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June 23, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3221-NC
P.O. Box 8013
7500 Security Boulevard
Baltimore, MD 21244-8013

Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models [CMS-5517-P]

Dear Acting Administrator Slavitt:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the "Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models" proposed rule, published in the Federal Register on May 9, 2016.

ASTRO members are medical professionals, practicing at hospitals and cancer treatment centers in the United States and around the globe, and who make up the radiation therapy 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, and treat more than one million cancer patients each year. We believe this multidisciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy.

In this comment letter, we address the following issues:

- General Comments about the Proposed Quality Payment Program
- Merit Based Incentive Payment Program
    - MIPS Composite Performance Score Methodology
    - MIPS Eligible Clinicians
    - MIPS Eligible Clinician Identifier
    - Virtual Groups
    - Quality Performance Category
    - Resource Use Performance Category

  - Clinical Practice Improvement Activities Performance Category
  - Advancing Care Information Category
- Alternative Payment Models
  - Advanced APM Entity
  - APM Base Rate and Incentive Payment
  - APM Reconciliation
  - Notification of APM Eligibility
  - Qualifying APM Participants and Partial Qualifying APM Participants
  - MIPS Eligible APM Entities
  - Physician Focused Payment Models

General Comments on Proposed Quality Payment Program

In 2015, the Medicare Access and Children's Health Insurance Program Reauthorization Act (MACRA) repealed the Sustainable Growth Rate (SGR) and replaced it with the Merit-Based Incentive Payment System (MIPS) and the Alternative Payment Model (APM) program. ASTRO supported Congressional repeal of the SGR and we applaud CMS' efforts to develop a new value based payment system. This is in the best interest of physicians and the patients they serve.

Despite our shared goals for a successful Quality Payment Program, ASTRO is very concerned that the pace with which CMS is transitioning to the new MIPS and APM programs is much too fast. We urge CMS to consider a more cautious and measured implementation period that can be phased in over a period of time to ensure successful participation and meaningful system reform. We urge CMS to make modifications in the final rule to reduce the complexity of the programs and better ensure chances for successful participation for many physicians, especially those in solo and small practices.

ASTRO is also greatly concerned that the proposed MIPS and APM programs do not adequately account for the significant investment of time and resources that many practices will need to undertake to participate in the new Quality Payment Program. CMS acknowledges this issue in the Advanced APM section of the proposed rule regarding the calculation for nominal risk, but said that such costs will vary by practice and as such will be difficult to quantify. **ASTRO urges CMS to reconsider this decision and explore ways to account for such investments, such as through the collection of receipts and verifications of employment of case managers and other investments to improve care coordination, and apply the value of those investments to both the MIPS and APM programs.** We also urge CMS to work with specialty groups to identify and account for these types of investments as they will vary by specialty. While perhaps difficult to quantify, these additional investments are real and represent a significant barrier to participation that must be addressed.

Beginning in 2018, the Physician Quality Reporting System (PQRS), value-based payment modifier (VM), and Electronic Health Records (EHR) Incentive Program (Meaningful Use) will be consolidated and replaced by MIPS. MIPS includes four distinct measures categories: Quality, Resource Use, Clinical Practice Improvement Activity (CPIA), and Advancing Care Information. ASTRO supports the agency's decision to maintain some stability in the transition

to MIPS, but we have serious concerns about the inefficiencies and burdensome requirements that are being carried over from these programs.

In early 2015, Health and Human Services Secretary Sylvia Matthews Burwell announced a timetable to move the Medicare program, and the healthcare system at large, toward paying providers based on quality, rather than volume. Secretary Burwell set a goal of tying 30 percent of traditional, or fee-for-service, Medicare payments to quality or value through alternative payment models by the end of 2016, and tying 50 percent of payments to these models by the end of 2018. MACRA sets the stage for moving America's health care system toward this goal by establishing alternative payment models as a new way to pay health care providers for the care they provide beneficiaries. ASTRO strongly supports these goals and efforts, and we are committed to working with CMS and other stakeholders on the development of APMs that are viable and meaningful to oncology care. ASTRO is concerned with an apparent overemphasis on the untested Oncology Care Model, and we urge CMS to fully allow medical specialties, such as radiation oncology, the opportunity to develop and test models that are simple to implement and flexible enough to allow physicians to provide patient centered care that yields improved patient outcomes.

Below are general recommendations to improve the implementation of MACRA, our detailed comments follow:

- Treat the first two years as a transitional period, and amend and shorten the performance period to allow clinicians sufficient time to prepare and adopt appropriate processes to meet the program requirements.
- Provide physicians with more timely and actionable feedback in a clearly understandable format.
- Reduce the thresholds for reporting on quality measures.
- Permit proposals for more relevant objectives and measures for the Advancing Care Information category, rather than carrying over the current Meaningful Use objectives and measures.
- Grant full credit for the Clinical Practice Improvement Activity category to those clinicians participating in ASTRO's APEx accreditation program.
- Increase the weight of the Clinical Practice Improvement Activity category.

MIPS Composite Performance Score Methodology

The Composite Performance Score (CPS) methodology applies to both Eligible Clinicians (ECs) and groups of ECs. CMS intends to keep scoring as simple as possible while providing flexibility for the variety of practice types and reporting options. Overall, we welcome the shift from the "all-or-nothing" reporting requirements to partial reporting credit in all the categories, in addition to the advancing care information category.

However, there are many technicalities and levels of complexity within the program requirements in each of the categories, which are cause for concern. Currently, the four categories are broken down into subcategories with different scoring methodologies, which only

adds to the complexity of the overall program. Where possible, CMS should try to create a straightforward scoring process that has the fewest number of different point categories.

Additionally, as noted in Table 63, CMS estimates that a little over a half of radiation oncologists (56 percent) will receive a positive adjustment, while the remaining (44 percent) are likely to receive a negative adjustment. Furthermore, the smaller the practice size, the greater the burden of participation and increased likelihood of a negative adjustment. After the proposed rule was issued, CMS issued a fact sheet[1] indicating that the table was based on 2014 data that is not representative of reporting by smaller practices. The 2014 data is the most recent data available to the public and is also the only data available to providers as part of their feedback reports. The fact that the 2014 data cannot be used to forecast participation or used for analysis and CMS' decision to distance itself from information published in the proposed rule erodes our confidence in the ability to implement and evaluate the MIPS program. **Given the unchartered nature of the program and the challenging complexities and nuances proposed, we question whether the agency will be able to accurately calculate physician payment adjustments; and therefore strongly urge CMS to pursue a more cautious, methodical approach to implementation to ensure the effectiveness of the MIPS program to improve patient care and outcomes.**

It is also unclear what benchmarks will be used for the performance and payment thresholds. The way the program is currently proposed, the higher the performance threshold, the greater the likelihood that poor performers will get the lowest adjustment. Low-scoring performers will find it increasingly difficult to participate and achieve a higher score each year. This could have unintended consequences, as cumulative negative adjustments could potentially jeopardize access to care for patients who rely on solo and small practices, particularly in rural areas. This will restrict and limit cancer patients' access to necessary care because they will be required to travel further to larger practices in order to receive their treatments. In areas where CMS is comparing performance of clinicians, CMS should take into account the size and resources a practice is able to devote to their MIPS performance. The scoring methodology should not provide distinct advantages for practices simply because they are large and should not penalize others for their size or unique patient population. Additionally, it is unclear how the benchmark payment is set each year. Is the MIPS adjustment included or excluded in the base rate for services each year? Is it similar to APMs where the base rate is reset each year? ASTRO asks CMS to provide further clarification on this issue.

ASTRO strongly urges the agency to consider the first two years of the program as a trial and error period for providers to learn and implement the program. We encourage the agency to seek options to eliminate or mitigate negative payment adjustments in 2019 and 2020, based on 2017 and 2018 performance. We believe it would be more beneficial and valuable to build the data and grow the program, allowing providers to adapt to the

[1] Flexibilities and Support for Small Practices; https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Small-Practices-Fact-Sheet.pdf

program requirements, similar to the opportunity being provided to non-eligible MIPS clinicians.

MIPS Eligible Clinicians

CMS proposes that in the first two years of the program, MIPS eligible clinicians (ECs) subject to the payment adjustment will include: physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and groups of two or more providers. Qualifying APM Participants (QPs) and Partial Qualifying APM Participants (Partial QPs), new Medicare-enrolled clinicians, and low-volume threshold clinicians will be exempt from participation in the MIPS program. Low-volume threshold clinicians are defined as those who have Medicare charges less than or equal to $10,000 and who provide care for 100 or fewer Medicare Part B beneficiaries.

ASTRO supports the exclusion of low-volume threshold clinicians who may be unduly burdened if subjected to the program requirements. However, we are concerned that the same low volume threshold would apply to clinicians reporting as individuals and those reporting as groups. We understand CMS' efforts to minimize confusion and adopt consistent methodologies, but this proposal would make it considerably more difficult for a group practice to be excluded from MIPS. This could result in situations where a single individual who does not necessarily represent the practice patterns of the overall practice disqualifies that group from what would otherwise be a clinically appropriate exemption. For example, if only one member of the group has charges or provides care to a number of beneficiaries above the threshold, the entire group is considered MIPS eligible, even if no other member of the group exceeds the threshold. A solution may be to scale the minimum number of Part B-enrolled Medicare beneficiaries and Medicare billed charges to the number of physician group members.

