ASTRO
TARGETING CANCER CARE

251 18th St. South, 8th Floor
Arlington, VA 22202

Main: 703.502.1550 · Fax: 703.502.7852
www.astro.org · www.rtanswers.org

September 10, 2018

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
P.O. Box 8013
7500 Security Boulevard
Baltimore, MD 21244-8013

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

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program" published in the Federal Register as a proposed rule on July 27, 2018.

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 cancer patients 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.

The proposed rule updates the payment policies and payment rates for services furnished under the Medicare Physician Fee Schedule (MPFS) and modifies requirements associated with the Merit Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) as part of the Quality Payment Program (QPP) effective January 1, 2019. ASTRO appreciates the overall focus on reducing administrative burden and the efforts that CMS is pursuing as part of its "Patients Over Paper Work" initiative. In the following letter, ASTRO seeks to provide input on these important initiatives and how they impact the field of radiation oncology. We look forward to opportunities where we may be able to work with CMS and Administration officials to refine and implement many of these initiatives. Key issues addressed in this letter follow:

- Update to Direct Practice Expense Inputs for Supply and Equipment Pricing
- Evaluation and Management Code (E/M) Modifications

- CPT Code 77401 Radiation Treatment Delivery, Superficial and/or Orthovoltage, per day
MIPS Scoring Methodology
- Appropriate Use Criteria for Advanced Diagnostic Imaging
- MIPS Clinician Eligibility
- MIPS Determination Period
- Application of MIPS Bonus Points
- Virtual Groups
- Performance Category Measures, Weights, Performance Periods and Scoring
- Qualified Clinical Data Registry
- Alternative Payment Models
- Improving Healthcare Price Transparency

Proposed Update to Direct Practice Expense Inputs for Supply and Equipment Pricing

CMS is proposing to update the Direct Practice Expense (PE) inputs for supply and equipment pricing. In order to pursue the update, CMS contracted with the StrategyGen Co. to perform a Direct Practice Input Market Research Report. To address significant changes in payment, CMS is proposing to phase in the new direct PE inputs over a four-year period.

ASTRO appreciates CMS' efforts to acquire current pricing information in order to accurately value services. However, we are concerned that the decision to contract with StrategyGen was done with limited stakeholder input and as a result the analysis contains some significant deficiencies.

The StrategyGen analysis relies on a variety of market research methodologies, including telephone surveys, aggregate database reviews, vendor interviews, market scans, market analysis, physician substantiation, and statistical analysis, in the development of its recommendations. As previously mentioned, we are concerned that the report contains several deficiencies regarding expensive radiation oncology equipment. The titles of the supplies/equipment items themselves are often incomplete or possibly outdated. For example, names of products and supplies change as a result of manufacturer mergers and acquisitions; however, those names are not updated in the CMS PE input. It is unclear whether the StrategyGen analysis is based on the new name of the corresponding PE input or the old name, as identified in the CMS database. In an effort to price the exact name of the CMS item, we suspect as a condition of the contract, StrategyGen may have priced upgrades or refurbished items. The contractor would need sufficient radiation oncology expertise to be aware of manufacturer changes, product name changes, mergers, acquisitions, etc. in order to accurately price equipment inputs.

We also question the ability of StrategyGen to identify information that demonstrates current and appropriately valued equipment in radiation oncology. For example, the recommended price for ER083 SRS System, SBRT, Six Systems, Average is $931,965, which results in a 77 percent reduction from the current price. CMS is also recommending a price of $3,000,966 for ER089 IMRT accelerator. SBRT technology is distinct from and more sophisticated than the IMRT accelerator. A contractor with radiation oncology expertise would know that the price of a

complete SBRT 'system' is $4 million, which is consistent with the current price. We suspect that the proposed $931,965 price is solely an add on package to equip an IMRT accelerator for SBRT. Such an add-on package could reasonably be valued at the recommended price of $931,965 but does not come close to reflecting the full SBRT system cost of $4 million. Therefore, we believe that the recommended stand-alone price of $931,965 is a technical error. **We recommend CMS maintain the current pricing of the SBRT system at $4 million effective January 1, 2019.**

Similarly, we suspect that the proposed price of $111,426 for the ER003 HDR Afterload System, Nucletron Oldelft and the proposed price of $157,393 for ED033 treatment planning system, IMRT (Corvus w-Peregrine 3D Monte Carlo) are not based on the purchase of a new equipment. The HDR Afterload System is used for the delivery of High Dose Rate (HDR) brachytherapy, which involves the use of high-intensity radioelements, with a radioactivity level too great to allow manual handling and loading. The IMRT treatment planning system provides more conformal target coverage and normal tissue sparing than conventional 2-D or 3-D treatment planning. **CMS should maintain the current pricing of $375,000 for the HDR Afterload System and $350,545 for IMRT treatment planning system.**

Additionally, we are concerned that CMS is attempting to re-price items that were recently reviewed by the RUC. The RUC review process is a thorough review process, which includes the submission of paid invoices by physicians in the office setting. One example of equipment that was recently reviewed by the RUC, including the submission of invoices, that CMS is proposing to reprice is ES052 Brachytherapy Treatment Vault. CMS is proposing a recommended price of $134,998, which is 23 percent less than the current value of $175,000. **ASTRO recommends that CMS maintain the current pricing of ES052 of $175,000 for the brachytherapy vault.**

As previously stated, ASTRO is concerned that StrategyGen's equipment analysis has significant flaws, particularly for three key pieces of equipment. We urge CMS to retain the current prices of the ER083 SRS System, SBRT, Six Systems, ER003 HDR Afterload System, Nucletron Oldelft, IMRT treatment planning and ES052 Brachytherapy Treatment Vault.

Finally, ASTRO urges CMS to develop a confidential process and mechanism that ensures equipment vendors and medical specialties can confidentially share invoices so that equipment is appropriately valued. Currently barriers exist that prevent the sharing of invoices for use in valuation, including concerns about protecting non-disclosure agreements, and proprietary information. These restrictions make it increasingly difficult to produce invoices that support the actual costs of acquiring these expensive pieces of equipment used by radiation oncologists in the treatment of cancer and other disease. It is our understanding that the Advanced Medical Technology Association (AdvaMed) has worked with its radiation oncology equipment vendors and Avalere Health to produce a report in an effort to provide CMS with information regarding equipment pricing without exposing proprietary information. We urge CMS to consider the contents of this report as it reviews feedback related to the repricing proposal as put forth by StrategyGen.

Evaluation and Management Code (E/M) Modifications

CMS is proposing changes to the documentation and billing requirements for E/M services. The Agency is proposing these modifications to reduce documentation burden for physicians by allowing physicians to choose whether to use decision making or time when billing E/M codes. CMS proposes to retain the existing E/M CPT codes, which denote specific levels of care; however, levels 2-5 of the codes will be cross-walked to a single blended payment rate.

ASTRO is appreciative of efforts to reduce the administrative burden associated with documentation requirements involving E/M codes. We agree that physicians should be given more flexibility regarding the documentation of patient services, so they may spend more time focusing on patient care and improving healthcare outcomes. However, ASTRO is concerned that the proposal could devalue typical E/M visits for radiation oncologists with cancer patients, and we urge the Administration to work with ASTRO and the medical community to refine the proposal before finalizing.

CMS is also proposing a series of adjustments to capture the variety of resource costs associated with different types of care provided in E/M visits. These include the establishment of GCG0X *Visit Complexity Inherent to Evaluation and Management* and GPRO *Prolonged Evaluation and Management or Psychotherapy Service(s)*. Based on the August 22 CMS *Physician Fee Schedule Proposed Rule: Understanding 3 Key Topics* listening session, we understand that the complexity add-on code can be applied to radiation therapy services and that the code is not limited to those specialties listed in the proposed rule (Allergy/Immunology, Cardiology, Endocrinology, Hematology/Oncology, Interventional Pain Management-Centered Care, Neurology, Obstetrics/Gynecology, Otolaryngology, Rheumatology, and Urology). The listening session also clarified that there are no restrictions on the application of the prolonged service code, which can be applied in addition to a complexity add on code.

