



Alliance for Proton Therapy Access  
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September 16, 2019

Ms. Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5527-P  
P.O. Box 8013  
7500 Security Boulevard  
Baltimore, MD 21244-8013

**Submitted electronically:** <https://www.regulations.gov/comment?D=CMS-2019-0101-0001>

Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures

Dear Administrator Verma,

The Alliance for Proton Therapy Access (Alliance) is writing to offer comments on the “Medicare Program: Specialty Care Models to Improve Quality Care and Reduce Expenditures” proposed rule.

The Alliance is a patient-focused advocacy organization striving to make sure all cancer patients seeking proton therapy for appropriate clinical indications receive fair and timely payment decisions from their health insurers. We work directly with patients and caregivers who have benefited greatly from proton beam therapy (PBT), and with those who have had to endure health risks, anxiety, and financial hardship associated with unfair delays and denials of care after their physician recommended PBT as their best hope for survival and highest quality of life.

We are writing to share our significant concerns related to the proposed Radiation Oncology Model (RO Model). We hope the agency will give serious consideration to excluding PBT from the RO Model, or short of that, we ask that you change the model in ways that will not drastically limit patient access to life-saving PBT.

**We respectfully ask that you exclude PBT from the RO Model.**

Unfortunately, CMS cites two outdated reports from the 2014 Institute for Clinical and Economic Review (ICER) and the Medicare Patient Advisory Commission (MedPAC), which both suggest that PBT is of lower value when compared with other forms of radiation. If the RO Model is based on these old findings, we believe there is strong reason to reconsider and exclude PBT. More recent clinical evidence has led the National Comprehensive Care Network (NCCN) and the Washington State Health Technology Assessment this year to review and expand their guidelines and indications for PBT and conclude it is an effective, evidence-based treatment for many clinical indications. Moreover, anecdotal evidence from the patients we work with confirms that they have great experience with PBT, including low rates of debilitating side effects and complications, leading to less hospitalizations, less time away from normal family life and work and much better quality of life. Their physicians recommended the treatment because of its ability to fight their disease with fewer side effects and lower risk of secondary cancer. While PBT may be more expensive initially, our patients firmly believe that it saves money in the long run because they are able to quickly return to a more normal life (whether it's working or pursuing other activities), and are not chronically consuming more health care because of unnecessary side effects that are avoided by using PBT.

**If you will not exclude PBT completely, we ask that you make the following changes to minimize the negative impact this RO Model would have on cancer patients who benefit from proton therapy:**

- 1. Make the RO Model voluntary.** This will ensure that reducing patients' access to proton therapy is not an unintended consequence of this experimental payment model.
- 2. Encourage more evidence-gathering on proton therapy** by expanding the exclusion parameters to include proton patients enrolled in any trials and data registries.
- 3. Create a more appropriate base rate for reimbursement that won't disincentivize providers from recommending proton therapy when it's the best treatment option.**

Overall, the Alliance is concerned that CMS's large cost-saving goal and scope of this RO Model puts patients at risk. We fear this aggressive approach will be disruptive to providers who are likely to no longer offer these life-saving services because the reimbursement rates you are proposing will not come close to covering the cost of PBT, thereby preventing Medicare beneficiaries from accessing this medically proven method of treating certain types of cancer. We believe that Medicare patients should be able to receive the best treatment that is recommended by their oncologists, and this rule may prevent thousands of Medicare beneficiaries from doing so. Cancer patients deserve the right to work directly with their doctors to make the best choices about their treatment options – choices that improve their chances of survival and preserve their quality of life. In our opinion, the proposed rule will take away those choices from far too many patients, leading to potentially devastating consequences including unnecessary suffering and, in some cases, death.

We strongly urge you to **consider the experience of cancer patients** before you move forward with the final RO Model. We believe that the RO Model as currently proposed will have a potentially crippling financial effect on proton therapy providers, and that in turn will mean limited access to this powerful treatment for cancer patients of all ages, including pediatric cancer patients who are most vulnerable to the impacts of excessive radiation.

