

# AMERICAN SOCIETY FOR RADIATION ONCOLOGY

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#### September 7, 2023

Chiquita Brooks-LaSure, Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services ATTN: CMS-1784-P P.O. Box 8016 Baltimore, MD 21244-8016

Submitted electronically: http://www.regulations.gov

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:

The American Society for Radiation Oncology (ASTRO)¹ appreciates the opportunity to provide written comments on the "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," published in the Federal Register as a proposed rule on August 7, 2023.

The proposed rule updates the payment policies, payment rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule (MPFS) effective January 1, 2024. In the following letter, ASTRO seeks to provide input on the policy change proposals that have a significant impact on radiation oncology. Key issues addressed in this letter include:

- Payment Rates for Radiation Oncology Services
- Evaluation and Management (E/M) Visit Complexity
- Payment for Medicare Telehealth Services

<sup>&</sup>lt;sup>1</sup> ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists, and social workers. They treat more than one million patients with cancer each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

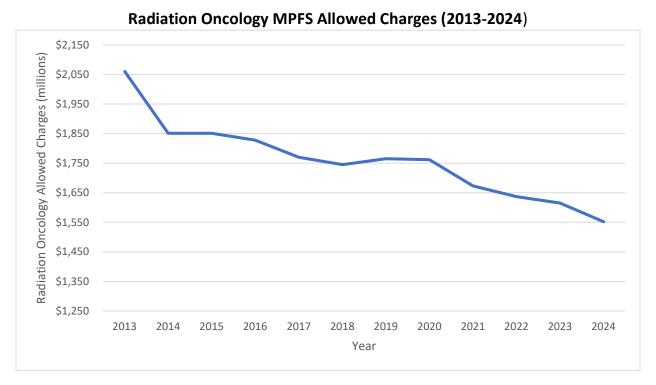
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- Direct Supervision via Use of Two-way Audio/Video Communications Technology
- Payment for Dental Services Linked to Specific Covered Medical Services
- Request for Information (RFI): Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding
- Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology
- Services Addressing Health-Related Social Needs
- Quality Payment Program

### **Payment Rates for Radiation Oncology Services**

In the 2024 proposed MPFS, CMS is proposing significant reductions for radiation oncology services. The Conversion Factor is proposed to be set at \$32.75, a payment decrease of over 3% over the final 2023 Conversion Factor update. This includes the 1.25% increase for CY 2024 provided for in the Consolidated Appropriations Act of 2023.

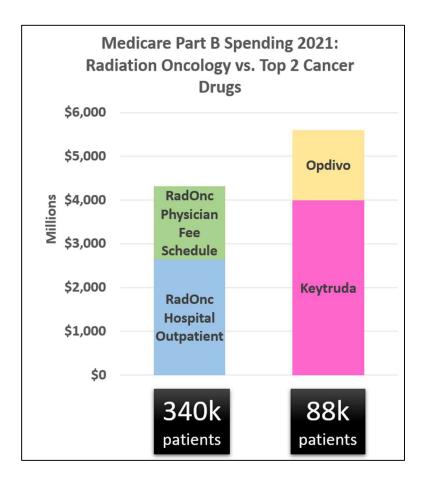
The proposed rule reduces payments for radiation oncology services for 2024 by approximately 2%. As demonstrated in the chart below, radiation oncology has experienced a 25% reduction in Medicare reimbursement under the Medicare Physician Fee Schedule since 2013.



Year over year cuts to radiation oncology MPFS reimbursements are unsustainable and jeopardize patient access to care. In recent years, these cuts come at a time when radiation oncology practices continue to struggle with the impact of inflation on practice expenses, as well as troubling staff shortages. According to a 2023 ASTRO member survey, practice operating costs are up 23%, on average,

compared to before the COVID-19 pandemic. Additionally, more than 90% of radiation oncologists report that their practices face shortages of key clinical staff, including nurses, therapists, physicists, dosimetrists, and trial coordinators. What's more, 80% said the shortages are worse than last year. More than half (53%) of the doctors said the shortages are creating treatment delays for patients, and 44% say they are causing increased patient anxiety.<sup>2</sup>

More than half of all cancer patients will receive radiation therapy during their course of illness<sup>3</sup>, but these ongoing cuts to reimbursement threaten to undermine equitable access to this life-saving treatment. Additionally, these cuts fail to recognize that radiation oncology is a high-value form of cancer treatment. Medicare expenditures for radiation oncology services under Medicare Part B are less than the top two chemotherapy drugs and cover a broader number of Medicare beneficiaries as seen in the chart below.



