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TARGETING CANCER CARE

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September 5, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Submitted electronically: http://www.regulations.gov

Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

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 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments," published in the Federal Register as a proposed rule on July 31, 2024.

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, 2025. 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:

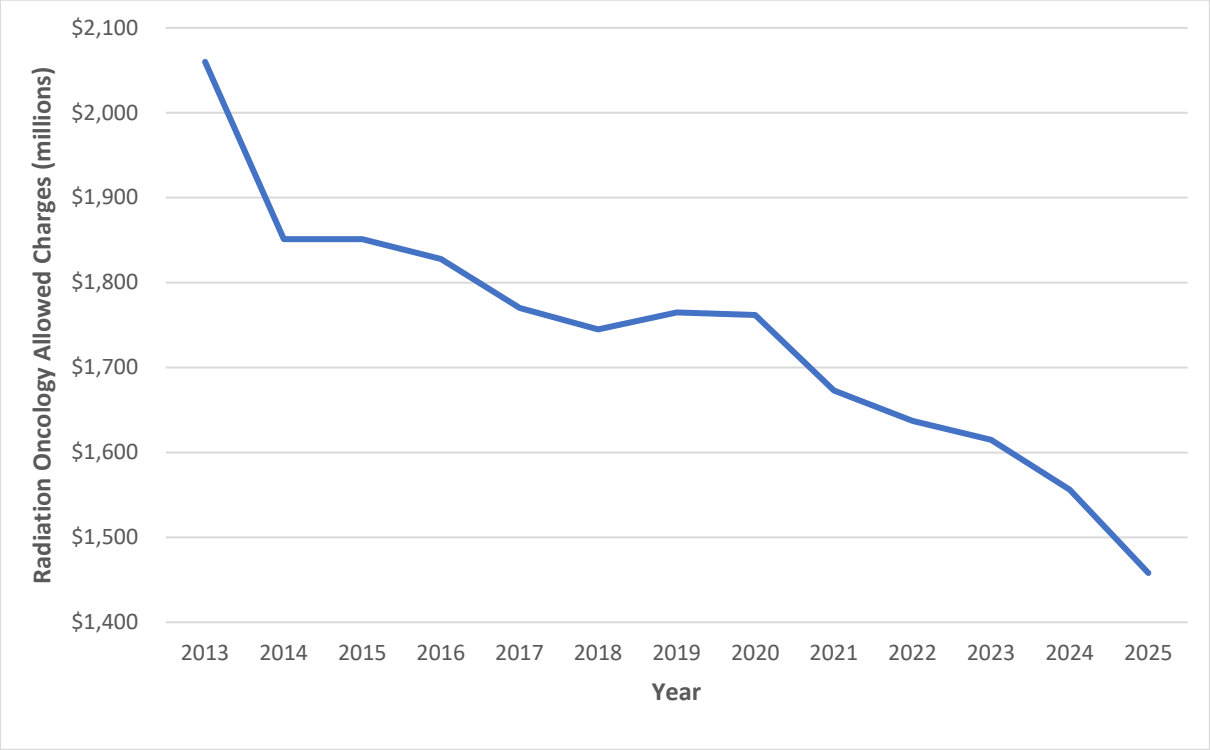
- Payment Rates for Radiation Oncology Services
- Development of Strategies for Updates to Practice Expense (PE) Data Collection and Methodology

[1] 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.

- Payment for Medicare Telehealth Services under § 1834(m) of the Act
- Payment of Radiopharmaceuticals in the Physician Office
- Global Surgical Package Proposal
- Request for Information for Services Addressing Health-Related Social Needs (Community Health Integration (G0019, G0022), Principal Illness Navigation (G0023, G0024), Principal Illness Navigation-Peer Support (G0140, G0146), and Social Determinants of Health Risk Assessment (G0136))
- Merit-Based Incentive Payment System (MIPS)
- MIPS Value Pathways (MVPs)
- Alternative Payment Models (APM)
- Requests for Information

Payment Rates for Radiation Oncology Services

In the 2025 proposed MPFS, CMS estimates that there will be no impact on payment rates for radiation oncology services; however, many services will see reduced rates due to a decline in the Conversion Factor and implementation of the final year of clinical labor pricing updates. According to the American Medical Association, the true impact of these policies would have an estimated impact of -2.7% in 2025. Since 2011, payments for radiation oncology services have fallen by 23% (reflected in the chart below).



