

September 5, 2019

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 2020

Dear Administrator Verma:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the “Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations” published in the *Federal Register* as a proposed rule on August 14, 2019.

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 Quality Payment Program (QPP) effective January 1, 2020. 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:

- Conventional Treatment Delivery, IMRT and Image Guidance Codes (G6001-G6015)

- CPT Code 55874 *Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed*
- Proposed Updates to Direct Practice Expense Inputs for Supply and Equipment Pricing
- Evaluation and Management Code (E/M) Modifications
- Geographic Practice Cost Indices (GPCIs)
- Malpractice RVUs
- Merit-based Incentive Payment System (MIPS)
- Alternative Payment Models (APMs)

Conventional Treatment Delivery, IMRT and Image Guidance Codes (G6001-G6015)

In the 2015 MPFS final rule, CMS rejected the RUC-recommended revaluations for the radiation therapy conventional treatment delivery, Intensity Modulated Radiation Therapy (IMRT) and image guidance codes. CMS established G codes G6001 through G6015 to recognize the services and cross-walked the values back to the 2014 CPT codes that had been deleted.

In December 2015, the Patient Access and Medicare Protection Act (PAMPA) effectively froze the definitions, work RVUs and direct practice expense inputs for the G codes at 2016 rates through the end of 2018. The Bipartisan Budget Act of 2018 extended this provision through 2019.

CMS is proposing to retain the G codes in the 2020 MPFS to ensure payment stability. Additionally, the Agency is proposing to continue to include a 60 percent utilization rate assumption for equipment item: ER089: “IMRT Accelerator”.

ASTRO appreciates CMS’ proposal to retain the G codes through 2020. As the Agency is aware, the Centers for Medicare and Medicaid Innovation Office (CMMI) introduced a proposed radiation oncology alternative payment model (RO Model) on July 10, 2019 that is expected to be implemented in 2020. The RO Model is inextricably linked to the payment stability of the radiation oncology treatment delivery and image guidance codes, which have been recognized by G codes in the MPFS since 2015 and represent roughly half of what Medicare pays for radiation oncology services under the MPFS. While ASTRO continues to support the CPT code revisions and RUC-recommended values associated with the conventional treatment delivery, IMRT and image guidance codes, we recognize that simultaneously moving to the RO Model while implementing the new code set for freestanding centers could be disruptive, particularly if some centers are required to participate in the alternative payment model. **ASTRO urges CMS to finalize the proposal to retain the frozen payment rates for these G codes through 2020 in order to allow radiation oncology practices the opportunity to successfully make the transition to value-based payment.**

In the interest of payment stability for radiation oncology, we urge the Agency to seriously consider ASTRO’s comments on the proposed RO Model. ASTRO is concerned that, according to the proposed rule, CMS is testing whether reducing payments will preserve or enhance quality of care. We believe such a test -- implemented in a broad, mandatory fashion -- is deeply flawed and would jeopardize cancer patient access to radiation therapy services. In our comments, ASTRO will propose significant reforms to the RO Model to

ensure that the finalized version achieves shared goals of realigning payment incentives to improve quality.

CPT Code 55874 Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

CPT Code 55874 *Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed* went into effect in the 2018 MPFS. For CY2020, the non-facility PE RVUs are projected to decrease 13 percent, which we believe is attributed to the current specialty mix utilizing the code. CPT Code 55876 *Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple* was used as the specialty mix override code for CPT Code 55874. CPT Code 55876 has a specialty mix of 67 percent urology and 29 percent radiation oncology. We believe the projected decrease for 2020 is due to the Agency using the first year of actual claims data, which has a specialty mix of 56 percent urology and 40 percent radiation oncology. To further compound the problem, radiation oncology and urology have very different direct PE percentages of 43 percent and 27 percent, respectively. Separately, the direct scaling adjustment decreased by 3 percent, which largely impacts codes that have a significant amount of direct PE. **ASTRO requests that the Agency address the proposed decreases for CPT Code 55874 in the 2020 Final Rule.**

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

In the 2019 MPFS final rule, CMS finalized its decision to update the Direct Practice Expense (PE) inputs for 1,300 supplies and 750 equipment items, including key equipment items related to radiation oncology. CMS initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the MPFS direct PE inputs for supply and equipment pricing for 2019. To address significant changes in payment, CMS phased in the new direct PE inputs over a four-year period.