Additionally, we urge CMS to modify the exclusion so that clinicians with Medicare charges less than or equal to $10,000, *or* those who provide care for 100 or fewer Medicare Part B beneficiaries would be exempt from participation. This modified threshold more appropriately accounts for those clinicians who should not be subject to the MIPS program requirements.

Additionally, ASTRO requests information on whether locum tenens and the services they provide will be exempt or assessed under the MIPS program. If they are assessed under the MIPS program, would they be assessed individually, or would the services they provide be attributed to the primary EC or group for whom they are providing coverage? In which case, how should locum tenens be held accountable, and what appropriate incentives should be put in place, for their contribution to the EC's performance in each of the categories?

MIPS Eligible Clinician Identifier

CMS proposes that ECs can participate and report performance data either individually or as part of a group, but they must participate using the same option for all four MIPS performance categories. Furthermore, regardless of whether the EC participates individually or as part of a

group, CMS proposes to use a single identifier – the National Provider Identifier (NPI)/ Tax Identification Number (TIN) combination – for assessing performance and applying the payment adjustment for each EC.

ASTRO supports the agency's proposed use of the existing NPI/TIN identifier for performance and payment assessment. The creation of a new MIPS identifier would only increase administrative burden, create confusion, and result in reporting errors. **However, ASTRO recommends that the agency consider allowing for greater flexibility in the reporting requirements by allowing providers to participate either individually or as a group for each of the categories.** Depending on the ECs' practices, it may be reasonable to report individually for some categories and as a group for other categories. For example, ECs may opt to report individually for the quality and resource use categories, but then report as part of a group for the CPIA and Advancing Care Information categories because those activities are performed and monitored at the group level in their practice. Thus, we believe that the MIPS program would benefit from greater flexibility in allowing a combination of individual and group reporting for the different categories, while using a single NPI/TIN identifier for assessing performance and applying the payment adjustment.

Virtual Groups

CMS has decided to delay the implementation of virtual groups to 2018. ASTRO appreciates the agency taking additional time to thoroughly and successfully develop this reporting option, so that potential issues for end-users are minimized. The agency has requested comments on the factors that should be established for virtual groups.

ASTRO believes that virtual groups could provide flexibility for providers who may otherwise be at a disadvantage because of their geographic location, small practice size, or demographically (skewed patient population). Virtual groups allow these providers, specifically the solo practitioners and small groups that are at a disadvantage under MIPS, to band together and establish a level playing field with peer groups. While ASTRO supports a minimum size for virtual groups, such as a minimum of ten providers, we do not believe that a virtual group's eligibility and composition should be otherwise restricted by characteristics such as proximity to other providers or single-specialty groups. Rather, ASTRO encourages the agency to explore broad options for virtual groups outside the norm of NPI/TIN or geographical grouping. As an example, virtual groups could be formed based on diagnosis, such as specific ICD-10 codes for breast or prostate cancer. We strongly encourage the agency to develop these options with physician and specialty society input.

MIPS Performance Period

CMS proposes using calendar year 2017 as the performance period for the 2019 payment adjustment for all four categories of the program. This perpetuates the inefficient 2-year gap between the performance period and payment adjustment year. In previous rulemaking, CMS has stated that it is operationally infeasible to create a 12-month reporting period for the payment adjustment year any later than two years prior to the adjustment year. **ASTRO recognizes the**

operational and technical limitations of the Medicare program's data submission and claims processing procedures, and therefore proposes that the reporting period be shortened to six consecutive months in a single calendar year, with the ideal reporting period being from July 1 – December 31. We recommend this later, shorter reporting period because the final rule for MIPS and APMs will be released in the fall, and the 2-month turn-around period to participate by January 1, 2017 is unrealistic for successful and meaningful participation in the program. A reporting period that begins July 1 allows providers more time to understand the program requirements and to adopt new processes for implementation and participation. We also believe that a six month reporting period is equally representative of a physician's practice as a full calendar year and that there is tremendous value from a quality improvement perspective from timely and actionable feedback reports to physicians.

A later start date would also provide CMS with more time to address several issues that were absent from the proposed rule, including the development of virtual groups, improved risk-adjustment and attribution methods, further refinement of episode-based resource measures and measurement tools and enhanced data feedback to participants. Statements in the proposed rule indicate that CMS did not have sufficient time, was waiting upon report findings, or needed to upgrade its systems before it could fully implement these changes that were required as part of the MACRA statute. If this is the case, we believe CMS should take such time and provide a later start date. To be clear, we are not asking that CMS continue the existing program (PQRS, MU, and VBM) in 2017; the current programs should still end, which avoids having CMS and physicians try and report and calculate performance twice for 2017.

A shortened reporting period also allows for successful data collection in the second half of the calendar year and the opportunity for CMS to provide more timely and actionable feedback reports. ECs and group practices then have sufficient time to analyze the data in their feedback reports, assess their performance, and develop action plans for improving performance in each of the categories for the next reporting period. This not only eliminates the 2-year gap between the performance period and payment adjustment year, but also eliminates the 2-year delay of the adoption and implementation of processes and behaviors that result in lower-cost and higher-quality care. Furthermore, the shorter reporting period eliminates the participation burden and confusion for ECs who may switch practices mid-year and have to track and report data for multiple NPI/TIN combinations under the proposed full calendar year reporting period.

Quality Performance Category

Measures

The quality performance category will account for 50 percent of the composite performance score (CPS) in the first year of the program. CMS proposes to retain the majority of the existing measures within the PQRS program, but eliminates the measures group reporting option and replaces it with a specialty-specific measures set reporting option. The specialty-specific measures sets categorize the individual measures available in the program based on the American Board of Medical Specialties (ABMS). ASTRO is concerned that several *oncology*

measures are inappropriately listed under the *radiology* umbrella. **Radiation Oncology is a separate and distinct specialty from radiology. Therefore, we urge CMS to remove these measures from the radiology category, and create a new category specifically for "Radiation Oncology," under which the radiation oncology measure set would reside.**

CMS also proposes that Qualified Clinical Data Registry (QCDR) non-MIPS measures must go through a rigorous approval process during the QCDR self-nomination process, and then be assigned a unique identifier that can only be used by the QCDR that proposed the measure. ASTRO appreciates CMS' support for the development of "home-grown measures." However, prohibiting the sharing of non-MIPS quality measures between QCDRs will inhibit the efficient and cost-effective use and dissemination of such measures. Allowing QCDRs to share their non-MIPS quality measures will permit the QCDR that develops a measure to recoup some of its costs while also expanding the number of physicians reporting on those measures, thus enhancing the ability of QCDRs and CMS to detect and analyze patterns in the QCDR data on home-grown measures. In addition to supporting the shared use of non-MIPS measures, ASTRO is also seeking clarification regarding whether or not non-MIPS measures approved for use in a QCDR qualify as MIPS comparable measures in the Advanced APM program.

MACRA authorizes $75 million over five years to fund the development of physician quality measures for use in MIPS. ASTRO continues to be concerned about the lack of expediency CMS has shown in distributing these funds, especially in light of the anticipated performance year beginning in January 2017. The funding was intended to go to physician-led organizations that have devoted substantial time and resources to developing and refining quality improvement and/or measure development activities. Developing measures through and with physician-led organizations, such as the Physician Consortium for Performance Improvement (PCPI®), will enhance physician engagement and trust in the process and assist with the successful implementation of the MIPS program. A preference for measure development by organizations such as PCPI and specialty societies will further ensure that new measures are harmonized with specialty societies' clinical data registry activities, a reporting mechanism encouraged by MACRA. Additionally, it will allow the profession to prioritize measurement efforts, coordinate activities, and ensure an inclusive process.

ASTRO would also like to encourage CMS to provide funding for measure testing, in addition to measure development. We are pleased with the MACRA provision that provides funding for quality measure development, a long-term objective of medicine. We are particularly encouraged that this will expand CMS' ability to support the development of meaningful measures used by physicians who participate in new payment and delivery models designed to improve the quality and efficiency of care. A portfolio of appropriate quality measures that meets the needs of the various physician specialties will be key to achieving the legislation's goals. **Part of the commitment by CMS to move towards improving the quality of care must also include the funding of measure testing, not just funding measure development.** Measure testing allows for measure developers to not just test for validity and reliability, but to take into consideration real-world experience when developing and refining a measure.

Reporting Criteria

Currently, the PQRS program requires reporting of nine measures covering at least three National Quality Strategy (NQS) domains. CMS proposes to modify this for the quality performance category by eliminating the NQS domains criteria, and by requiring ECs and groups to report six measures, including one cross-cutting measure and one outcome measure. If an outcome measure is not available, then the EC or group must report another high priority measure (appropriate use, patient safety, efficiency, patient experience, or care coordination measure). If the measures are reported using a QCDR, EHR, or a qualified registry, then the measures must be reported for 90 percent of all patients to which each the denominator of the measure applies, regardless of the payer. If the measures are reported via claims, then the measures must be reported for 80 percent of Medicare Part B patients to which each measure applies.