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.

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 stemmed from the payment reductions that did not prioritize value or quality.

Subsequently, ASTRO developed an alternative payment approach for certain radiation therapies that would:

- Save Medicare approximately $200 million over 10 years;
- Ensure access to technologically advanced cancer treatments close to where patients live;
- Align payment incentives with clinical guidelines by supporting shorter treatments for certain cancers, therefore allowing patients more time to work and spend time with loved ones;
- Remove transportation-related barriers to treatment for rural and underserved patients;
- Improve upon already excellent quality through practice accreditation incentives;
- Provide opportunities for new technologies to be incorporated into the program after 10 years;
- Unify payments across different care settings; and
- Update payments for medical inflation on an annual basis.

This proposed approach was introduced as the bipartisan Radiation Oncology Case Rate (ROCR) Value Based Program Act of 2024 in the Senate (S. 4330) on May 14, 2024, and in the House (H.R. 8404) on May 15, 2024. **ASTRO seeks to work with the Agency on ROCR and other policies to improve access, enhance quality, and reduce disparities.**

Development of Strategies for Updates to Practice Expense (PE) Data Collection and Methodology

In the CY 2023 and 2024 MPFS rules, the Agency issued a request for information (RFI) to solicit public comment on strategies to update PE data collection and methodology, and it has expressed a continued interest in "developing a roadmap for updates to [its] PE methodology that account for changes in the health care landscape… [A]llocations of indirect PE continue to present a wide range of challenges and opportunities." In the CY 2025 MPFS proposed rule, the Agency stated that it is continuing to consider alternatives to the American Medical Association's Physician Practice Information Survey (PPIS) to improve the stability and accuracy of its overall PE methodology.

ASTRO continues to support the AMA's PPIS and encourages the Agency to wait until the latest PPIS is completed and analyzed later this year. Furthermore, 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 MPFS.

CMS also requests feedback from interested parties regarding scheduled, recurring updates to PE inputs for supply and equipment costs. It is proposing establishing a cycle of timing to update supply and equipment cost inputs every four years, which may be one means of advancing shared goals of stability

and predictability. CMS would collect available data, including, but not limited to, submissions and independent third-party data sources, and it proposes a phase-in period over the following four years. The phase-in approach maps to the Agency's experience with previous updates. Additionally, CMS believes that more frequent updates may have the unintended consequence of disproportionate effects of various supplies and equipment that have newly updated costs.

ASTRO supports CMS's proposal to implement a phased-in approach for any updates to supply and equipment cost inputs, and a four-year phase-in is in line with other updates the Agency has pursued in prior years. Gradually phasing in cost changes helps to prevent abrupt and potentially harmful effects on specific providers or services. However, establishing a cycle of updates every four years is not advisable. Updates this frequent could amplify the impact of short-term market fluctuations, in addition to increasing the administrative burden for both CMS and health care providers.

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

Proposal to Extend Definition of "Direct Supervision" to Include Audio-Video Communications Technology through 2025

In the absence of evidence that patient safety is compromised by virtual direct supervision, CMS remains concerned that an abrupt transition to the pre-PHE policy that defines direct supervision to require the physical presence of the supervising practitioner would present a barrier to access to many services, such as incident-to services. According to the proposed rule, the Agency believes that physicians and/or other supervising practitioners, in certain instances, need time to reorganize practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology.

CMS acknowledges the utilization of this flexibility and recognizes that many practitioners want to maintain it; however, the Agency seeks additional information regarding potential patient safety and quality of care concerns. It believes an incremental approach is warranted, particularly in instances where unexpected or adverse events may arise for procedures which may be riskier or more intense.

In light of these potential safety and quality of care implications, and exercising an abundance of caution, CMS is extending this flexibility for all services on a temporary basis only. It is therefore proposing to continue to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2025.

ASTRO believes the proposed extension of virtual direct supervision through the end of 2025 offers a pragmatic approach that balances quality of care concerns with the realities of current practice patterns. This extension will allow for additional time to gather information on the impact of virtual direct supervision on patient safety and access to care. ASTRO commends this measured approach and looks forward to continued dialogue with CMS on this issue.