The Biden Moonshot initiative touts the need to invest in targeted treatments and therapies to improve the lives of patients with cancer. Unfortunately, continued cuts make tried and true radiation therapy treatments that cure the majority of cancers inaccessible. This misalignment between the President's

<sup>&</sup>lt;sup>2</sup> https://www.astro.org/News-and-Publications/News-and-Media-Center/News-Releases/2023/Widespread-staff-shortages-exacerbate-pressures-fa

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3298009/#B9

goal of reducing the cancer mortality rate and the continued cuts to radiation therapy services must be addressed. The Medicare physician fee schedule is failing cancer patients in need of radiation therapy. Urgent, major reforms are needed, and ASTRO is ready to work with the Agency and Congress to achieve payment stability and higher quality care.

The chart below indicates that several high-volume radiation oncology codes will experience significant cuts in 2024.

CPT Code	MOD/SOS	CPT Descriptor	2023 National Rate	2024 National Rate	2024 Impact
G6015		Radiation tx Delivery IMRT	\$364.97	\$349.74	-4%
77427		Radiation tx Management x5	\$192.82	\$186.66	-3%
77014		CT Scan for Therapy Guide	\$122.33	\$117.56	-4%
77301		Radiotherapy Dose Plan IMRT	\$1,861.76	\$1,813.23	-3%
G6012		Radiation Treatment Delivery	\$238.23	\$225.63	-5%
77014	26	CT Scan for Therapy Guide	\$45.07	\$43.55	-3%
77263		Radiation Therapy Planning	\$170.11	\$164.07	-4%
77301	26	Radiotherapy Dose Plan IMRT	\$423.25	\$409.02	-3%
77373		SBRT Delivery	\$1,018.99	\$977.84	-4%
G6013		Radiation Treatment Delivery	\$238.90	\$226.61	-5%
77334	26	Radiation Treatment Aid(s)	\$60.66	\$58.95	-3%
99205		Office o/p new hi 60-74 minutes	\$220.94	\$216.79	<b>-2</b> %
77336		Radiation Physics Consult	\$87.43	\$87.44	0%
77338		Design Mlc Device for IMRT	\$469.68	\$460.10	-2%
77338	26	Design Mlc Device for IMRT	\$227.04	\$219.41	-3%
77435		SBRT Management	\$646.91	\$627.44	-3%

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77300	26	Radiation Therapy Dose Plan	\$33.21	\$31.77	-4%
77300		Radiation Therapy Dose Plan	\$66.76	\$65.17	<b>-2</b> %

In 2017, CMS recognized that the Medicare payment systems were not adequately addressing radiation oncology services and the CMS Innovation Center released a report on pursuing an alternative payment model for radiation oncology (RO Model) to address the payment shortcomings in the PFS and OPPS. However, strong opposition to the methodology prompted Congress to delay implementation of the RO Model twice and the Innovation Center indefinitely delayed the model in 2022. Significant opposition to the RO Model stems from the payment reductions that did not prioritize value or quality.

Though the flaws in the PFS and OPPS system persist, and the RO Model was delayed, ASTRO has developed an alternative payment approach for certain radiation therapies that would:

- Establish stable, unified payments for radiation oncology across settings;
- Recognize the value of shorter courses of treatment for certain patients and cancers;
- Improve access and reduce disparities in radiation oncology; and
- Achieve spending reductions in Medicare (estimated over \$200 million in the first five years)

The proposed approach is built on an episode-based radiation oncology case rate (ROCR) payment for 15 disease sites and the Health Equity Achievement in Radiation Therapy (HEART) payment to reduce disparities in access to radiation oncology. ASTRO is currently in the process of introducing the ROCR proposal<sup>4</sup> in Congress.

