March 1, 2016

Eric Gilbertson
CMS MACRA Team
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3133 East Camelback Road
Suite 240
Phoenix, AZ 85016-4545

Re: CMS Quality Measures Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs)

Dear Mr. Gilbertson,

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide comments on the CMS Quality Measures Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) (DRAFT). As required by section 102 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS has posted this draft plan for quality measures development for MIPS and APMs.

ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers. They treat more than one million cancer patients each year. ASTRO is dedicated to promoting excellence in patient care and safety, and improving the quality and value of radiation therapy care.

The Measures Development Plan (MDP) draws on measures and strategies from the current Physician Quality Reporting System (PQRS), Value-based Payment Modifier (VM), and Electronic Health Records Incentive Program (Meaningful Use). ASTRO supports the agency's efforts to utilize the existing programs and resources as the foundation for the transition to MIPS and APMs. We believe this steadiness will allow for a smoother and less confusing transition to MIPS and APMs as providers familiarize themselves with new participation and reporting requirements. However, the Agency should be cautious about implementing a blanket adoption of the current measures, strategies, and specifications. There are many issues with the existing measures and requirements in these programs. ASTRO believes that the MDP is an opportunity to adopt only those measures that are effective tools for assessing quality of care. In these comments, we respond directly to the strategies, goals, and principles outlined in the MDP.

Measure Development for MIPS and APMs

MACRA requires the MDP to include measures that could be used in APMs, and requires those measures used in APMs to be comparable to the quality measures used in MIPS. ASTRO believes that measures for MIPS and APMs should not be exclusive or belong specifically to one program. Alternatively, we believe it would be valuable if the measures developed were put forth for adoption by either or both programs. The focus and goal of improving the quality of care provided to patients is a constant regardless of the reimbursement methodology providers participate in (MIPS or APMs).

CMS Strategic Vision – Measure Development Priorities

The MDP highlights CMS's goal of developing a patient-centered portfolio of measures that will address gaps; facilitate alignment across federal, state, and private programs; and promote efficient data collection, all while balancing individual and shared physician accountability. CMS will also develop additional measures using MACRA funding. Measure developers who receive funding will be required to fully incorporate the CMS Quality Strategy and explicitly link measure concepts to the Quality Strategy goals and address the foundational principles.

ASTRO has invested significant resources to improve the quality of care in radiation oncology through assessing and improving patient care and patient safety, reducing variations in quality, and decreasing overall costs. ASTRO's efforts and goals are consistent with the mission and goals of the CMS Quality Strategy, and we have actively promoted participation in the agency's quality initiatives. Additionally, ASTRO is interested in working collaboratively with CMS on measure development and requests additional information from the agency on the process for stakeholders to receive MACRA funding for this effort. Additional funding and guidance from CMS would be valuable in ensuring the creation of measures that fill gaps in the existing programs. We urge the Agency to work closely with specialties like radiation oncology that currently lack a robust set of quality measures to help ensure the implementation of more applicable and valuable measures.

CMS Measures Management System (MMS)

Measures recommended for development under MACRA must meet the criteria set forth in the CMS Measures Management System (MMS) Blueprint: importance to measure and report the measure topic (evidence, performance gap, and impact); scientific acceptability of measure properties (reliability and validity); feasibility; usability and use; and related and competing measures (harmonization). Specifically, CMS solicits comments on how to use measures identified by the Institute of Medicine (IOM) in Vital Signs: Core Metrics for Health and Health Care Progress, and approaches to develop remaining measures within the broad IOM categories that could be used in MIPS and APMs. ASTRO believes that the IOM categories and measures identified are very similar to the domains and criteria in the CMS Quality Strategy and MMS Blueprint. Instead of directing measure developers to three separate documents all with very similar categorizations and requirements, ASTRO recommends abridging the different sources into one set of clear criteria as a reference for measure developers.

Additionally, ASTRO has also developed a Blueprint for Measures Development (Measures Blueprint), which aligns with the goals of the CMS Quality Strategy, MMS, and the IOM categories and measures. The purpose of the Measures Blueprint is to identify quality indicators and develop measures that address gaps in care and variation in treatment; to provide oversight on the use of measures in ASTRO programs and make recommendations about the use of measures in federal programs; and to evaluate and make recommendations about the maintenance of measures. Furthermore, the Measures Blueprint outlines a development strategy for radiation oncology measures that includes the development of process, outcome, and structures measures in the various domains identified by the IOM and in the CMS Quality Strategy.