Payment for Medicare Telehealth Services under § 1834(m) of the Act

CPT code 77427, *Radiation tx management 5x*, was added to the Telehealth List on a temporary basis during the COVID-19 Public Health Emergency (PHE) and through various regulatory actions, was continued through the end of 2024. While ASTRO initially supported the addition of 77427 to the telehealth list during the immediate onset of the PHE, radiation oncology clinics were able to quickly put policies in place that enabled them to resume face-to-face visits. In October 2020, ASTRO asked CMS to remove the code from the list given the critical nature of the in-person comprehensive physical examination. In the CY 2021 MPFS final rule, the Agency stated that 77427 would be removed from the Telehealth List at the end of the PHE, but through various Congressional and Agency actions, it remained on the telehealth List through the end of 2024. The Agency is now proposing to remove 77427 from the telehealth list in CY 2025.

Face-to-face engagement between radiation oncologists, clinical treatment teams, and patients undergoing treatment is the most appropriate way to manage care. Given that both the patient and the radiation oncologist are present to receive and supervise treatment, respectively, face-to-face visits are logistically feasible. While appropriate to protect patients and radiation oncologists from infection spread during the COVID-19 PHE, ASTRO believes that the use of telehealth for the face-to-face portion of radiation treatment management is no longer necessary now that the PHE has concluded. The physical examination is an integral part of patients' cancer treatment management during the course of radiation therapy and ensures quality of care. While occasional exceptions and flexibilities may be needed to address rural and underserved communities, ASTRO believes that it is essential for the radiation oncologist to conduct the face-to-face portion of the weekly management code in-person.

The side effects of radiation therapy are cumulative and vary from patient to patient. They can occasionally be severe, and patients need to be seen by the radiation oncologist in-person to discuss and address any symptoms. Additionally, many patients receive concurrent systemic therapies, like chemotherapy, which may make side effects more acute. Given that many Medicare beneficiaries have comorbidities which can exacerbate side effects, close physician surveillance is important. The ability of the radiation oncologists to respond to a question during the on-treatment visit with a physical clinical exam is paramount to high-quality care and patient safety. 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, as stated above, 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.

ASTRO agrees with CMS's proposal to remove CPT code 77427, *Radiation tx management x5* from the Medicare Telehealth List beginning in 2025 and encourages the Agency to finalize this proposal to support patient safety and high quality of care.

Payment of Radiopharmaceuticals in the Physician Office

In accordance with the law, radiopharmaceuticals are not required to be paid using payment methodology under section 1847A of the Social Security Act, as currently described in the Medicare Claims Processing Manual (MCPM) Chapter 17, § 20.1.3. The manual instructs Medicare Administrative Contractors (MAC) to determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003, before the passage of the Medicare Prescription Drug, Improvement, and

Modernization Act of 2003, in the case of radiopharmaceuticals furnished in settings other than the hospital outpatient department.

CMS is proposing to clarify that *any* methodology that was in place to set pricing of radiopharmaceuticals in the physician office setting prior to November 2003 can be used by *any* MAC, whether or not that specific MAC used the methodology prior to November 2003.

ASTRO appreciates the Agency's clarification of the MCPM language regarding reimbursement for radiopharmaceuticals furnished in the office setting. The field of radiopharmaceutical therapy (RPT) is expanding rapidly, and its potential for more personalized treatment of certain cancer types means it is likely to see continued growth in the future. However, RPT providers incur significant costs in bringing this treatment to patients, including specialized facilities and equipment, staff, compliance costs, as well as the acquisition costs of the radiopharmaceuticals. ASTRO encourages CMS to closely monitor and evaluate how MACs reimburse for radiopharmaceuticals furnished in a physician office to ensure that patients continue to have access to this personalized therapy.

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. As a result, freestanding centers are paid significantly less than a HOPD facility and may not be able to justify offering RPT because of the low reimbursement. This discrepancy is limiting access to care for patients with cancer in many communities.