# **Clinical Labor Pricing Update**

2024 will be the third year of the four-year phase-in of the clinical labor pricing update. CMS did not receive new wage data or other information related to clinical labor pricing prior to the 2024 MPFS proposed rule's release, so it is proposing that 2024 clinical labor pricing be based on 2023 pricing.

While phasing in the clinical labor pricing update over a four-year period reduces the immediate drastic impact on many specialties, it does not remedy the overall effect it has on practices. Again, we urge the Agency to work with ASTRO and other medical specialty societies on a more comprehensive solution to the significant payment shifts that policy changes generate due to the budget neutral environment. We also continue to urge CMS to hold harmless the specialties that bear the brunt of this clinical labor pricing update and look for more equitable ways to continue the update.

#### Evaluation and Management (E/M) Visit Complexity

After a three-year delay, CMS is proposing to implement a separate add-on payment for HCPCS code G2211. The full descriptor for this code is:

<sup>&</sup>lt;sup>4</sup> https://www.astro.org/Advocacy/Key-Issues/ROCR

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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)

The Agency believes this add-on code will better recognize the resource costs associated with E/M visits for primary care and longitudinal care of complex patients. This policy was originally finalized in the 2021 MPFS final rule, but Congress suspended the use of the code by prohibiting CMS from making additional payment under the MPFS for complex E/M visits before January 1, 2024.

ASTRO continues to believe that code G2211 is not a separately identifiable service, given the extensive changes to the office/outpatient E/M codes. Specifically, CMS stated in the CY 2019 final rule that the code was created "to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits." That rationale no longer holds true under the revised 2021 policy that allows physicians bill a higher-level E/M code for such visits, based on the level of medical decision making (MDM) or time. We note that the American Medical Association and almost all medical and surgical specialties agree that G2211 is not necessary, given the ability to code based on MDM or time.

ASTRO urges the Agency to delete HCPCS Code G2211 prior to the scheduled January 1, 2024, implementation. Allowing G2211 to go into effect is not appropriate and will cause further erosion of the MPFS. However, if the Agency chooses to proceed with its implementation, clear coding guidance on its use is needed, as we anticipate that it will be used frequently by radiation oncologists given the complexity associated with cancer care.

# **Payment for Medicare Telehealth Services**

Through the Consolidated Appropriations Acts (CAA) of 2022 and 2023, several provisions for Medicare telehealth flexibilities adopted during the COVID-19 PHE were extended through the end of 2024. In part, these flexibilities removed restrictions on telehealth originating sites to recognize services delivered to patients located in any site in the United States at the time of the telehealth service, including an individual's home, as well as coverage of audio-only services for services on the Medicare Telehealth Services List. CMS proposes to align MPFS payment policies with the CAA by also extending these telehealth flexibilities through the end of CY 2024.

ASTRO appreciates the Agency's commitment to telehealth expansion both during and at the conclusion of the PHE. We also applaud the Agency's efforts to align the MPFS payment policies with the extension of the telehealth flexibilities provided in the Consolidated Appropriations Act of 2023 to avoid confusion in the health care community. However, any possible further extensions of these flexibilities will need to be re-evaluated via future rulemaking that involves broad stakeholder engagement regarding the impact these policies may have on the quality of care delivered and care delivery outcomes.

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# <u>Direct Supervision via Use of Two-way Audio/Video Communications Technology</u>

Direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service. The Agency has established this "immediate availability" requirement to mean in-person, physical, not virtual, availability. During the COVID-19 public health emergency (PHE), CMS changed the definition of "direct supervision" as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using two-way, real-time audio/video technology, instead of requiring their physical presence. Via various rules, this policy was extended through the end of 2023, after which the pre-PHE supervision rules would apply.

CMS is concerned about an abrupt transition to its pre-PHE policy (requiring the physical presence of the supervising practitioner) because practitioners have established new patterns of practice during the PHE. In the absence of evidence that patient safety is compromised by virtual direct supervision, CMS believes that an immediate reversion to the pre-PHE definition of direct supervision 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. The Agency believes practitioners will need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision. Therefore, CMS proposes to extend PHE flexibility of virtual direct supervision through the end of 2024.