The following chart details those radiation oncology equipment items that were proposed to experience the greatest decline in reimbursement as a result of this new policy. ASTRO opposed these proposed changes and was pleased that the Agency mitigated some of the significant reductions that were initially proposed.

| Equipment Item | 2018 Price | 2019 Final Price | 2020 Proposed Price | 2022 Final Price | Percentage Change Over 4-Year Transition Period |
|--|-------------|------------------|---------------------|------------------|---|
| ER003 HDR Afterload System, Nucletron - Oldelft | \$375,000 | \$314,393.70 | \$253,787 | \$132,575 | -64.6% |
| ED033 Treatment Planning System, IMRT (Corvus w- Peregrine 3D Monte Carlo) | \$350,545 | \$312,220.50 | \$273,896 | \$197,247 | -43.7% |
| ER083 SRS System, SBRT, Six Systems, Average | \$4,000,000 | \$3,743,430 | \$3,486,86 | \$2,973,722 | -25.7% |

As anticipated, the second year of the four-year phase-in will have a negative impact on a number of radiation oncology services, particularly CPT Code 77373 *SBRT Treatment Delivery*, which is proposed to experience a significant percentage reduction in PE RVUs. The SRS LINAC (ER082) and SBRT LINAC (ER083) systems are similar in both technological complexity and pricing in the current marketplace, yet the new recommended pricing methodology sets the value of ER083 at \$2,973,722, a small fraction of the value of ER082, which is set at \$4,195,100.

All equipment items shown in Table 1 have recommended prices that are below industry standards. Given the high cost of these items and their substantial utilization in certain radiation oncology delivery codes, it is imperative that CMS inputs accurately reflect the marketplace pricing.

ASTRO appreciates CMS' efforts to acquire current pricing information in order to accurately value services. However, **ASTRO recommends that CMS conduct additional research regarding fair and accurate market pricing for medical equipment items ED003, ER003 and ER083. ASTRO remains concerned that the decision to contract with StrategyGen to conduct the market research study was done with limited stakeholder input and has resulted in an analysis that contains some significant flaws, particularly with regard to ER083, which is proposed to experience a significant price reduction compared to similar technologies (ER082).**

ASTRO urges the Agency to pursue similar activities through a collaborative stakeholder process in the future. ASTRO encourages the Agency to work with the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) Practice Expense Committee to review the identified supply and equipment items CMS would like updated. Undervaluing equipment inputs has the potential to create access to care issues and potentially reduce the utilization of services that provide high quality patient outcomes.

Evaluation and Management Code (E/M) Modifications

In the 2019 MPFS final rule, CMS finalized changes to the documentation and billing requirements for E/M services, effective January 1, 2021. These modifications were implemented to reduce documentation burden for physicians by allowing physicians to choose whether to use medical decision making or time when billing E/M codes. CMS stated, “these policies would allow practitioners greater flexibility to exercise clinical judgment in documentation so they can focus on what is clinically relevant and medically necessary for the beneficiary.” CMS retained the existing E/M CPT code structure, which denotes specific levels of care; however, the new payment structure would cross-walk levels 2-4 of the E/M codes to a single blended payment rate for office/outpatient E/M visit, a move that drew opposition from many physician groups, including ASTRO, who expressed concern that the changes could lead to unintended consequences.

In the 2020 MPFS proposed rule, CMS proposes to implement modifications to the E/M codes that were finalized in the 2019 MPFS. For 2021, CMS proposes to adopt the new coding structure for the office/outpatient evaluation and management (E/M) codes recommended by the AMA, as well as the RUC recommended times and values. CMS proposes to retain five levels of coding for established patients, reduce the number of levels to four for new patients, and revise the code definitions.

The proposed changes also revise the times and medical decision-making process for all the E/M codes. Physicians can choose the E/M visit level based on either medical decision making or time. Medical history and physical exams should continue to be performed as medically appropriate; however, these elements will no longer be a consideration for code level selection. These proposed changes were largely developed in concert with the AMA CPT Editorial Panel.

CMS proposes to adopt the AMA's RUC-recommended payment rates, which were derived from a survey of over 50 specialty societies and stakeholders. CMS proposes payments based on each code descriptor to pay for each level of service, rather than utilizing a “blended rate” for E/M code levels 2 through 4. According to the proposed rule, the Agency is committed to implementing these changes January 1, 2021.

ASTRO is appreciative of efforts to reduce the administrative burden associated with documentation requirements involving E/M codes. We appreciate the confidence CMS displays in the RUC process in proposing to adopt the RUC recommended work values, physician times and practice costs for the stand-alone E/M office visits. We urge the Agency to finalize the CPT codes, CPT guidelines and RUC recommendations submitted by the RUC, including applying the updated values to E/M visits within 090-day global period services.

Proposed Add-On Code GPC1X

In the 2019 MPFS final rule, CMS finalized a series of adjustments to capture the variety of resource costs associated with different types of care provided in E/M visits. These included the establishment of GCG0X *Visit Complexity Inherent to Evaluation and Management* and GPRO

Prolonged Evaluation and Management or Psychotherapy Service(s). In the 2020 MPFS proposed rule, CMS supports the establishment of add-on codes, stating that “there is still a need for add-on coding because the revised office/outpatient E/M code set does not recognize that there are additional resource costs inherent in furnishing some kinds of office/outpatient E/M visits.” However, CMS proposes to revise the descriptor for HCPCS code GPC1X and delete HCPCS code GCG0X, consolidating the two add-on codes into a single add-on code and revising the single code descriptor to better describe the work associated with visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient’s single, serious, or complex chronic condition. The chart below provides the revised descriptor and associated times/RVU values for the revised add-on code.