Currently, Radiation oncologists use level 4 and level 5 E/M codes frequently due to the complexity involved in reviewing the patient's chief complaint and history of present illness (HPI), performing a comprehensive multisystem examination, and walking the patient and their family through decision making that involves multiple diagnosis and management options that are often associated with a moderate to high risk of complications, morbidity and mortality.

ASTRO appreciates the proposed establishment of a complexity adjustment, as well as a prolonged visit adjustment. Should CMS move forward with this proposal, CMS should clarify the use of these critical add-on codes, as we anticipate that they will be used frequently by radiation oncologists given the complexity associated with cancer care.

MPPR

CMS proposes a multiple procedure payment reduction (MPPR) of 50 percent that is applied to the least expensive procedure or visit furnished on the same day by the same physician. This policy would apply to 5,000 codes, and, in most cases, it would reduce the office visit payment by 50 percent. **ASTRO believes the MPPR proposal is duplicative of existing RUC policy**

that is applied during the code valuation process. The RUC works diligently to ensure that there are no duplicative resource costs embedded in procedure codes that are typically performed with E/M services. ASTRO urges CMS to reconsider this proposal.

Unintended Consequences

To achieve the new blended rate for E/M services CMS proposes to modify the practice expense (PE) methodology by blending the PE per hour across all specialties that bill E/M codes, which is then weighted by the volume of those specialties' allowed E/M services. **ASTRO is concerned that the establishment of a payment based on pooled resources distorts the relativity of the Resource-Based Relative Value Scale, which is the foundation of the current payment system.**

In the 2007 proposed rule, when CMS changed the practice expense formula to its current "bottom up" methodology, there was a detailed step-by-step description regarding how the PE RVUs were calculated. CMS posted the data files needed to replicate this methodology on its website with the rule. In this rule, the PE calculation methodology description has not changed. However, the changes made to the inputs for the PE calculation are proposed to change in order to implement the E/M policy. The change to the service volume count in the utilization file, which is the starting point for the calculation, has large and unexplained changes in volume for services compared to the actual paid claims counts available in the 2017 Physician Supplier Procedure Summary File. These changes are also greater than the changes that are documented in the analytic crosswalk file that was released with the rule. It is important to note that CMS added a specialty of "E/M" to the PE per hour file but that new category does not appear on the utilization file. Presumably the office visit codes should be mapped to the EM specialty, but exactly which codes and how this was done is not explained.

Furthermore, it appears that as a result of these changes to accommodate the proposed E/M policy, the Indirect Practice Expense Cost Indices (IPCI) change significantly for some specialties. A new IPCI for office visits is proposed, and the indirect practice costs related to office visits are consequently excluded from each specialty's IPCI. IPCIs change the payment rates for all other, non-office procedure codes in the MPFS and in this rule they are particularly significant. The purpose of the IPCI is to adjust the practice expense payment for every service to account for variation in indirect practice costs by volume-weighted specialty. Based on the proposal, the radiation oncology IPCI would decline from 1.13118 in 2018 to 1.098763 in 2019, a 2.9 percent reduction. While this is a modest reduction in comparison to the significant shifts other specialties will experience should this proposal be finalized, it still represents an inappropriate reduction as a result of an error. **ASTRO urges the Agency to release all the data and the steps needed to replicate the methodology, so stakeholders can further analyze the implications of these changes and make meaningful contributions to the process.**

Finally, ASTRO recognizes that CMS is eager to accomplish efforts to streamline the E/M documentation process effective January 1, 2019. The AMA CPT/RUC Evaluation and Management Work Group was recently established to undertake such an effort and it may yield valuable approaches to improving the E/M documentation and billing process. We

urge CMS to remain open to modifying the E/M documentation and billing requirements as new concepts are brought forth.

CPT Code 77401 Radiation Treatment Delivery, Superficial and/or Orthovoltage, per day

In the proposed 2018 MPFS, CMS proposed to make separate payment for the professional planning and management associated with Superficial Radiation Therapy (SRT) using a HCPCS code G code. CMS received numerous responses regarding this proposal, none of which formulated any consensus around valuing the professional services associated with delivering SRT. In the final 2018 MPFS, CMS did not finalize the G code.

In the 2019 MPFS proposed rule, CMS continues to believe that coding gaps exist for SRT-related professional services. While the Agency is not proposing changes to SRT coding in this proposed rule, it is asking for stakeholder input regarding whether it would be appropriate to create multiple G-codes specific to services associated with SRT, such as planning, initial patient simulation visit, treatment device design and construction associated with SRT, SRT management and medical physics consultation.

ASTRO has provided guidance in previous comment letters recommending that this issue be addressed through the CPT/RUC process. However, in light of CMS' interest in developing G codes to account for services associated with SRT, ASTRO supports the establishment of three G-Codes to account for the planning, devices and management related to SRT. **We urge CMS to establish a series of three G-Codes based on crosswalks to existing codes. While we believe the work associated with the SRT steps below are not currently described by existing CPT codes, we believe the resources associated with the existing CPT codes below more closely approximates the resources used in these steps of the SRT process of care.** Below is a chart depicting the proposed crosswalk:

G-Code Description	Crosswalk Code	RVU Value
GRRR1 – SRT Treatment Planning (billed once per course of treatment)	77261 – Therapeutic Radiation Treatment Planning; Simple	1.30
GRRR2 – SRT Treatment Device (billed once per course of treatment)	77332 – Treatment Devices; Simple	0.45
GRRR3 – SRT Treatment Management (billed once per week)	99213 Office or Other Outpatient Visit for the Evaluation and Management of an Established Patient	0.97

Additionally, it has come to our attention that there is a significant increase in the billing of simulation, dosimetry, and image guidance services with superficial radiation therapy. It is ASTRO's opinion that a single simple simulation (CPT code 77280) and a single basic dosimetry calculation (CPT code 77300) to set up the field and calculate the monitor units may be billed for the whole course of treatment, if performed. Image guidance and tracking, however, are

indicated only when precise target localization is medically necessary. For example, this occurs when the target is known to move with respect to external or bony landmarks, when very precise localization of the target in three dimensions is necessary due to tight margins and immediately adjacent organs at risk, and when the chosen technology is capable of identifying that target movement/position or critical organ motion. **Superficial treatment of skin cancers do not meet these requirements, and therefore image guidance and tracking should not be billed with superficial treatments. ASTRO urges CMS to monitor and address the inappropriate use of these codes associated with the delivery of superficial radiation therapy.**

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act (PAMA) directs the establishment of appropriate use criteria (AUC) for advanced diagnostic imaging services. Evidence based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients. In the 2019 proposed MPFS, CMS' proposes that AUC consultation may be performed by "clinical staff working under the direction of the ordering professional, subject to applicable State licensure and scope of practice law." The Agency recognizes that the statute does not explicitly provide for consultations under the AUC program to be fulfilled by other professionals, individuals or organizations on behalf of the ordering professional. We appreciate that CMS is seeking ways to minimize the burden of the AUC program. **ASTRO supports flexibility for ordering professionals to delegate the AUC consultation to certain clinical staff with appropriate training, but not to non-clinical personnel.** We recommend that CMS revise its proposal to reflect language used in the preamble, "clinical staff," rather than "auxiliary personnel." Additionally, the we recommend that CMS require that the clinical staff be required to confer with the ordering professional and document it in the patient's medical record should the AUC consultation result in "not adhere" feedback. This would maintain the educational aspect of the program while allowing some flexibility for ordering professionals to delegate the AUC consultation to their clinical staff.

