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September 16, 2021

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:

The Alliance for Proton Therapy Access (Alliance) is writing to offer comments on "[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" 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 are requesting that the agency give serious consideration to excluding PBT from the RO Model in the same manner as you have now done for 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.[1] (Emphasis added)

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

The Alliance 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. It is our understanding that 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 motivation for CMS to launch the proposed RO model.

The short-term financial gains will result in negative long term health outcomes for the patients we represent. 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. 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 CMS's 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 you did for brachytherapy. CMS must recognize the concerns from proton therapy stakeholders regarding the unintended consequences on beneficiaries' access to innovative cancer treatment.***

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.[2] 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. I am including here a link to an op-ed I wrote for Morning Consult laying out our concerns.[3]

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

[1] 86 FR42293
[2] https://abc6onyourside.com/news/local/president-biden-tours-james-cancer-hospital-talks-innovation-in-cancer-research
[3] https://morningconsult.com/opinions/biden-must-push-to-make-proton-therapy-accessible-to-all-cancer-patients/

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 remove PBT from the RO Model in the same manner as you did for brachytherapy. If you have questions or need further information, please feel free to contact me at 202-999-8923 or dsmith@allianceforprotontherapy.org.

Sincerely,

Daniel E. Smith
Executive Director
Alliance for Proton Therapy Access