TABLE 28: Proposed Revaluation of HCPCS Add-on G code Finalized for CY 2021

| HCPCS Code | Proposed Code Descriptor Revisions | FR 2019 total time (mins) | FR 2019 Work RVU | Proposed total time (mins) | Proposed Work RVU |
|------------|--|---------------------------|------------------|----------------------------|-------------------|
| GPC1X | Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex chronic condition. (Addon code, list separately in addition to office/outpatient evaluation and management visit, new or established) | 8.25 | 0.25 | 11 | 0.33 |

Suggested Modifications to Coding Guidelines – Prolonged Services

Additionally, CMS implemented a new "prolonged visit" code (GPRO1) in the 2019 MPFS final rule that allowed physicians to receive higher payment rates for spending additional time with patients whose visits are coded at levels 2 through 4. In the 2020 MPFS proposed rule, CMS proposes to accept the AMA RUC recommended values for CPT code 99XXX without refinement. The RUC provided a recommendation for a new CPT code 99XXX (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes.* CMS proposes to delete the HCPCS add-on code finalized in last year’s proposed rule for extended visits (GPRO1) and adopt the new CPT code 99XXX. CMS is seeking comment from the public and stakeholders regarding these proposed changes.

ASTRO appreciates the proposed establishment of a complexity adjustment, as well as a prolonged visit adjustment. However, ASTRO has concerns with the Agency’s projected utilization of the prolonged add-on code. It appears that CMS assumes that add-on code would

be applied to nearly 50 percent of the claims for a subset of specialties. **CMS must explain the projected use of the prolonged add-on code in detail, in order to ensure that the projected impacts are accurate. We request that CMS articulate all of the underlying assumptions regarding the potential use of this code and develop a specific impact table in the Final Rule indicating the impact by specialty.**

Combined Impacts

In the 2020 MPFS proposed rule, CMS continues to refine the E/M proposal. The chart below provides an estimate of the potential impact on radiation oncology. Although CMS is not proposing changes to E/M coding and payment for 2020, the Agency is proposing certain changes for 2021. CMS believes these estimates provide insight into the magnitude of potential changes for certain physician specialties.

Table 111: Estimated Specialty Level Impacts of Proposed E/M Payment and Coding Policies if Implemented in CY 2021

| (A) | (B) | (C) | (D) | (E) | (F) |
|--|-----------------------|----------------------------|--------------------------|--------------------------|------------------|
| Specialty | Allowed Charges (mil) | Impact of Work RVU Changes | Impact of PE RVU Changes | Impact of MP RVU Changes | Combined Impact* |
| Total | \$92,979 | 0% | 0% | 0% | 0% |
| Radiation Oncology and Radiation Therapy Centers | \$1,756 | -2% | -2% | 0% | -4% |

According to the chart, the impact on radiation oncology is a combined reduction of 4 percent. That’s a 2 percent cut in Work RVU and 2 percent cut in PE RVUs associated with E/M codes that are frequently billed by radiation oncologists. **ASTRO is concerned about the validity of the published impacts and seeks more information the negative impact the proposed E/M changes will have on radiation oncology payments.**

Geographic Practice Cost Indices (GPCIs)

CMS is required to review and adjust the Geographic Practice Cost Indices (GPCIs) at least every three years and adjust as necessary. In the Proposed Rule, CMS identified two technical refinements to the GPCI methodology used to calculate GPCI adjustments. These refinements relate to the work GPCI, the employee wage index, and purchased services index components of the practice expense GPCI.

1. CMS proposes to weight by total employment when computing county median wages for each occupation code as occupation wage can vary by industry within a county; and

2. CMS proposes to use a weighted average to calculate the final county-level wage index, which removes the possibility that a county index would imply a wage of 0 for any occupation group not present in the county's data.

ASTRO appreciates the Agency's proposal to review and adjust GPCI methodologies to more accurately calculate GPCI adjustments. These proposed methodological refinements could yield improved mathematical precision over the current methodology and be beneficial to all fields of medicine.

Malpractice RVUs

In the 2018 MPFS proposed rule, CMS proposed to collect malpractice insurance premium data from all 50 states, the District of Columbia and Puerto Rico in order to update the Malpractice RVUs for each specialty. The criteria for collecting the premium data required rate filings being available from at least 35 states to establish the minimum amount of premium data necessary to establish a malpractice RVU rate. Although premium data were collected from all states, the District of Columbia, and previous filings for Puerto Rico were utilized, not all specialties had distinct premium data in the rate filings from all states. Specialties for which premium data were not available for at least 35 states, and specialties for which there were not distinct risk groups (surgical, non-surgical, and surgical with obstetrics) among premium data in the rate filings, were cross-walked to a similar specialty, either conceptually or based on available premium data. Data for radiation oncology was only available based on 23 states' worth of premium rate filings data. CMS cross walked the risk factor for the radiation oncology to the diagnostic radiology Malpractice RVU.

