



September 12, 2025

VIA Electronic Submission to www.regulations.gov

Dr. Mehmet Oz
Administrator
Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program [CMS-1832-P]

Dear Administrator Oz:

On behalf of the National Association for Proton Therapy (“NAPT”), we are pleased to submit comments to the Centers for Medicare & Medicaid Services (“CMS”) in response to the above-captioned CY 2026 Medicare Physician Fee Schedule (“MPFS”) Proposed Rule (the “Proposed Rule”).¹

NAPT is a nonprofit organization of world-renowned cancer centers, a number of whom are National Cancer Institute (“NCI”)-designated comprehensive cancer centers and National Comprehensive Cancer Network (“NCCN”) members.² 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.

Our comments on the CY 2026 MPFS Proposed Rule address the following:

- Request for Comments on National Pricing for Free-standing Proton Therapy Centers
- Proposed Imaging Code Bundling
- Direct Practice Expense Inputs - Radiation Treatment Vault
- Efficiency Adjustment

By way of background, proton therapy is a radiation treatment modality that has the ability to reduce side effects for patients by limiting the amount of normal tissue exposed to radiation. Unlike conventional x-ray radiation, which has both entrance and exit doses, proton therapy delivers radiation directly to the target, with little to no radiation extending beyond the target. By reducing

¹ 90 Fed. Reg. 32352 (July 16, 2025) (CY 2026 MPFS Proposed Rule): <https://www.federalregister.gov/d/2025-13271>

² Listing of members can be found on the NAPT website, please visit: <https://proton-therapy.org/findacenter/>



unnecessary radiation, proton therapy lowers the risk of acute and long-term toxicities and secondary malignancies and improves patients' overall quality of life.³ Because of these lower risks, proton therapy is the standard of care for pediatric cancers, and growing evidence supports its use for re-irradiation cases and tumors located near critical structures such as the brain, head and neck, and spine.⁴ These uses indicate that proton therapy providers treat a disproportionately complex case mix compared to other outpatient radiation oncology providers.

NAPT and its members are deeply committed to expanding the evidence base for proton therapy. More than 75% of the nation's leading NCI-designated and NCCN Comprehensive Cancer Centers offer or are actively expanding access to proton therapy.^{5 6} While market conditions have evolved, the core factors influencing the value of proton therapy have remained relatively stable and proton therapy accounts for only ~2% of all radiation oncology episodes.⁷

Beyond the patient-level benefits, proton therapy has the potential to reduce total healthcare system costs. Analysis of 100% Medicare Fee-for-Service Research Identifiable Files data from 2019 to 2022 confirms these points by showing that, when compared to other radiation therapy modalities, proton therapy offered:

- Lowest 90-day mortality rate (~2%) across all years,
- Lower inpatient admission rates (10–11%) compared to other modalities (≥14%),
- Longest time between treatment and ER visits, and
- Lowest cost per ER visit.⁸

Earlier this year, Food and Drug Administration Commissioner, Dr. Martin Makary, publicly recognized proton therapy as an area where the United States leads the world.⁹ We believe this underscores the importance of ensuring Medicare payment policy supports continued patient access to this high-value treatment.

A. Request for Comments on National Pricing for Free-standing Proton Therapy Centers

NAPT appreciates CMS seeking comment on establishing national payment rates for proton therapy services. We understand CMS's interest in aligning payment policies in ways that promote predictability and stability in the MPFS. ***For the reasons set forth herein, we believe that national pricing for free-standing proton therapy services could be appropriate as soon as CY 2026 so long as the ultimate methodology used for such pricing appropriately values the reasonable costs for delivering this critical service to certain Medicare beneficiaries fighting cancer given the unique circumstances of each respective geographic market.*** Adopting an accurate nationally

³ Chung CS, Yock TI, Nelson K, et al. Incidence of second malignancies among patients treated with proton versus photon radiation. *Int J Radiat Oncol Biol Phys.* 2013 Sep 1;87(1):46-52:

[https://linkinghub.elsevier.com/retrieve/pii/S0360-3016\(13\)00459-8](https://linkinghub.elsevier.com/retrieve/pii/S0360-3016(13)00459-8)

⁴ Hartsell WF, Simone CB 2nd, Godes D, et al. Temporal Evolution and Diagnostic Diversification of Patients Receiving Proton Therapy in the United States: A Ten-Year Trend Analysis (2012 to 2021) From the National Association for Proton Therapy. *Int J Radiat Oncol Biol Phys.* 2024;119(4):1069-1077.