Additionally, CMS is seeking comment on whether it should consider extending this flexibility beyond 2024. Specifically, it is interested in input from interested parties on potential patient safety or quality concerns when direct supervision occurs virtually; for instance, if virtual direct supervision of certain types of services is more or less likely to present patient safety concerns, or if this flexibility would be more appropriate for certain types of services, or when certain types of auxiliary personnel are performing the supervised service. It is also interested in potential program integrity concerns, such as overutilization or fraud and abuse, that interested parties may have about this policy.

ASTRO appreciates the Agency's recognition that practices have established new patterns of practice during the PHE and that an abrupt return to pre-PHE supervision rules could lead to confusion. Therefore, ASTRO supports the extension of the direct supervision flexibility, allowing for the supervising professional to be immediately available through virtual presence using two-way, real-time audio/video technology, through the end of 2024. However, any extension of direct supervision flexibility beyond 2024 should be evaluated via the CY 2025 MPFS rulemaking process to allow time for additional analysis of the flexibility's impact on patient care.

In the proposed rule, the Agency states that there has been an "absence of evidence that patient safety is compromised by virtual direct supervision...." There needs to be clarification around what harm to the patient is in the context of direct supervision before indefinitely extending virtual flexibilities. Radiation therapy treatment is irreversible, and a patient may not experience a problem until after the treatment has been provided. In radiation oncology, it is critical that practices provide direct supervision, not virtual, in certain situations to ensure patient safety, such as for the delivery of

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stereotactic radiosurgery, stereotactic body radiation therapy, brachytherapy or weekly treatment management.

Furthermore, the side effects of radiation therapy can be severe, and patients need the ability to be seen by the radiation oncologist in-person to discuss their symptoms and receive treatment to address those symptoms. ASTRO believes that a board-certified/board-eligible radiation oncologist is the clinically appropriate physician to supervise radiation treatments, as well as for follow up care related to those treatments. However, we recognize that some flexibility is necessary for those practices that deliver care to rural or underserved populations who may experience access to care issues.

### Payment for Dental Services Linked to Specific Covered Medical Services

In the 2023 MPFS final rule, CMS identified certain clinical scenarios where payment is permitted under both Medicare Parts A and B for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act. Dental services for which payment can be made under Parts A and B must be "inextricable linked to" and substantially related to the clinical success of a covered service.

For 2024, CMS is proposing to codify the previously finalized payment policy for dental services prior to, or during, head and neck cancer treatments. Additionally, the Agency seeks comment on whether it should consider radiation therapy in the treatment of cancer more broadly (not in conjunction with chemotherapy, and not in relation to head and neck cancer treatment) as medical services that may be inextricably linked to dental services. CMS does not believe that radiation therapy alone necessarily leads to the same level of treatment-induced immunosuppression as for cancer patients receiving chemotherapy, since radiation specifically targets malignant cells and has more targeted and localized effects on the body as compared to system-wide immunosuppression effects of chemotherapy for cancer treatment. However, it seeks comment on whether dental services prior to radiation therapy in the treatment of cancer, when furnished without chemotherapy, such as second line therapy for metastasized cancer in the head and neck, would be inextricably linked to the radiation therapy services, and therefore payable under Medicare Parts A and B.

ASTRO appreciates the Agency's attention to coverage for dental services, particularly involving radiation therapy. For patients undergoing radiation therapy for any type of head and neck cancer, it is important that they receive a thorough initial dental evaluation, including dental x-rays, with special attention to any teeth that may require timely procedures, such as root canals and extractions, prior to radiation therapy. Cleaning and preparation work for radiation therapy also is critical to the clinical success of radiation therapy, including the preparation of a fluoride carrier to protect teeth in an ongoing fashion. After radiation therapy, patients should receive ongoing dental evaluations to identify possible problems.

For these reasons, ASTRO encourages the Agency to permit payment for dental services under Parts A and B when they are necessary for the treatment of all head and neck cancers, as reported with International Classification of Diseases, Tenth Revision (ICD-10) codes C00.0 through C14.8, C30.0-

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C30.1, C31.0-C31.9, C32.0-C32.9, C47.0, C49.0, C76.0, C77.0, C73.9, and D37.0.5

# Request for Information (RFI): Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding

In an effort to promote coding and payment consistency and patient access to infusion services, CMS is seeking comment and information regarding the relevant resources involved, as well as inputs and payment guidelines and/or considerations, that could be used in determining appropriate coding and payment for complex non-chemotherapeutic drug administration. The Agency is seeking comment on whether or not it should revise its policy guidelines to better reflect how these specific infusion services are furnished and should be billed.