ASTRO applauds the Agency for easing the reporting criteria by eliminating the NQS domains criteria and reducing the number of measures required from nine to six. However, ASTRO believes the patient thresholds stated in the proposed rule for the measures significantly increases the burden for providers who have been participating in PQRS using the measures group reporting option. **ASTRO recognizes and supports the Agency's goals for collecting meaningful quality data, and recommends phasing in the new threshold reporting requirements. Phasing in the requirements will not only decrease the burden of reporting on physicians, but it will also allow for a smooth transition from manual data entry via online forms and excel uploads to automatic EHR abstraction, a key feature of registry technology. Thus, ASTRO recommends that CMS decrease the thresholds for both categories to 50 percent the first two years of the program.**

Additionally, while ASTRO supports the Agency's goal of emphasizing and measuring improved outcomes, we believe that requiring specific measures may create potential barriers for specialties lacking a robust set of measures. For example, outcome measures at the physician level can be particularly challenging to construct for two primary reasons—small sample sizes and the difficulty of identifying outcomes for which the physician can and should be held accountable (i.e., outcomes that are truly representative of the quality of care received and not other factors). Therefore, until more valid and reliable outcome measures are developed, ASTRO believes that CMS should keep flexibility of measures throughout and lift the requirement that certain types of measures be reported, such as outcomes-based or cross-cutting measures.

Resource Use Performance Category

The Resource Use performance category will account for 10 percent of the CPS the first year of the program. The basis for this category will be the existing condition- and episode-based measures, the total per capita cost measure, and the Medicare Spending per Beneficiary measure that are part of the current Value-based Payment Modifier (VM) program. Performance for these measures will be attributed and assessed based on administrative claims data, rather than data submitted by ECs or groups. Additionally, CMS states it will continue to develop care episode

groups, patient condition groups, and patient relationship categories to incorporate into this category.

ASTRO has several concerns with this proposal for the resource use category. The proposal fails to make needed improvements in several key areas, such as attribution and risk adjustment, which are necessary to make this category valid for physicians. The existing VM program contains several flaws, key among them is the fact that many of the measures were created for hospitals, not individual physicians and are therefore inappropriate to assess physician performance. In the proposed rule, CMS states that many providers are already familiar with these measures, but this is inaccurate. 2015 was the first participation year that solo practitioners and groups of two to nine eligible providers (a majority of radiation oncologists fall into this category) were subject to performance on these measures. 2018 will be the first year that these providers will be subject to a possible downward adjustment in the VM program. Thus, many providers lack the familiarity and understanding of these complex measures that will be factored into their CPS.

ASTRO urges CMS to replace measures, such as total per capita costs and Medicare Spending Per Beneficiary that were developed for use in hospitals and other settings, with measures that have been developed and tested for use in physician offices. In order to make the Resource Use category more useful, CMS should focus on methodological improvements, including more sophisticated risk-adjustment, more granular specialty comparison groups, and improved attribution methods. CMS should direct special effort to eliminating flaws that penalize practices with the most high-risk patients.

Furthermore, it is unclear how patients will be attributed to specialists, such as radiation oncologists. ASTRO has sought clarification on the issue of attribution in the past, but the attribution methodology remains unclear and will likely become further complicated with the addition of patient relationship categories and codes. No resource use measures should be mandated until Care Episode Groups, Patient Condition Groups, and Patient Relationship Categories have been developed and gained support from the professional societies whose members treat the majority of patients falling into a particular episode.

In light of these key issues, ASTRO recommends that the weight of this category be decreased to five percent, with the remaining five percent shifted to the CPIA category (reasoning discussed below) in the first two years of the program. Alternatively, if radiation oncologists (or other specialists) do not meet the attribution threshold, we recommend that the entire ten percent be reallocated to the CPIA category. The weight of the category can increase after the first two years, when there is a better understanding of the attribution and impact of measures.

Choosing Wisely

ASTRO agrees with CMS that *Choosing Wisely* guidelines should be used in the creation of resource use measures applicable to specialties. ASTRO has released 10 *Choosing Wisely* [2] recommendations for radiation oncology treatments that are commonly ordered but may not always be appropriate or necessary. Converting these recommendations into measures would help determine and address underuse, overuse, and appropriate use of resources in these clinical areas. **ASTRO encourages CMS to facilitate and aid specialty societies in the conversion of these guidance recommendations into applicable and valuable measures for the resource use category.**

Clinical Practice Improvement Activities (CPIA) Performance Category

The CPIA category will account for 15 percent of the CPS in the first year of the program. CMS proposes that this category will reward clinical practice improvements, such as activities focused on care coordination, beneficiary engagement, and patient safety. Clinicians may report on activities that match their practices' goals from a list of more than 90 options. Points will be assigned for each reported activity within two categories: medium-weighted, worth 10 points, and high-weighted activities, worth 20 points. CMS proposes that the highest potential score will be 60 points for the 2017 performance period.

One of the activities in the CPIA list is participation in a patient safety organization (PSO). ASTRO and the American Association of Physicists in Medicine (AAPM) cosponsor RO-ILS: Radiation Oncology-Incident Learning System®, which is part of Clarity PSO, a federally-listed PSO. The mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment. RO-ILS is the only medical specialty society-sponsored radiation oncology incident learning system, allowing providers to learn from actual and potential adverse events that could occur in radiation therapy and improve the quality and safety of patient care. Participants are not only able to track and analyze internal incidents, but they are also contributing to a national database. ASTRO thanks the agency for including participation in a PSO as a CPIA as this will be valuable in improving the quality of care provided to cancer patients.

ASTRO recommends two changes to the proposals for this category. First, we believe that ECs and groups participating in an approved accreditation program aligned with multiple activities in the CPIA category satisfy this requirement at 100 percent, similar to that laid out for participation in Patient Centered Medical Homes. ASTRO's Accreditation Program for Excellence (APEx) is organized around five pillars: the process of care; the radiation oncology team; safety; quality management; and patient-centered care. This underlying focus on a culture of quality and safety, as well as patient-centered care, aligns with the CMS goal for this category of using a patient-centered approach to program development that leads to better,

[2] Choosing Wisely: Things Physicians and Patients Should Question https://www.astro.org/Patient-Care/Patient-Education/Choosing-Wisely/

smarter, and healthier care. APEx accredited facilities have in place the systems, personnel, policies and procedures necessary to provide high quality and safe patient care.

ASTRO conducted a comparison of the CPIA activities and the APEx standards and mapped approximately 15 activities to APEx evidence indicators required for accreditation (Appendix A), and therefore we believe a practice achieving APEx accreditation would *exceed* the 60-point maximum threshold. **ASTRO recommends that CMS include language in the final rule stating that APEx accreditation satisfies the CPIA category and that those physicians participating in the program receive a 100 percent score.** Furthermore, providers should be able to demonstrate their CPIA performance via APEx through a simple annual attestation process. There are additional health care accreditation programs that may also satisfy this requirement, and ASTRO asks CMS to establish a vehicle for accreditation programs to demonstrate they align with the CPIA activities to be included in a list of approved programs.

Second, ASTRO urges CMS to increase the weight of this category from 15 percent to 25 percent. CMS seeks to improve the health of Americans by developing incentives and policies that drive improved patient health outcomes. Of all the MIPS categories, we believe CPIA is the most influential category that will contribute to higher quality care and will facilitate the shift from volume-based care to value-based care. This category is highly physician-driven and is where actual change and innovation occurs. **Therefore, we recommend that the resource use and advancing care information categories be reweighted to five percent and 20 percent, respectively, and that the CPIA category should be reweighted to 25 percent.**

Third, ASTRO recommends that CMS encourage the broader use of QCDRs as a method for benchmarking, linking measurement improvement to performance, and tracking quality of care improvements as prescribed in the CPIA category.

Finally, ASTRO seeks inclusion of accredited continuing medical education (CME) [and board-certification] activities in the list of CPIAs. Such activities can improve clinical practice and care delivery, leading to improved patient outcomes. Accredited CME is designed to address the learning needs and practice gaps of eligible clinicians and is structured in a way to avoid commercial influence or other bias. We urge CMS to explicitly recognize relevant performance and quality improvement CME activities as qualifying CPIAs.

Advancing Care Information (ACI) Performance Category

The Advancing Care Information category will account for 25 percent of the CPS in the first year of the program. CMS eliminates the all-or-nothing approach in the current Meaningful Use (MU) program by removing the thresholds for a majority of the measures and allowing for greater flexibility. ECs and groups will be assessed on their base score and performance score. The base score will be a yes/no statement for the applicable measures, with only “yes” counting for credit toward 50 percent of the advancing care information category. The performance score will be based on performance in the objectives and measures for Patient Electronic Health Access, Coordination of Care through Patient Engagement, and Health Information Exchange.