Merit-based Incentive Payment System (MIPS)

ASTRO appreciates the Agency's continuing efforts to drive consistency in MIPS from the 2018 performance year, but we remain concerned about the eligibility and incentive structure of the program, given the high cost of program compliance. The budget neutrality aspect of MIPS results in a limited amount of funds available for sharing among clinicians. Maintaining a high low-volume threshold reduces the number of eligible clinicians and further shrinks the available funds. Introducing the new opt-in performance opportunity decreases the pool more, as only clinicians participating fully in the program will likely opt-in. ASTRO members practicing in community or free-standing centers reported high performance, most scoring above the exceptional performance threshold of 70 points in 2017. However, those members who shared their data with ASTRO reported an average payment adjustment of approximately $30,000 in 2019, despite spending an average of $90,000 on system upgrades, data submission tools, staff time, and more to comply with MIPS program requirements. While some of these costs might be viewed as "one-time purchases," the complexity of the program, along with everchanging rules, means that practices will still be required to focus resources on

reporting, rather than improving patient care. The American Hospital Association estimates that "an average-sized community hospital devotes 4.6 FTEs – over half of whom are clinical staff – and spends approximately $709,000 annually on the administrative aspects of quality reporting. Duplicative and misaligned reporting requirements, many of which require manual data extraction, create inefficiencies and consume significant financial resources and clinical staff time."[1] **ASTRO recommends streamlining the MIPS program so that quality improvement can be achieved without the burden and significant cost of the current reporting requirements.**

MIPS Performance Threshold

CMS is proposing an increase in the performance threshold from 15 to 30 points. **ASTRO is requesting clarification on what data was utilized to determine the performance threshold increase. We understand that the goal of MIPS is to increase participation over time; however, we feel that setting performance expectations based on legacy programs is a flawed methodology that does not follow the intentions of the Medicare Access and CHIP Reauthorization Act (MACRA).**

In the proposed rule, CMS seeks comment on their approach to estimating the performance threshold for the 2022 MIPS performance year, which is based on the estimated mean final score for the 2019 MIPS payment year. **ASTRO believes that performance thresholds should be set at the mean, especially while participation levels vary.**

CMS also seeks comment on whether establishing a path forward to a performance threshold for the 2022 MIPS performance year that provides certainty to clinicians and ensures a gradual and incremental increase from the performance threshold for the 2019 MIPS performance year would be beneficial. **ASTRO believes that CMS should be using actual performance data rather than an arbitrary gradual threshold, and therefore we recommend that CMS use the mean moving forward.**

Clinician Eligibility

The proposed rule makes changes to the MIPS eligibility requirements by assessing low volume thresholds only against covered professional services paid under or based on the Physician Fee Schedule (PFS), instead of all Part B expenses, as in previous performance years. The proposed rule continues to set eligibility thresholds at greater than $90,000 in covered professional services and 200 Medicare Part B beneficiaries, who are furnished covered professional services. In addition, the proposed rule adds a new eligibility criterion: more than 200 covered professional services under PFS. Exceeding all criteria in the low volume threshold means that a physician or group will be included in the MIPS program for the 2019 performance year. CMS proposed the third criterion in its 2018 proposed rule but did not finalize it for the 2018 performance year. **ASTRO appreciates efforts to refine eligibility criteria; however, we**

[1] "Regulatory Overload Report: Assessing the Regulatory Burden on Health Systems, Hospitals, and Post-Acute Care Providers," American Hospital Association, October 2017, https://www.aha.org/system/files/2018-02/regulatory-overload-report.pdf

believe this new criteria will not have a meaningful impact on radiation oncology and should be removed. As we mentioned in our comment letter on the 2018 proposed rule, the existing two criteria appropriately identify whether an eligible clinician can participate in MIPS. **We believe that adding services furnished to Medicare enrollees has the potential to incentivize clinicians to focus on volume of services, rather than the value of services provided to patients.**

The Agency also proposes to allow clinicians or groups to opt-in to MIPS if they meet or exceed one or two criteria, but not all, of the low-volume threshold criterion. **ASTRO supports the proposal to allow clinicians to opt-in to the MIPS program; however, as mentioned above, we oppose the addition of the third criterion.** Additionally, we believe that the Agency's assumed numbers of clinicians who would opt-in are high, given the burden in reporting that has been documented. The Agency is also proposing that clinicians choosing to opt-in would be required to indicate their decision via the Quality Payment Program (QPP) website to receive a MIPS payment adjustment. ASTRO thanks CMS for allowing new and/or low-volume clinicians the opportunity to test their own data. **ASTRO requests that CMS provide detailed, widely disseminated and accessible educational materials to explain the opt-in policy to mitigate potential clinician confusion.**

Determination Period

CMS is proposing a single MIPS determination period that would be used for purposes of the low-volume threshold and to identify MIPS eligible clinicians and non-patient facing, small practice, hospital-based, and Ambulatory Surgical Center (ASC)-based, as applicable. The Agency is not proposing to include the facility-based or virtual group eligibility determination periods or the rural and Health Professional Shortage Areas (HPSA) determinations in the MIPS determination period, as they each require a different process or timeline that does not align with the other determination periods, or do not utilize determination periods. **ASTRO supports this proposal, as it aims to streamline an already complex process. We appreciate that the Agency recognized the burden placed on clinicians, especially those that may find out late in a performance year that they are no longer eligible to participate in MIPS, after significant resource outlay.**

Bonus Points

Complex Patients

CMS is proposing to keep the additional five bonus points to the overall Composite Performance Score (CPS) for complex patients based on the combination of the dual eligibility ratio and the average Hierarchical Conditions Category (HCC) risk score as finalized in the 2018 Final Rule. **ASTRO appreciates the Agency's consistency from year-to-year, and urges CMS to keep the complex patient bonus for future performance years.**

Small Practice Bonus

CMS proposes to continue to award five points to small practices for the 2019 performance year to be applied to the 2021 payment year. However, the small practice bonus will be added to the Quality performance category, rather than in the MIPS final score calculation. **While ASTRO appreciates CMS' support for additional opportunities for small practices to succeed in the MIPS program, we believe that the Small Practice Bonus should not be added to the Quality performance category and instead should remain a separate item in the final score calculation.** By moving this bonus to the Quality category, CMS will be removing an opportunity for a bonus from those clinicians who do not, or cannot, report quality measures. Additionally, the five points becomes inflated in cases where one or more performance categories are reweighted, giving an unfair advantage to those clinicians. Part of the burden of the MIPS program, as currently constructed, is the ongoing changes from year to year. Small practices feel this acutely, as they struggle to find the administrative resources to follow the details and adjust to program changes from year to year. Consistency in program rules, especially around scoring, is imperative for program success for small practices.

Virtual Groups

Under the proposed rule, CMS maintains the option for solo practitioners and groups with ten or fewer MIPS eligible clinicians to establish Virtual Groups. For all performance categories, the achievement of individual members of the Virtual Group will be combined to determine the entire groups' score. Virtual Groups must complete required contracting and notify CMS of their intention to become a Virtual Group by December 31, 2018 for the 2019 performance year. **ASTRO continues to support the concept of virtual groups as a means of supporting small practice participation in MIPS.** In light of the 2017 feedback data using the "Pick Your Pace" option, we believe clinicians need more time to review their own data, as well as potential partners' data, before entering into a Virtual Group agreement. Is it unclear why the election needs to be made prior to the performance period. **ASTRO recommends that CMS postpone the deadline until the third quarter of the performance year.** Other clinicians do not have to report or identify reporting participation intentions prior to a performance year, including those that can newly opt-in, and neither should virtual groups.

Finally, ASTRO once again seeks clarification on the intended benefits of virtual groups. In some ways, forming a virtual group may penalize some clinicians. For example, a practice defined as a small group could lose the designation by forming a virtual group and exceeding the 15-clinician threshold. In this case, the group would benefit more from the small practice benefits than the potential benefits of a virtual group.