In the CY2020 Proposed Rule, CMS is seeking comments on three proposed changes to the Malpractice RVU (MP RVU) component to fee schedule rates in order to expand the specialties and amount of filings data used to develop the proposed risk factors, which are used to develop the proposed MP RVUs.

1. CMS is proposing to change its schedule for updating its malpractice premium data (used in calculating MP RVUs) from every five years to every three years. CMS is statutorily required to annually review and update the MP RVU value to reflect changes in 1) Medicare's practitioner mix; and 2) the intensity and complexity of services rendered. However, every five years CMS also pulls updated malpractice insurance premium data from private insurers to adjust the specialty level risk factors used to calculate MP RVUs. CMS is proposing to switch the MP RVU update schedule to every three years to align it with CMS' current schedule for updating MP GPICs. If the updates were aligned, CMS would next review and update MP RVUs in 2020 and, thereafter, review and update both the GPCI and MP RVU in CY 2023.
2. CMS proposes the following methodological improvements to the development of MP premium data and CMS seeks comment on these proposed improvements.

- a. Pull malpractice insurance premium and claims data for more than just those listed as ‘physicians’ or ‘surgeons’ in order to create a larger dataset for calculating MP RVUs.
 - b. Combine ‘minor surgery’ and ‘major surgery’ malpractice insurance premiums to create a single surgery service risk group for calculating MP RVUs. (Currently, CMS only uses ‘major surgery’ data to calculate MP RVUs).
 - c. Substitute malpractice premiums data (in all or part) from other physician specialties to replace or fill-in data when a private insurer does not capture data for a particular physician specialty.
3. CMS is proposing to assign the default risk factor (1.00) to all technical-component only services for calculating MP RVUs for such services. CMS notes that this value matches the lowest physician specialty-level risk factor and is a necessary proxy because private insurers do not have sufficient professional liability premium data on the full range of clinicians who provide technical-component only services. CMS is seeking comment for proposals for alternative proxies.

While ASTRO supports efforts to improve the premium data collection process, we are concerned about inconsistencies that have led to the undervaluation of certain specialties. ASTRO urges CMS to collect further data to ensure that different risk factors are identified across various specialties. ASTRO also urges CMS to retain the current risk factors for TC-only services until comprehensive data is acquired rather than assigning the lowest physician specialty-level risk factor to these services.

Merit-based Incentive Payment System (MIPS)

Scoring Methodology

CMS proposes an increase in the performance threshold from 30 to 45 points for the 2020 performance year, and 60 points for the 2021 performance year. The exceptional performance threshold is proposed to increase from 75 to 80 for 2020, and 85 for 2021. ASTRO remains concerned that the increase in the performance threshold will adversely affect small and rural practices and lead to consolidation, which may limit patient access to vital cancer treatments. However, we understand the need to increase the requirements for the program, even though CMS data show that small practices receive more negative payment adjustments than larger practices. **We therefore recommend that the Agency provide more bonus opportunities for small and rural practices.**

Performance Category Reweighting

CMS continues to provide Promoting Interoperability hardship applications for the 2020 performance period. The Agency believes this is particularly important for small practices. The exemption reweights the Promoting Interoperability category to zero, shifting an additional 25 percent to the Quality category. **ASTRO is disappointed that the Agency is not proposing to**

equally redistribute the weights between both the Quality and the Improvement Activities category. We continue to believe redistributing weights to Improvement Activities more accurately weights that category, which is the one performance category that we believe has the power to transform a practice and drive true quality improvement. Quality measures only track what a physician is doing, while Improvement Activities effect the entire care team.

CMS is proposing to reweight performance categories in rare events due to compromised data outside the control of the MIPS eligible clinician. MIPS eligible clinicians or third-party intermediaries can inform CMS that they believe they are impacted by providing information on a relative event. If CMS determines that reweighting for compromised data is appropriate, the Agency will redistribute points to the Promoting Interoperability and Quality performance categories, and in rare instances, to the Cost performance category. **ASTRO requests clarification on what constitutes compromised data, and how the Agency will determine if the compromised data was outside the control of the MIPS eligible clinician.**

Targeted Review

CMS is proposing that beginning with the 2019 performance period, all requests for targeted review would be required to be submitted within 60-days of the release of the MIPS payment adjustment factor(s) with performance feedback. **ASTRO supports this proposal as it will allow for a consistent period of time to submit requests for targeted review and gives the Agency flexibility if the feedback reports are delayed for any reason.**

Quality Performance Category

CMS is proposing to increase the data completeness threshold for the Quality Performance Category from 60 to 70 percent of Medicare Part B patients for the 2020 performance year, with a minimum of 20 cases per measure. This policy does not apply to small practices, who will continue to earn three points for submitting measures that do not meet data completeness. **ASTRO appreciates the Agency maintaining the 3-point designation for measures that do not meet data completeness requirements. However, we are concerned with the increase in the data completeness threshold from 60 to 70 percent. ASTRO requests clarification regarding whether the 1-point floor for measures that do not meet data completeness requirements will remain in place for the 2020 performance year.**