As proposed, the base score carries over the problematic all-or-nothing structure of the current MU program: if a physician fails to report/attest to just one requirement, the physician earns a zero for not only the base category, but the *entire* ACI category. Missing one base measure earns a zero score regardless of whether that physician achieved 100 percent on every other ACI requirement. CMS' justification for retaining this approach is that the base score requires a simple yes/no or one patient reporting for each measure. Yet, by using this scoring methodology, CMS maintains a structure where failure to report does not simply harm your performance but renders all of your other efforts meaningless. The potential for complete failure due to an inadvertent error or mistake continues to dominate the program, and the incentive to try is diminished.

To remedy this problem, CMS should award credit for each measure reported under the base score, and make clear that a physician will not fail the entire ACI category if they fail to report all base measures. This allows the base score to reflect a physician's actual success in achieving requirements, rather than simply awarding zero or fifty points with no differentiation. We urge CMS to not add to the complexity of the base score but maintain its intent—to show functionality or the capability of doing each measure. The score should continue to use yes/no or one patient reporting and measures should be equally weighted across the base score so that physicians do not become confused or burdened by an intricate system of points and weights.

Additionally, the base score should be re-weighted from 50 percent to 75 percent of the total score for the ACI category. The base score represents the foundation of the ACI category, requiring physicians to initially complete each measure at least once. It therefore makes sense that CMS first seek to ensure MIPS participants are focused on and working to fulfill the base score requirements before moving on to the performance score. A 75 percent weighting of the base score would highlight the importance of the base requirements before moving on to the more complex performance component. **We emphasize that greater weighting of the base score should only occur if CMS also moves away from the pass-fail approach to scoring this section, as described above.** We do not support a greater base score weight if CMS maintains the proposed pass-fail scoring approach.

As discussed above, ASTRO believes that this category should be reweighted to 20 percent. ASTRO greatly appreciates CMS previously recognizing the hurdles in the current Meaningful Use program by providing more flexibility and time to allow providers to update their software, train staff, and change practice workflows to accommodate new technology. However, the proposed scoring for the Advancing Care Information category seems to reverse course by creating multiple tiers and adds a new level of complexity to the Meaningful Use program.

ASTRO supports the straightforward base score methodology of "yes/no" attestation reporting for all the measures. However, the performance score methodology is much more confusing and will be difficult to translate into easily understood performance and reporting requirements for providers. **ASTRO requests further clarification and recommends that CMS issue an FAQ or fact sheet on the scoring methodology for the objectives and measures for Patient Electronic Health Access, Coordination of Care through Patient Engagement, and Health Information Exchange.**

While we understand the need for stability during the transition period, we strongly urge CMS to work closely with physician societies, such as ASTRO, to develop program standards that are meaningful and applicable to each specialty. ASTRO has repeatedly voiced concern over the extreme difficulty for radiation oncologists to achieve the Meaningful Use objectives and measures due to their lack of applicability. For example, the Patient Electronic Access objective and measures are particularly challenging. Many radiation oncology patients are elderly cancer patients who may not be familiar with or have access to electronic messaging mediums. Furthermore, given the nature of the specialty, patients may see their radiation oncologists for just a few weeks and then return to their referring providers. Thus, it is difficult to incentivize and encourage patients to use patient portals or other electronic mediums to communicate with their radiation oncologists. The standards can be unduly burdensome and require radiation oncologists to change their standard practices and adopt new processes, including workflow changes and training staff to implement these changes. We believe that there should not be a blanket definition of "meaningful use of EHR technology," but rather one that is flexible and takes into account the needs of different specialists and their patients.

CMS should allow for the testing of alternative participation models for demonstrating meaningful use. **ASTRO recommends basing performance in this category on the adoption and use of EHR technology tailored to a specialty-appropriate assessment of meaningful use. ASTRO urges CMS to work closely with physician societies to develop meaningful and applicable program standards and definitions for specialties, as well as hardship exceptions.** There should be a natural fit between the use of health IT and the achievement of certain interoperability goals. Such an approach could be accomplished by focusing on specialty-specific interoperability use cases rather than the quantity of data exchanged.

Alternative Payment Models (APM)

CMS proposes development of three distinct groups of APMs: Advanced APMs, MIPS APMs, and Physician Focused Payment Models (PFPMs). Physicians who are deemed to be Qualified APM Participants (QP) may participate in an Advanced APM and qualify for the 5 percent annual bonus payment. Eligible clinicians participating in MIPS APMs and PFPMs will be required to continue reporting MIPS measures and they will not be eligible for the 5 percent Advanced APM bonus payment.

CMS has developed multiple APM pathways in an effort to recognize different approaches to value based payment. ASTRO urges CMS to further consider how to establish pathways to Advanced APMs for those APM entities that initially pursue MIPS APMS and PFPMs to achieve the 5 percent bonus. Additionally, ASTRO is concerned that continuing to require MIPS reporting, even with the modified category weights, in all but the Advanced APM, may prove a disincentive to participating in MIPS APMS and PFPMs due the challenge of meeting compliance requirements in two distinct programs. **ASTRO believes that if a MIPS APM or PFPM contains MIPS comparable measures, includes certified electronic health record technology (CEHRT), and puts a nominal amount at risk, they should be exempt from the MIPS reporting requirement and receive the 5 percent bonus. ASTRO is extremely concerned that the requirements needed to meet Advanced APM status are complex and**

too strenuous for many practices to achieve, especially small physician practices. Significant modifications are necessary to make this model achievable by practices of all shapes and sizes.

Advanced APM Entity

According to MACRA, Advanced APMs must use CEHRT; provide for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS; and bear financial risk for monetary losses in excess of a nominal amount or be a CMS designated Medical Home Model. **As stated above, ASTRO is very concerned about the overwhelming complexity of the proposed APM program and urges to CMS to make significant revisions to simplify the program to ensure ample opportunity for physician participation in APMs, particularly for small practices.**

Certified Electronic Health Record Technology (CEHRT)

CMS proposes requiring at least 50 percent of Advanced APM eligible clinicians, designated as QPs and enrolled in Medicare, to utilize CEHRT to document and communicate clinical care with patients and other health care professionals during the first performance period (2017). Proposed participation levels increase to 75 percent by 2018. **ASTRO is supportive of the 50 percent threshold; however, we suggest that the 50 percent requirement be maintained in 2018 and beyond until experience indicates that providers can move to the higher threshold. We also recommend that the calculations exclude clinicians who have their MIPS Advancing Care Initiative component weight reduced to zero, due to being hospital based, having insufficient internet coverage, or lacking face-to-face patient interaction.**

CMS also seeks comments on appropriate health IT functionalities for APMs and what new health IT standards and certification criteria should be required for widespread interoperability. **ASTRO encourages CMS to identify interoperability measures or standards that allow for a natural fit between the use of health IT and the achievement of interoperability goals. Such an approach could be achieved by focusing on specialty-specific use cases, rather than on more general healthcare or hospital based interoperability goals. For example, focusing on the information and tests that must be transferred between a radiation oncologist and medical oncologist in order for a radiation oncologist to develop a treatment plan for the patient. These use cases should be developed with physician and specialty society input to ensure that interoperability goals align with patient needs and contribute to increasing the efficiency and quality of care provided.** While we support the end goal of achieving complete interoperability of all information and between all systems, we believe that the immediate, short-term interoperability goals should be patient-focused.

Quality Measures Comparable to MIPS Measures

CMS proposes including payment for professional services based on MIPS comparable quality measures. CMS proposes the following principles for selecting Advanced APM measures to enhance comparability with MIPS measures:

- Measures chosen should have an evidence-based focus.
- Measures chosen should harmonize high priority measures with those of MIPS.
- Measures chosen should be those most appropriate to an APM's population, as determined by the APM participants.
- Some, but not all, quality measures for which an APM is assessed must be MIPS comparable.
- Some, but not all, quality-based payments made to Advanced APM entities must be contingent upon MIPS-comparable measures.
- Payments not tied to quality measures are not required to be MIPS comparable.

Additionally, CMS proposes that the Advanced APM include at least one quality measure tied to payment based on the following measure types:

- Any of the measures on the proposed annual list of MIPS quality measures.
- Quality measures endorsed by a consensus-based entity.
- Quality measures developed under the CMS Quality Measures Development Plan.
- Quality measures submitted in response to the MIPS Call for Quality Measures.
- Any other quality measures determined by CMS to have an evidence-based focus.

ASTRO appreciates that CMS proposes providing APMs with some flexibility in determining appropriate quality measures for inclusion in APMs. Flexibility will be key to ensuring that each APM is able to utilize measures that are specific and relevant to the services provided. For instance, it would be inappropriate to include a breast measure in a prostate model. Too general an approach could result in measures that are inappropriate for inclusion in a model, simply to achieve a predetermined quantity threshold.

ASTRO seeks additional insight on the types of measures that CMS is classifying as tied to payment. Are measures for cost specifically listed in the national quality domain, or are they simply quality measures within an APM that have been tied to cost? As an example, bone scan for low risk prostate cancer can be tied to cost and used as a measure for reducing the cost of care. We seek CMS' guidance on whether or not this type of measure meets the measure tied to payment requirement. If it does, then will CMS attribute the measure to the ordering physician, in this case the radiation oncologist, regardless of who provides the service?

