The Radiation Oncology Alternative Payment Model

COMPPARE Conference
Amelia Island, FL
January 18th, 2020

Jennifer Maggiore

Executive Director

National Association for Proton Therapy

Educate. Awareness. Access. Research.

- 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

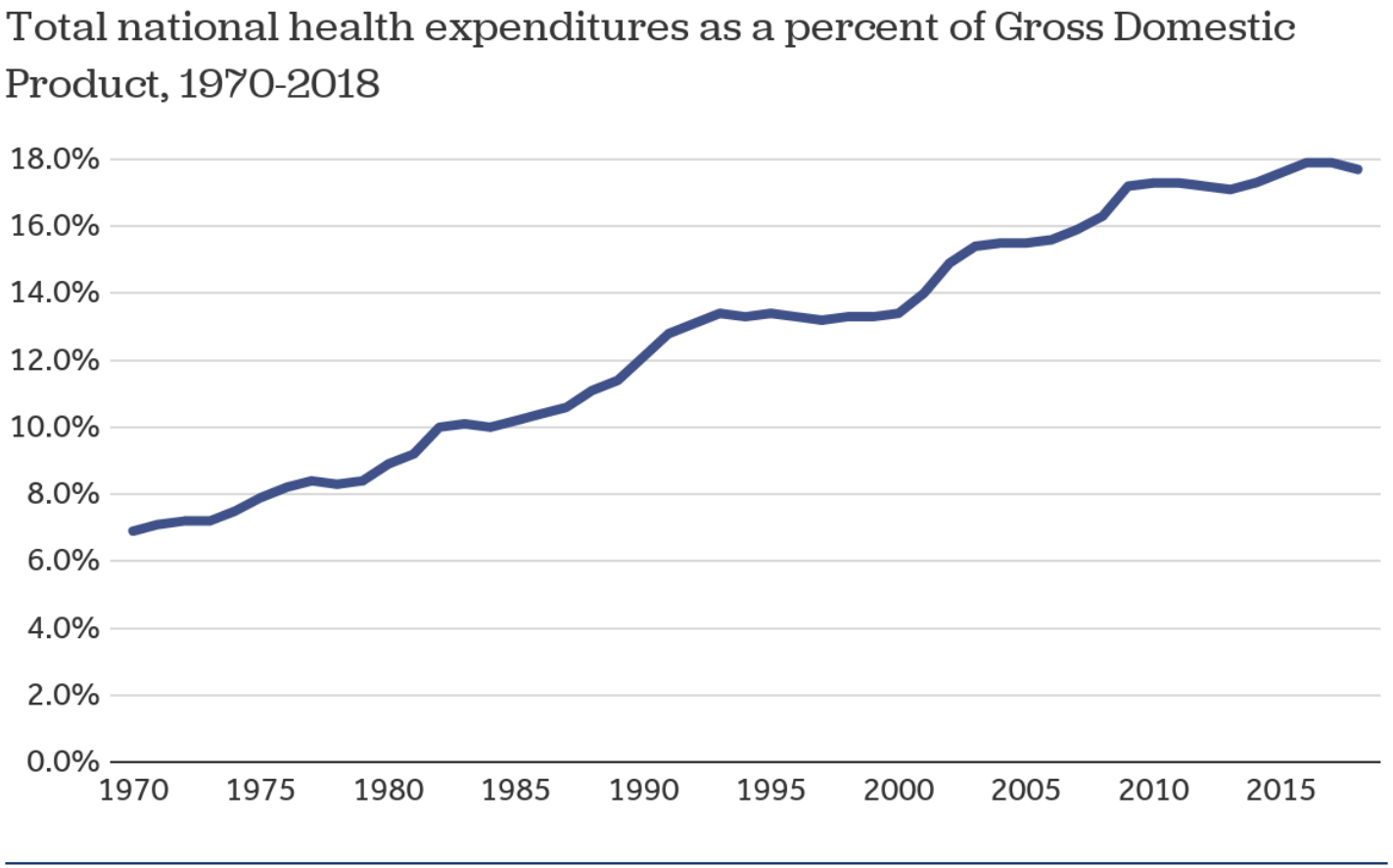
Members of NAPT

- 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%

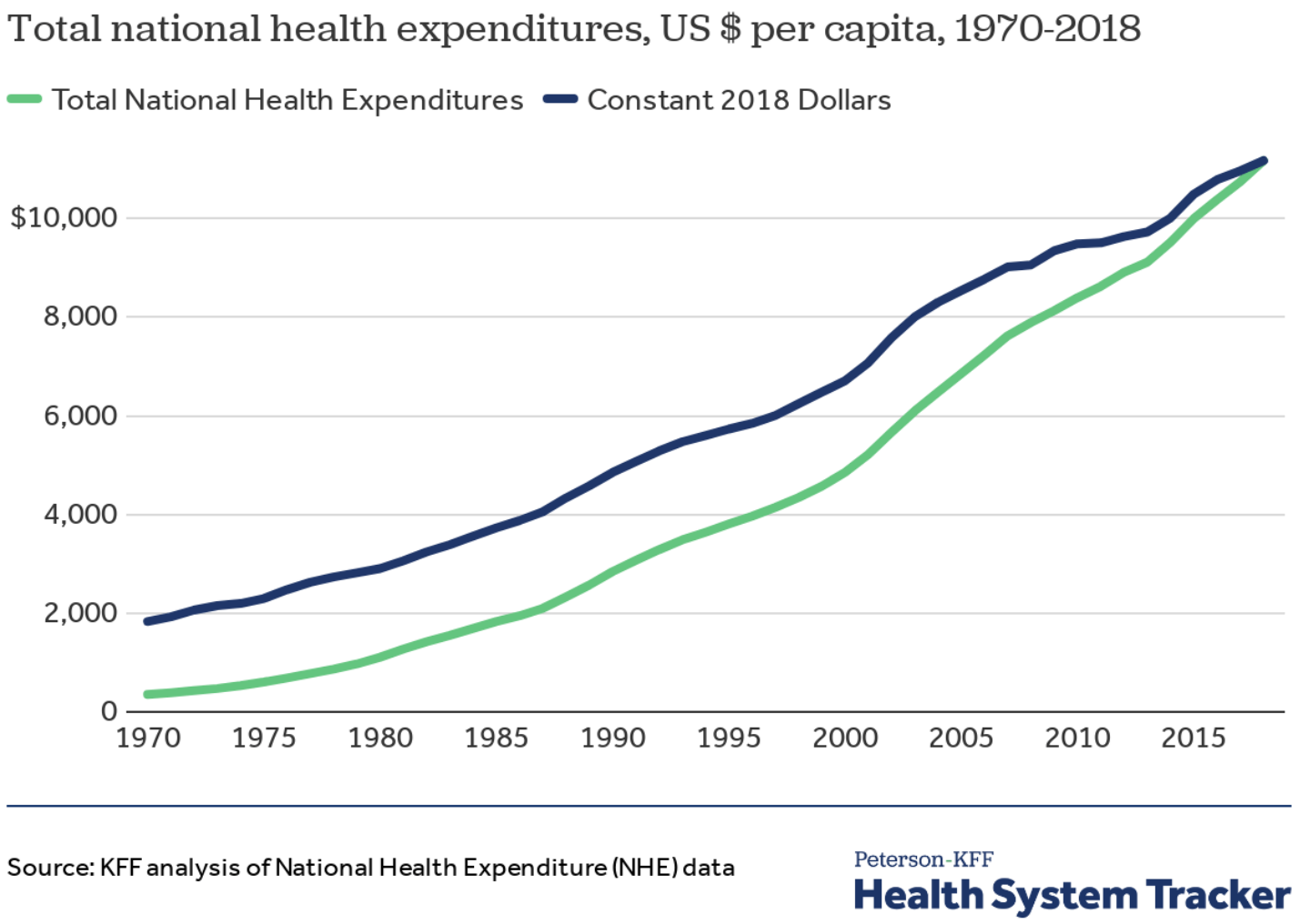
2018- 17.7%