<u>Strategies for Improving Global Surgery Payment Accuracy</u>
Over the past decade, CMS has articulated several concerns with the global packages related to the accuracy of valuation and payment under the MPFS. In the CY 2025 Proposed MPFS proposed rule, CMS proposes requiring the use of the appropriate transfer of care modifier (modifier -54, -55, or - 56) for all 90-day global surgical packages in any case when a practitioner plans to furnish only a portion of a global package, both when there is a formal, documented transfer of care (current policy) and when there is an informal, non-documented but expected transfer of care.

Radiation oncology reports several 090-day global services (e.g., 58346, 77750, 77761, 77762, 77763), some of which are subject to the multiple procedure payment reductions**. If CMS implements the transfer of care modifier policy, ASTRO recommends the Agency issue clarification on the interaction of modifiers 51, 54, 55 and 56.**

The evaluation and management services incorporated into the 010-day and 090-day surgical global periods remain inconsistent with the values for those services outside the global surgical packages. **ASTRO urges CMS to apply the full physician work for the inpatient hospital and observation care visits (99231-99233, 99238 and 99239), and office visits (99202-99215) into the surgical global periods for each CPT code with a global of 010-day and 090-day.**

Furthermore, in this proposal, CMS refers to both formal transfers of care as well as informal, non-documented but expected transfers of care. **If CMS implements this proposal, ASTRO recommends**

that the Agency issue regulatory guidance defining "informal" transfers of care.

Request for Information for Services Addressing Health-Related Social Needs (Community Health Integration (G0019, G0022), Principal Illness Navigation (G0023, G0024), Principal Illness Navigation-Peer Support (G0140, G0146), and Social Determinants of Health Risk Assessment (G0136))

For CY 2025, CMS is issuing a broad request for information (RFI) on the newly implemented Community Health Integration (CHI) (HCPCS codes G0019, G0022), Principal Illness Navigation (PIN) (HCPCS codes G0023, G0024), Principal Illness Navigation- Peer Support (PIN-PS) (HCPCS codes G0140, G0146), and Social Determinants of Health Risk Assessment (SDOH RA) (HCPCS code G0136) services to engage interested parties on additional policy refinements for CMS to consider in future rulemaking.

ASTRO encourages the Agency to provide clarity on how to bill these codes in a multidisciplinary setting or for the situation in which a patient receives concurrent care from multiple physicians. Many cancer patients receive concurrent therapies (e.g., radiation therapy and chemotherapy), and if the physicians are all practicing in the same office, can only one physician bill the code? If that is the case, which physician is the billing provider?

Merit-Based Incentive Payment System (MIPS)

MIPS Scoring Methodology

ASTRO appreciates the Agency's decision to align data submission requirements across all performance categories. We also appreciate the Agency's proposal to mitigate negative scoring impacts on clinicians who submit data without a numerator or denominator.

Performance Category Reweighting

ASTRO is pleased that the Agency is recognizing that circumstances occur outside of the physician's control and is proposing criteria by which eligible clinicians can request reweighting. We also appreciate the Agency's recognition that eligible clinicians should not be punished for those circumstances.

Quality Performance Category

Multiple Submissions

ASTRO is concerned about CMS's proposal to score the most recent submission when multiple submissions are received for an individual clinician, group, subgroup, or virtual group from the same organization. We believe this will cause confusion and unnecessarily punish MIPS participants. MIPS consistently uses the higher score if there are multiple submissions in other situations, and we question why this departure is necessary. In other parts of this proposed rule, the Agency has proposed simplifying what were once burdensome requirements, while this proposal would further complicate an already complicated reporting program. **ASTRO urges CMS to assign the higher of the scores for multiple submissions in all cases.**

Measure Removals

ASTRO opposes the removal of Oncology: Medical and Radiation – Plan of Care for Pain [Quality #144] from the MIPS Program. This measure is not duplicative of, but rather paired with Oncology: Medical

and Radiation – Pain Intensity Quantified [Quality #143]. The measures should be implemented sequentially to achieve a comprehensive clinical quality outcome, with Quality #143 confirming that the patient's pain was evaluated and Quality #144 validating that a patient care plan for pain was developed based on that assessment. The intent is for applicable clinicians to report on both measures as a unit, while resulting in individual measure scores. Second, both measures were recently re-endorsed by the CMS-certified consensus-based entity, Battelle, as part of its Fall 2023 Endorsement and Maintenance cycle. Battelle applied a rigorous evaluation process including measure importance, feasibility, scientific acceptability, use, and usability. In addition, the observed performance rates of this measure within the MIPS-Quality Program from the 2019-2021 performance periods indicate opportunity for improvement at both the individual clinician and practice level.