Additionally, ASTRO urges CMS to include non-MIPS measures, included in QCDRs, as an option for meeting this Advanced APM requirement. This will ease the transition for many physicians seeking to transition from MIPS to Advanced APMs.

Nominal Financial Risk

The proposed rule requires participating Advanced APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount or be a CMS-designated Medical Home Model. CMS proposes the following framework for establishing that the Advanced APM has put a nominal amount at risk for monetary losses:

- At least 4 percent of the spending target must be put at risk.
- Marginal risk levels must be at least 30 percent. Marginal risk is a portion of the maximum amount at risk that the APM would be responsible for if actual expenditures exceed expected expenditures.
- Minimum loss rate (MLR) is the amount clinician spending can exceed the benchmark before they become responsible for financial losses. The MLR cannot exceed 4 percent.

CMS seeks comment on the risk construct, particularly whether it should be applied to the Advanced APM benchmark or to actual revenues. Additionally, CMS is seeking feedback on whether the risk construct could be successful without the MLR.

The eligible APM entity definition in MACRA gives CMS discretion in defining what it means to "bear financial risk for monetary losses under an alternative payment model that are in excess of a nominal amount." This is made clear by a decision of Congress to provide no statutory details on what is meant by "nominal" amount of financial risk. Congress would have built the concept of two-sided risk into the eligible APM entity definition had that been its intent, but Congress did not do so. It recognized the principle from the Accountable Care Organization (ACO) authorizing statute that one of the purposes of providing for the creation of ACOs is to "encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery." That investment – the cost of switching to a fundamentally different approach to patient care – is in and of itself a substantial risk.

ASTRO is extremely concerned that the risk construct is so complex that it may prove to be a barrier to the implementation of many promising Advanced APMs. HHS has long defined "significant" impact as the loss of 3 percent of a physicians' revenue. The 4 percent of total expenditures standard in the proposed rule could represent as much as 20 percent or more of a physician practice's revenue. Additionally, "more than nominal risk" should be set at a small percentage of the physician professional service revenues, not expenditures under the APM. Physician Fee Schedule services account for just 19 percent of total Medicare Part A and Part B expenditures. Physicians should not have to take risks for expenditures outside their control. ASTRO supports the inclusion of a MLR to provide some protection against small overages. This will be especially important as models are initially being launched.

ASTRO is disappointed that CMS did not propose including business risk or the investments necessary to establish an APM in its consideration of "nominal financial risk". In the proposed rule, CMS recognizes this is a valid issue but expressed concern that these costs will vary significantly by APM, and as such believes it would be difficult to quantify. **ASTRO urges CMS to reconsider this decision and explore ways to value investments, such as through the collection of receipts and verifications of employment of case managers and other investments to improve care coordination. It will be especially important for CMS to work with specialty groups as these types of investments will vary. As a starting point, we recommend that CMS consider increasing the MLR to a higher percentage to account for these expenses in the early years until a more accurate calculation can be carried out.**

ASTRO is also concerned that CMS has neglected to recognize the savings achieved by changes in practice patterns that some APMs will naturally create as a result of payment modification. The ASTRO Radiation Oncology Palliative Care Model is an example of demonstrating savings when a model focuses on practice changes. The ASTRO model addresses both the underutilization, as well as the overutilization, of radiation therapy for the palliative treatment of bone metastases. With respect to overutilization, research shows that patients with bone metastases should receive 10 or fewer fractions of radiation therapy. However, despite ASTRO's evidence-based guidelines and Choosing Wisely recommendations that support fewer than 10 fractions, many patients still receive greater than 10 fractions. ASTRO's palliative care for bone metastases model contains a base rate that limits payment to the average reimbursement rate for 10 fractions and creates financial incentives to provide patients with higher quality care, such as measures to ensure rapid treatment and documentation of pain outcomes. The proposed nominal risk methodology would not recognize the immediate savings featured in the ASTRO model. We believe this is shortsighted.

Additionally, the nominal risk proposal does not account for innovative approaches that give physicians the flexibility to deliver patient centered services based on evidence based standards of care. ASTRO's Breast Cancer APM is an example of a model that allows physicians the flexibility to deliver patient-centered breast cancer care using different modalities. The model establishes base rates that are a composite of the various modalities of care and are appropriate and cost-effective for the treatment of early-stage breast cancer. The cost of each modality varies, but an average weighted cost produces a base rate that accounts for various modalities. This allows physicians and patients the flexibility to determine an appropriate treatment, while taking away any financial incentive to choose a given treatment based on reimbursement.

APM Base Rate and Incentive Payment

CMS proposes to use the full calendar year prior to the payment year as the incentive payment base period from which to calculate the estimated aggregated payment amounts. Additionally, CMS proposes to omit MIPS adjustments included in the base period payment from the incentive payment calculation. CMS also notes that MACRA explicitly states that the 5 percent incentive payment will not be included in determining actual expenditures under an APM or for determining or rebasing benchmarks under the APM.

CMS proposes to make the incentive payment to the TIN associated with the APM entity. **ASTRO urges CMS to consider alternative methods for making the incentive payment directly to physicians who wish to receive payment, rather than the APM entity. Individual physicians have more control over their performance and can respond more quickly to incentives. Additionally, paying physicians directly will encourage them to become more engaged in the APM and its potential impact on patient care.**

APM Reconciliation

According to the proposed rule, if actual expenditures under the APM exceed expected expenditures during the performance period, CMS can withhold payment for services to the

APM Entity or the APM Entity's eligible clinicians; reduce payment rates to the Advanced APM Entity and/or the Advanced APM Entity's eligible clinicians; or require the APM Entity to reimburse CMS.

ASTRO appreciates that CMS is proposing three methods for collecting expenditures in excess of the target. However, it is unclear as to when and how these collections will take place, or whether the physician can determine how they will comply with the collection process. ASTRO urges CMS to consider implementing a timeline and framework for how this process will be carried out.

Notification of APM Eligibility

CMS proposes that notification of Advanced APM eligibility/participation will be issued annually before the performance year beginning January 2017. With a start date for APM participation of January 1, 2017, physicians would need to already be participating in an APM before the final regulations are published defining whether the APM would qualify as an APM under MACRA, either as a MIPS APM, PFPM or Advanced APM. Especially as the identification of APM participating physicians will be based on participant lists as of December 31, 2016, there is no justification for requiring that eligible APMs be implemented and physicians be participating in them on January 1, 2017.

Very few APMs qualify as Advanced APMs, PFPMs, or MIPS APMs under the proposed rule, which makes it impossible for all but a handful of physicians to meet the proposed January 2017 deadline. ASTRO is hopeful that CMS will work closely with the Physician Focused Payment Model Technical Advisory Committee (PTAC) and move quickly to implement additional Advanced APMs during 2017 that meet the requirements of the law and rule so that as many physicians as possible can participate in APMs, which is what Congress intended when they passed MACRA.

Qualifying APM Participants (QP) and Partial Qualifying APM Participants

Qualifying APM Participants (QP) and Partial QPs are exempt from MIPS participation. Eligible QPs will receive a 5 percent incentive payment or bonus. However, Partial QPs will not receive the bonus payment but they may opt to participate in MIPS. All other eligible clinicians participating in APMs, that are not Advanced APMs, are MIPS eligible and must report MIPS measures.

In order to qualify as QP, CMS proposes that eligible clinicians in the Advanced APM Entity collectively have at least a specified percentage of their aggregate Medicare Part B payments for covered professional services, or patients who received covered professional services, through the Advanced APM.

- QPs must have 25 percent of their Part B payments tied to Advanced APMs beginning in 2019. That percentage grows to 50 percent in 2021 and 75 percent in 2023.

- QP patient thresholds start at 20 percent in 2019 and then grow to 50 percent beginning in 2023. The thresholds for Partial QPs are lower and a new All Payer Combination threshold requirement begins when that program is launched in 2021.

CMS proposes that the payment methodology will be the aggregate of all payments for Medicare Part B professional services provided by an Advanced APM (numerator) over the aggregate of all payments for Medicare Part B professional services provided to attribution-eligible beneficiaries by the eligible clinician (whether or not the services were actually provided during the period).

ASTRO understands this to mean that for an APM targeting patients with a particular disease, condition or episode, the denominator would be the patients with that disease, condition or episode, and the numerator would be the patients with the disease, condition or episode who were attributed to the APM. This methodology includes attribution-eligible beneficiaries and it is not entirely clear how CMS will identify that population. CMS proposes to issue an APM patient attribution list. **ASTRO urges CMS to provide more information and opportunity to comment on the definition of attribution-eligible beneficiaries.**

MIPS Eligible APM Entities (MIPS APMS)

CMS proposes that Eligible Clinicians, who are not QPs, may choose to participate in an MIPS Eligible APM Entity (MIPS APM) formed under an agreement with CMS. Criteria for MIPS APMs include the following:

- APM Entities participate in the MIPS APM under an agreement with CMS;
- The APM Entities include one or more MIPS eligible clinicians on a Participation List; and
- The APM bases payment on performance (either at the APM Entity or eligible clinician level) on cost/utilization and quality measures.