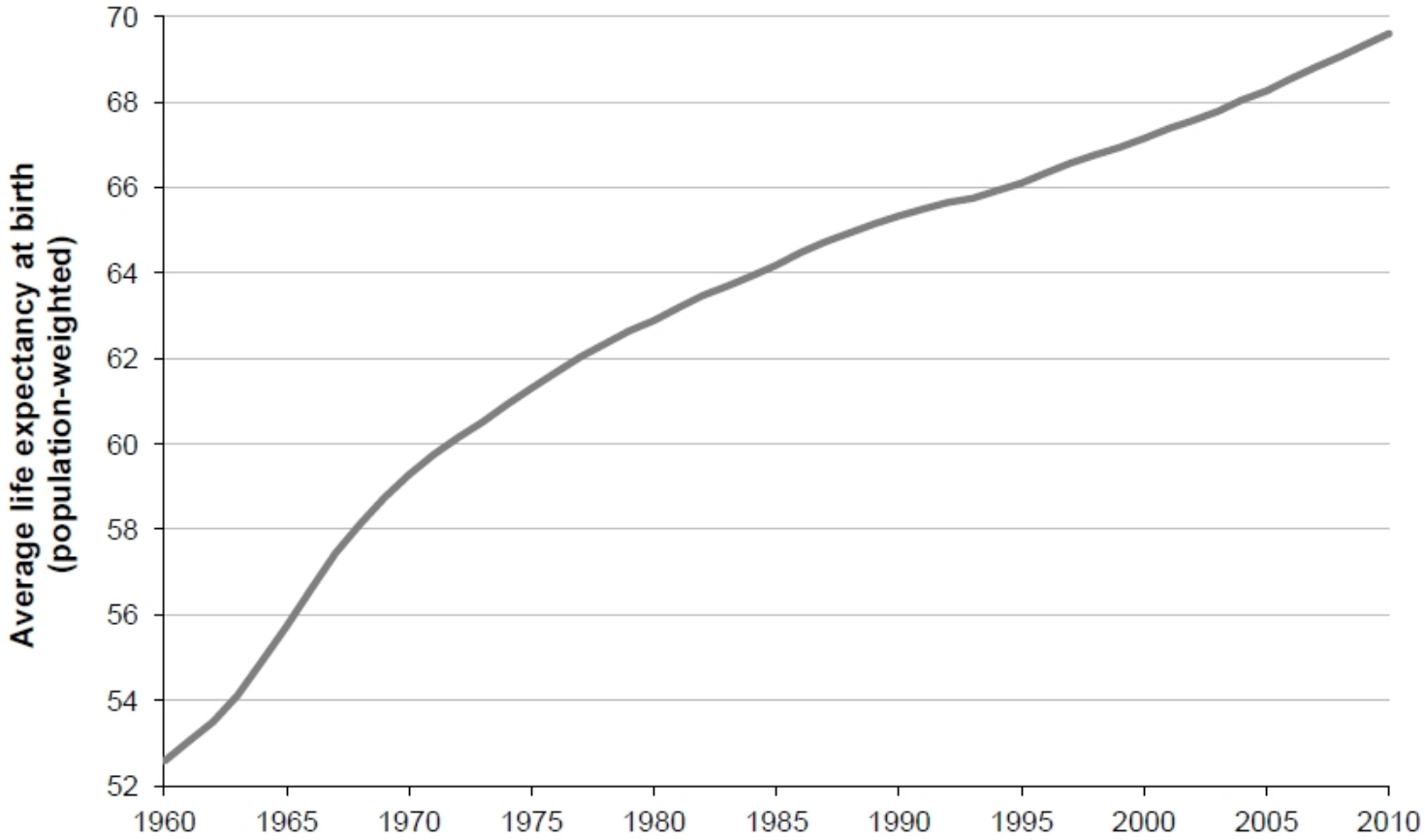
Source: KFF analysis of National Health Expenditure (NHE) data

Peterson-KFF Health System Tracker

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.



Significant Rise in Life Expectancy in last 50 years

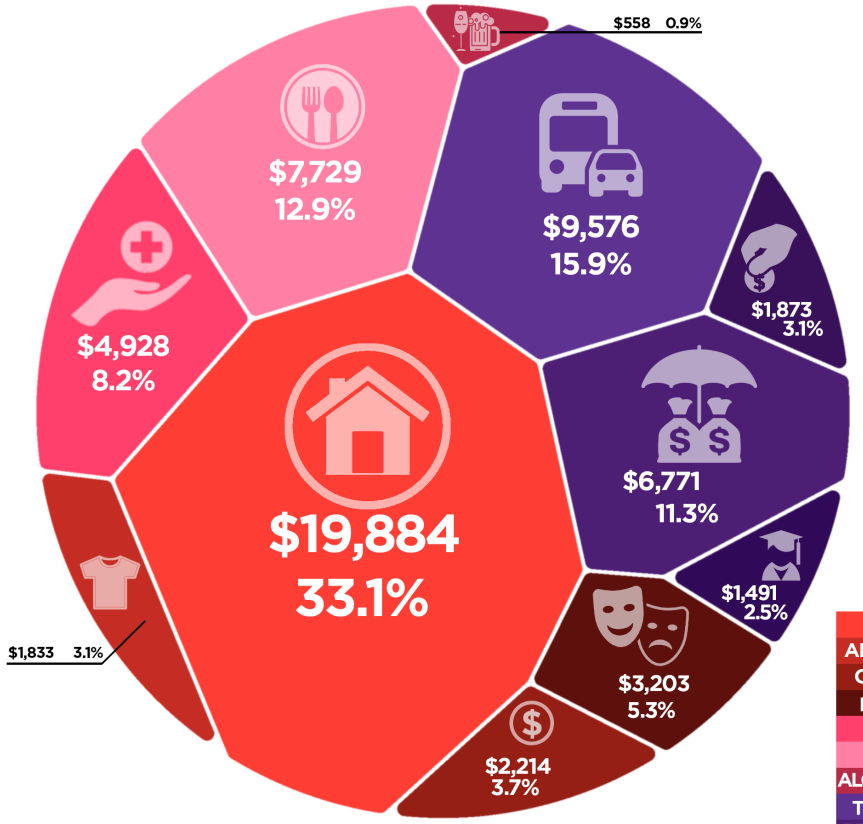


8.2%

Consumer Spending on Health Care

Consumer Spending in the United States

Average Annual Personal Expenditures by Category



Total Spending
$60,060

Category
HOUSING
APPAREL & SERVICES
OTHER EXPENSES
ENTERTAINMENT
HEALTHCARE
FOOD
ALCOHOLIC BEVERAGES
TRANSPORTATION
PERSONAL INSURANCE AND PENSION
CASH CONTRIBUTIONS
EDUCATION

*Report released by Bureau of Labor Statistics in April 2019

Article and Sources:

https://howmuch.net/articles/consumer-spending-in-the-united-states

U.S. Bureau of Labor Statistics - Consumer Expenditure Survey, 2017 - https://www.bls.gov

howmuch.net

Single Payer Health Care

Preserving Patient Choice

Too Good to Be True?

