The Radiation Oncology Alternative Payment Model
COMPPARE Conference
Amelia Island, FL
January 18th, 2020

Jennifer Maggiore
Executive Director
National Association for Proton Therapy
Independent non-profit organization founded in 1990

Mission
- Educate and raise awareness of clinical benefits of proton therapy
- Ensure patient choice and access
- Encourage cooperative research and innovation

Supporting members are world-renowned cancer centers

Resource for cancer patients when researching treatment options

Many are NCI-designated comprehensive cancer centers & members of the NCCN

Only organization that monitors and tracks treatment volumes and indications treated with proton therapy
Members of NAPT

- Ackerman Cancer Center
- Baylor University / US Oncology Texas Center for Proton Therapy
- Beaumont Health Proton Therapy Center
- California Protons Cancer Therapy Center
- Cincinnati Children’s / University of Cincinnati Proton Therapy Center
- Emory University Proton Therapy Center
- Georgetown Lombardi Comprehensive Cancer Center
- Hampton University Proton Therapy Institute
- Huntsman Cancer Hospital at the University of Utah
- Inova Schar Cancer Institute
- James Slater Proton Treatment & Research Center at Loma Linda University
- Johns Hopkins National Proton Therapy Center
- Laurie Proton Therapy Center
- Mayo Clinic Proton Beam Therapy Center – Arizona
- Mayo Clinic Proton Beam Therapy Center – Minnesota
- McLaren Proton Therapy Center
- MD Anderson Cancer Center Proton Therapy Center
- Miami Cancer Institute at Baptist Health South Florida
- New York Proton Center - Memorial Sloan-Kettering - Mount Sinai - Montefiore New York Proton Center
- Northwestern Medicine Chicago Proton Center
- Oklahoma Proton Center
- ProCure Proton Therapy Center – New Jersey
- Proton International at University of Alabama Birmingham
- Provision CARES Proton Therapy Center – Knoxville
- Provision CARES Proton Therapy Center – Nashville
- The Roberts Proton Therapy Center at the University of Pennsylvania
- Seattle Cancer Care Alliance Proton Therapy Center
- S. Lee Kling Proton Therapy Center at Washington University
- South Florida Proton Therapy Institute
- Texas Center for Proton Therapy
- University Hospitals Seidman Cancer Center at Case Western University
- University of Florida Health Proton Therapy Institute
- University of Kansas Cancer Center
- University of Maryland Proton Treatment Center
- Marjorie & Leonard Williams Proton Therapy Center at Orlando Health
- Willis-Knighton Proton Therapy Center
Percentage of GDP attributed to health care

1970 - 6.9%
2018 - 17.7%

Total national health expenditures as a percent of Gross Domestic Product, 1970-2018

Source: KFF analysis of National Health Expenditure (NHE) data
On a per capita basis, health spending has increased over 31-fold in the last four decades, from $355 per person in 1970 to $11,172 in 2018.

Source: KFF analysis of National Health Expenditure (NHE) data
Significant Rise in Life Expectancy in last 50 years
8.2% 

Consumer Spending on Health Care

*Report released by Bureau of Labor Statistics in April 2019
Article and Sources: https://howmuch.net/articles/consumer-spending-in-the-united-states
Preserving Patient Choice
Too Good to Be True?
Evidence-based medicine is an approach to medical practice intended to optimize decision-making by emphasizing the use of evidence from well-designed and well-conducted research.

Although all medicine based on science has some degree of empirical support, EBM goes further, classifying evidence by its epistemologic strength and requiring that only the strongest types can yield strong recommendations; weaker types can yield only weak recommendations.

The term was originally used to describe an approach to teaching the practice of medicine and improving decisions by individual physicians about individual patients. Use of the term rapidly expanded to include a previously described approach that emphasized the use of evidence in the design of guidelines and policies that apply to groups of patients and populations. It has subsequently spread to describe an approach to decision-making that is used at virtually every level of health care as well as other fields.
Evolutions of Value Based Care
How did we get here?

- **2010** Affordable Care Act which includes CMS Innovation Center (CMMI)
- **2014** CMS exploring potential ways to test an episode-based payment model for RT services.
- **2015** Congress passed the Patient Access and Medicare Protection Act (PAMPA) which required the Secretary of Health and Human Services to submit to Congress a report on “the development of an episodic alternative payment model” for RT services
- **2017** Episodic Alternative Payment Model for Radiation Therapy Services submitted to Congress
- **July 2019** Radiation Oncology Alternative Payment Model Proposed Rule
The Centers for Medicare & Medicaid Services (CMS) defines value-based care as those programs that “reward health care providers with incentive payments for the quality of care they give to people with Medicare.”

In order for the Secretary to exercise this authority, a model must either reduce spending without reducing the quality of care, or improve the quality of care without increasing spending, and must not deny or limit the coverage or provision of any benefits.
This won't be the most comfortable process for many entrenched players. But those who are interested in working with us to build a value-based system will have the chance to take advantage of a market where consumers and patients will be in charge of healthcare ... Change represents opportunity, and I exhort all of you to take advantage of the opportunities represented by what I've discussed today. Because I assure you: Change is possible, change is necessary, and change is coming.” – Alex Azar
"Value-based payment under the Trump administration is the future," said Verma. "So, make no mistake — if your business model is focused merely on increasing volume rather than improving health outcomes, coordinating care and cutting waste, you will not succeed under the new paradigm."
What is the Radiation Oncology Proposed Rule?