Some measures require a large amount of data collection, which adds to physician burden. For example, within the radiation oncology measures set, measures #143 *Pain Quantified* and #144 *Plan of Care for Pain* need to be reported for every treatment management visit, which occurs every five treatments. For a radiation oncology patient receiving 35 radiation treatment fractions, a physician would need to report data for these measures at least seven times just for one patient. If reporting as a group, the case number could be in the thousands. This level of reporting forces practices to invest significant time and money in systems and infrastructures to collect and report data as the electronic health records (EHRs) may not capture the necessary data elements or

submit data on behalf of their clients. **The increased burden this requirement places on clinicians reduces time and resources that could otherwise be spent focusing on patients, which runs directly counter to the “Patients over Paperwork” initiative.**

CMS proposes to remove MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for two consecutive performance periods. The Agency believes that removing measures using this methodology ensures that the MIPS quality measures available in the program are truly meaningful. **ASTRO opposes this proposal and recommends that CMS allow appropriate time for measures to receive enough data to set benchmarks.** We disagree with the Agency’s assertion that measures’ low reporting rates point to a measure concept that is not meaningful. Currently, there is no incentive for clinicians to use measures that do not include a benchmark. Without an incentive, the measure will not be used, and therefore data will not be gathered to determine appropriate benchmarks. **We recommend that CMS consider changing the current scoring methodology specifically around measures that do not have benchmarks so that clinicians are incentivized to use the measures, and benchmarking data can then be gathered and used.** Additionally, we believe removing measures based on available benchmarks prior to changing the benchmarking process is premature.

As mentioned, the Agency is proposing a new methodology surrounding quality measure achievement points, including setting different class designations and flat benchmarks to accommodate inappropriate treatment. **We thank the Agency for recognizing the need for a specialized approach in some situations; however, we warn against the added complexity this brings.** MIPS scoring is highly variable, which causes confusion and uncertainty among clinicians. Continuing to add new scenarios to an already complex program should be avoided.

The Agency seeks comment on whether the data completeness threshold for quality measures that are identified as extremely topped out, but are retained in the program due to the limited availability of quality measures for a specific specialty, should be increased. **ASTRO believes that the current requirements are appropriate and should not be changed.**

CMS also seeks comment as to whether the Agency should consider aligning the measure update cycle with that of the eCQM annual update process. **ASTRO agrees that the Agency should align the measure update cycle with that of the eCQM annual update process to ensure consistency across all programs.**

Cost Performance Category

Total Per Capita Cost Measure (TPCC)

CMS proposes changing the attribution methodology for TPCC to more accurately identify clinicians who provide primary care services, with the addition of service category exclusions and specialty exclusions. Specifically, as proposed, candidate events are excluded if they are performed by clinicians who (i) frequently perform non-primary care services (for example, global surgery, chemotherapy, anesthesia, radiation therapy) or (ii) are in specialties unlikely to be responsible for providing primary care to a beneficiary (for example, podiatry, dermatology,

optometry, ophthalmology). While radiation therapy would be excluded from this measure, physician assistants and nurse practitioners are not among the proposed exclusions. **ASTRO appreciates that the Agency recognizes the need to more accurately identify clinicians who provide primary care services. However, we are concerned that those practices that include physician assistants and nurse practitioners will be negatively affected. We understand that these clinician types do provide some similar services; however, they do not replicate the role of the primary care physician and, even when no other primary care physician is attached to a patient, these clinician types act under the supervision of a medical specialist focusing on a specific disease. We recommend that the Agency also exclude from the TPCC measure physician assistants and nurse practitioners that are part of a specialty group or supervised by a medical specialist focusing on a specific disease.**

Medicare Spending Per Beneficiary (MSPB) Clinician

The Agency proposes to change the attribution methodology for the MSPB clinician measure, including distinguishing between medical episodes and surgical episodes and attributing based on the claims billed during the inpatient stay. A medical episode is first attributed to the TIN billing at least 30 percent of the inpatient E/M services on Part B physician/supplier claims during the inpatient stay. The episode is then attributed to any clinician in the TIN who billed at least one inpatient E/M service that was used to determine the episode's attribution to the TIN. Medical episodes are attributed first at the clinician group (TIN) level, and then at the clinician (TIN-NPI) level. **ASTRO appreciates that the Agency is attempting to address previous attribution errors and make the policy clearer. We look forward to seeing the outcome of these changes.**

Improvement Activities Performance Category

CMS proposes the following criteria for removal of improvement activities:

- The activity is duplicative of another activity
- An alternative activity exists with stronger relationship to quality care or improvements in clinical practice
- The activity does not align with current clinical guidelines or practice
- The activity does not align with at least one meaningful measures area
- The activity does not align with Quality, Cost, or Promoting Interoperability performance categories
- There have been no attestations of the activity for three consecutive years
- The activity is obsolete

ASTRO appreciates CMS outlining the criteria for removal of Improvement Activities and supports finalization of this proposal. However, we recommend that CMS defer the removal of activities based on the “activity does not align with Quality, Cost, or Promoting Interoperability performance categories” requirement until the MIPS Value Pathways

(MVP) (see discussion below) have been finalized, implemented and assessed. We understand that this is the direction MIPS is moving toward, but CMS should delay removing improvement activities based on this criterion.