CMS proposes to establish a scoring standard for MIPS eligible clinicians participating in APMs that will reduce participant reporting burden by eliminating the need for these APM eligible clinicians to submit data for both MIPS and their respective APMs. CMS proposes to use the APM scoring standard for MIPS eligible clinicians in APM entity groups that are identified as MIPS APMs. One CPS will be issued for each MIPS eligible clinician within the APM Entity Group. A separate APM Entity Group CPS score would be used to evaluate the APM.

The proposed APM scoring standard for MIPS APMs contains several key features not shared with eligible clinicians outside the MIPS APM program. CMS proposes to reduce the MIPS quality and resource use category weight to zero for all MIPS eligible APM entities. The first year, the APM Entity group will submit quality measures to CMS that are required by the APM to serve as measures in future years. The resource use category is reduced to zero due to the fact that MIPS APMs are already subject to cost and utilization performance standards. As a result of these two changes, the CPIA category weight will increase from 15 percent to 25 percent and for the first performance period only, eligible clinicians who submit either individual or group level

MIPS data may earn a minimum score of 50 percent of the highest potential CPIA performance category. MIPS APMS should receive a score higher than 50 percent of the highest potential CPIA performance category, due to the limited ability of MIPS/APMs to attain Advanced APM status. Additionally, the Advancing Care Information category weight will grow to 75 percent.

ASTRO is concerned that this is a significant weighting change and could be challenging for many providers, particularly those providers with little control over the IT choices and decisions made by their employers. **ASTRO recommends basing performance in this category on the adoption and use of EHR technology tailored to a specialty-appropriate assessment of meaningful use. ASTRO urges CMS to work closely with physician societies to develop meaningful and applicable program standards and definitions for specialties, as well as hardship exceptions. As discussed previously, ASTRO appreciates that CMS is offering several APM options but urges the agency to develop pathways so that each method can achieve Advanced APM status.**

Physician Focused Payment Model

The proposed rule provides the PTAC with criteria for evaluating physician focused payment models (PFPM). The PTAC is expected to review, comment on and provide recommendations to the Secretary of HHS regarding PFPMs. CMS does not believe that PFPMs should automatically receive recognition as Advanced APMs. **While ASTRO agrees that there should not be automatic recognition, we believe CMS has gone too far in restricting the ability of APMs to become Advanced APMs and should ensure a more realistic and attainable pathway allowing physician-developed APMs focused on improving quality and lowering costs to be recognized.** We believe the proposed restrictions are inconsistent with congressional intent, undermine the ability for physicians to participate in the program, and will ultimately dilute the effectiveness of the program.

CMS proposes that PFPMs should promote value over volume and provide incentives for physicians to deliver high-quality health care. Model payment methodology must be different from current payment methodology. Submissions should describe the type and degree of financial performance risk assumed by the PFPM. They should also include details on how Medicare and other payers will pay APM entities.

Additionally, CMS proposes that PFPMs should contain methods for evaluation of their effectiveness in care delivery improvement and involve integration and care coordination among practitioners. PFPMs should encourage greater attention to the health of the population served while also supporting the unique needs and preferences of patients and aim to improve patient safety. Finally, models should encourage the use of HIT to inform care.

CMS proposes that a PFPM must either 1) directly address an issue in payment policy that broadens and expands the APM portfolio or 2) include APM Entities whose opportunities to participate in APMs have been limited. A model should either address a new issue or include a new specialty; a PFPM that includes multiple specialties would meet this criterion if at least one of the specialties is not currently addressed by another APM. The scope of the model should

include efforts to directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM entities whose opportunities to participate in APMS have been limited. Separately, CMS proposes that models must address an issue not already part of the CMS APM portfolio.

ASTRO urges CMS to provide a clear pathway for models recommended by PTAC to be implemented as APMS under MACRA. We commend the efforts of PTAC to put in place a timely and predictable review process for stakeholder models, but remain concerned that CMS is unwilling to do the same. Congress clearly foresaw MACRA providing for the development of a robust array of PFPMs that could help improve care for patients with Medicare and other insurance.

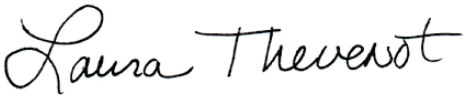
Additionally, ASTRO is concerned with the criterion that PFPM proposals address an issue that broadens and expands the APM portfolio. This language should be revised to clarify that the availability of current APMs addressing a disease, condition or episode does not preclude PFPM proposals that may address the same disease, condition or episode with a different payment model. Instead, PFPMs should make multiple APMs available for physicians to qualify for bonus payments. In particular, ASTRO is concerned that the language CMS uses is vague and can be interpreted to mean, for example, that the agency is uninterested in models that address cancer care because the Oncology Care Model (OCM) has already been approved as an Advanced APM. **ASTRO notes that the Oncology Care Model has not yet been launched, let alone proven over time to effectively improve quality at lower cost. CMS should recognize these limitations in the OCM and encourage, not limit, development of a variety of oncology models, particularly physician-developed models vetted and approved by PTAC**.

ASTRO stands by our previously stated concerns that the OCM discourages the medically reasonable use of radiation therapy. The OCM does not recognize that in many instances chemotherapy is just one of several methods used for the effective treatment of cancer. Nearly two-thirds of all cancer patients will receive radiation therapy during their illness. As it is constructed, the OCM has the potential to discourage multidisciplinary coordinated care, including the use of radiation therapy, by giving participating practices an unintended incentive to reduce the utilization of potentially beneficial therapies because of their relative costs. In particular, the OCM may lead to avoidance of neo-adjuvant chemotherapy, because the subsequent surgery and or radiotherapy then "count" towards total Part B costs within the six month episode of care. This could change established practice patterns, which support this treatment approach for certain cancers such as lung, bladder, breast, rectal and esophagus. CMS must pursue other models that address this issue. One potential solution would be to remove the cost of radiotherapy services from the tally of costs within a 6 month episode of care within the OCM. In this way the focus would shift toward emphasizing the importance of trying to avoid unnecessary hospitalizations and other expensive interventions that are not direct anti-cancer therapies. Considering these concerns, we urge CMS to recognize that the OCM has not yet been implemented, let alone evaluated to conclusively demonstrate that it achieves its goals, and therefore is no more worthy of being recognized as an Advanced APM than any other oncology-related APM that has been implemented or conceived. ASTRO looks forward to working with

the agency to correct this through the development of both broad oncology payment models and disease site-specific models that meet the goals of the program.

ASTRO appreciates the opportunity to provide CMS with comments on the proposed "Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models" rule. Any questions regarding our comments can be submitted to Anne Hubbard, Director of Health Policy, at anne.hubbard@astro.org or 703- 839-7394.

Sincerely,



Laura I. Thevenot
Chief Executive Officer

Attachment: Appendix A

Appendix A
CPIA to APEx Evidence Indicator Comparison

Subcategory/ Weighting	Activity	APEx Standard/Evidence Indicator
Expanded Practice Access High	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent and emergent care (e.g., eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: • Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); • Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or • Provision of same-day or next-day access to a consistent MIPS eligible clinician, group or care team when needed for urgent care or transition management.	**Standard 6: Safe Staffing Plan** **Evidence Indicator 6.3.1:** The Radiation Oncology Practice (ROP) requires a qualified radiation oncologist to be on-call 24 hours a day, seven days a week to address patient needs and/or emergency treatments. **Evidence Indicator 6.4.1:** The ROP has a process for referring patients to emergency care during both operating and non-operating hours.
Expanded Practice Access Medium	Collection of patient experience and satisfaction data on access to care and development of an improvement plan, such as outlining steps for improving communications with patients to help understanding of urgent access needs.	**Standard 16: Performance Measurement and Outcomes Reporting** The radiation oncology practice measures and evaluates the patient experience and takes actions to improve performance. **Evidence Indicator 16.1.1:** The ROP measures and evaluates, at least annually, the patient experience using a survey and/or other tools. **Evidence Indicator 16.2:** The ROP has a procedure in place for addressing patient grievances by accepting patient complaints and evaluates and responds to complaints. • *Patients should have the opportunity to register complaints using the measurement tool in Evidence Indicator 16.1 as well as directly with staff.*

		• *The ROP should inform patients of the opportunity to provide feedback.*
Population Management Medium	Provide episodic care management, including management across transitions and referrals that could include one or more of the following: Routine and timely follow-up to hospitalizations, ED visits and stays in other institutional settings, including symptom and disease management, and medication reconciliation and management; and/or Managing care intensively through new diagnoses, injuries and exacerbations of illness.	**Standard 1: Patient Evaluation, Care Coordination and Follow-up** The radiation oncologist is accountable for patient evaluation, ongoing assessment and follow-up, as well as for coordinating and communicating with other providers involved in the patient's care **Evidence Indicator: 1.4.1:** Following the initial patient evaluation, the ROP transmits a copy of the comprehensive patient evaluation to other involved providers (including the referring provider and primary care provider) within four weeks following the date of the comprehensive patient evaluation. **Evidence Indicator: 1.4.2:** Following treatment completion, the ROP transmits a copy of the post-treatment summary to other involved providers (including the referring provider and primary care provider) within four weeks of treatment completion. **Evidence Indicator: 1.5.1:** The ROP participates periodically in multidisciplinary review programs, such as tumor board, with other members of the patient's care team (medical oncologist, surgeon and other specialists) either remotely or on-site.