Radiopharmaceuticals are a class of drugs that deliver radiation therapy directly and specifically to cancer cells. The various types of radiopharmaceutical therapies involve the use of radionuclides that are either conjugated to tumor-targeting agents or concentrate in tumors through natural mechanisms. Radiopharmaceutical therapy is highly complex and is not self-administered by the patient.

Under the Hospital Outpatient Prospective Payment System (HOPPS), radiopharmaceuticals are considered a "drug" and are paid at Average Sales Price (ASP) + 6%. The additional 6% is meant to reimburse for the complexity of the drugs, many of which are used to treat various types of cancer. However, under the MPFS, radiopharmaceuticals are not considered a "drug," and are therefore considered a carrier-priced procedure by the Medicare Administrative Contractors (MACs). As a result, freestanding centers are paid significantly less than a HOPD facility and cannot justify offering radiopharmaceutical therapies because of the low reimbursement, which frequently does not cover the cost of acquisition. This discrepancy is limiting access to care for patients with cancer in many communities. Radiopharmaceuticals are no less complex to administer in the freestanding setting than the HOPD setting, and they should be reimbursed in comparable ways.

ASTRO encourages CMS to treat radiopharmaceuticals as a drug under the MPFS, as it does under HOPPS, and reimburse at ASP + 6%.

# <u>Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology</u>

In the CY 2023 MPFS final rule, CMS issued a request for information (RFI) on strategies to update practice expense (PE) data collection and methodology. The Agency currently relies on the AMA's Physician Practice Information Survey (PPIS), which it notes "may represent the best aggregated available source of information at this time." Many RFI responses, including ASTRO's, asked CMS to wait for the AMA to complete a refresh of its survey data, but the Agency is concerned that "waiting for refreshed survey data would result in CMS using data nearly 20 years old to form indirect PE inputs to set rates for services on the PFS."

<sup>&</sup>lt;sup>5</sup> https://training.seer.cancer.gov/head-neck/abstract-code-stage/codes.html

<sup>&</sup>lt;sup>6</sup> https://www.cancer.gov/news-events/cancer-currents-blog/2020/radiopharmaceuticals-cancer-radiation-therapy

 $<sup>\</sup>frac{\text{https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6310043/\#:}^{\text{::text=Radiopharmaceutical}\%20 therapy\%20 (RPT)\%20 in wolves\%20 the, occur%20 predominantly\%20 in \%20 neoplastic\%20 cells.}$ 

CMS is again asking interested parties to provide feedback on how to achieve optimal PE data collection and methodological adjustments over time. Specifically, CMS requests feedback on the following questions, and ASTRO's responses follow each:

- 1. If CMS should consider aggregating data for certain physician specialties to generate indirect allocators so that PE/HR calculations based on PPIS data would be less likely to over-allocate (or under-allocate) indirect PE to a given set of services, specialties, or practice types. Further, what thresholds or methodological approaches could be employed to establish such aggregations?
  - The updated AMA PPIS is using stratification to control the distribution of sampled cases, either to match the distribution of the population or to differ from it in a controlled way. This should improve estimate precision. ASTRO agrees with the RUC recommendation to postpone any consideration of the level of granularity of specialty-level data until after the PPIS demonstrates the differences and similarities of practice costs by specialty.
- 2. Whether aggregations of services, for purposes of assigning PE inputs, represent a fair, stable and accurate means to account for indirect PEs across various specialties or practice types?
  - Resource costs in the MPFS are developed through an extremely granular "bottom-up" methodology in which the necessary resource costs are added line by line to achieve the actual costs for the physician to provide the care. In contrast, payment via aggregations of services, as in OPPS, is calculated on the geometric mean of the costs of services in the same APC codes. To equate the rigorously developed line-item costs associated with services performed in the non-facility setting, with charges that are intended to be an average of "similar" services when performed in the facility is severely flawed because the two systems are making payments under vastly different assumptions.