Furthermore, the American Society of Clinical Oncology (ASCO), the measure steward, is currently evaluating a proposal to re-specify Quality #143 and Quality #144 into a single, combined measure. ASTRO recommends that both Quality #143 and Quality #144 be retained as paired measures until ASCO can confirm whether and when the re-specification effort would begin. ASTRO believes that retaining Quality #143 and Quality #144 until a clear and comprehensive replacement is available is an approach that will offer reporters of these measures increased consistency and stability.

Quality Measure Scoring

ASTRO supports the proposal to remove the 7-point topped out measure score cap for clinicians reporting measures included in certain specialty measures. Radiation oncology has a limited set of measures, and this proposal will have a positive impact. However, we strongly recommend that CMS address the benchmarking methodology and the timing of removing measures in a holistic manner. Benchmarks remains an issue with quality measures because CMS removed measures, therefore driving benchmarks up for the remaining measures. Additionally, the process for setting benchmarks for new measures is flawed and dissuades people from using them because there are no benchmarks.

<u>Cost Performance Category</u>

Prostate Cancer Cost Measure

The Agency is proposing to include a Prostate Cancer Cost measure which establishes an episode of care based on the combination of a trigger code followed by a confirming code that are tied to an ICD-10 diagnosis code indicating prostate cancer. The episode of care is attributed to the physician who bills at least 30% of related prostate cancer treatment services. The ratio of observed to expected costs associated with the episode is compared with national cost data and then used to determine the cost measure score. Additionally, this new cost measure aligns with quality measure Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy or MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low-Risk Prostate Cancer Patients.

ASTRO is supportive of high-value approaches to cancer treatment, however the establishment of a prostate cost measure is an ineffective way to achieve high-value care. In previous communications with the Agency and its contractor Acumen LLC, ASTRO has explained that prostate cancer is particularly complex and inappropriate for cost measure development given the variety of stages and treatment scenarios involved. Treatment can run the gamut between radical prostatectomy, which involves

inpatient surgery, and radiation therapy, which is typically delivered in the outpatient setting. This variation results in significant fluctuation in the cost of care. In previous letters we urged CMS and Acumen, LLC to consider more narrowly defined disease sites with more distinct treatment regimens that are better suited for cost measure development.

Despite our recommendation, CMS is proposing to move forward with a prostate cost measure. We urge the Agency to reconsider, particularly given that members of the Acumen LLC Prostate Measure Work Group believe that the measure has not been sufficiently developed and tested. The Chair of the work group, Dr. Join Luh, a radiation oncologist, was given the impression that measure was not moving forward due to the heterogeneity within prostate cancer treatment that made it impossible to impose a uniform cost measure without taking into account risk stratification and stage. Additionally, once Acumen LLC pursued refinements to the measure after the testing period, the refined measure was never tested to ensure its accuracy.

In addition to our concerns that the measure is insufficient we are also concerned that the work group process is performative at best since it is clear that the decision making is done seemingly behind closed doors. **ASTRO urges CMS to refrain from implementing the cost measure until the work group has been reformed and testing has been completed on the refined measure that involves the broader oncology community.**

Cost Measure Removal Criteria
ASTRO supports the proposed criteria for removing a cost measure, as we believe the proposal is straightforward and reasonable.

Improvement Activities Performance Category
ASTRO supports the Agency's proposal to remove several improvement activities that are covered in other assessment areas, like Promoting Interoperability.

Activity Weighting
ASTRO supports the proposal to remove activity weightings to simplify scoring and complement the Agency's ongoing efforts to refine and improve the inventory. This proposal would streamline the scoring process by removing unnecessary levels of complexity.