MIPS Performance Categories

Performance Category Reweighting

CMS proposes to continue the automatic Promoting Interoperability (PI) exemption for hospital-based practices and hardship applications for the 2018 performance period. The Agency believes this is particularly important for small practices. The category exemptions re-weight the PI

category to zero. In previous performance years, category points were reweighted completely to the Quality performance category. CMS has heard from stakeholders in previous years that the reweighting policies place undue weight on the Quality performance category, and, although they continue to believe the policies are appropriate, they seek comment on alternative redistribution policies in which they would also redistribute weight to the Improvement Activities performance category. This policy would redistribute the weight of the Promoting Interoperability performance category to the Quality and Improvement Activities categories by redistributing 15 percent of the Promoting Interoperability performance category weight to the Quality performance category, and 10 percent to the Improvement Activities performance category. **ASTRO thanks CMS for acknowledging stakeholder views on reweighting. We believe redistributing weights to Quality and Improvement Activities more accurately weights the Improvement Activity category, which is the one performance category that we believe has the power to transform a practice and drive true quality improvement.**

Reporting Period for Promoting Interoperability and Improvement Activities Performance Categories

The Agency is seeking comments on changing the reporting period for the Promoting Interoperability and Improvement Activities categories to a full year for future performance years. **ASTRO opposes this change and believes that a 90-day reporting period is sufficient for both categories and does not need to be increased to a full calendar year.**

Quality Performance Category: Reporting Period

The Agency proposes to continue the full calendar year reporting period for the Quality category and is seeking comments on continuing the full calendar year for future program years. **ASTRO is disappointed that CMS is proposing to continue a full calendar year reporting period for the Quality category. A full year does not allow clinicians to assess measures, implement them into workflows and address quality improvement requirements. When compounded with the 60 percent data completion requirement, a full year of reporting is unreasonable for measures associated with a high volume of a clinician's patient population. Additionally, the year-long reporting period puts undue pressure on measure developers and registry vendors implementing new measures.**

Quality Performance Category: Data Completeness

CMS is proposing to maintain the data completeness threshold of 60 percent for the 2019 performance year, with a minimum of 20 cases per measure. CMS is also maintaining the 1-point floor for measures that do not meet data completeness requirements. This policy does not apply to small practices, who will continue to earn three points for submitting measures that do not meet data completeness. **We thank CMS for being consistent and helping small practices.**

CMS is proposing that measures impacted by clinical guideline changes, or other changes that CMS believes may pose patient safety concerns, will be given a score of 0 and the Quality performance category denominator would be reduced by 10. If this situation occurs, the clinician would be required to submit data for one less measure. **We appreciate that CMS recognizes**

that evidence can and does change, and the agency will notify clinicians in a timely manner. We ask that CMS establish an easy route of communication such as a dedicated web portal or email address for notification by measure developers to CMS of clinical guideline changes.

Quality Performance Category: Meaningful Measures Initiative

CMS has implemented the Meaningful Measures Initiative, which is a framework that applies a series of cross-cutting criteria to keep the most meaningful measures with the least amount of burden and greatest impact on patient outcomes. **ASTRO appreciates the Agency's effort, but we are concerned that the Agency will repeat domain requirements from legacy programs and believe that specialties, such as radiation oncology, will have difficulty developing and reporting measures in each of the domains. We therefore recommend a phased-in approach to ensure that all specialties can meaningfully contribute and participate.**

ASTRO also is concerned with CMS placing emphasis on outcome measures, as meaningful outcomes in a calendar year are difficult to measure in some diseases, including cancer. **Given that cancer treatment and meaningful outcomes cannot be measured neatly in the course of one year, ASTRO recommends that CMS continue to support the use of process measures until they can feasibly be converted to meaningful outcome measures in cancer care.**

Quality Performance Category: Topped-Out Measures

CMS is proposing to retain the 4-year process for identifying and phasing out "topped out measures". **ASTRO appreciates the consistency of these rules, but reiterates our previous concerns that removing topped out measures does not support the MIPS program nor quality improvement, especially when there are limited new measures to introduce.** CMS is also proposing that for those measures that reach a new designation of "extreme topped out" status (measures that are topped-out with an average performance rate between 98-100%), the Agency may propose removal during the next rulemaking instead of waiting through the four-year cycle. **ASTRO opposes the inclusion of a new category of topped out measures.** Measure development is a long, resource intensive process, and measure developers need time to develop new measures to take the place of those that are topped out. Further, the current topped out measure designation is still based either on Physician Quality Reporting System (PQRS) data or MIPS data from "Pick Your Pace", and therefore data is being used to set performance rates that is not representative of the current program. **We urge the Agency to remain conservative in the designation of topped out measures to balance the number of measures removed from MIPS with the number of new measures added to the program.** Removing topped out measures, including extreme topped out measures, from MIPS will significantly reduce reporting options for specialties and small practices.

As part of the extreme topped out designation, the Agency is proposing to remove Radiation Dose Limits to Normal Tissue (NQF #0382) measure. **ASTRO opposes the removal of this measure as it promotes patient safety and actively reduces toxicity.**

Finally, because approximately 69 percent of the Medicare Part B claims measures are topped out, the Agency is proposing allowing small practices to submit quality data for covered

professional services through the Medicare Part B claims submission type for the Quality performance category, while removing that option for everyone else. **ASTRO appreciates that CMS is trying to ease burden for small practices; however, the removal of claims reporting contradicts the provisions in the Balanced Budget Act of 2018 (BBA) that move the Agency toward accepting more claims data.** ASTRO requests a clear directive from CMS so measure developers and reporting clinicians can develop long-term plans for success. Additionally, CMS is not including individual clinicians in the small practice designation for this policy when the definition of small practices is 15 clinicians or less, including individual clinicians**. CMS should use consistent definitions and designations throughout the program and provide individual clinicians the opportunity to submit Quality data using claims.**

Quality Performance Category: Future Scoring

CMS is requesting feedback on Quality scoring options in future years, including a proposal to value each quality measure against the Agency's priorities. Some values would equate to higher weights, which could decrease the number of measures required. CMS is exploring a new system where measures are classified at a particular value (gold, silver, or bronze) and points are awarded based on the value of a measure. For example, higher value measures that are considered "gold", could include outcome measures, composite measures, or measures that address agency priorities. Second tier or "silver" measures could be process measures that are directly related to outcomes and have a good gap in performance. Lower value measures or "bronze" measures could be standard of care process measures or topped out measures. **ASTRO thanks CMS for recognizing the burden of reporting on quality measures and agrees that valuing measures is important. We request the Agency be transparent with its chosen methodology and urge CMS to work closely with specialties to ensure appropriate valuation of measures. Additionally, ASTRO requests aligning the naming convention of valued measures with that of the Improvement Activities category, i.e. high weight. This consistent naming will help clinicians understand the change. Additionally, ASTRO requests clarification on how this proposal, specifically the low (bronze) weighted measures, would integrate with the 4-year topped out measure cycle.**

CMS offers one option for simplification, which would restructure the quality requirements with a predetermined denominator, for example, 50 points, but no specific requirements regarding the number of measures that must be submitted. As part of this proposal, the Agency suggests restricting the number of lower tier measures that could be submitted and/or requiring a certain number of high tier measures. **ASTRO supports the concept of restructuring the requirements for scoring the Quality category, thereby streamlining the Quality scoring and aligning it with the scoring for the Improvement Activities category. We are concerned, however, that there are specialties that do not have complex measures that would fall into the high-priority or "gold" status. Further, we believe that restricting submission of lower tier measures, and mandating a number for higher tier measures, should not be implemented until specialties have an opportunity to create measures to align with this new direction.**

