of our nation's ongoing dire public health emergency.

## IV. Research Exclusion

CMS proposed that proton therapy is excluded from model when the care is furnished to a RO Model beneficiary participating in a federally funded, multi-institutional, randomized control trial. Over the last year, NAPT and key physician leaders have engaged in numerous discussions with CMMI on the current state of research in the proton therapy community, the limitations of federal funding, the challenges with conducting randomized control trials in radiation oncology, and our request for the broadening of this research exclusion. See **Appendix B** for our May 2021 presentation with CMMI.

Even though proton therapy episodes represent only 1.6% of all radiation treatment episodes and proton therapy being a relatively new technology (only 1 center in the 1990s, only 4 centers in the 2000s), the proton community is exceptionally dedicated to research as evidenced by the 4,836 publications in PubMed on proton therapy and cancer.[9]

[9] Over four thousand (4,048) of the 4,836 (84%) proton publications have come since 2013 when the data was obtained for the 2014 ICER Report, one of the sources that CMMI used as the basis for its evidentiary conclusions regarding proton therapy.

We were encouraged when President Biden recently met with doctors at the James Comprehensive Cancer Center at The Ohio State University (OSU) and expressed unequivocal enthusiasm about his administration's commitment to cancer research and proton therapy. As articulately described, the innovation taking place at proton therapy providers like OSU are "a source of hope" for cancer patients, and should be nurtured.

As a low volume modality, proton therapy research is critical to continue measuring outcomes for Medicare Beneficiaries. The proton therapy community has a **long and meaningful history committed to research** that provides evidence-based research supporting the value of proton therapy. Multi-center registries have historically provided robust data providing significant contributions to the research community. It is critical to nurture proton therapy as a critical advanced technology of the future that is part of the President's solution of ending cancer as we know it. ***As such, NAPT supports CMMI maintaining flexibility for the scope and administration of the proton therapy research exclusion.***

## V. Clinical Data Elements

With the publication of the CY 2022 OPPS Proposed Rule, CMMI also issued the quality measure and clinical data elements collection and submission guide. NAPT reviewed and submitted feedback on the guide to CMMI per the requested process. As CMMI and CMS are reviewing and considering these quality measures and clinical data elements, NAPT asks the Agency to consider these requirements in the context of the model's overall goals. As articulated on the RO Model website, the model "aims to improve the quality of care for cancer patients receiving radiotherapy (RT) and move toward a simplified and predictable payment system." How are the administrative burdens created by these requirements getting to the key questions of the model (i.e., did the patients in the model receive better, equivalent or worse short, medium and long term outcomes irrespective of the discounts afforded the Medicare program under the model)?

As currently defined in the submission guide, all clinical data elements will need to be manually reported utilizing Excel templates provided by the Agency. This will take significant time and resources. Freestanding RO Model participants, who may not have registrars in place to collect this data, may be forced to hire and/or train staff to interpret and record the various elements in the patient record, and then manually input them correctly into the template. In addition, given the complexity of these templates, physicians and clinical staff may also be required to assist in collecting this data, taking time away from delivering critical patient care. This is coming at a time when practices are still reeling from the financial impact of COVID-19, many are currently experiencing staffing shortages, and may not have the financial resources to hire the needed staff due to the magnitude of cuts they are facing under this Model. According to numerous of NAPT's RO Model participants, this manual process could take 10 – 20 minutes to input each of the data points for each breast cancer case. Coupled with the CDE reporting requirements for the five other disease sites, this presents a significant burden for practices whose providers and clinicians, as noted above, are focused on navigating care for cancer patients who have experienced delay in diagnosis and treatment due to, or experienced financial hardship during the PHE. CMS must allow for greater flexibility in the data submission requirements, recognizing that some practices may not have the resources necessary to readily extract this data from existing systems and submit it to the Agency. We are disappointed that the Agency is pursuing a manual, labor intensive process rather than exploring existing data elements that can be extracted from existing electronic health records.

***Given the immense requirements laid out in this submission guide, NAPT concurs with our fellow members of the radiation oncology community and requests a two-year delay of the CDE reporting.*** While NAPT acknowledges the efforts by CMMI to reduce the requirements from the original RFI, the requirements are still too extensive to expect compliance in less than 5 months in a normal year and that much more challenging during the public health emergency. The delay requested above would allow RO participants the appropriate amount of time to develop work flows to consistently document the proposed data elements and provide time for the different EHR vendors to support these requirements. Additionally, time is needed to clarify gaps and ambiguities in the instructions involving the clinical data elements and engage in necessary hiring and/or training. RO Model participants could still be compliant with quality reporting through the quality measures, if the CDE component is delayed.

* * * * *

NAPT has several continuing, grave concerns with the design and implementation of the RO Model. In particular, we believe that CMMI continues to incorrectly view proton therapy as a "low value" treatment option rather than a high value treatment option, in spite of the overwhelming published evidence on proton therapy's efficacy and precision in targeting and treating tumors and its ability to reduce costly side effects and future secondary malignancies.[10] The proposed substantial cuts in reimbursement put financial pressure on institutions already burdened by the impact of the ongoing pandemic, thus, straining their ability to ensure quality care and participate in clinical research.

We appreciate the opportunity to submit comments in response to the Proposed Rule. Please contact Jennifer Maggiore at jennifer@proton-therapy.org if you have any questions or need additional information.

Sincerely,

Jennifer Maggiore

Executive Director, NA

Dr. Anita Mahajan, M.D.

President, PTCOG-NA

[10] See Attachment letter from physician leaders in the proton therapy community to CMMI. http://www.proton-therapy.org/wp-content/uploads/2021/07/RO-APM-Physician-Letter-to-Director-Fowler.pdf

**Appendix A.**

**NAPT Comment Letter to Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures** [CMS-5527-P]

**Appendix B.**

**NAPT/PCG Meeting on RO Model PBT Clinical Trial Exclusion**