- **Mandatory model** created to promote quality and financial accountability
- Goal to test (experiment) whether a prospective episode would preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare spending
- Site neutral
- 40% participation defined by a core based statistical area (CBSA)
- 90 day period
- 17 cancer sites
- 4 quality measures
  - Plan of care of pain
  - Depression screening
  - Advance care plan
  - Treatment summary communication
  - Patient Experience in year 3
Why is Proton Beam Therapy included in bundled payment?

CMS states:

- From 2010 to 2016, spending and volume for PBT in Fee or Service Medicare grew rapidly, driven by a sharp increase in the number of proton beam centers and Medicare’s board coverage of this treatment.
- There has been a debate regarding the benefits of proton beam relative to other less expensive modalities.
- Given the continued debate around the benefits of PBT, and understanding that PBT is more costly, we believe that it would be appropriate to include in the RO Model’s test.
- We are considering excluding PBT from the included modalities in instances where a RO beneficiary is participating in a federally-funded, multi-institution, randomized control clinical trial for PBT so that further clinical evidence assessing its health benefit comparable to other modalities can be gathered.
- Did not consult with clinical experts in field prior to characterizing service as low value
- Relied on older evidence (pre-2015) including the ICER report and claims data without context
- Limited understanding of clinical benefits of proton beam therapy
Higher upfront costs but lowers Medicare spending short and long term

CMS is tasked with lower costs now not long term
Proton Beam Therapy has a long clinical history of providing superior results to cancer patients.

It is the *standard of care treatment for multiple diagnoses* and clinical evidence has demonstrated its value in other common cancers.

Growth of indications has been through *clinical trials and evidence development*. Growing body of research has illustrated the benefits of proton therapy and supported the increase of its use for a variety of tumor sites.

Proton Beam Therapy *provides significant value* to Medicare beneficiaries.

Its clinical value has been recognized by world renowned academic medical centers and other high-quality healthcare systems with stringent evidence base requirements.
Base rates represent nearly a **50% cut** across the top 5 cancer sites
- Comparing 2017 total payments vs. total estimated payments using proposed national base rates

<table>
<thead>
<tr>
<th>Indication</th>
<th>2017 Episodes *</th>
<th>Total Payments (2017)</th>
<th>Total Payments, RO Model</th>
<th>Difference</th>
<th>% Diff.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>173</td>
<td>$3,126,422</td>
<td>$1,943,937</td>
<td>($1,182,485)</td>
<td>-37.8%</td>
</tr>
<tr>
<td>Head/Neck</td>
<td>228</td>
<td>$7,760,947</td>
<td>$4,263,389</td>
<td>($3,497,558)</td>
<td>-45.1%</td>
</tr>
<tr>
<td>Lung</td>
<td>231</td>
<td>$6,168,306</td>
<td>$2,989,881</td>
<td>($3,178,424)</td>
<td>-51.5%</td>
</tr>
<tr>
<td>Prostate</td>
<td>1,386</td>
<td>$61,865,723</td>
<td>$30,436,067</td>
<td>($31,429,656)</td>
<td>-50.8%</td>
</tr>
<tr>
<td>Upper GI</td>
<td>109</td>
<td>$3,138,769</td>
<td>$1,567,587</td>
<td>($1,571,182)</td>
<td>-50.1%</td>
</tr>
<tr>
<td><strong>All Protons</strong></td>
<td><strong>2,453</strong></td>
<td><strong>$90,830,305</strong></td>
<td><strong>$45,761,289</strong></td>
<td><strong>($45,069,016)</strong></td>
<td><strong>-49.6%</strong></td>
</tr>
<tr>
<td><strong>All Other Modalities</strong></td>
<td><strong>172,232</strong></td>
<td><strong>$2,476,506,846</strong></td>
<td><strong>$2,377,795,022</strong></td>
<td><strong>($98,711,824)</strong></td>
<td><strong>-4.0%</strong></td>
</tr>
</tbody>
</table>
Significant number of communities do not currently have access to proton beam therapy. Only 35% of U.S. population has access to proton therapy due to upfront investment required to establish proton therapy centers.

Currently only 4 centers in the Western United States offer proton therapy. This is greatly disproportionate to the Eastern U.S. and balance my never occur ii RO-APM includes proton therapy.

A model that creates disincentives to treat beneficiaries with clinically appropriate care will further limit access, particularly to rural and underserved communities.

Given the randomization in the selection of CBSAs, the model may also create unintended competitive imbalances, limiting access in an unequitable fashion.
Unsustainable payment rates will put centers’ viability at risk. It will also prevent cancer centers from adding this technology due to inefficient payment rates further limiting access to this treatment.

- Given the prevalence of cancer in the Medicare population, Medicare is a material payor for most of our members.

