The National Association for Proton Therapy

September 8, 2023

VIA Electronic Submission to www.regulations.gov

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-1784-P] Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure:

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 CY 2024 Medicare Physician Fee Schedule ("MPFS") proposed rule.

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 Care Network (NCCN) members.[1] 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 2024 MPFS Proposed Rule address the following:

- Request to Address Drop in Conversion Factor;
- Implementation of the Complexity Code, G2211;
- Direct Supervision via Use of Two-way Audio/Video Communications Technology;
- Payment of Dental Services related to Head and Neck Cancer;
- Proposal for New Services Addressing Health-Related Social Needs; and
- Payment for Telehealth Services.

Our detailed comments are presented below.

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A. Request to Address the 3.36% Reduction to Conversion Factor

Medicare physician payment is based on the application of a dollar-based conversion factor (CF) to work, practice expense (PE) and malpractice relative value units (RVUs), which are then

[1] Listing of members can be found on the NAPT website, please visit: http://www.proton-therapy.org.

geographically adjusted. The CY 2024 proposed resource-based relative value scale (RBRVS) CF is $32.7476, a decrease of $1.1396 or negative 3.36 percent from the CY 2023 RBRVS CF of $33.8872. NAPT has grave concerns about the magnitude of the cuts to payments that providers continue to face. We recognize the limited authority CMS has to modify statutorily mandated budget neutrality adjustment when calculating updates to the conversion factor. However, we are concerned about the continuing cascading impact that these drops in the RBRVS CF have on both physician practices and clinical patient outcomes.

Full resolution of this issue may require action by Congress and others outside of CMS. NAPT strongly urges CMS to use all administrative authority it can lawfully take as well as to coordinate with these entities to mitigate these significant cuts to the fee schedule. The magnitude of the proposed cuts to the RBRVS CFs is not insignificant in light of the continuing financial struggles for practices seeking to recover from the COVID-19 pandemic. The proposed RBRVS CF of $32.7476 is almost $4 less than the RBRVS CF in 1998 of $36.6873, the first year that CMS established a single RBRVS CF. We ask CMS to take measures to protect our nation's medical providers and the patients that they serve.

B. Implementation of Complexity Code G2211

In 2020, CMS established a new add-on code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition (add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)* to capture the additional evaluation and management (E/M) work associated with complex patients. Initially, CMS had intended for this code to become effective January 1, 2021 but its effective date was delayed due to the Consolidated Appropriations Act, 2021. In this proposed rule, CMS proposes to implement G2211 effective January 1, 2024 with refinements to its previous utilization assumptions.

In the CY 2020 MPFS final rule, CMS had estimated that the 21 specialties that bill E/M codes would bill this complexity code with 100% of their office/outpatient visits. Since that proposed rule, CMS has revised its utilization numbers, estimating that this code would be reported with approximately 38% of all office or outpatient E/M visits for CY 2024. Even with this refinement to utilization estimates, the implementation of this code would have a substantial impact on the fee schedule as it triggers a budget neutrality adjustment. For CY 2024, approximately two-thirds of the decrease in the CY 2024 MPFS CF (2.17%) is due to a budget neutrality adjustment, of which 90% can be attributed to the implementation of the complexity add on code G2211 and the remaining 10% can be attributed to other proposed valuation changes.

While the utilization estimates have changed substantially since the 2021 final rule (100% versus 38%), NAPT remains concerned about the utilization estimates and the impact of this add-on code on the proposed RBRVS CF. CMS notes that while the initial estimate is that this code will be reported with 38 percent of office/outpatient E/M codes, that number will increase to 54 percent once fully adopted. As such, the budget neutrality adjustment for the adoption of this complexity code will have an impact not only in 2024 but also subsequent years. We are also concerned about the disproportional effect that this policy, if finalized, would have on a subset of specialties. CMS expects that the primary care specialties will have a highest utilization while surgical and non-primary specialties will have lower utilization. As a result, the surgical and non-primary specialties (e.g., radiation oncology) will not benefit from this proposed policy but will bear the reduction in the conversion factor triggered by the budget neutrality requirement.