Our advocates' experiences demonstrate the value of proton therapy and underscore the need to ensure the treatment is available to all cancer patients, including Medicare beneficiaries, whose physicians feel it is their best chance for survival and a high quality of life. Below are two of the many stories cancer survivors and family members are [sharing on the Alliance website](#).

### **Joseph Sansbury**

*At 76 years old Joseph Sansbury was focused on enjoying retirement following 36 years as a federal employee. He looked forward to spending time with family, gardening, and traveling. But all of that changed in the fall of 2018.*

*A routine medical examination found an elevated prostate-specific antigen, which worried Joe's doctor. Joe was referred to a urology specialist, who conducted a series of tests, exams, and a biopsy, the pathology report revealed a Gleason score of 7 (intermediate risk), which meant that Joseph's cancer would require treatment. He got a second opinion and this time the cancer was determined to be a Gleason score of 9 (aggressive, and high risk). The doctors recommended hormone treatments and traditional radiation.*

*Curious about other options, Joe did some independent online research and discovered proton therapy. It seemed like a compelling treatment option. After reading about the MD Anderson Cancer Center in Houston, Texas and its well-regarded proton treatment center, Joseph scheduled a visit. He filled out paperwork, underwent a blood test, and met with the cancer care team. His team agreed that Joe would not be a good candidate for surgery and instead recommended proton therapy along with hormones. Joseph ultimately chose proton therapy because of the many advantages it offered. Medicare paid for Joseph's treatment.*

### **Tom Garrett**

*Singing is one of my greatest passions.*

*As the lead singer of The Classics IV, I perform regularly, singing such hits as "Stormy," "Spooky," and "Traces (of Love)" to audiences around the world.*

*But in March 2016, I was diagnosed with throat cancer. A tumor threatened to rob me of my gift and profession. The thought of this possibility terrified me. I've been a singer my entire life, and to have that pulled out from underneath me was something that I wasn't prepared to face.*

*Initially, doctors recommended that I undergo surgery, followed by traditional radiation and potentially chemotherapy to treat my tumor. The surgery along with traditional radiation would have left me battling a lifetime of side effects—including a severe speech impediment—that could have ended my career. When the gravity of this diagnosis and treatment fully registered with me, I immediately began looking for another option.*

*That's when a Google search led me to Northwestern Medicine to learn about proton therapy. Unlike standard radiation that uses photons, proton therapy allows physicians to precisely target the bulk of its cancer-fighting proton energy on the cancerous cells, minimizing extraneous radiation doses to healthy tissues, preserving organ function, and potentially reducing harmful side effects. For me, proton therapy meant that I wouldn't have to give up on my passion and would avoid many of the side effects that are common with traditional radiation.*

*By July 2016, I had received 33 rounds of treatment and was relieved to learn that I was finally cancer free. Eight weeks after my final proton therapy treatment, I reunited with The Classics IV for a show in Las Vegas. That performance was gut-wrenching. I was there with my bandmates, we're family. I was able to walk out on the stage, address the audience, and share my story with them.*

*Thanks to proton therapy, I was able to return to the stage and perform for fans. Finding proton therapy was a miracle. I am blessed to be able to now tell my story. This was truly the journey of a lifetime and I'd recommend that anyone at least take a shot and see what proton therapy does for them.*

The Alliance appreciates the opportunity to comment on the proposed RO Model. We hope that you will take into account our significant concerns with the pilot as proposed and the negative impact we believe it would have on patients' access to proton therapy, and either completely remove PBT from the RO Model, or ensure that the reimbursement rates for PBT providers included in the model are adequate to ensure Medicare beneficiaries will be able to access this life-saving treatment.

Sincerely,



Daniel E. Smith  
Executive Director  
Alliance for Proton Therapy Access