Promoting Interoperability (PI) Performance Category

The Agency proposes retaining both the 25 percent weight for the PI category and the 90-day minimum performance period for 2020. Additionally, CMS proposes to continue the requirement that eligible clinicians use 2015 Edition CEHRT for 2020. For the 2021 performance year, CMS is proposing to continue the PI performance period of a minimum of a continuous 90-day period within the calendar year that occurs two years prior to the applicable MIPS payment year, up to and including the full calendar year. **ASTRO appreciates the Agency maintaining current requirements to provide stability and continuity for the program.**

CMS proposes that the Query of Prescription Drug Monitoring Program measure require a yes/no response for the current (2019) performance year, instead of a numerator and denominator. For the 2020 performance year, the Agency proposes to keep this measure as optional. CMS proposes to remove the Verify Opioid Treatment Agreement measure beginning in the 2020 performance period. **ASTRO appreciates both the proposal to change the response mechanism and the optional reporting requirement for the Query of Prescription Drug Monitoring Program. We also support the proposal to remove the Verify Opioid Treatment Agreement measure beginning in the 2020 performance period.**

For the 2019 performance year, CMS proposes to redistribute the Support Electronic Referral Loops by Sending Health Information to the Provide Patients Access to Their Health Information measure if an exclusion is claimed. **ASTRO appreciates CMS providing clarification on the redistribution of the Support Electronic Referral Loops by Sending Health Information measure; however, we believe that this proposed change could have been made earlier in the performance year to provide guidance for the affected eligible clinicians.**

CMS seeks input through the following Requests for Information:

(1) Potential Opioid Measures for Future Inclusion in the Promoting Interoperability performance category and NQF and CDC Opioid Quality Measures

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 take this into consideration as they move forward with implementing the goals of the Administration.**

(2) A Metric to Improve Efficiency of Providers within EHRs, Provider to Patient Exchange Objective, Integration of Patient-Generated Health Data into EHRs Using CEHRT, and Engaging in Activities that Promote the Safety of the EHR

ASTRO appreciates the continued and increased focus on CEHRT as an indicator of quality care. The care coordination and patient access that EHRs provide can be

transformative. We have consolidated our recommendations and concerns for all of the topics identified above.

As we have mentioned in previous comment letters, **ASTRO urges CMS to include the use of an electronic health record (EHR) to participate in a qualified clinical data registry (QCDR) as an interoperability activity.** Allowing providers to receive credit under Promoting Interoperability for interoperability activities will reduce health care provider burden while giving providers the flexibility to pursue innovative applications of health IT. The inclusion of electronic reporting through a QCDR as an interoperability activity is consistent with Congress's mandate under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) that encourages the use of QCDRs and certified EHR technology for reporting measures under the Quality performance category of the MIPS.

ASTRO encourages CMS to consider interoperability challenges between the same EHRs and electronic clinical documentation portals within a system, in addition to the challenges of interoperability between different systems. ASTRO members report that often their EHR or electronic clinical documentation portals cannot communicate with the same EHR or electronic clinical documentation portals in a different office, often causing a disruption in care coordination between two providers. This lack of data exchange can also lead to delayed treatment and/or potential patient safety scenarios.

ASTRO believes that patient matching – the linking of one patient's data within and across health care providers – is an important component of HIT interoperability; however, we caution the Agency to not overlook the complexity of multi-modal care. For example, ASTRO members report that even if a consulting physician uses the same EHR as the ASTRO member, they often have difficulty communicating electronically, and need to find work-arounds to get patient information from one office to the other. Patient matching certainly can facilitate “improved patient safety, better care coordination, and advanced interoperability” when data from one system aligns with the data from another; however, more work needs to be done to achieve this goal.

We are aware that vendors are required to upgrade their products to maintain compliance with federal regulations, requiring significant investment in the products. However, these costs are often passed on directly to physicians. As we have mentioned previously in other comment letters, we are concerned that vendors will use every new, regulatorily-required update or module as an opportunity to generate additional charges and fees for their products. These excess charges are a financial burden for many practices, especially for small and rural practices, which often find these costs prohibitive. **ASTRO recommends that CMS carefully consider the downstream financial impact of new requirements, and how they almost certainly result in increased costs for practices. These unfunded mandates undercut the potential benefits of health IT and remove critical funds that should be targeted toward patient care and must be avoided. As new functionality is required from information system vendors, we ask that the Agency consider a cost sharing approach to lessen the financial burden it puts on medical practices.**

Facility-Based Quality and Cost Performance Categories

CMS is proposing to clarify the definition of facility-based clinician to state that a MIPS eligible clinician is facility-based if the clinician can be assigned to a facility with a value-based purchasing score for the applicable period. **ASTRO supports this proposal and thanks the Agency for the clarification.**

Qualified Clinical Data Registry (QCDR)

The Agency also proposes that beginning in the 2021 performance period, feedback reports include information on how participants compare to other clinicians within the QCDR cohort who have submitted data on a given measure. **ASTRO believes that constant and real-world feedback is important to clinicians, and thanks CMS for this proposal.** We believe it is valuable for clinicians to understand the average practices of similar practices and this proposal supports that.