VALUE BASED CARE

Evidence Based Medicine

- 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.

Purpose of Innovation

HHS Secretary Alex Azar

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

Administrator Seema Verma

"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?

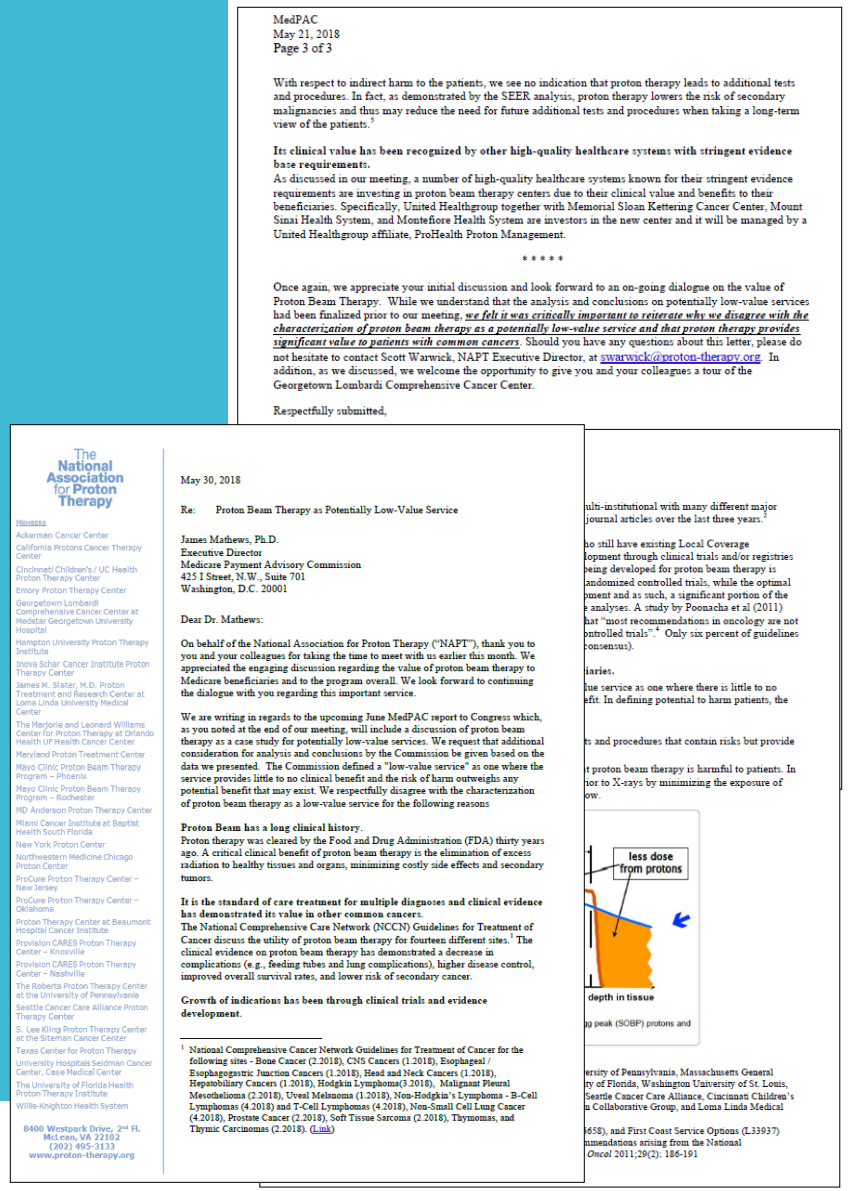
- **Mandatory model** created to promote quality and financial accountability
- Goal to test (experiment) whether a prospective episode would preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare spending
- Site neutral
- 40% participation defined by a core 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

MedPAC: Relied on Dated Evidence



MedPAC
May 21, 2018
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With respect to indirect harm to the patients, we see no indication that proton therapy leads to additional tests and procedures. In fact, as demonstrated by the SEER analysis, proton therapy lowers the risk of secondary malignancies and thus may reduce the need for future additional tests and procedures when taking a long-term view of the patients.[5]

Its clinical value has been recognized by other high-quality healthcare systems with stringent evidence base requirements.
As discussed in our meeting, a number of high-quality healthcare systems known for their stringent evidence requirements are investing in proton beam therapy centers due to their clinical value and benefits to their beneficiaries. Specifically, United Healthgroup together with Memorial Sloan Kettering Cancer Center, Mount Sinai Health System, and Montefiore Health System are investors in the new center and it will be managed by a United Healthgroup affiliate, ProHealth Proton Management.