CMS also proposes an alternative of keeping the current approach for the Quality performance category requiring 6 measures, including one outcome measure, with every measure worth up to

10 measure achievement points in the denominator, but change the minimum number of measure achievement points available to vary by the measure tier. **ASTRO believes that this approach adds complexity to an already complex scoring methodology and recommends that if the Agency is going to change the scoring for the Quality category, they choose the first option.**

Cost Performance Category: Overall Category

CMS is proposing to add 8 newly developed episode-based cost measures. Cost measures will continue to include Medicare Spending Per Beneficiary (MSPB) and total per capita cost for all attributed beneficiaries. **ASTRO appreciates the opportunity to work with the Agency and Acumen LLC on the development of meaningful episode-based cost measures as part of the Lumpectomy/Partial Mastectomy Clinical Subcommittee. While this has been a valuable experience, we urge CMS and the Acumen team to focus on developing episode-based cost measures that are specific to discrete episodes of care. While there seems to be interest in developing broader episode-based cost measures that encompass a variety of services, this can be challenging because there is so much variation in the delivery of care. Once costs associated with discrete episodes are fully developed, then they can be aggregated to establish broader episode-based cost measures, which can account for variation within specialty-specific services leading to more comprehensive measure development.**

The BBA provided flexibility in the weighting of the Cost category, and CMS is proposing a 15 percent weight for the category for 2019, with a 5 percent increase each year until the 2022 performance year when the category will be weighted at 30 percent. **ASTRO is pleased that the Agency is taking advantage of the flexibility provided to it by the BBA of 2018 in weighting the Cost category.** CMS is seeking comments on redistributing weight to the Cost performance category in future years. **ASTRO recommends that the Agency continue to delay an increase in the weighting of the Cost category until all specialties can meaningfully contribute to the Cost category.**

The BBA of 2018 also retroactively delayed implementation of improvement scoring in the Cost category until the 2022 performance year. As a result, improvement scoring would be removed from the 2019 performance year. **ASTRO supports this decision and thanks Congress for enacting legislation to delay this requirement.**

Cost Performance Category: Future Performance Periods

CMS is seeking comment on expanding the performance period for the cost performance category measures from a single year to 2 or more years in future rulemaking. The Agency believes this would allow them to more reliably measure a larger number of clinicians. For radiation oncology, and other specialties, the attribution of the current measures is not about the amount of measurement time, but rather that the cost measures are not geared toward radiation oncology. **ASTRO does not support the extended measurement period without knowledge that radiation oncology has valid and reliable cost measures meaningful to the specialty. Further, we are concerned that implementing a 2-year cycle would add complexity to the program and would complicate scoring of this category.** Additionally, we request clarification on how payment would be adjusted during the "off years".

Improvement Activities Performance Category: Overall Category

ASTRO appreciates the Agency's decision to maintain most elements of the Improvement Activities performance category. Consistent requirements and expectations help clinicians succeed. CMS has proposed new Improvement Activities and modifications to existing activities and **ASTRO is pleased to see so much focus on the patient experience and overall care.**

CMS is proposing to remove the availability of a bonus score within the Promoting Interoperability performance category for attesting to completing one or more specified Improvement Activities using certified EHR technology (CEHRT) for the 2019 performance year. **ASTRO opposes the removal of the bonus score; however, we appreciate that the Agency is proposing to automatically apply high-weighting for Improvement Activities employing CEHRT.**

Promoting Interoperability Performance Category: Performance Threshold

The performance threshold for the Promoting Interoperability category is set at 100 points under MIPS. While at the same time, clinicians reporting under the PPS-Exempt Cancer Hospitals Quality Reporting (PCHQR) Program only need to achieve 50 points to "pass" the same metrics. **ASTRO recommends that CMS align all quality reporting programs, including the PCHQR, Hospital Outpatient Quality Reporting (HOQR) Program, and MIPS.** Alignment across all programs will reduce physician burden and confusion and would provide CMS with more meaningful and comparative quality data.

Promoting Interoperability Performance Category: EHR Certification

CMS is proposing that eligible clinicians must use 2015 Edition CEHRT for the 2019 performance year. **ASTRO is disappointed that CMS is removing the option of using 2014 Edition CEHRT.** Not all radiation oncology EHR vendors have a 2015 Edition available and removing the 2014 Edition option could harm radiation oncologists' chances to succeed in the MIPS program, through no fault of their own. Eligible clinicians do not have control over the EHR products issued by vendors and penalizing providers for not achieving any level of CEHRT status must be avoided at all cost. **ASTRO recommends that CMS continue to allow the use of 2014 Edition CEHRT for those clinicians that do not have a 2015 CEHRT product available to them until all EHR vendors, across all specialties, are 2015 certified. Further, we strongly recommend that the Agency require EHR vendors to comply with 2015 Edition requirements.**

We appreciate that clinicians can utilize the hardship application if they do not have access to 2015 CEHRT, and that 2014 CEHRT will not be decertified. We request information on whether there will be a time limit for the uncontrollable circumstances hardship for 2014 CEHRT.

Promoting Interoperability Performance Category: Scoring Methodology

The Agency is proposing a new scoring methodology based on performance on a set of required measures, with the goal of increasing focus on patient care and health data exchange through

interoperability. **While we appreciate the Agency's goal of the new Promoting Interoperability performance category, we believe that the new goal will be very difficult to achieve.** Radiation oncology data, for example, is housed in multiple electronic systems, including treatment planning software, oncology specific EHRs, hospital EHRs and others. Most of these systems struggle to interface with one another, making true interoperability difficult to achieve. **We again urge the Agency to mandate that EHR vendors comply with the requirements set forth in the MIPS program and not hold physicians accountable for the lack of EHR infrastructure to meet program goals. We also ask that the Agency broaden their scope of interoperability to promote that data exchanged, whether between EHRs, from EHR to registry or to a digital device, be exchangeable, usable and impactful toward patient care.**

Under the Promoting Interoperability category, clinicians are required to report measures from each of the newly reduced objectives (e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange). If a clinician fails to report on a required measure, or claims an exclusion for a required measure, the clinician would receive a total score of zero for the PI performance category. Each measure would be scored based on the performance for that measure, which is based on the submission of a numerator and denominator, except for the measures associated with the Public Health and Clinical Data Exchange objective, which requires "yes or no" submissions.

While CMS is further implementing the program, we believe that the new scoring methodology removes much of the flexibility found in past years. These proposed changes, coupled with the requirement for 2015 Edition CEHRT, may level the playing field, but it will increase clinician burden.

The following chart shows the proposed scoring methodology:

Objectives	Measures	Maximum Points
e-Prescribing	e-Prescribing	10 points
	Bonus: Query of Prescription Drug Monitoring Program	5 bonus points
	Bonus: Verify Opioid Treatment Agreement	5 bonus points
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points

Public Health and Clinical Data Exchange	Choose two of the following: • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting	10 points

The Agency is proposing two new bonus measures to the e-Prescribing objective: Query of Prescription Drug Monitoring Program (PDMP) and Verify Opioid Treatment Agreement. **ASTRO appreciates the low-threshold required (1 in the numerator) to receive the bonus, and we understand why CMS is proposing inclusion of these bonus measures; however, we request that they remain as bonus measures until the Agency can confirm that all health IT vendors have incorporated them into their systems.** If, however, the Agency finalizes the proposal of requiring these measures beginning in the 2020 performance year, the Agency is proposing that for those clinicians who request an exemption, the points will be redistributed to the e-Prescribing objective. This is problematic for those clinicians, such as radiation oncologists, who already request an exclusion from the e-Prescribing objective. **ASTRO recommends that instead of redistributing the points to an objective that many clinicians are excluded from, the Agency either lower the denominator or provide flexibility in redistributing the points.**