ASTRO agrees with the RUC recommendation that the PE methodology for the MPFS needs to have a sufficient level of granularity to reflect actual practice costs incurred by physician practices.

- 3. If and how CMS should balance factors that influence indirect PE inputs when these factors are likely driven by a difference in geographic location or setting of care, specific to individual practitioners (or practitioner types) versus other specialty/practice-specific characteristics (for example, practice size, patient population served)?
  - Again, ASTRO encourages the Agency to await the AMA's updated PPIS. The PPIS is controlling for the number of sampled practices within strata defined by (1) specialty, (2) proportion of time in the facility setting, (3) practice size, (4) ownership type (individual ownership vs. more complex ownership types), (5) geographic region, and, among practices with complex ownership, whether (6) the practice is part of a vertically integrated health system, and (7) private equity ownership.

The AMA and Mathematica could provide recommendations related to this question once the PPIS is completed.

4. What possible unintended consequences may result if CMS were to act upon the respondents' recommendations for any of highlighted considerations above?

The difference between the MPFS and other Medicare payment methodologies are significant and have been growing. These distinctions have led to a decline in the number of private practices and resultant growth in practice consolidation. It is important that any changes to the PE methodology do not further exacerbate these differences. The focus should be on correcting site of service inconsistencies.

5. Whether specific types of outliers or non-response bias may require different analytical approaches and methodological adjustments to integrate refreshed data?

ASTRO defers to the AMA RUC's response, which states,

The AMA and Mathematica will develop final analysis weights to adjust for probability of selection, practice eligibility, and cooperation, ensuring selected weighted totals match marginal population totals from the sample frame. The AMA and Mathematica will evaluate the potential for nonresponse bias by conducting a nonresponse bias analysis. The AMA and Mathematica are using strata for our initial sampling, as described above. Also, if there is variance in the response rates between different practice types, these criteria will be utilized to adjust the sampling midway through the data collection period.

If potential deficiencies are identified within the Mathematic/AMA PPI survey, ASTRO supports the use of specialty specific supplemental survey data to address the deficiencies.

Request for Comment on whether AMA RUC is the Entity Best Positioned to Provide Recommendations to CMS on Resource Inputs for Work and PE Valuations

ASTRO supports the AMA RUC as the entity best positioned to provide recommendations to CMS on resource inputs for work and PE valuations. The physicians and other health care professionals involved in the RUC process provide their expertise to the RUC regarding time, intensity, and relativity for services that are familiar in their respective fields. Through the RUC process, recommendations are made to CMS, which allows for the development of fair and appropriate relativity in the Medicare Physician Fee Schedule.

#### **Services Addressing Health-Related Social Needs**

CMS believes that medical practice has evolved to increasingly recognize the importance of addressing health-related social needs; however, this work is not explicitly identified in current coding. The Agency is proposing to create new coding to identify and value these services for MPFS payment and distinguish them from current care management services. CMS expects that its proposed new codes would also support the CMS pillars for equity, inclusion, and access to care for the Medicare population and improve patient outcomes, including for underserved and low-income populations where there is a disparity in access to quality care. They would also support the White House's National Strategy on Hunger, Nutrition and Health, as well as the Cancer Moonshot Initiative.

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CMS is proposing five new codes recognizing services that may be provided by auxiliary personnel incident to the billing physician or practitioner's professional services, and under the billing practitioner's supervision, when reasonable and necessary to diagnose and treat the patient.

ASTRO supports the Agency's initiative to address health-related social needs and believes the creation of these new G codes has the potential to support patients with cancer. However, we believe further work needs to be done prior to the implementation of new G codes for community health integration services, SDOH risk assessment, and principal illness navigation (PIN) services provided by social workers, community health workers, and other auxiliary personnel.

ASTRO has long advocated for the adoption of standards for collection of data related to social determinants of health (SDOH). Radiation oncology treatments frequently involve daily treatment regimens that take place over a period of several weeks. This presents a challenge for minority and rural patients who are frequently labeled "non-compliant" and effectively blamed for their inability to initiate or continue treatment. Delays or interruptions in radiation treatment can negatively impact a patient's ability to control disease progression. Resource investment and interventions are necessary to address the issues experienced by these populations to ensure that they have adequate access to treatment, otherwise disparities in care will persist.