doi:10.1016/j.ijrobp.2023.12.041: <https://www.sciencedirect.com/science/article/abs/pii/S0360301623083153>

⁵ NCI-Designated Cancer Centers: <https://www.cancer.gov/research/infrastructure/cancer-centers/find>

⁶ NCCN Member Institutions: <https://www.nccn.org/home/member-institutions>

⁷ Radiation Oncology Model, Center for Medicare and Medicaid Innovation, 2017–2019 Baseline Episode File: <https://web.archive.org/web/20230306090841/https://innovation.cms.gov/media/document/ro-model-episode-file-2017-2019>

⁸ Analysis of 100% Medicare Fee-for-Service Research Identifiable Files data from 2019 to 2022

⁹ "President Trump Participates in a MAHA Commission Event." YouTube, uploaded by The White House, May 22, 2025: <https://www.youtube.com/live/dDkYJxE9WTc?si=ZRvcLZf05WSVyFpd&t=1221>

defined payment methodology would provide greater consistency for providers and create a more predictable structure to support patient access to proton therapy.

At the outset, we recognize that CMS has proposed to significantly change the coding and pricing methodology by which conventional x-ray therapy is reimbursed in the free-standing site of service.¹⁰ We appreciate CMS publishing a clarifying FAQ in August of 2025 which has greatly helped us better understand how CMS has established these payment rates and the relevant ratio (or relationship) that CMS has proposed (approximately .80 to 1). ***As noted below, given the relative costs of proton therapy being largely constant across the various sites of service, we believe that the use of the x-ray therapy ratio (or relationship) is not appropriate for proton therapy. Instead, we believe a one-to-one ratio between hospital and free-standing proton therapy sites of services, taking into account the unique circumstances of each respective geographic market, is more appropriate.***

As CMS has previously acknowledged, there is a higher cost to delivering proton therapy treatments compared to other modalities.¹¹ This cost is primarily due to the higher cost of the capital equipment required to deliver the proton therapy, the higher cost of operating and maintaining a proton center, and the greater complexity of proton treatment planning and delivery – all of which are comparable regardless of the site of service, including, but not limited to, equipment, utilities, and staffing.

Equipment

Proton therapy requires equipment that is more than ten times the cost of a conventional linear accelerator used to deliver x-ray therapy. Delivering proton therapy necessitates highly specialized facility build-outs, including massive shielding, advanced cooling and water circulation systems, and infrastructure to manage significant power demands. As illustrated in the attached photos (Figures 1 to 4) of proton centers, the cyclotron, and the beamline, these highly specialized infrastructure components require extensive customized construction and infrastructure investments that go far beyond conventional radiation facilities.

Utilities

Free-standing proton therapy centers may not be capable of sharing critical resources or spreading fixed costs across multiple sites or service lines. High utility utilization for operating proton equipment adds to ongoing operating expenses. Maintenance arrangements with system manufacturers are critical to operating proton therapy systems and such arrangements are significantly more expensive than for x-ray-based systems.

Staffing

Free-standing proton therapy centers must maintain larger, highly trained teams of staff per patient compared to x-ray-only centers. Patients treated with proton therapy often require extensive physician, physics, and dosimetry consultation, as well as coordinated multi-disciplinary care that demands longer planning time and extensive patient education about the proton treatment process. Proton centers typically have extended business hours in order to meet patient demand, which requires additional staffing costs and overtime pay. To ensure safe and uninterrupted proton treatment delivery, many proton centers also employ full-time,

¹⁰ We believe that there may be an error in the underlying data-source CMS used in calculating proposed pricing for one of the x-ray therapy code

¹¹ 85 Fed. Reg. 84472, 84626 (Dec. 28, 2020) (CY 2021 MPFS Final Rule):
<https://www.federalregister.gov/citation/85-FR-84626>

on-site engineers from the equipment vendor — an expense not typically borne by other outpatient service providers. Beyond clinical staff, free-standing proton centers support critical but unreimbursed roles, including social workers that assist families navigating complex logistics, child life specialists that support pediatric patients, and staff coordinating travel and housing for out-of-town patients. These staffing requirements reflect another unique investment required by proton centers and underscore the need for proton therapy reimbursement rates that properly account for the distinct resource demands required to sustain proton center operations.