CMS is seeking comment on the impact that implementing these measures could have on patients who receive opioids due to medical diagnoses such as cancer or receiving hospice care, as well as treatment of patients under a program involving substance abuse education, treatment, or prevention under 42 CFR Part 2. **ASTRO understands that the Administration wants to curb opioid use to reduce addiction rates; however, use of opioids to reduce pain in cancer patients is an important tool that should not be disincentivized. We urge the Agency to continue to take this into consideration as they move forward with implementing the goals of the Administration.**

CMS is seeking comment on adoption of the proposed new measure, Electronic Referral Loops by Sending Health Information, that combines the Request/Accept Summary of Care and Clinical Information Reconciliation measures, or whether either or both of the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures should be retained in lieu of this proposed new measure. **ASTRO believes that the Agency should keep the existing measures to provide more flexibility in reporting. In addition, if the measures are combined, we request an exemption for those specialties that refer less than 100 patients per year. If no exemption is offered, then we request clarification on how clinicians, who would otherwise be exempt from one of the measures, comply with this requirement.**

CMS seeks comment on the impact these proposed modifications may have for health IT developers in updating, testing, and implementing new measure calculations related to these proposed changes. Specifically, the Agency is seeking comment on whether the Office of the

National Coordinator (ONC) should require developers to recertify their EHR technology as a result of the changes proposed, or whether they should be able to make the changes and engage in testing without recertification, and on the appropriate timeline for such requirements factoring in the proposed continuous 90-day performance period within the calendar year for clinicians. **ASTRO believes that interoperability among all EHRs will reduce burden for everyday practice, but shouldn't necessarily be tied to a recertification requirement, as this enhancement will inevitably be transferred to an expensive upgrade requirement for clinicians. ASTRO recommends that CMS put pressure on EHR vendors to increase interoperability in a way that will not require significant resource outlay by clinicians.**

CMS is also seeking comment on two potential new measures for future rulemaking (*Support Electronic Referral Loops by sending Health Information Across the Care Continuum* and *Support Electronic Referral Loops by Receiving and Incorporating Health Information Across the Care Continuum*) to enable MIPS eligible clinicians to exchange summary of care records to support care coordination across a wide range of settings. **ASTRO applauds the new measures promoting safe transitions for the frailest community; however, we request that implementation of these measures include an exemption. Some medical specialties, such as radiation oncology, may not meet an appropriate threshold to report these measures. ASTRO also appreciates the new flexibility for relevant Consolidated Clinical Document Architecture (CCDA) documents; however, some clinicians will still have technical issues as an EHR cannot electronically send a CCDA if the receiver does not have Direct Secure Messaging ability.**

In 2018, CMS retroactively created exclusions for some Promoting Interoperability metrics for clinicians that could not meet a certain threshold of cases. One of these measures was e-Prescribing, whereby a clinician could claim an exclusion if they e-prescribed less than 100 times during a performance year. CMS is proposing that if a MIPS eligible clinician claims the exclusion in 2019, the 10 points available would be redistributed equally among the two measures under the Health Information Exchange objective. **ASTRO is seeking clarification as to what happens if neither of the Health Information Exchange measures are available to clinicians**. **We request that reweighting should be more flexible to account for the patient populations of different practices and specialties. We recommend consistency with the Quality category rules – if a clinician does not have anything to report, the denominator is decreased.**

Promoting Interoperability Performance Category: Measures

CMS is proposing that the Protect Patient Health Information objective and its associated measure, Security Risk Analysis, would remain part of the requirements for the Promoting Interoperability performance category, but would no longer be scored as a measure and would not contribute to the performance category score. The Agency believes that MIPS eligible clinicians should already be meeting the requirements for this objective and measure, as it is a requirement of the Health Insurance Portability and Accountability Act (HIPAA). **ASTRO recommends removing the Security Risk Analysis from the MIPS program, if it will not be part of scoring, since it is already mandated by HIPAA compliance requirements.**

CMS intends to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022. The agency is seeking public comment on whether MIPS eligible clinicians will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective is removed, as well as other policy levers outside of the Promoting Interoperability performance category that could be adopted for continued reporting to public health and clinical data registries, if necessary. **ASTRO recognizes the important role that sharing public health and clinical data plays in furthering cancer research, and we believe that these measures, shared across tools and registries, support this important goal.**

Facility-Based Quality and Cost Performance Categories

CMS is proposing to expand facility-based scoring for the 2019 performance year to physicians in on-campus outpatient hospitals, where facility-based clinicians can use their facility's Hospital Value-based Purchasing (VBP) score as a proxy for their Quality and Cost Performance Categories. The scoring proposal will apply to MIPS eligible clinicians who furnish 75 percent or more of their covered professional services in an inpatient hospital (POS code 21) or on-campus outpatient hospital (POS code 22) or an emergency room (POS code 23), based on claims for a period prior to the performance period. However, the clinician must have at least a single service billed with the POS code used for the inpatient hospital or emergency room. The Agency is proposing that the facility-based measurement be automatically applied to MIPS eligible clinicians and groups who are eligible and who would benefit by having a higher combined Quality and Cost score. **We applaud CMS for looking at quality and value in a holistic approach by proposing to include this option for the 2019 performance year. We recommend that CMS include this eligibility with the special status listed on the QPP website early in the performance year to reduce burden for physicians.**

In the case of an eligible clinician providing services at multiple facilities, attribution is to the hospital at which they provide services to the most Medicare patients. A facility-based group is attributed to the hospital at which a plurality of its facility-based clinicians is attributed. If a clinician's performance cannot be attributed to a facility with a VBP score, then that clinician is not eligible for facility-based measurement and will have to participate in MIPS by other methods. **ASTRO appreciates CMS' recognition that many clinicians work in a variety of clinical settings and believes that this proposal will be meaningful.**

<u>Qualified Clinical Data Registry (QCDR)</u>

ASTRO supports CMS' proposal to modify the definition of a QCDR to require that an approved entity have clinical expertise in medicine and quality measurement, starting in the 2020 MIPS performance year. **ASTRO appreciates CMS's observations that approved entities should have expertise in medicine and quality measure development and supports this new definition. We request further information on how "clinical expertise" will be defined, as many commercial entities can still have 1 to 2 clinicians on staff.**

The Agency is proposing that, starting with the 2020 MIPS performance year, QCDRs must have at least 25 participants by January 1 of the year prior to the performance period—in this case, the

2019 performance year. **ASTRO opposes this proposal because it hinders the growth of new QCDRs.** New QCDRs will not have enough participants by January 1 and will therefore not be able to grow their database.

While not included in the proposed rule, CMS recently announced by email that all QCDRs must be "up and running on January 1 for the 2018 performance period." Coupled with the proposal for QCDRs to have 25 participants by January 1 of the year prior to the performance period, this requirement is unrealistic. CMS does not publish QPP quality measure specifications until the end of December of the year prior to the performance period—for example, 2019 QPP measure specifications are not scheduled to be published until December 27, 2018. This provides only two business days to implement the measures based on the new specifications—which is simply not feasible. While most specifications do not change, even minor revisions take significantly longer than two days to enter and test. Additionally, few providers are prepared to begin reporting and monitoring quality on January 1, as submissions for the prior year are just commencing at that time. We recommend that CMS work with stakeholders to develop a timeline that is feasible and leads to properly functioning QCDRs that can meet the goals of the MIPS program and the requirements of the MACRA law.

CMS is proposing a revision to an established self-nomination period by moving the submission date earlier by two months. This change could have significant effect on QCDR owners and measure developers. **ASTRO opposes this revision, as the newly proposed self-nomination deadline would fall prior to the proposed rule for the same performance year, thereby removing any insight and proposals that CMS might offer in the rule.**

To encourage reporting of QCDR measures, CMS seeks comment on an approach to develop QCDR measure benchmarks based off historical measure data, requiring QDCRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS. **ASTRO supports this approach, as most QCDRs likely have historic data to show a performance gap. However, ASTRO requests clarification on how this would be handled in the case of a new measure concept.** Current MIPS measures are graded against PQRS data, which had different eligibility, so we do not believe requiring the historical data to be from only MIPS eligible clinicians would be necessary.