Preliminary analysis of Medicare data shows that minority patients are nearly 33% more likely than white patients to not even begin their radiation therapy treatments, despite having completed the treatment planning process. While it is unclear what prevents some minority patients from beginning radiation therapy treatment, evidence points to lack of transportation, lower socioeconomic status, lack of childcare, inability to take the necessary time off work, underinsured/uninsured, and limited social supports as key barriers.

Similarly, rural health care providers and their patients face many challenges in the delivery of care, including limited availability of physicians, treatments, transportation barriers, and financial issues among many other difficulties. These challenges often apply acutely to radiation oncology care in rural areas, where studies have long documented health disparities between rural patients and their urban/suburban counterparts. To address these challenges, ASTRO's Radiation Oncology Case Rate (ROCR) payment program includes a \$500 increase in technical payments to cover costs associated with transportation services for those patients who experience challenges securing adequate transportation so they can initiate and complete their treatment.

While the proposed rule addressed some issues related to operationalizing the G codes, more must be outlined before the G codes become effective. For example, CMS ties much of the G code reporting to E/M reporting. What if a patient is discovered to have no viable transportation options after their course of radiation has begun? An E/M code is not typically reported (unless for an unrelated, problem-focused event). Can the G codes be reported with CPT Code 77427 *Weekly Treatment Management*? Do the health-related social health codes always have to be tied to an E/M?

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After a standardized assessment is performed, a documented intervention must be made, otherwise the collection of these sensitive data is not necessary. CMS appropriately states, "An SDOH risk assessment without appropriate follow-up for identified needs would serve little purpose." Large clinics might have the appropriate staff knowledgeable about local resources (e.g., how to apply for Medicaid, knowing the Medicaid rules, in-network resources, local resources, if a patient qualifies for other programs or grants). However, small practices might not have the appropriate staff to perform the intervention. And most importantly, who will absorb the cost for the documented intervention? It is a disservice to perform an SDOH assessment, bill patients for their cost share portion of the assessment, determine if they need, for example, transportation and provide a flyer or a list of numbers to call for transportation and there ends the "intervention."

CMS expressed concern about potential fragmentation when addressing health-related social needs. A solution to that challenge may be to limit reporting of the G codes to one practitioner per beneficiary per calendar month. Operationalizing the 'one practitioner limitation' will be challenging, with a potential of discovering another practitioner has reported an instance of the G Code only after receiving a denial for the submission.

The descriptions of work as well as related definitions (i.e., addressed) need further refinement before implementation.

ASTRO supports the direction of the G codes and recommends that CMS work with the AMA CPT/RUC as well as other stakeholders to define appropriate health related social needs CPT codes. ASTRO also recommends CMS work with stakeholders on operationalizing health-related social needs codes to address issues before implementation. Without addressing these and other similar issues, we are concerned that performing social needs assessments will be a cyclical issue with no improvement to patient outcomes.

Finally, if CMS chooses to move forward with implementing these codes, ASTRO encourages the Agency to exclude them from budget neutrality calculations. Creating new codes that are reimbursed under the MPFS has the effect of reducing the RVUs of other codes, which is an unsustainable path for many specialties, including radiation oncology.

### **Quality Payment Program**

Following are ASTRO's comments to CMS's specific questions regarding modification of policies under the Quality Payment Program to foster clinicians' continuous performance improvement and positively impact care outcomes for Medicare beneficiaries:

1. What potential policies in the Merit Based Incentive Payment System (MIPS) program would provide opportunities for clinicians to continuously improve care?

Current MIPS policies do not lend themselves to continuous improvement. They are too focused on primary care without regard to the specific needs of specialty care. Additionally, MIPS reporting requirements are burdensome and do not provide meaningful feedback. One way to make MIPS relevant to medical specialties is to require accreditation from nationally recognized accrediting bodies. Accreditation is a quality improvement tool intended to help practices

identify gaps in processes and helps practices address them. Accredited practices have the systems, personnel, policies, and procedures in place to demonstrate dedication to high-quality patient care, a respect for protecting the rights of patients and being responsive to patient needs and concerns.