Other

Despite the increased complexity of proton therapy planning and treatment delivery, proton therapy uses the same treatment planning and imaging CPT codes as photon therapy. Current proton therapy CPT codes do not reflect the added physician, physics, and dosimetry effort required for proton therapy treatments, nor the additional clinical resources required to manage complex patient populations. The loss of IGRT codes, as discussed further below, represents a further financial strain on operating proton centers.

In 2017, the American Medical Association (“AMA”) RVS Update Committee (“RUC”) conducted a comprehensive survey of free-standing proton therapy center providers. Based on the results, proton therapy pricing remained carrier-based. Since then, only three free-standing proton therapy centers have opened, suggesting that the fundamental cost structure underlying the original survey may still be applicable today and supporting the application of a one-to-one ratio between hospital and free-standing sites of services.

The methodology CMS uses to determine payment rates for proton therapy is of particular importance given the modality’s unique characteristics and relatively small footprint in the Medicare program. As a highly specialized and complex therapy with limited geographic availability, proton therapy may still not be well-suited for broad, generalized rate-setting approaches that may be appropriate for more common services. Clear understanding of the methodology CMS intends to use is critical for stakeholders like NAPT to provide meaningful input on potential national pricing, and to ensure that any resulting rates accurately reflect the reasonable costs of care delivery. We recommend that the methodology be grounded in actual and validated cost data. If actual and validated costs for each respective geographic market are not appropriately considered, a national proton therapy rate risks eroding access to proton therapy.

From a patient access perspective, future payment stability is critical not only for sustaining operations at existing proton therapy centers but also for enabling the continued and responsible development of new centers in underserved regions. Without confidence in the long-term adequacy of reimbursement, future development of proton therapy centers may falter, which would limit beneficiary access to clinically appropriate proton therapy.

B. Proposed Imaging Code Bundling

CMS and the AMA have proposed bundling certain imaging services into the x-ray treatment delivery codes, including the services reportable under the following codes: CPT 77014 (CBCT), G6002 (kV Imaging) and G6017 (Surface Guidance). CMS and the AMA have also proposed to delete such imaging codes. However, proton therapy suppliers and providers also provide these reasonable and necessary imaging services and, as a result, also report such imaging codes. ***As such, we recommend that CMS and / or the Medicare Administrative Contractors either (1) increase the value of the proton therapy treatment delivery codes in any national or carrier-based pricing methodology, or (2) maintain imaging codes for purposes of proton therapy episodes of care***

(e.g., maintain the existing codes with a procedure-to-procedure edit). Otherwise, this represents a meaningful degradation in value for providers and suppliers offering one of the most targeted cancer therapies available.

C. Direct Practice Expense Inputs - Radiation Treatment Vault

CMS reiterates in the Proposed Rule that construction costs for radiation treatment vaults (ER056) are classified as indirect practice expense (“PE”) inputs and therefore not included in direct PE calculations. The rationale, consistent with prior rulemaking,¹² is that such costs resemble building maintenance or office rent and are not allocable to a specific patient encounter.

The radiation treatment vault is unlike anything else in medicine, serving a unique medical need that cannot be repurposed for other uses. Each treatment vault is distinct from a medical imaging treatment room, as it is designed and constructed to safely house a specific high-energy radiation treatment machine within its space. A change in treatment machine may require extensive modifications to the vault. The vault must comply with specific federal and state licensing regulations to protect patients, clinic staff, and the public from radiation exposure during the delivery of high-energy radiation therapy. In addition, the Internal Revenue Service rules treat radiation treatment vaults as medical equipment – separately depreciable from the building itself – thereby supporting its inclusion as a direct PE.

NAPT supports maintaining the classification of the vault as a direct PE input and encourages CMS to consider alternative methods for identifying and valuing the vault separate from general construction expenses. We echo previous comments from the American Society for Radiation Oncology (“ASTRO”) noting that the vault is not a fungible facility asset but a modality-specific, high-cost, and patient-critical component of care delivery.

D. Efficiency Adjustment

CMS is proposing a significant change to how it values physician services, aiming to improve accuracy and account for efficiencies in medical practice. CMS has relied on the AMA RUC to estimate practitioner time, work intensity, and practice expense for the purpose of establishing relative value units (“RVUs”) for codes used for payment under the MPFS. In the 2025 MPFS, CMS received comments expressing concern with using RUC data as a source of valuation and identifying a need for empirical data in the context of valuing advanced primary care management services. Additionally, CMS has expressed concern in prior years about not accounting for efficiencies gained in work RVUs for non-time based services included in codes describing procedures, radiology services, and diagnostic tests.