We understand that a subset of professional societies sent a letter to CMS, urging CMS to not finalize this policy given the potential impact and the lack of need for this code in light of recent E/M changes. NAPT concurs and asks CMS to delay the implementation of this policy given the concerns about the utilization estimates and the rationale (or lack thereof) for the complexity code.

C. Direct Supervision via Use of Two-way Audio/Video Communications Technology

Under Medicare, direct supervision has been defined as requiring the physician or other supervising practitioner to be present in the office (but not necessarily in the same room) and the immediate available to furnish assistance or direction during the performance of a procedure. The Agency has previously established this “immediate available” requirement to mean in-person, physical availability rather than virtual availability. During the COVID-19 public health emergency (PHE), as part of its flexibilities, CMS changed the definition of “direct supervision” as it pertains to physicians' services and some hospital outpatient services to allow the supervising professional to be immediately available virtually using two-way, real-time audio/video technology, rather than requiring their physical presence. In recent rulemaking cycles, this policy was extended through the end of 2023, after which the supervision rules would revert to those in place pre-pandemic.

Given the length of the public health emergency, CMS is concerned about the impact of an abrupt transition to its pre-PHE policy because practitioners have established new practice patterns over the last three years. In the absence of evidence that patient safety is compromised by virtual direct supervision, CMS acknowledges that an immediate reversion to the pre-PHE policy would prohibit virtual direct supervision, which may present a barrier to access to many services, such as those furnished incident-to a physician’s service. Therefore, CMS proposes to extend PHE flexibility of virtual direct supervision through the end of 2024.

NAPT commends CMS for acknowledging how practices have evolved in terms of how they deliver care over the last three years. We agree that reversing the policy back to pre-pandemic requirements at the end of CY 2023 could have a detrimental impact on access to critical services, particularly as practices are still coping with the financial and operational strain of the PHE. NAPT supports the extension of the PHE flexibility until the end of CY 2024 and recommends that CMS revisit whether to make this flexibility permanent in the CY 2025 rulemaking cycle.

D. Payment for Dental Services Related to Head and Neck Cancer

Currently under Medicare Part A and Part B, there are limited circumstances where dental services may be reimbursed specifically when that service is an integral part of specific treatment of a beneficiary's primary medical condition. The existing list of services for which payment is permitted include:

(A) Dental or oral examination performed as part of a comprehensive workup in the inpatient or outpatient setting prior to covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the organ transplant, cardiac valve replacement, or valvuloplasty procedure;

(B) Dental ridge reconstruction performed as a result of the surgical removal of a tumor;

(C) Stabilization or immobilization of teeth in connection with the reduction of a jaw fracture, and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints; and

(D) Extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.

In the CY 2023 MPFS Final Rule, CMS established a process for the public to submit additional dental services that may be inextricably linked to other covered services.

For CY 2024, based on a review of the submissions and supporting evidence received by stakeholders, CMS has proposed to pay for dental services as inextricably linked to chemotherapy, CAR-T, and administration of high-dose bone-modifying agents (anti-resorptive therapy) when used in the treatment of cancer. Finally, amending the regulations finalized in last year's rule, CMS proposes to allow for payment under Medicare Part A and B for:

(1) Dental or oral examination in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer; and

(2) Medically necessary diagnostic and treatment services to eliminate an oral or dental infection in either the inpatient or outpatient setting prior to the initiation of, or during, Medicare-covered treatments for head and neck cancer.