Required Activities
ASTRO is disappointed that CMS is proposing that eligible clinicians must report two improvement activities to receive full credit, while non-patient facing eligible clinicians, small practices, and practices located in rural areas only must report one to receive full credit. In other parts of the proposed rule, CMS is removing complexity, which we appreciate. **ASTRO recommends that all eligible clinicians, whether they are patient facing or not, submit two improvement activities to receive full credit.**

Multiple Submissions
CMS is proposing to score the most recent submission when multiple submissions are received for an individual clinician, group, subgroup, or virtual group from the same organization. ASTRO is concerned that this proposal will cause confusion and unnecessarily punish MIPS participants. MIPS consistently

uses the higher score if there are multiple submissions in other situations, and we question why this departure is necessary. In other parts of this proposed rule the Agency has proposed simplifying what were once burdensome requirements, while this proposal would further complicate an already complex reporting program. **As mentioned above, ASTRO urges CMS to assign the higher of the scores for multiple submissions in all cases.**

MIPS Value Pathways (MVPs)

In 2021, CMS introduced the Merit Based Incentive Program Value Pathways (MVPs). MVPs are a subset of measures and activities, established through rulemaking, that can be used to meet MIPS reporting requirements beginning in the 2023 performance year.

In the 2023 MPFS final rule, CMS established the Advancing Cancer Care MIPS Value Pathway (MVP), which specifically applies to medical, hematological, and gynecological oncologists. ASTRO issued comments in response to the initial Advancing Cancer Care proposal highlighting the omission of radiation oncology. In the 2025 MPFS proposed rule, CMS is proposing to add seven quality measures, two improvement activities, and one cost measure, while removing three improvement activities from the Advancing Cancer Care MVP.

ASTRO appreciates that CMS continues to explore and refine alternative pathways to value based payment for oncology services, but again the Agency falls short by not recognizing the complexity of cancer care that frequently involves the services of a surgical oncologist, a medical oncologist and a radiation oncologist.

Requests for Information

Guiding Principles for Patient-Reported Outcome Measures in Federal Models, and Quality Reporting and Payment Programs Request for Information

In general, ASTRO is supportive of Patient-Reported Outcome Measures (PROMs), however, it is not clear how PROMs would be weighed against more traditional measures, such as process and outcomes measures. PROMs should be patient goal and experience oriented, which can make them broadly applicable, accessible, and reportable. Creating clinically specific PROMs, on the other hand, will inevitably lead to an unmanageable number of measures.

Public Health Reporting and Data Exchange

In general, ASTRO agrees with the Agency's goals for policy change relating to public health reporting and data exchange. Our comments to specific questions outlined in the RFI are below.

Questions for Goal #1: Quality, Timeliness, and Completeness of Public Health Reporting

Should CMS shift to numerator/denominator reporting requirements for current and future measures in the Public Health and Clinical Data Exchange objective? If so, should CMS prioritize only certain measures for numerator/denominator reporting?

ASTRO believes that shifting to numerator/denominator reporting would be time consuming and would not accurately measure the capability of the systems because it is only a snapshot of what is being done and requires manual data collection and reporting.

New technical approaches such as the use of Fast Healthcare Interoperability Resources (FHIR) Application Programming Interface (APIs) to support information exchange with Public Health Agencies (PHAs) could enable PHAs to query healthcare provider systems directly, after an initial trigger, rather than relying on a healthcare provider to take action to share information. Healthcare providers having to take action to share information adds burden to the healthcare providers and increases the time it takes for the PHA to receive the information. How could performance be measured under approaches such as the use of FHIR APIs to support information exchange with PHAs? Would numerator/denominator reporting be appropriate under such approaches?

ASTRO agrees that available technology should be leveraged, and existing infrastructures be tested. However, as we have said in numerous comment letters, providers should not be penalized for system limitations. Creating and testing the infrastructure should fall on the vendors themselves, not the providers.

Continued expansion of the measures under the Public Health and Clinical Data Exchange objective to address different reporting use cases can incentivize MIPS eligible clinicians to make more comprehensive information available to PHAs. We are seeking public comment on the following questions:

ASTRO cautions CMS on introducing new measures in the Promoting Interoperability category. We believe that CMS should be aligning the work that the ONC is doing with USCDI+ and other programs, with current CMS programs and requirements, instead of adding to the library.

Should CMS create a new measure for each new type of data or use case added to the Public Health and Clinical Data Exchange objective? What are the risks of including too many measures under the objective?