Population Management Medium (Continued)		**Standard 15: Patient Education and Health Management** The ROP educates the patient and assists the patient in managing side effects. The ROP educates patients on: **Evidence Indicator: 15.2.1:** Options for treatment and the rationale for each option (for example, surgical, chemotherapy or choices of radiation modality). **Evidence Indicator: 15.4.1:** The ROP provides therapeutic interventions to manage treatment-related side effects. **Evidence Indicator: 15.5.1:** The ROP has a patient referral process for specialized radiation therapy and/or other services not provided by the ROP.
Population Management Medium	Manage medications to maximize efficiency, effectiveness and safety that could include one or more of the following: Reconcile and coordinate medications and provide medication management across transitions of care settings and eligible clinicians or groups; Integrate a pharmacist into the care team; and/or Conduct periodic, structured medication reviews.	**Standard 1: Patient Evaluation, Care Coordination and Follow-up** A comprehensive patient evaluation must include the following elements: **Evidence Indicator: 1.1.1b:** Current medications. **Evidence Indicator: 1.2.4aa:** Pain management plan.

Care Coordination Medium	Performance of regular practices that include providing specialist reports back to the referring MIPS eligible clinician or group to close the referral loop or where the referring MIPS eligible clinician or group initiates regular inquiries to specialist for specialist reports which could be documented or noted in the certified EHR technology.	**Standard 1: Patient Evaluation, Care Coordination and Follow-up** Coordination of care and communication information by: **Evidence Indicator 1.4.1:** Transmitting a copy of the comprehensive patient evaluation (Evidence Indicator 1.1) to other involved providers (including the referring provider and primary care provider) within four weeks following the date of the comprehensive patient evaluation. **Evidence Indicator 1.4.2:** Transmitting a copy of the post-treatment summary (Evidence Indicator 1.3) to other involved providers (including the referring provider and primary care provider) within four weeks of treatment completion.
Care Coordination Medium	Implementation of practices/processes that document care coordination activities (e.g., a documented care coordination encounter that tracks all clinical staff involved and communications from date patient is scheduled for outpatient procedure through day of procedure).	**Standard 1: Patient Evaluation, Care Coordination and Follow-up** **Evidence Indicator 1.5.1:** The ROP participates periodically in multidisciplinary review programs, such as tumor board, with other members of the patient's care team (medical oncologist, surgeon and other specialists) either remotely or on-site.
Beneficiary Engagement High	Collection and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan.	**Standard 16: Performance Measurement and Outcomes Reporting** **Evidence Indicator 16.1.1:** The ROP measures and evaluates, at least annually, the patient experience using a survey and/or other tools. **Evidence Indicator 16.2:** The ROP:

		Evidence Indicator 16.2.1: Accepts patient complaints. **Evidence Indicator 16.2.2:** Evaluates and responds to complaints.
Beneficiary Engagement Medium	Regularly assess the patient experience of care through surveys, advisory councils, and/or other mechanisms.	**Standard 16: Performance Measurement and Outcomes Reporting** **Evidence Indicator 16.1.1:** The ROP measures and evaluates, at least annually, the patient experience using a survey and/or other tools. **Evidence Indicator 16.2:** The ROP: **Evidence Indicator 16.2.1:** Accepts patient complaints. **Evidence Indicator 16.2.2:** Evaluates and responds to complaints.
Beneficiary Engagement Medium	Incorporate evidence-based techniques to promote self-management into usual care, using techniques such as goal setting with structured follow-up, teach back, action planning or motivational interviewing.	**Standard 15: Patient Education and Health Management** **Evidence Indicator 15.1.1:** The ROP assesses patient educational needs for self-management of treatment-related side effects before treatment begins and at least one time during the course of treatment.
Beneficiary Engagement Medium (Continued)		**Standard 15: Patient Education and Health Management** **Evidence Indicator 15.2.1:** Options for treatment and the rationale for each option (for example, surgical, chemotherapy or choices of radiation modality). **Evidence Indicator 15.2.2a:**

		The intent of treatment (curative/palliative). **Evidence Indicator 15.2.2b:** What to expect in the treatment process. **Evidence Indicator 15.2.3:** Management of treatment-related side effects involving: **Evidence Indicator 15.2.3a:** pain. **Evidence Indicator 15.2.3b:** skin care. **Evidence Indicator 15.2.3c:** nutrition support (weight loss, diet, etc.). **Evidence Indicator 15.2.3d:** other side effects that are suitable for self-care.
Beneficiary Engagement Medium (Continued)		**Standard 15: Patient Education and Health Management** **Evidence Indicator 15.3.1:** The ROP uses written or online materials in addition to verbal communication to educate patients. **Evidence Indicator 15.4.1:** The ROP provides therapeutic interventions to manage treatment-related side effects.
Patient Safety and Practice Assessment Medium	Participation in an AHRQ-listed patient safety organization.	**Standard 7: Culture of Safety** **Evidence Indicator 7.5.1:** The ROP reports to and participates in a patient safety organization (PSO). RO-ILS (Radiation Oncology Incident Learning System). ROPs

		participate in this comprehensive patient safety database.
Patient Safety and Practice Assessment Medium	Use of tools that assist specialty practices in tracking specific measures that are meaningful to their practice, such as use of the Surgical Risk Calculator.	**Standard 6: Safe Staffing Plan** The ROP identifies staffing requirements for each professional discipline that includes: **Evidence Indicator 6.1.1:** Documentation of staffing requirements for each professional discipline that are derived from the measurable criteria. **Standard 6: Safe Staffing Plan** **Evidence Indicator 6.1.2:** Specification of the number of each professional discipline required to be on-site, directly involved in patient treatment (including at least two radiation therapists per patient when EBRT is being delivered) or available remotely during operating and non-operating hours.
Patient Safety and Practice Assessment Medium	Use decision support and protocols to manage workflow in the team to meet patient needs.	**Standard 3: Patient-specific Safety Interventions and Safe Practices in treatment Preparation and Delivery** **Evidence Indicator 3.1.1:** The ROP verifies patient identity for each patient at each point in which patient-specific information is transferred from one information system to another, using two patient-specific identifiers. **Evidence Indicator 3.2.1:** Verification of patient identity using at least two patient-specific identifiers.

		Evidence Indicator 3.2.2: Verification of patient treatment site.
Patient Safety and Practice Assessment Medium (Continued)		**Evidence Indicator 3.2.3:** Verification of correct patient positioning. **Evidence Indicator 3.2.4:** Verification of treatment delivery parameters against the approved prescription and plan. **Evidence Indicator 3.3.1:** For each patient a medical physicist performs an end-of-treatment review of the medical record within one week of the completion of therapy. **Evidence Indicator 3.4:** The ROP establishes and follows written clinical SOPs (from simulation to treatment) for each radiation therapy treatment technique offered by the practice, irrespective of frequency. Each SOP must specify: • The professional disciplines (radiation oncologist, medical physicist, dosimetrist, radiation therapist, and any other necessary staff) involved and should include: o Number of individuals required o Roles o Responsibilities o Quality assurance (QA) activities for the technique • Motion management

		Imaging procedures **Evidence Indicator 3.4.1:** External beam radiation therapy, including simple calculations, 2-D, 3-D and 4-D; photons and electrons. **Evidence Indicator 3.4.2:** Intensity modulated radiation therapy (IMRT), including volumetric modulated arc therapy (VMAT). **Evidence Indicator 3.4.3:** Stereotactic Radiosurgery (SRS). **Evidence Indicator 3.4.4:** Stereotactic Body Radiation Therapy (SBRT)/ Stereotactic Ablative Radiotherapy (SABR). **Evidence Indicator 3.4.5:** Particle Beam therapy; including protons, neutrons and carbons. **Evidence Indicator 3.4.6:** Intra-operative Radiation Therapy (IORT). **Evidence Indicator 3.4.7:** Brachytherapy, including low dose rate (LDR), high dose rate (HDR), and electronic brachytherapy. **Evidence Indicator 3.4.8:** Unsealed radioactive sources. **Evidence Indicator 3.4.9:** Other. (TBI, TSET, SXRT, hyperthermia, etc.) **Evidence Indicator 3.5.1a:** Treatment plan compared to the treatment prescription prior to treatment implementation. **Evidence Indicator 3.5.1b:**