2. Should we consider, in future rulemaking, changes in policies to assess performance to ensure ongoing opportunities for continuous performance improvement?

See response to question number 1 above.

3. Should we consider, for example, increasing the reporting requirements or requiring that specific measures are reported once MVPs are mandatory?

There are only a handful of operational MVPs at this time, and mandatory requirements should not be implemented until MVPs are more established and achieving the intended goals. Until there is actionable data coming from MVPs, increasing reporting requirements or requiring specific measures is a fix in search of a problem.

4. Should we consider creating additional incentives to join APMs in order to foster continuous improvement, and if so, what should these incentives be?

One incentive the Agency could offer is to implement a gold-card program to alleviate prior authorization burden for participants in All-Payer APMs. Prior authorization causes unnecessary and life-threatening treatment delays for cancer patients. Additionally, it is a significant administrative burden, consuming significant amounts of time and resources that would be better spent on patient care. This is particularly true for practices participating in an APM focused on driving value through greater efficiency. We recommend that CMS consider requiring All-Payer APMs that encompass Medicare Advantage plans to be exempt from prior authorization requirements when performing treatments considered standard of care. Creating a gold-card program and standardizing denial rationale will reduce the time that providers and patients spend waiting on prior authorization decision.

5. We acknowledge the potential increase in burden associated with increasing measure reporting or performance standards. How should we balance consideration of reporting burden with creating continuous opportunities for performance improvement?

See response to question number 1 above regarding practice accreditation.

6. While we are aware of potential benefits of establishing more rigorous policies, requirements, and performance standards, such as developing an approach for some clinicians to demonstrate improvement, we are also mindful that this will result in an increasing challenge for some clinicians to meet the performance threshold. Are there ways to mitigate any unintended consequences of implementing such policies, requirements, and performance standards?

ASTRO recommends that CMS carefully consider the downstream financial impact of new requirements, and how they almost certainly will result in increased costs for practices. CMS must also consider whether the eligible clinician has control over the requirements being implemented. For instance, clinicians do not have control over the EHR products issued by vendors, and penalizing providers for noncompliance must be avoided. Additionally, CMS must carefully consider the relevance of new policies and whether those requirements are measuring meaningful improvement.

#### MIPS

MIPS Scoring Methodology

CMS is proposing to increase the performance threshold from 75 to 82 points for the 2024 performance year based on the mean scores from the 2017-2019 performance years. CMS believes that the increase, which would be applicable to all three MIPS reporting options (traditional MIPS, MVP, and the APP), aligns with the Agency's goal to provide practices with a greater return on their investment in MIPS participation by giving an opportunity to achieve a higher positive payment adjustment.

ASTRO opposes the proposed performance threshold increase, which could significantly disadvantage eligible clinicians in a program that has been largely paused since 2019 due to the significant disruptions caused by the COVID-19 pandemic. We therefore recommend that the Agency maintain a 75-point performance threshold.

Targeted Review Submission period

CMS is proposing to open the targeted review submission period upon release of MIPS final scores and to keep it open for 30 days after MIPS payment adjustments are released.

ASTRO supports this change as it will streamline the targeted review process.

Promoting Interoperability (PI) Performance Category

CMS is proposing to update the CEHRT definition to align with the Office of the National Coordinator for Health IT's (ONC) regulations. In a recent proposed rule, ONC signaled a move away from the "edition" construct for certification criteria. Instead, all certification criteria will be maintained and updated at 45 CFR 170.315. The Agency is proposing to align with this new definition for QPP and the Medicare Promoting Interoperability Program.

ASTRO supports this proposal as it will promote alignment across all quality programs.

Promoting Interoperability Performance Period

CMS is proposing to increase the performance period to a minimum of 180 continuous days within the calendar year beginning with the 2024 performance period. This proposal ensures that the MIPS Promoting Interoperability performance category continues to align with the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals.

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# ASTRO supports this proposal as it will promote alignment across all quality programs.

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Adam Greathouse, Assistant Director, Health Policy, at (703) 839-7376 or Adam.Greathouse@astro.org.

Respectfully,

Laura I. Thevenot Chief Executive Officer

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