To consider changes in medical practice and better reflect the resources involved in furnishing services paid under the MPFS, the Agency is proposing an efficiency adjustment to the work RVUs, as well as corresponding updates to the intraservice portion of physician time inputs for non-time-based services. The proposed efficiency adjustment sums all productivity adjustment percentage values included in the final Medicare Economic Index (“MEI”) updates from the most recent five-year period. That summed amount is then deducted from the work RVU values of all CPT codes that were reviewed by the RUC and CMS during that look back period. For CY 2026, CMS is proposing to apply the efficiency adjustment to CPT Codes reviewed during the look-back period CY 2022 through 2026. According to the rule, this would result in a reduction of 2.5% to the work RVU of those codes.

¹² CY 2021 MPFS Final Rule *supra* note 10


CMS seeks comment on the initial look back period, as well as the use of the MEI productivity adjustment percentage values for the calculation of the efficiency adjustment for 2026.

NAPT urges CMS to revisit its proposed efficiency adjustment to work RVUs, as the reduction does not appear to reflect the resources required to furnish patient care, particularly advanced services like proton therapy. Applying an adjustment based on the MEI is especially problematic given that the MPFS lacks an annual inflationary update, creating a compounding effect where providers are expected to absorb efficiency gains without recognition of rising practice costs. We therefore request that CMS reconsider both the initial look-back period and the reliance on MEI productivity adjustment percentages, and instead base any such adjustments on robust, specialty-specific data that more accurately reflects real efficiencies.

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We appreciate the opportunity to submit comments in response to the CY 2026 MPFS Proposed Rule and look forward to working with CMS on these issues. Please contact Jennifer Maggiore at jennifer@proton-therapy.org if you have any questions or need additional information.

Sincerely,

A handwritten signature in cursive script that reads "Jennifer Maggiore". The signature is written in a dark ink and is positioned below the word "Sincerely,".