		Treatment plan compared to the treatment prescription if changes are made to the treatment plan. **Evidence Indicator 3.5.2a:** Verification of dosimetric results before treatment implementation. **Evidence Indicator 3.5.2b:** Verification of dosimetric results if changes are made to the plan. **Evidence Indicator 3.5.3a:** Patient-specific plan quality assurance before treatment implementation. **Evidence Indicator 3.5.3b:** Patient-specific plan quality assurance if changes are made to the treatment plan. **Evidence Indicator 3.6.1:** A medical physics staff member performs periodic checks of the accuracy of treatment delivery in relation to both the formal treatment prescription and plan at least once every five treatment fractions. **Evidence Indicator 3.6.2:** A medical physics staff member checks the accuracy of treatment setup parameters in relation to both the formal treatment prescription and plan at least every five treatment fractions.
Patient Safety and Practice Assessment Medium	Measure and improve quality at the practice and panel level that could include one or more of the following: Regularly review measures of quality, utilization, patient satisfaction and other measures that may be useful at the practice level	**Standard 7: Culture of Safety** **Evidence Indicator 7.3:** The ROP conducts interdisciplinary safety rounds at least quarterly to: **Evidence Indicator 7.3.1:**

	and at the level of the care team or MIPS eligible clinician or group(panel); and/or Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.	Promote a team-based approach to safety. **Evidence Indicator 7.3.2:** Review all patient safety event and unsafe condition data from patients, staff and equipment. **Evidence Indicator 7.3.3:** Proactively assess the ROP's structure and processes that promote safety. **Evidence Indicator 7.3.4:** Develop, implement and assess progress of action plans to improve safety. **Standard 16: Performance Measurement and Outcomes Reporting** **Evidence Indicator 16.1.1:** The ROP measures and evaluates, at least annually, the patient experience using a survey and/or other tools. **Evidence Indicator 16.2:** The ROP: **Evidence Indicator 16.2.1:** Accepts patient complaints. **Evidence Indicator 16.2.2:** Evaluates and responds to complaints.
Patient Safety and Practice Assessment Medium	Adopt a formal model for quality improvement and create a culture in which all staff actively participates in improvement activities that could include one or more of the following: • Train all staff in quality improvement methods; • Integrate practice change/quality improvement into staff duties;	**Standard 7: Culture of Safety** **Evidence Indicator 7.1:** The ROP has a policy on patient safety that: **Evidence Indicator 7.1.1:** Articulates the practice's approach to patient safety.

	• Engage all staff in identifying and testing practices changes;	**Evidence Indicator 7.1.2:** Specifies that patient safety incidents and near misses are to be reported and tracked within the ROP.
Patient Safety and Practice Assessment Medium	• Designate regular team meetings to review data and plan improvement cycles; • Promote transparency and accelerate improvement by sharing practice level and panel level quality of care, patient experience and utilization data with staff; and/or • Promote transparency and engage patients and families by sharing practice level quality of care, patient experience and utilization data with patients and families.	**Evidence Indicator 7.1.3:** Identifies methods for staff to report patient safety events and unsafe conditions, including a method for staff to report anonymously. **Evidence Indicator 7.1.4:** Encourages timely reporting of patient safety events and unsafe conditions by all staff. **Evidence Indicator 7.1.5:** Specifies periodic reporting back to staff on activities and findings of the Culture of Safety Program. **Evidence Indicator 7.1.6:** Specifies that procedures are not started until all questions and/or concerns are resolved. **Evidence Indicator 7.1.7:** Provides assurances that there will be no reprisals based on reporting of patient safety events and unsafe conditions. **Evidence Indicator 7.1.8:** Identifies a role for patients in the Culture of Safety Program. **Evidence Indicator 7.2:** The ROP designates an accountable individual from the practice leadership who is responsible for: **Evidence Indicator 7.2.1:** Implementing the requirements of the culture of safety program. **Evidence Indicator 7.2.2:**

		Collecting information and investigating patient safety events and unsafe conditions. **Evidence Indicator 7.2.3:** Convening interdisciplinary safety rounds. **Evidence Indicator 7.2.4:** Providing leadership to the practice's Culture of Safety Program. **Evidence Indicator 7.3:** The ROP conducts interdisciplinary safety rounds at least quarterly to: **Evidence Indicator 7.3.1:** Promote a team-based approach to safety. **Evidence Indicator 7.3.2:** Review all patient safety event and unsafe condition data from patients, staff and equipment. **Evidence Indicator 7.3.3:** Proactively assess the ROP's structure and processes that promote safety. **Evidence Indicator 7.3.4:** Develop, implement and assess progress of action plans to improve safety. The indicators below address the ROP's commitment to assess and report events that impact the patient. If a patient safety incident occurs: **Evidence Indicator 7.4.1:** The ROP undertakes an immediate review, with the goal of understanding underlying factors

		and taking action to prevent future occurrence. **Evidence Indicator 7.4.2:** The ROP complies with institutional, state, local and national requirements for reportable patient safety incidents. **Evidence Indicator 7.5.1** The ROP reports to and participates in a patient safety organization (PSO).
Patient Safety and Practice Assessment Medium	Ensure full engagement of clinical and administrative leadership in practice improvement that could include one or more of the following: Make responsibility for guidance of practice change a component of clinical and administrative leadership roles;	**Standard 7: Culture of Safety** **Evidence Indicator 7.1:** The ROP has a policy on patient safety that: **Evidence Indicator 7.1.1:** Articulates the practice's approach to patient safety. **Evidence Indicator 7.1.2:** Specifies that patient safety incidents and near misses are to be reported and tracked within the ROP.
Subcategory/Weighting	**Activity**	**APEx Standard/Evidence Indicator**
Patient Safety and Practice Assessment Medium (Continued)	Allocate time for clinical and administrative leadership for practice improvement efforts, including participation in regular team meetings; and/or Incorporate population health, quality and patient experience metrics in regular reviews of practice performance.	**Evidence Indicator 7.1.3:** Identifies methods for staff to report patient safety events and unsafe conditions, including a method for staff to report anonymously. **Evidence Indicator 7.1.4:** Encourages timely reporting of patient safety events and unsafe conditions by all staff. **Evidence Indicator 7.1.5:**

		Specifies periodic reporting back to staff on activities and findings of the Culture of Safety Program. **Evidence Indicator 7.1.6:** Specifies that procedures are not started until all questions and/or concerns are resolved. **Evidence Indicator 7.1.7:** Provides assurances that there will be no reprisals based on reporting of patient safety events and unsafe conditions. **Evidence Indicator 7.1.8:** Identifies a role for patients in the Culture of Safety Program. **Evidence Indicator 7.2:** The ROP designates an accountable individual from the practice leadership who is responsible for: **Evidence Indicator 7.2.1:** Implementing the requirements of the culture of safety program. **Evidence Indicator 7.2.2:** Collecting information and investigating patient safety events and unsafe conditions. **Evidence Indicator 7.2.3:** Convening interdisciplinary safety rounds. **Evidence Indicator 7.2.4:** Providing leadership to the practice's Culture of Safety Program. **Evidence Indicator 7.3:** The ROP conducts interdisciplinary safety rounds at least quarterly to: **Evidence Indicator 7.3.1:**

		Promote a team-based approach to safety. **Evidence Indicator 7.3.2:** Review all patient safety event and unsafe condition data from patients, staff and equipment. **Evidence Indicator 7.3.3:** Proactively assess the ROP's structure and processes that promote safety. **Evidence Indicator 7.3.4:** Develop, implement and assess progress of action plans to improve safety. The indicators below address the ROP's commitment to assess and report events that impact the patient. If a patient safety incident occurs: **Evidence Indicator 7.4.1:** The ROP undertakes an immediate review, with the goal of understanding underlying factors and taking action to prevent future occurrence. **Evidence Indicator 7.4.2:** The ROP complies with institutional, state, local and national requirements for reportable patient safety incidents. **Evidence Indicator 7.5.1** The ROP reports to and participates in a patient safety organization (PSO).
Patient Safety and Practice Assessment	Implementation of fall screening and assessment programs to identify patients at risk for falls and address	**Standard 9: Emergency Preparation and Planning**

Medium	modifiable risk factors (e.g., clinical decision support/prompts in the electronic health record that help manage the use of medications, such as benzodiazepines, that increase fall risk).	**Evidence Indicator 9.1:** The ROP has a written plan for emergencies that addresses: **Evidence Indicator 9.1.1:** Patient clinical emergencies such as: **Evidence Indicator 9.1.1a:** falls **Evidence Indicator 9.1.1b:** cardiac events **Evidence Indicator 9.1.1c:** threats of violence **Evidence Indicator 9.1.1d:** anesthesia events **Evidence Indicator 9.1.1e:** allergic events **Evidence Indicator 9.1.1f:** other emergencies **Evidence Indicator 9.1.2:** Radiation equipment failure while a patient is undergoing treatment. **Evidence Indicator 9.1.3:** Clinical continuity. **Evidence Indicator 9.1.4:** Evidence of annual training for staff in emergency procedures.
Emergency Response and Preparedness Medium	Participation in Disaster Medical Assistance Teams, or Community Emergency Responder Teams. Activities that simply involve registration are not sufficient. MIPS eligible clinicians and MIPS eligible clinician groups must be registered for a minimum of 6 months as a volunteer for disaster or emergency response.	**Standard 9: Emergency Preparation and Planning** **Evidence Indicator 9.2:** The ROP identifies and plans for other emergencies or disasters based on a formal disaster analysis or other assessment and prepares for applicable potential events, including:

		Evidence Indicator 9.2.1: Power failure. **Evidence Indicator 9.2.2:** Information system failure, with preparation and a back-up plan that addresses business continuity, including data redundancy and recovery plan. **Evidence Indicator 9.2.3:** Radioactive material release. **Evidence Indicator 9.2.4:** External threats including natural disasters.