As providers who regularly treat patients with head and neck cancer with proton therapy[2], NAPT comments CMS for this proposed revision to the regulations for CY 2024, acknowledging the importance of these types of services whether the head or neck cancer is primary or metastatic. As part of standard practice, it is recommended that any patient with head and neck radiation treatment have a dental evaluation for teeth extractions prior to radiation therapy to prevent osteoradionecrosis (ORN), oral fluoride trays to ensure dental health due to changes in the microbial environment with salivary gland dysfunction, and stent for radiation treatment planning to reduce radiation exposure to the maxillae or mandible with unnecessary radiation. These proposed revisions to the regulations will allow for these critical services, integral to the patient's overall cancer treatment, to be appropriately reimbursed under Medicare Part A or B. We ask CMS to finalize the proposed revision to the regulations as proposed with one modification - not limiting the dental services to those patients specifically with head and neck cancers, primary or metastatic, but rather any type of cancer that anatomically impacts the patient's head or neck.

E. Payment for New Services Addressing Health-Related Social Needs

Over the last few years, in particular, CMS has explored ways and sought feedback from stakeholders on how to appropriately identify and value work performed by practitioners and their staff when assisting patients with serious illnesses navigate the healthcare system or removing health-related social barriers that are interfering with their ability to execute a medically necessary and clinically appropriate plan of care. Most recently, CMS issued a request for information in last year's rule where it sought additional feedback regarding Medicare Part B payment for services furnished by community health workers.

For CY 2024, in response to stakeholder feedback, CMS proposes the creation of new codes and the establishment of payment for community health integration (CHI) services, social determinants of health risk (SDOH) assessment, and principal illness navigation (PIN) services provided by social workers, community health workers and other auxiliary personnel. CHI services address unmet SDOH needs that affect the diagnosis and treatment of the patient's medical problems while PIN services help people who are diagnosed with high-risk conditions (e.g., cancer) identify and connect with appropriate clinical and support resources. For the SDOH assessments, CMS proposes the creation of a new stand-alone G code (GXXX5) to recognize when practitioners spend time and resources assessing social determinants of health factors that may impact their ability to treat the patient. This

[2] In CY 2022, an estimated 14.6% percent of patients treated at proton centers had head and neck cancers, according to the annual survey conducted by NAPT.

risk assessment would be added to the annual wellness visit as an optional additional element with an additional payment. Specific to CHI and PIN services, CMS proposes to create four codes (GXXX1-GXXX2 and GXXX3-GXXX4 respectively) for these services that could be furnished monthly following certain initiating E/M visits where unmet social needs are identified. These initiating E/M visits – a pre-requisite visit – would be conducted by the billing practitioner who will be furnishing the CHI or PIN services in subsequent calendar months.

NAPT commends CMS for recognizing the importance of these navigation services for patients with complex illnesses such as cancer. For patients diagnosed with cancer and seeing a multi-disciplinary team including a radiation oncologist, they often need guidance and direction on following through with their care plan during a very difficult and overwhelming time. These patients also may require additional social services, particularly for those with a limited support network. This proposed policy is consistent with the Administration's focus on promoting health equity and is supportive of the White House's Cancer Moonshot Initiative. For these reasons, NAPT urges CMS to finalize this proposal as proposed.

F. Payment for Telehealth Services

For CY 2024, CMS proposes to implement the telehealth flexibilities that were included in the Consolidated Appropriations Act 2023 (CAA) by waiving the geographic and originating site requirements for Medicare telehealth services through the end of CY 2024. By doing so, patients across the country will retain the ability to access telehealth services, particularly from their own homes. Per the CAA, CMS proposes extending payment for the CPT codes for audio-only telephone visits as well as all other services that were on the 2022 Medicare Telehealth Services List through 2024. ***NAPT strongly supports the proposal to extend the application of certain Medicare telehealth flexibilities for CY 2024 and requests that CMS finalize as proposed.***

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We appreciate the opportunity to submit comments in response to the Proposed Rule. Please contact Jennifer Maggiore at jennifer@proton-therapy.org if you have any questions or need additional information.

Sincerely,

Jennifer Maggiore
Executive Director, NAPT