* * * * *

Once again, we appreciate your initial discussion and look forward to an on-going dialogue on the value of Proton Beam Therapy. While we understand that the analysis and conclusions on potentially low-value services had been finalized prior to our meeting, ***we felt it was critically important to reiterate why we disagree with the characterization of proton beam therapy as a potentially low-value service and that proton therapy provides significant value to patients with common cancers***. Should you have any questions about this letter, please do not hesitate to contact Scott Warwick, NAPT Executive Director, at swarwick@proton-therapy.org. In addition, as we discussed, we welcome the opportunity to give you and your colleagues a tour of the Georgetown Lombardi Comprehensive Cancer Center.

Respectfully submitted,

The National Association for Proton Therapy

Members
Ackerman Cancer Center
California Protons Cancer Therapy Center
Cincinnati Children's / UC Health Proton Therapy Center
Emory Proton Therapy Center
Georgetown Lombardi Comprehensive Cancer Center at Medstar Georgetown University Hospital
Hampton University Proton Therapy Institute
Inova Schar Cancer Institute Proton Therapy Center
James M. Slater, M.D. Proton Treatment and Research Center at Loma Linda University Medical Center
The Marjorie and Leonard Williams Center for Proton Therapy at Orlando Health UF Health Cancer Center
Maryland Proton Treatment Center
Mayo Clinic Proton Beam Therapy Program – Phoenix
Mayo Clinic Proton Beam Therapy Program – Rochester
MD Anderson Proton Therapy Center
Miami Cancer Institute at Baptist Health South Florida
New York Proton Center
Northwestern Medicine Chicago Proton Center
ProCure Proton Therapy Center – New Jersey
ProCure Proton Therapy Center – Oklahoma
Proton Therapy Center at Beaumont Hospital Cancer Institute
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S. Lee Kling Proton Therapy Center at the Siteman Cancer Center
Texas Center for Proton Therapy
University Hospitals Seidman Cancer Center, Case Medical Center
The University of Florida Health Proton Therapy Institute
Willis-Knighton Health System

8400 Westpark Drive, 2nd Fl.
McLean, VA 22102
(202) 495-3133
www.proton-therapy.org

May 30, 2018

Re: Proton Beam Therapy as Potentially Low-Value Service

James Mathews, Ph.D.
Executive Director
Medicare Payment Advisory Commission
425 I Street, N.W., Suite 701
Washington, D.C. 20001

Dear Dr. Mathews:

On behalf of the National Association for Proton Therapy ("NAPT"), thank you to you and your colleagues for taking the time to meet with us earlier this month. We appreciated the engaging discussion regarding the value of proton beam therapy to Medicare beneficiaries and to the program overall. We look forward to continuing the dialogue with you regarding this important service.

We are writing in regards to the upcoming June MedPAC report to Congress which, as you noted at the end of our meeting, will include a discussion of proton beam therapy as a case study for potentially low-value services. We request that additional consideration for analysis and conclusions by the Commission be given based on the data we presented. The Commission defined a "low-value service" as one where the service provides little to no clinical benefit and the risk of harm outweighs any potential benefit that may exist. We respectfully disagree with the characterization of proton beam therapy as a low-value service for the following reasons

Proton Beam has a long clinical history.
Proton therapy was cleared by the Food and Drug Administration (FDA) thirty 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 tumors.

It is the standard of care treatment for multiple diagnoses and clinical evidence has demonstrated its value in other common cancers.
The National Comprehensive Care Network (NCCN) Guidelines for Treatment of Cancer discuss the utility of proton beam therapy for fourteen different sites.[1] The clinical evidence on proton beam therapy has demonstrated a decrease in complications (e.g., feeding tubes and lung complications), higher disease control, improved overall survival rates, and lower risk of secondary cancer.

Growth of indications has been through clinical trials and evidence development.

[1] National Comprehensive Cancer Network Guidelines for Treatment of Cancer for the following sites - Bone Cancer (2.2018), CNS Cancers (1.2018), Esophageal / Esophagogastric Junction Cancers (1.2018), Head and Neck Cancers (1.2018), Hepatobiliary Cancers (1.2018), Hodgkin Lymphoma(3.2018), Malignant Pleural Mesothelioma (2.2018), Uveal Melanoma (1.2018), Non-Hodgkin's Lymphoma - B-Cell Lymphomas (4.2018) and T-Cell Lymphomas (4.2018), Non-Small Cell Lung Cancer (4.2018), Prostate Cancer (2.2018), Soft Tissue Sarcoma (2.2018), Thymomas, and Thymic Carcinomas (2.2018). (Link)

less dose from protons

depth in tissue

- 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 is High Value Care

- 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.

The model would effectuate a 49.6% reduction in payment for proton beam therapy; the discount across all other modalities is 4.0%.