QCDRs would be required to attest during the self-nomination process that they can provide performance feedback at least four times a year. In instances where the QCDR does not receive data from their clinician until the end of the performance period, the QCDR could be exempted from this requirement. **Therefore, ASTRO supports the proposed requirement of QCDRs providing feedback at least four times a year and the proposed exemption.**

CMS is seeking comment for future notice-and-comment rulemaking on whether the Agency should require MIPS eligible clinicians, groups, and virtual groups who utilize a QCDR to submit data throughout the performance period, and prior to the close of the December 31st performance period. ASTRO requests clarification on the rationale for this requirement. Specifically, we are interested in understanding whether this requirement is for clinicians to submit the data to receive feedback throughout the year, or is it so that the QCDR can report back to CMS? As mentioned earlier, ASTRO believes that this requirement will cause undue burden on those clinicians who cannot submit throughout the year, either because of already-set workflow practices, or other logistical reasons. **Therefore, we recommend that CMS not adopt this proposal.**

CMS is also seeking comment for future notice-and-comment rulemaking, on whether clinicians and groups can start submitting their data starting April 1 to ensure that the QCDR is providing feedback and the clinician or group during the performance period. This would allow QCDRs some time to provide enhanced and actionable feedback to MIPS eligible clinicians prior to the data submission deadline. **ASTRO is supportive of this proposal, as long as it is voluntary.**

CMS proposes that beginning with the 2023 MIPS payment year (2021 performance year), QCDRs must foster services to clinicians and groups to improve the quality of care provided to patients by providing educational services in quality improvement and leading quality improvement initiatives. **ASTRO does not believe that QCDRs are structured to furnish these types of educational services.** QCDRs are not structured around quality improvement,

they are structured around data collection. It would be difficult, and the turnaround too quick, for QCDRs to change their business models to adopt this additional functionality.

CMS proposes that beginning in the 2020 performance period, in instances in which multiple, similar QCDR measures exist that warrant approval, the Agency may provisionally approve the individual QCDR measures for one-year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures in order to be considered for the program in subsequent years. Duplicative QCDR measures would not be approved if QCDRs do not elect to harmonize identified measures as requested by CMS within the allotted timeframe. **ASTRO thanks the Agency for allowing more time than has been provided in the past; however we are concerned that if finalized, this requirement may still not allow sufficient time for QCDRs to test and refine measures to satisfy the requirements.** Additionally, we ask clarification on the following:

1. What is the criteria CMS will use to determine whether the measures are similar and will need to be refined?
2. What is the timeline for CMS to notify QCDRs that they will need to make changes?
3. How quickly will QCDRs have to finalize the changes?
4. Is there a planned appeals process if the measure stewards believe that the measures are not duplicative?

CMS proposes that beginning in the 2021 performance period, at the time of self-nomination, QCDRs must identify a linkage between their QCDR measures and the following: cost measure, Improvement Activity, or CMS developed MIPS Value Pathways (MVPs) (see section on MVP below). In the discussion section of the proposed rule, CMS indicates that the QCDR must identify a linkage between the QCDR measure to one of the three items listed above. However, the regulatory language requires that the linkage must be made to all three. There are very few, if any, QCDR measures that could be linked to all three and it is more likely that these measures can be linked to just one. Therefore, **ASTRO recommends that CMS make the following change (in red):**

- (G) Beginning with the 2021 performance period—
- (I) That QCDRs link their QCDR measures to the following at the time of self-nomination:
 - (i) Cost measure,
 - (ii) Improvement activity, **or**
 - (iii) An MVP.

Additionally, the proposal to begin this in 2021 is too soon. Measure developers and QCDR owners are currently working on the most recent Agency priorities, i.e. patient reported outcomes, meaningful measure alignment, and have not had time to consider the new agenda (MVPs, Cost). Measure development and testing takes 1-2 years at minimum, which does not align to the 2021 start date. Also, many medical specialties are not represented by either episode-based Cost measures or the two existing Cost measures. This leaves specialists at a disadvantage

that will not be addressed for a number of years while Acumen continues its work. **ASTRO recommends deferring this proposal until the MVP framework is established and measure developers have the necessary time to establish new measures to align with this new focus.**

The Agency proposes that QCDR measures be fully developed with completed testing results at the clinician level and must be ready for implementation at the time of self-nomination. Specialty societies use QCDRs to test measures and to facilitate measure development with their members, and that process should be allowed to continue. ASTRO requests clarification on the level of testing for which CMS is asking. Is it full NQF-level specification and endorsement? Or just a feasibility and validity test within the QCDR? **As written, and without clarification, ASTRO opposes this requirement.**

CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure. **ASTRO requests CMS provide scenarios of what this proposal is trying to address.**