CMS is maintaining one benchmark for registries, including clinical quality measures (CQMs) and electronic clinical quality measures (eCQMs). **ASTRO, along with many other stakeholders, have requested the creation of a separate benchmark for eCQMs.** The data pulled directly from a practice EHR can have a very different result than cases specifically chosen for reporting and manually entered. ASTRO has data showing a difference of up to 30 points between manual entry and electronic benchmarks for multiple measures. In all cases the benchmark for the electronic data entry has been lower. Utilizing a combined benchmark is not accurate for those using manual entry, nor those using eCQMs.

CMS is proposing that beginning in 2019, a QCDR owner would be required to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure for purposes of MIPS. If a QCDR refuses to enter into such an agreement, the QCDR measure would be rejected and another measure of similar clinician concept or topic may be

approved in its place. **ASTRO thanks CMS for listening to the concerns from QCDR owners about measure sharing; however, we are very concerned about the possible infringements on intellectual property and having CMS act as a guardian to specialty specific measures instead of the specialty itself.** Additionally, we are concerned that, as proposed, the change would go into effect before the requirements are finalized for the 2019 performance year. We ask that other solutions be considered, such as a recommended process for sharing measures instead of a mandated legal agreement.

Other Issues

CMS is proposing that beginning with the 2020 MIPS performance period, MIPS eligible clinicians, other than small practices, will receive zero measure achievement points. Small practices will continue to receive 3 points. **ASTRO disagrees with this proposal and believes that if a practice submits data, they should receive recognition for achievement.**

CMS is seeking comment on combining measures so MIPS eligible clinicians could report once for credit across all three performance categories. One challenge identified is the lack of measures and activities that share identical and aligned requirements across the three performance categories. CMS is seeking comment on this reporting model, as well as measure and activity suggestions to enhance the link between the three performance categories. **ASTRO believes that this concept could reduce burden and align the separate performance categories. However, we agree that significant alignment is currently lacking and urge the Agency to work with stakeholders to ensure that all specialties can succeed with such a change.** To reiterate our previous comments, the importance of Improvement Activities should have more focus as they can lead to true practice transformation.

To promote measurement that provides clinicians with measures that are meaningful to their practices, CMS intends to consider proposing in future rulemaking MIPS public health priority sets across the four performance categories (Quality, Improvement Activities, Promoting Interoperability, and Cost). **ASTRO appreciates that CMS is considering public health priority sets across performance categories, and not just focusing on the Quality category. We request that the Agency work with stakeholders to ensure that all specialties can succeed in reporting these types of measures.**

In the discussion of advanced diagnostic imaging in the proposed rule, CMS sites Table II.8 of the 2014 Medicare Statistic Book, which combines many specialties into higher level groupings and displays the total number of practitioners participating in the Medicare program. Radiation Oncology is listed as a sub-specialty under Radiology. **We respectfully request that Radiation Oncology be moved under the "Medical" subheading under the "All Physician Specialties" heading, as radiation oncology and radiology are two distinct specialties.**

CMS invites comments on how the Agency can incorporate incentives for the use of electronic clinical quality measurement into future approaches, as well as other ways to encourage more efficient technology-enabled measurement approaches. **Unfortunately, what is clinically relevant in quality measurement is not always a codified field, meaning the specialty eCQMs are limited. We request assistance from the Agency on developing standards for**

cross-cutting and specialty specific data elements, thereby furthering the Administration's focus on interoperability and data access.

Alternative Payment Models (APMs)

ASTRO appreciates the Agency's efforts to clarify specific requirements within the APM program in the 2019 MPFS proposed rule. However, we remain concerned about the complexity of the APM program, as well as the lack of specialty-specific Advanced APMs. ASTRO continues to devote significant time and resources to support the development and adoption of a radiation oncology-focused APM that meets CMS criteria. We are hopeful that efforts to collaborate with the CMS Innovation Center on the development of such a model will prove fruitful and result in the launch of viable advanced APM option for the field of radiation oncology very soon.

Changes to Partial QP MIPS Participation Requirements

Clinicians who do not meet the Qualified APM Participant (QP) threshold but are participating in an advanced APM and meet a slightly lower threshold of APM participation are deemed Partial Qualified APM Participants or Partial QPs. Beginning with the 2019 performance year (2021 MIPS payment year), eligible clinicians who are deemed by CMS as Partial QPs can elect whether to report to MIPS. If the eligible clinician elects to report to MIPS, he or she will be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician elects not to report to MIPS, he or she will not be subject to MIPS reporting requirements and payment adjustments. For those eligible clinicians who do not affirmatively elect to report to MIPS, he or she will not be subject to MIPS reporting requirements and payment adjustments. Thus, CMS requires eligible clinicians who qualify as Partial QPs to actively affirm their interest in participating in MIPS. **ASTRO appreciates this clarification and the opportunity it provides for Partial QPs to either comply with MIPS reporting requirements or fully commit to participation in an Advanced APM. This option enables Partial QPs to fully focus on delivering value-based care that may not be enhanced by the MIPS reporting requirement.**

MIPS APMs

In last year's rulemaking, CMS finalized a MIPS APM scoring standard that would reduce the MIPS reporting burden for participants. As a result, MIPS eligible clinicians are scored at the APM entity group level and receive the APM entity's final MIPS score.

In the 2019 MPFS proposed rule, CMS seeks to clarify the requirement for MIPS APMs to assess performance on quality measures and cost/utilization; modify the Promoting Interoperability (PI) reporting requirement related to the shared savings program; and update the MIPS APM measure sets.

In the 2017 final rule, CMS finalized the following requirements for MIPS APMs: 1) APM entities participate in an APM under an agreement with CMS or by law or regulation; 2) the APM requires that the APM Entities include at least one MIPS eligible clinician on a

Participation List; and 3) the APM bases payment incentives on performance (either at the APM entity or eligible clinician level) on cost/utilization and quality measures.

Stakeholder feedback on the established criteria has indicated that there is some confusion regarding the intent of the third criterion. CMS proposes to modify the criterion to specify that a MIPS APM must be designed in such a way that participating APM Entities are incented to reduce costs of care or utilization of services, or both. According to the Agency, this makes it clear that a MIPS APM could take into account performance in terms of cost/utilization using model design features other than the direct use of cost/utilization measures.

ASTRO appreciates this clarification regarding MIPS APMs. However, we remain concerned that there are a limited number of Advanced APMs and even MIPS APMs for eligible clinicians to participate in, and we continue to urge the Agency to work with specialty groups to develop a broader array of options so that participation in alternative payment models can grow and develop.

Advanced APMs

CMS is proposing three key modifications to the Advanced APM requirements. First, the Agency proposes to increase the Advanced APM CEHRT threshold to 75 percent of eligible clinicians from the previous threshold of 50 percent for Medicare APMs in 2019 and All Payer Combination APMs in 2020. The Agency believes this proposed change aligns with increased adoption of CEHRT among providers and suppliers that is already taking place.

CMS is also proposing to streamline the definition of a MIPS comparable measures in the Advanced APM criteria to reduce confusion and burden. Specifically, the Agency is proposing that at least one of the quality measures upon which an Advanced APM bases payment on must be finalized on the MIPS final list of measures, be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidence-based, reliable and valid.

In past rulemaking, CMS required outcomes measures, when they are available, for Advanced APMs but has not provided explicit qualifiers for outcomes measures. In the 2019 proposed rule, CMS is seeking to explicitly require the use of at least one outcome measure that must be evidence-based, reliable, and valid. The Agency will continue to recognize that outcomes measures are not available or applicable to all APMs.