Payment Rates Inadequate for Protons

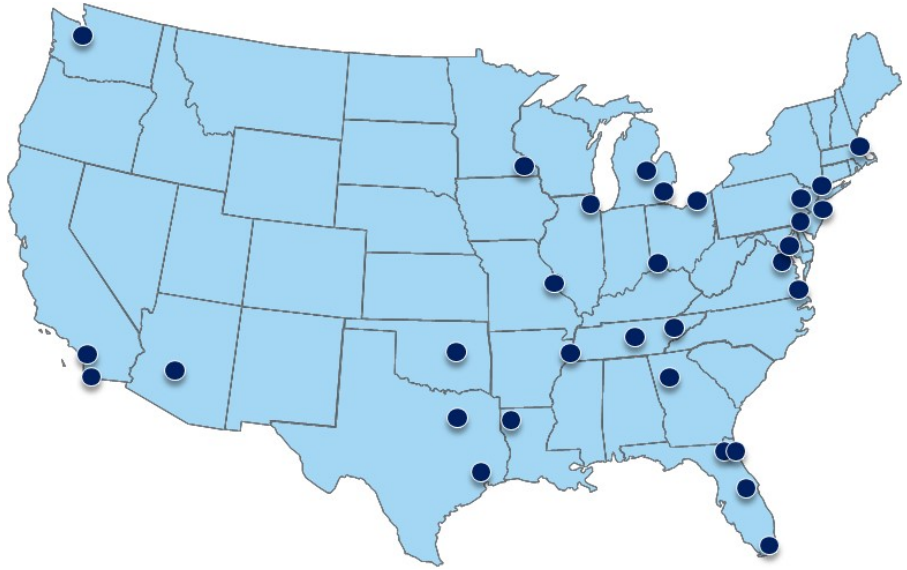
- Base rates represent nearly a ***50% cut*** across the top 5 cancer sites
  - Comparing 2017 total payments vs. total estimated payments using

Indication	2017 Episodes *	Total Payments (2017)	Total Payments, RO Model	Difference	% Diff.
Breast	173	$ 3,126,422	$ 1,943,937	($ 1,182,485)	-37.8%
Head/Neck	228	$ 7,760,947	$ 4,263,389	($ 3,497,558)	-45.1%
Lung	231	$ 6,168,306	$ 2,989,881	($ 3,178,424)	-51.5%
Prostate	1,386	$ 61,865,723	$ 30,436,067	($ 31,429,656)	-50.8%
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%**

*

Impact of Model on Potential Access

- 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.



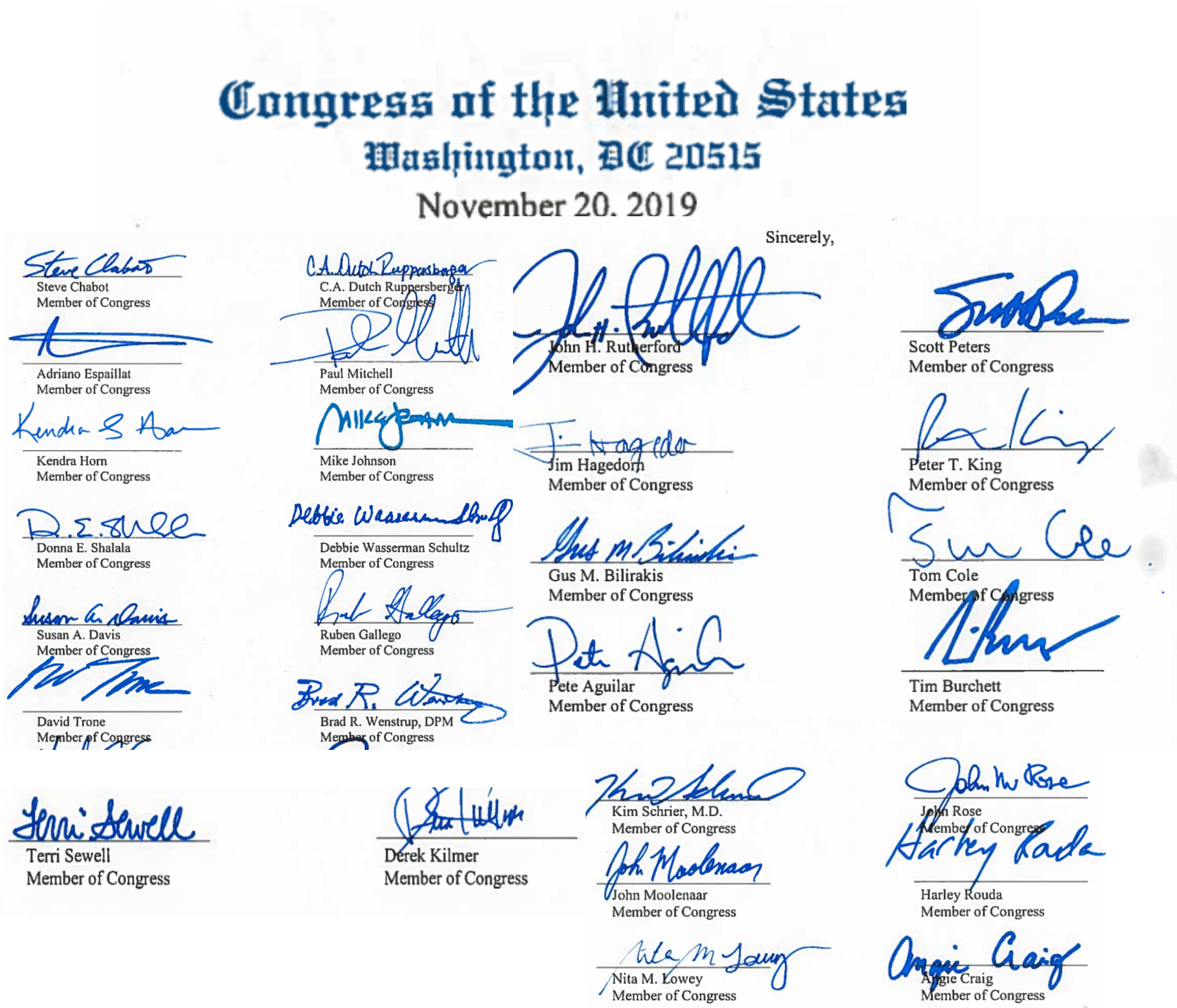
- A model that creates disincentives to treat beneficiaries with clinically appropriate care will further limit access, particularly to rural and underserved communities
- Given the randomization in the selection of CBSAs, the model may also create unintended competitive imbalances, limiting access in an unequitable fashion