CMS further proposes that a QCDR measure that does not meet case minimum and reporting volumes required for benchmarking after being in the program for two consecutive performance years, may not continue to be approved in the future. **As stated above, ASTRO opposes this proposal and recommends that CMS allow appropriate time for measures to receive enough data to set benchmarks.** Currently, there is no incentive for clinicians to use measures that do not include a benchmark. Without an incentive, the measure will not be used, and will therefore not gather data to determine appropriate benchmarks. **We further recommend that CMS consider changing the current scoring methodology for measures that currently do not have benchmarks so that clinicians are incentivized to use the measure, and benchmarking data can then be gathered and used.**

MIPS Value Pathways (MVP)

CMS proposes a new MIPS Value Pathways (MVP) framework, beginning with the 2021 MIPS performance period, to simplify MIPS, improve value, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians. The new framework would remove barriers to Alternative Payment Model (APM) participation and promote value by focusing on quality, interoperability, and cost. MVP allows for a more cohesive participation experience by connecting activities and measures from the four MIPS performance categories that are relevant to the population they are caring for, a specialty or medical condition. Additionally, MVP would create a cohesive and meaningful participation experience for clinicians by moving away from siloed activities and measures, toward an aligned set of measures that are more relevant to a clinician's scope of practice, while further reducing reporting burden and easing the transition to APMs.

CMS outlined four guiding principles for MVP in the proposed rule:

1. MVP should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.
2. MVP should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care.
3. MVP should include measures that encourage performance improvements in high priority areas.
4. MVP should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

The most significant change with MVP is that eventually all MIPS eligible clinicians will no longer be able to select quality measures or improvement activities from a single inventory. Instead, measures and activities in an MVP would be identified by clinician specialty or condition. Cost measures would be specific to the MVP and applied only when a clinician or group meets the case minimum.

In concept, ASTRO supports using the MVP as a pathway to transition MIPS participating practices to APMs; however, we have significant concerns about the lack of information provided in the Request for Information (RFI) regarding the program. **To this end, ASTRO requests that CMS issue a separate RFI with concrete proposals on the MVP.**

Specifically, it is unclear how the MVP will affect smaller specialties. For example, there are no cost measures specific to radiation oncology, so how will radiation oncologists participate in this program? Because of the multidisciplinary nature of cancer care, it is difficult to carve out the associated costs. How will the agency carve out specialty-specific approaches, ensuring that all clinicians are successful? Will the process be similar to the development of specialty specific APMs? Finally, we are concerned with the proposed timeframe given that the Agency is just now issuing an RFI and wants implementation to begin in 2021. There are limited quality measures in radiation oncology, none of which are related to improvement activities. Time is needed to understand the proposed framework, identify possible concepts and develop the measures required to make MVPs feasible for the entire field of Medicine. At the same time, any necessary changes to technology will need to be developed and tested before implementation. **ASTRO recommends that CMS provide more information and delay implementation of the MVP program until the Agency has had time to work with specialty societies to consider all details and ensure that necessary implementations have taken place.**

CMS expresses interest in exploring approaches to leverage participation in specialty accreditation programs, such as the American College of Surgeons' Commission on Cancer accreditation program. **We strongly support the use of programs, such as ASTRO's Accreditation Program for Excellence (APEX), to satisfy participation in federal quality reporting and value-based incentive programs. One issue that we have struggled with involves quality reporting programs operating on an annual basis while accreditation involves multi-year approvals. ASTRO requests more information and clarification on how the alignment could work.**

Alternative Payment Models

In the 2020 QPP, CMS is proposing modifications that are designed to address fluctuations in risk associated with risk-based APMs. According to the proposal, when a payment arrangement's marginal risk rate varies depending on the amount by which actual expenditures exceed expected expenditures, the Agency will use the average marginal risk rate across all possible levels of actual expenditures. This average marginal risk rate will be compared to the marginal risk rate to determine whether the payment arrangement has a marginal risk rate of at least 30 percent, as required by MACRA. The Agency proposes exceptions for large losses and small losses as provided in CMS regulations.

Additionally, CMS is proposing that beginning in the 2020 an eligible clinician will not be deemed a Qualified APM Participant (QP) Performance Period or Partial QP if the APM entity voluntarily or involuntarily terminates their Advanced APM contract before the end of the performance period or if the APM entity no longer bears financial risk. The proposal also clarifies that Partial QP status only applies to the TIN/NPI combination(s) through which an eligible clinician attains QP status.

ASTRO appreciates the Agency's efforts to address risk fluctuations associated with risk-based Advanced APMS. Significant fluctuations in risk have the potential to jeopardize the financial viability of participating practices. Advanced APMs should establish predictability and stability in payment rates, establishing a methodology for addressing risk fluctuations achieves that goal. ASTRO also appreciates the Agency's proposed clarification regarding the application of QP status.

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 Bryan Hull, Assistant Director of Health Policy, at (703) 839-7376 or Bryan.Hull@astro.org.

Respectfully,



Laura I. Thevenot
Chief Executive Officer