Jennifer Maggiore
Executive Director, NAPT

Figure 1. cyclotron, Cincinnati Children's/UC Health Proton Therapy Center, Ohio



Figure 2. cyclotron, Emory Proton Therapy Center, Georgia

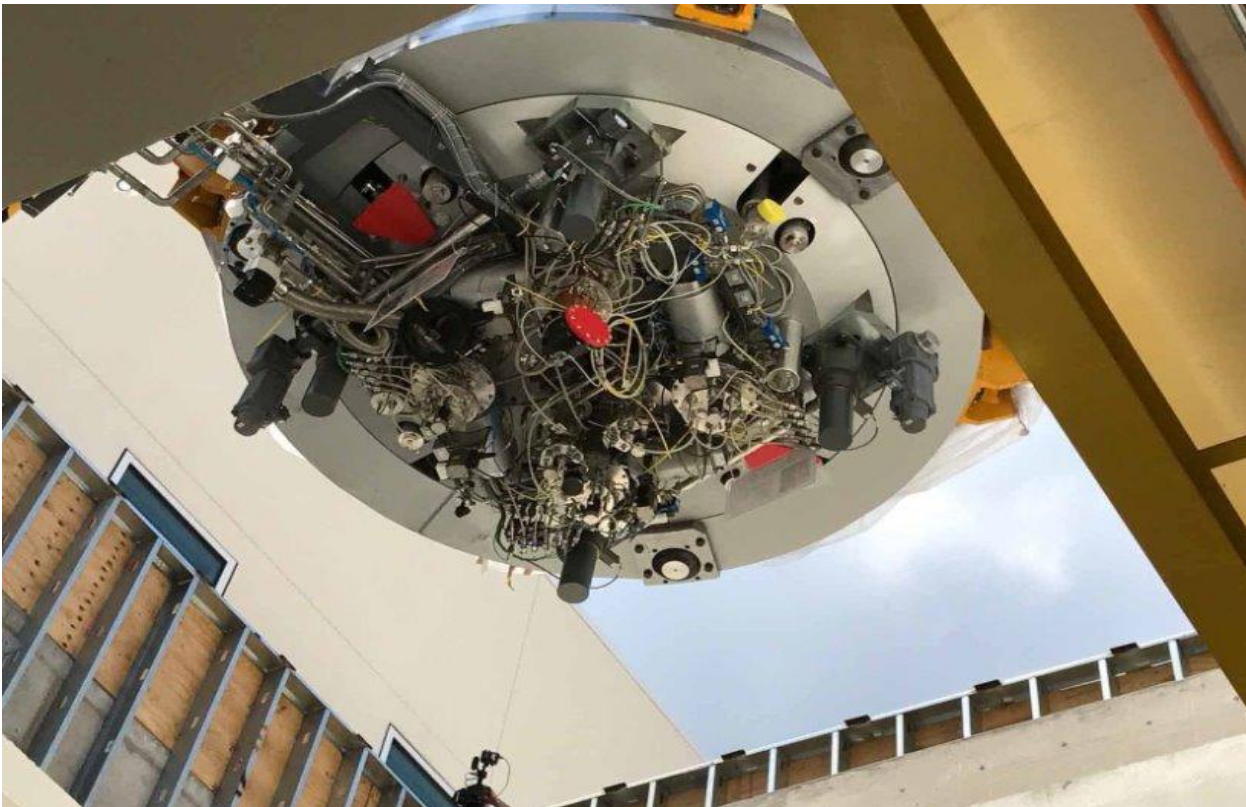


Figure 3. *beamline, Texas Center for Proton Therapy, Texas*

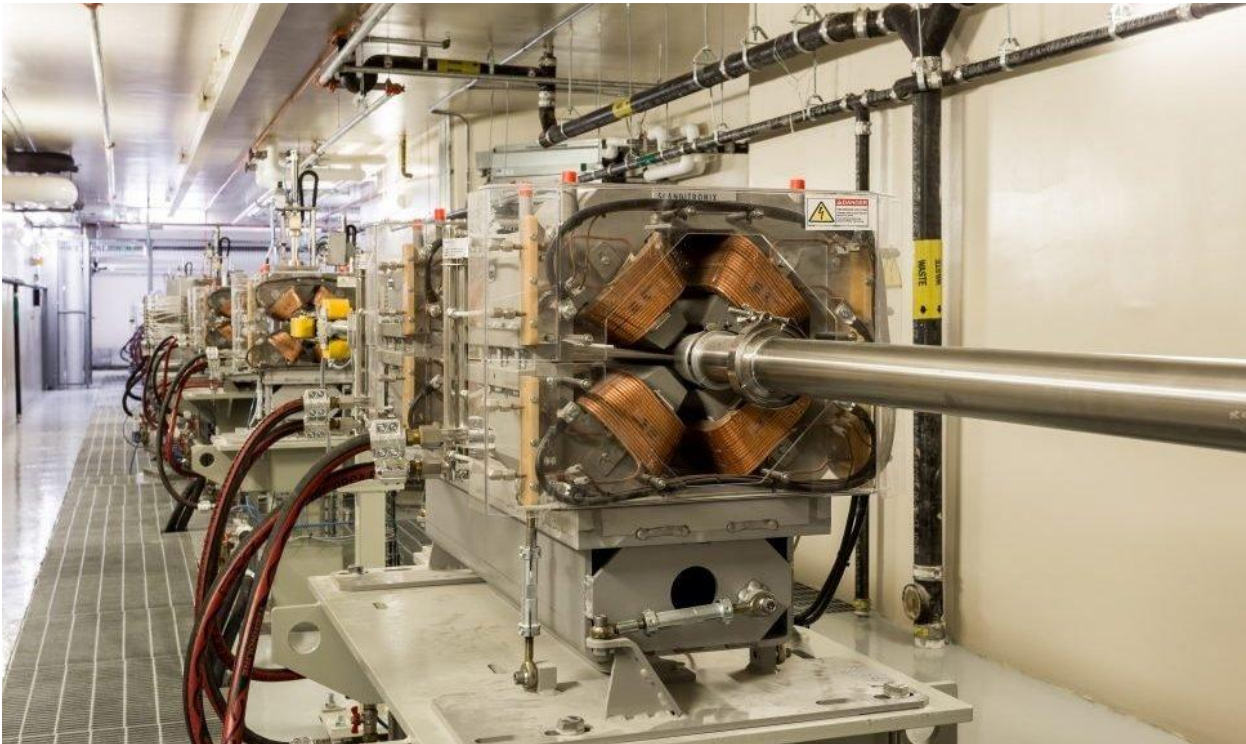


Figure 4. *construction site, University of Miami Drowskin Proton Therapy Center, Florida*