Inadequate Payment Rates Put Beneficiaries and Other Patients at Risk

- 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

Bipartisan House Letter Led by Congressman John Rutherford



Congress of the United States
Washington, DC 20515
November 20. 2019

Sincerely,

Steve Chabot
Member of Congress

C.A. Dutch Ruppersberger
Member of Congress

John H. Rutherford
Member of Congress

Scott Peters
Member of Congress

Adriano Espaillat
Member of Congress

Paul Mitchell
Member of Congress

Jim Hagedorn
Member of Congress

Peter T. King
Member of Congress

Kendra Horn
Member of Congress

Mike Johnson
Member of Congress

Gus M. Bilirakis
Member of Congress

Tom Cole
Member of Congress

Donna E. Shalala
Member of Congress

Debbie Wasserman Schultz
Member of Congress

Pete Aguilar
Member of Congress

Tim Burchett
Member of Congress

Susan A. Davis
Member of Congress

Ruben Gallego
Member of Congress

Kim Schrier, M.D.
Member of Congress

John Rose
Member of Congress

David Trone
Member of Congress

Brad R. Wenstrup, DPM
Member of Congress

John Moolenaar
Member of Congress

Harley Rouda
Member of Congress

Terri Sewell
Member of Congress

Derek Kilmer
Member of Congress

Nita M. Lowey
Member of Congress

Angie Craig
Member of Congress