Finally, CMS is proposing to retain the 8 percent revenue-based nominal amount standard for Advanced APMs through performance year 2024 that was initially established in the 2017 QPP final rule. CMS believes that 8 percent of APM entity Medicare Parts A and B revenues represents an appropriate standard for more than a nominal amount of financial risk.

ASTRO is pleased that the Agency plans to retain the 8 percent nominal revenue at risk standard through 2024. This decision provides APM entities and physicians with the stability necessary to achieve sustainable value-based payment over a period of time. MACRA already provides for steep increases in financial risk requirements for Advanced

APMs over time by increasing the percentage of participants' revenues that must come through the APM for participants to attain Qualified APM Participant (QP) status.

ASTRO remains concerned that the methodology to determine "more than nominal financial risk," whether it be expenditures or revenue, does not take into consideration the variation in operating costs associated with different specialties. The risk associated with operating a practice with high fixed costs is particularly acute for some specialties, including radiation oncology. Specialties with higher fixed costs must make significant investments in equipment and technology in comparison to other specialties, where the fixed costs are lower due to less reliance on capital-intensive investments. Practices with significant fixed costs have limited variable costs. Savings are typically generated on reducing variable costs, not fixed costs.

The minimum total capital required to open a freestanding radiation oncology center is approximately $5.5 million. These facilities require an additional minimum $2 million in annual operating and personnel expenses. These significant fixed investments far outweigh the variable costs of operating a radiation oncology clinic and should be given consideration as part of any alternative payment model nominal risk adjustment. While it is important to reduce the cost of care and drive value in healthcare, it is also important to ensure that efforts to generate savings do not cause access to care issues for patients treated in specialties with high fixed costs. This is particularly important for practices operating in rural areas. **ASTRO urges CMS to seriously consider this issue and its impact on specialties with high fixed costs. In order for high-fixed costs specialties to successfully participate in APMs, modifications must be made to the nominal financial risk methodology to account for this distinction.**

ASTRO appreciates clarification regarding "MIPS Comparable Measures" requirements for Advanced APMs. **Requiring APMs to include just one MIPS measure that is endorsed by a consensus-based entity; or otherwise determined by CMS to be evidence-based, reliable and valid will reduce the reporting burden. It will also give APMs the opportunity to test other measures that may be more meaningful to achieving the goals of the APM.**

As for outcomes measures, ASTRO appreciates CMS' recognition that they are not widely available or applicable to all APMs. **As previously stated, we remain concerned that CMS is placing too much emphasis on outcome measures, particularly given that cancer treatment and meaningful outcomes cannot be measured neatly within a distinct period of time, ASTRO recommends that CMS continue to support the use of process measures until meaningful outcome measures in cancer care are available.**

Finally, ASTRO urges CMS to retain the 50 percent CEHRT threshold requirement. As previously stated, we appreciate the Agency's goal of promoting interoperability, however we believe it will be difficult to achieve and additional time is required. Radiation oncology data, for example, is housed in multiple electronic systems, including treatment planning software, oncology specific EHRs, hospital EHRs and others. Most of these systems struggle to interface with one another, making true interoperability difficult to achieve. We again urge the Agency to mandate that EHR vendors comply with CEHRT requirements and not hold physicians accountable for the lack of EHR infrastructure to meet program goals. We also ask

that the Agency broaden their scope of interoperability to promote that data exchanged, whether between EHRs, from EHR to registry or to a digital device, be exchangeable, usable and impactful towards patient care.

Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

In an effort to encourage greater participation in alternative payment arrangements, CMS proposes to launch the MAQI Demonstration in the 2019 MPFS proposed rule. Currently, MIPS eligible clinicians are required to comply with MIPS reporting requirements, even if they are participating in an alternative payment arrangement with a Medicare Advantage Organization (MAO).

The MAQI demonstration exempts MIPS eligible clinicians from MIPS reporting requirements and is designed to test whether excluding MIPS eligible clinicians from MIPS reporting requirements will result in increased or continued participation in other payment arrangements similar to Advanced APMs. MIPS eligible clinicians seeking to participate in the MAQI demonstration must become a designated Qualified Participant (QP). To become an eligible QP the clinician must meet 1) either the patient or payment thresholds required for Advanced APM QP status and 2) submit required documentation regarding the MAO alternative payment arrangement.

The requirements for qualifying payment arrangements under the MAQI demonstration will be the same as the Advanced APM requirements, which include the use of CEHRT, MIPS comparable measures, and the establishment of two-sided risk that involving a nominal amount at risk.

ASTRO appreciates that CMS continues to expand its commitment to the establishment of alternative payment models. We agree that MIPS eligible clinicians participating in alternative payment arrangements with MAOs should qualify as Advanced APM participants if they meet established QP Standards. While we appreciate the desire to see more physicians participate in APMs, we remain concerned that the number of available APMs remains limited, particularly for radiation oncologists. ASTRO urges CMS to approve the radiation oncology APM that has been under consideration by the Agency over the last several months.

Request for Information on Price Transparency

In an effort to secure greater price transparency for health care services, CMS is seeking comment on whether providers can and should be required to inform patients about charge and payment information for healthcare services and out of pocket costs. Additionally, effective January 1, 2019, the Agency proposes to update its guidelines to require hospitals to make available a list of current charges via the Internet in a machine-readable format and to update this information at least annually, or more often as appropriate.

As part of a Request for Information, the Agency is considering additional actions that further engagement with consumers regarding the cost of care, particularly the patient's financial liability for services they obtain. CMS is seeking public comment on the following:

- How should we define "standard charges" in various provider and supplier settings? Is there a definition for those settings that maintain chargemasters, and potentially a different definition for those settings that don't maintain chargemasters?

- What types of information would be most beneficial to patients? How can CMS and providers help third parties create patient-friendly interfaces with these data?

- Should providers and suppliers be required to inform patients how much their out-of-pocket costs for a service will be?

- Can we require providers and suppliers to provide patients with information on what Medicare pays for a particular service?

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care?

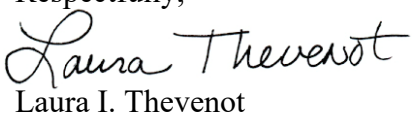
ASTRO appreciates CMS' interest in providing patients with more information regarding the cost of care. Financial toxicity has become a growing problem for patients, particularly for cancer patients, forcing many into bankruptcy. ASTRO recognizes that the process of setting prices for the cost of healthcare is exceedingly complex, which makes it difficult to provide patients with accurate pricing information. Payer coverage policies that vary by healthcare plan further complicate efforts to make healthcare pricing transparent and meaningful.

It is important to understand the distinction between costs and charges associated with a given healthcare service. The actual cost to the provider may not be reflected in the charges. This is further complicated in the Hospital Outpatient Prospective Payment System (HOPPS) setting, in which charge masters are not always regularly updated and could be based on inaccurate cost data. In addition, the provider/payer negotiation process frequently yields agreed upon pricing that sometimes is not reflective of the cost of services provided.

ASTRO believes that the most helpful information that can be provided to patients is information regarding out-of-pocket costs. These costs are the responsibility of the patient and will help them make decisions regarding their care. Additionally, this is information that providers can share, but it requires partnership with payers, including Medicare, to provide this information in an efficient and clear manner. We urge CMS to use caution in providing any information regarding the total cost of care, as per the discussion above, this is laudable goal but potentially unachievable. Additionally, many patients equate higher costs with higher quality of care, and therefore providing this type of information may only drive up the cost of care as patients continue to believe that money can buy them good care and good health.

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 Anne Hubbard, Director of Health Policy, at 703-839-7394 or anne.hubbard@astro.org.

Respectfully,



Laura I. Thevenot
Chief Executive Officer