CMS should resist the urge to continually add more measures at the risk of over burdening eligible clinicians and their practices without a clear rationale and need.

Alternatively, should CMS explore ways to group data types and use cases under a more limited set of Public Health and Clinical Data Exchange objective measure? If so, are there specific scenarios where doing so would make sense? Anecdotal reports suggest that some healthcare providers are attesting to active engagement with public health for the eCR measure if they report cases for at least one notifiable condition (for example, COVID-19).

ASTRO supports simplification where practicable.

<u>Questions for Goal #2: Flexibility and Adaptability of the Public Health Reporting Enterprise</u>
How can the Promoting Interoperability performance category support or incentivize response ready reporting capabilities for healthcare providers? What, if any, challenges exist around sharing data with PHAs?

Currently there is little motivation or incentive for vendor systems to adopt and implement standards like the Minimal Coding Oncology Data Elements (mCODE) standard. CMS should apply pressure or financial incentives for vendors to adopt these standards, which can facilitate data sharing with PHAs, other providers, and other entities.

How can CMS and ONC work with EHR vendors to ensure that provider systems are being continually updated to meet new data needs, such as those in rural areas?

The Promoting Interoperability focus to date has been to assess whether clinicians are using available technology, but this approach is flawed. Each vendor's interpretation and implementation of system requirements is different, and that is not being tested. Instead, CMS and the ONC need to test system capabilities to ensure consistent functionality. By testing vendor systems, CMS ensures that the technology supporting healthcare operations works as intended, allowing physicians to focus on patient care without being hindered by technical issues. CMS should require practices to submit the vendor systems and versions that they are using so the Agency can further understand what functionality is possible for each specific system.

Questions for Goal #3: Increasing Bi-Directional Exchange with Public Health Agencies
Both CDC's ACD and ONC's HITAC have recommended that CDC and ONC work together to establish certification criteria for public health technologies used by PHAs and implement a coordinated, phased approach to incentivize and eventually require their adoption. How, if at all, could the Promoting Interoperability performance category support or incentivize PHA adoption of certified systems and technologies?

CMS should learn from the Meaningful Use program. Under Meaningful Use, vendors attested to their level of certification; however, this allowed vendors to say they were meeting requirements without any verification. CMS needs to verify firsthand that the vendors are meeting requirements, increasing compliance and capability throughout the field, and not rely simply on attestation.

CMS previously finalized the Enabling Exchange under TEFCA measure under the HIE objective for MIPS eligible clinicians to attest to engaging in health information exchange. Should CMS introduce an additional measure to allow MIPS eligible clinicians to receive credit for the HIE objective by exchanging public health data through participation in TEFCA?

Clinical staff should not be required to satisfy alignment with TEFCA requirements. Alignment with TEFCA needs to be done through the vendor systems without penalizing physicians.

Questions for Goal #4: Significantly Reduce Reporting Burden for Healthcare Providers
Under the current Public Health and Clinical Data Exchange objective, which measures, or other requirements result in the most administrative burden for MIPS eligible clinicians?

Registry reporting requires massive infrastructure and additional staffing. This can be made better through shared and mandated standards. Data standards play a crucial role in facilitating reporting to healthcare registries by ensuring that information is consistent, accurate, and easily transferable across

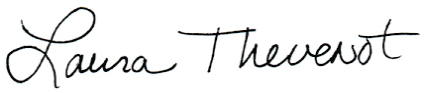
different systems. By adhering to standardized data formats and coding systems, healthcare providers can streamline the process of collecting, sharing, and analyzing data, thereby reducing errors enhancing interoperability between various healthcare systems, and allowing for more efficient aggregation of data from multiple sources. As a result, registries can more effectively track health outcomes, monitor trends, and support research and policy decisions that improve patient care and public health.

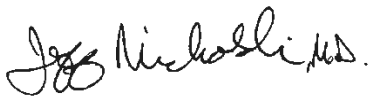
How can new technical approaches to data exchange with PHAs, such as the use of FHIR APIs, reduce burden for MIPS eligible clinicians? What are potential barriers to achieving burden reduction as these new approaches are implemented?

CMS should incorporate and further the USCDI work from ONC to mandate uniform standards in all data repositories, including information systems, public health repositories, and clinical registries, etc.

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,





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