Republican Letter led by Senator Marco Rubio

Marco Rubio
U.S. Senator

Richard Shelby
U.S. Senator

James M. Inhofe
U.S. Senator

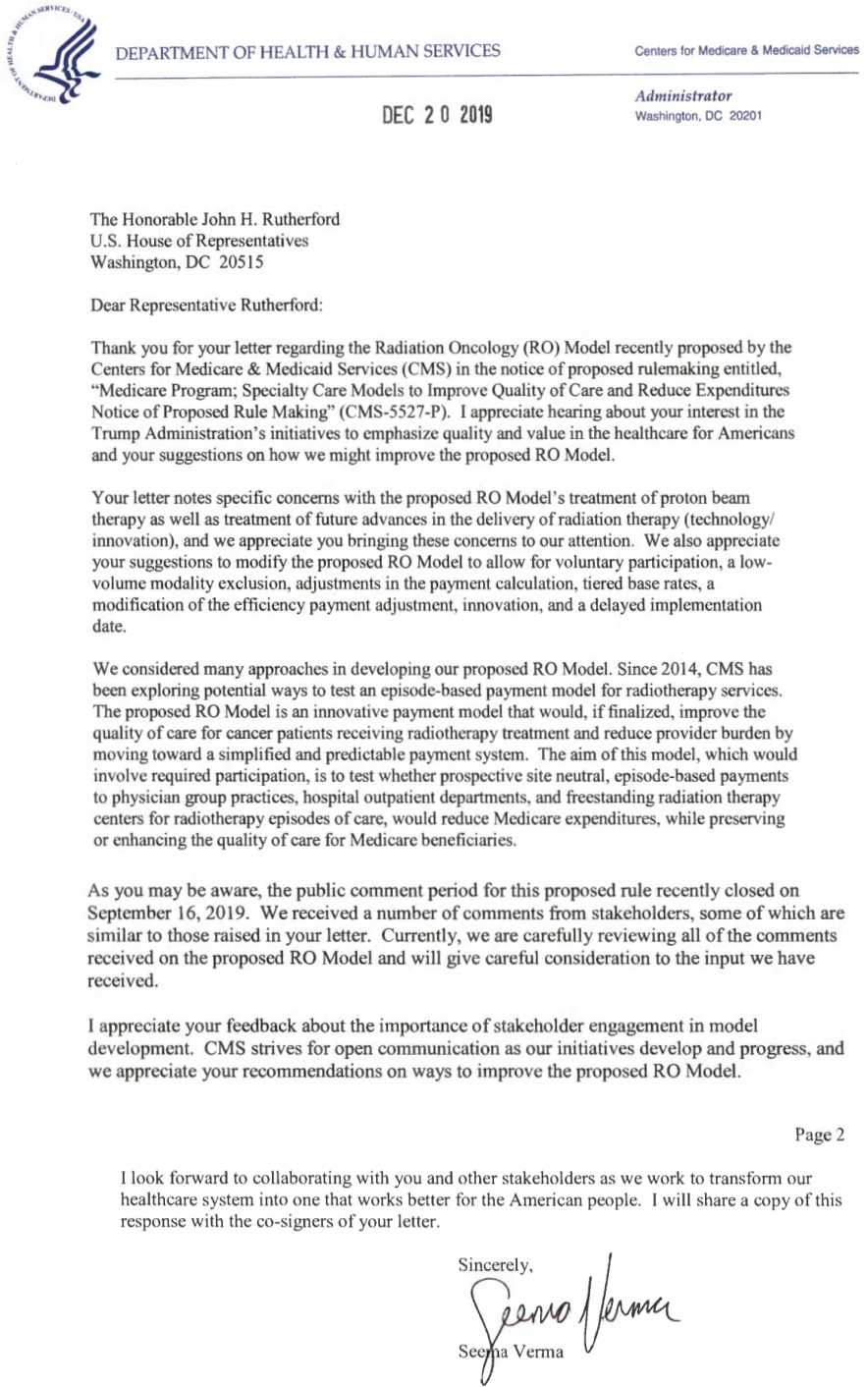
Rob Portman
U.S. Senator

David A. Perdue
U.S. Senator

James Lankford
U.S. Senator

Lisa Murkowski
U.S. Senator

Administrator Verma recognizes these concerns



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DEC 20 2019

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, tiered 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 radiotherapy services. The proposed RO Model is an innovative payment model that would, if finalized, improve the quality of care for cancer patients receiving radiotherapy 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 radiotherapy 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,

Seema Verma

Administrative Advocacy Barnes and Thornburg

Desk of the Vice President

Office of the Vice President

Grassroots Advocacy

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!

Tell Congress to Fight Back Against a New Medicare Rule That Would Limit Access to Proton Therapy!

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

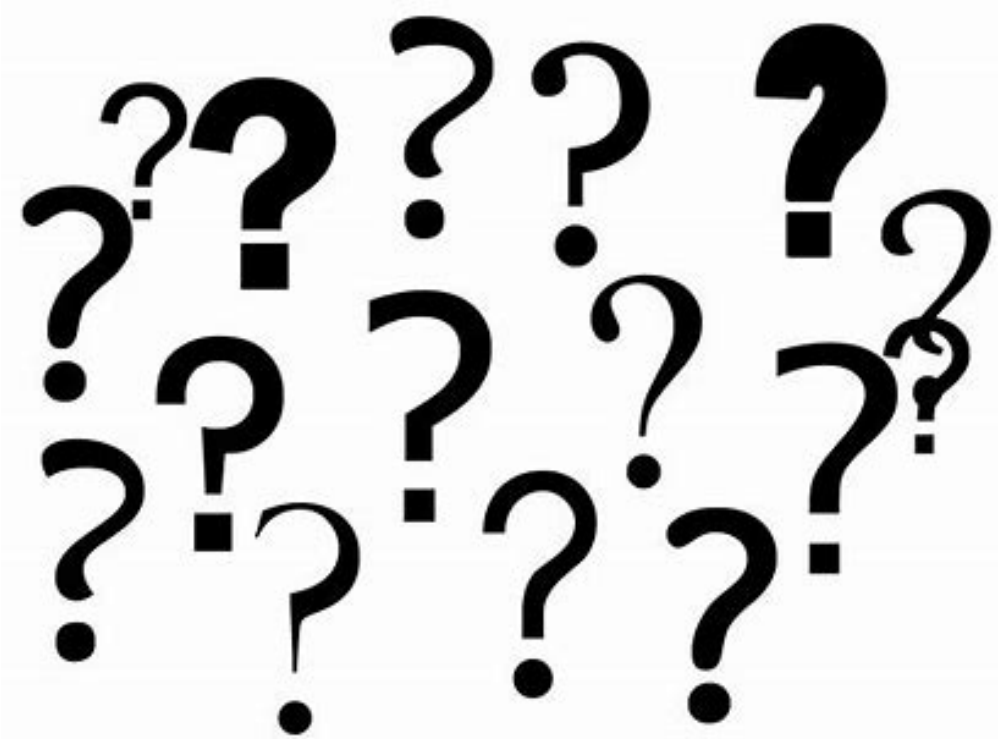
COMPPARE

- 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