- The model will also have an indirect impact on other patient populations. To the extent that centers cannot have a robust case mix, it puts the center’s viability at risk for a broader set of patients, including pediatric patients.

- Medicare beneficiaries that receive excess radiation to critical structures will face short, medium and long-term complications and possible secondary malignancies not accounted for in the model resulting in increased costs for the Trust Fund.
Congressional Advocacy
Forbes and Tate
Congress of the United States
Washington, DC 20515
November 20, 2019

Sincerely,

[Signatures]

Scott Peters
Member of Congress

John H. Rutherford
Member of Congress

[Signatures]

Bipartisan House Letter Led by Congressman John Rutherford
Republican Letter led by Senator Marco Rubio
The Honorable John H. Rutherford  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Rutherford:  

Thank you for your letter regarding the Radiation Oncology (RO) Model recently proposed by the Centers for Medicare & Medicaid Services (CMS) in the notice of proposed rulemaking entitled, “Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures Notice of Proposed Rule Making” (CMS-5527-P). I appreciate hearing about your interest in the Trump Administration’s initiatives to emphasize quality and value in the healthcare for Americans and your suggestions on how we might improve the proposed RO Model.  

Your letter notes specific concerns with the proposed RO Model’s treatment of proton beam therapy as well as treatment of future advances in the delivery of radiation therapy (technology/innovation), and we appreciate you bringing these concerns to our attention. We also appreciate your suggestions to modify the proposed RO Model to allow for voluntary participation, a low-volume modality exclusion, adjustments in the payment calculation, tumor base rates, a modification of the efficiency payment adjustment, innovation, and a delayed implementation date.  

We considered many approaches in developing our proposed RO Model. Since 2014, CMS has been exploring potential ways to test an episode-based payment model for radiation therapy services. The proposed RO Model is an innovative payment model that would, if finalized, improve the quality of care for cancer patients receiving radiation therapy treatment and reduce provider burden by moving toward a simplified and predictable payment system. The aim of this model, which would involve required participation, is to test whether prospective site neutral, episode-based payments to physician group practices, hospital outpatient departments, and freestanding radiation therapy centers for radiation therapy episodes of care, would reduce Medicare expenditures, while preserving or enhancing the quality of care for Medicare beneficiaries.  

As you may be aware, the public comment period for this proposed rule recently closed on September 16, 2019. We received a number of comments from stakeholders, some of which are similar to those raised in your letter. Currently, we are carefully reviewing all of the comments received on the proposed RO Model and will give careful consideration to the input we have received.  

I appreciate your feedback about the importance of stakeholder engagement in model development. CMS strives for open communication as our initiatives develop and progress, and we appreciate your recommendations on ways to improve the proposed RO Model.  

I look forward to collaborating with you and other stakeholders as we work to transform our healthcare system into one that works better for the American people. I will share a copy of this response with the co-signers of your letter.  

Sincerely,  

[Signature]  

Administrator Verma recognizes these concerns.
Desk of the Vice President
Office of the Vice President
Tell Congress to Fight Back Against a New Medicare Rule That Would Limit Access to Proton Therapy!

The Alliance for Proton Therapy Access is calling on Congress to oppose CMS Rule No. CMS-5527-P. Join us!

The Center for Medicare and Medicaid Services (CMS) is proposing a new regulation that would drastically limit cancer patients' access to proton therapy. If it moves forward, CMS's alternative payment model would cut reimbursement for proton therapy to a rate that doesn’t come close to the cost of treatment. Providers will be forced to steer Medicare patients to less effective forms of treatment, many proton centers will lose revenue, some centers may close, and new centers won’t be built.

The bottom line? Many fewer cancer patients will have access to this life-saving treatment.

CMS is arguing that the benefits of proton therapy are limited and not worth the extra costs. But as you know, thousands of cancer patients, survivors, and family members have seen first-hand the power of proton therapy to precisely target cancer cells, reduce side effects, and lower the risk of secondary cancer.
Solutions

- Voluntary Participation
- Low Volume Threshold
- National Case Rates.
- Tiered Base Rates with Proportional Application of Reductions
- Efficiency and Discount Factors
- Innovation
- Delayed Implementation
What’s Next?

- The proposed rule was released on July 18th 2019 with a comment period to end on September 16th 2019.
- Except for certain Medicare payment regulations and certain other statutorily mandated regulations, all Medicare final rules will be scheduled for publication within 3 years giving the RO APM a final target of July 2022.
- CMS will publish the rule sooner if possible.
- OMB must approve final rule.
- Currently classified as long term action.
· 3000 Participants

· This study will directly compare the potential benefits and harms of protons versus photons. It will emphasize patient-centered outcomes and will help future patients make informed treatment decisions.

· The results will also provide insurers with the data needed to make coverage and policy decisions around the use of proton therapy for prostate cancer.
Impact on Research

- Proton Therapy Centers invest 30 to 100 times more resources to deliver proton therapy.
- Current reimbursement is limited
- Limited Resources
- Complexity of Operations
  - Intake Department
  - Marketing and Public Relations
  - Patient Support
  - Insurance and Appeal
  - Clinical team
Importance of Research to Measure Outcomes
Questions