Measures Integration to Support MIPS and APMs

Existing measures from PQRS, Meaningful Use, and VM will be used in MIPS and APMs. As stated above, ASTRO understands and supports adoption of existing measures in the transition to MIPS and APMs. However, we caution the agency against carrying over elements of current programs, including measures, which are problematic. For example, the measures and objectives currently in the Meaningful Use program are of little or no value to many specialties including radiation oncology because they do not apply to the process of care for radiation therapy. Electronic health records and planning systems are integral to ensuring the delivery of high quality and safe radiation treatment to patients. However, under the current program requirements, radiation oncologists are unable to demonstrate Meaningful Use in a meaningful way. Instead, radiation oncologists are required to adopt new workflow processes that can be unnecessary for their planning or treatment purposes, and also take away from valuable patient care time. Similarly, with VM, the cost and resource use measures were adopted from the hospital value program and do not translate well in the physician world, resulting in beneficiary attribution and specialty applicability issues. ASTRO recommends that CMS carefully consider and evaluate previous stakeholder input and comments on the current programs, and their respective measures, before finalizing the list of measures for MIPS and APMs.

<u>Operational Requirements of the Quality Measure Development Plan</u>

Multi-Payer Applicability of Measures

MACRA requires the MDP to address how to incorporate measures from private payers and integrated delivery systems. The reasoning for this requirement is that public and private payers include many measures on the same topics, and while some measures may be complementary, some measures in the two systems are duplicative with similar specifications. ASTRO agrees that this results in redundancy, increases the administrative burden for providers, and limits the "opportunity for improved outcomes due to diffusion of focus for quality improvement." ASTRO supports the agency's efforts to reduce these burdens and redundancies by creating a core measures set that aligns across private and public payers.

The MDP also mentions leveraging the Measure Applications Partnership (MAP) and its process for gathering and providing input from stakeholders on measures that align with the needs of CMS and other payers to support multi-payer applicability. Additionally, the MDP discusses

how CMS will continue to actively participate in the Core Quality Measures Collaborative and consider adopting measures identified by the Collaborative through the rulemaking process. The Collaborative is a workgroup convened by America's Health Insurance Plans (AHIP). ASTRO supports measure collaboration and alignment to streamline reporting across various payers. However, ASTRO urges CMS to ensure that a transparent and collaborative approach is taken in the development of core process measures.

Coordination and Sharing Across Measure Developers

The focus of this MACRA requirement is to improve the coordination and sharing of knowledge and best practices between measure developers; and to allow for measure harmonization and alignment across programs, settings, and payers. CMS will build upon its established collaborative foundation to promote broader participation by other organizations. For example, measure developers currently may not have access to qualified clinical data registries (QCDR) measures, and QCDR measures may be limited to wider adoption. CMS has committed to promoting information sharing between QCDRs and other measure developers for a mutually beneficial relationship allowing for increased development and widespread adoption of measures. ASTRO agrees with this approach and believes that increased communication and coordination between measure developers will promote the creation of more refined and valuable measures. By gaining more insight and knowledge on measures developed by others, developers will be able to adopt similar practices and concepts to create analogous and meaningful measures for different specialties and care settings. Increased coordination and knowledge sharing will also further help reduce redundancy and allow for greater alignment (as discussed above). ASTRO strongly supports greater coordination between measure developing stakeholders and programs that would contribute to the adoption of quality measures that improve and track the quality of healthcare services.

Clinical Practice Guidelines

Under MACRA, development of quality measures must take into account the use of clinical best practices and guidelines. ASTRO commends the agency for recognizing the continued need and importance of developing process measures based on clinical best practices and guidelines. ASTRO adheres to the *IOM: Clinical Practice Guidelines We Can Trust* for developing measures from ASTRO clinical practice guidelines, and updates for these measures are aligned with updates of our clinical practice guidelines. ASTRO strongly agrees with and echoes the position in the MDP that process measures remain an important component of quality measurement as performance in these measures is directly under the provider's control.

Evidence Base for Non-Endorsed Measures

MACRA requires measures not endorsed by a consensus-based entity to have an evidence-based focus. However, MACRA neither defines evidence-based nor how to evaluate the evidence. Thus, CMS intends to use National Quality Forum (NQF) rating criteria to evaluate the quality, quantity, and consistency of the evidence-base for these types of measures. As part of this process, CMS will require the measures and supporting evidence to be submitted to a specialty-appropriate, peer-reviewed journal prior to inclusion in the final list of MIPS measures. ASTRO

supports the inclusion of measures that may not be endorsed by a consensus-based entity. In addition to peer-reviewed publications, ASTRO encourages CMS to have a preference for measures that have gone through a public comment period administered by the measure developer. ASTRO believes the process outlined in the MDP will allow for the inclusion of more specialty-specific measures in an efficient and timely manner.

Quality Domains and Priorities
MACRA identifies five quality domains that align with the National Quality Strategy priority areas and CMS Quality Strategy goals: clinical care, safety, care coordination, patient and caregiver experience, and population health and prevention. In addition to these, CMS proposes to include an efficiency and cost reduction quality domain. Furthermore, MACRA prioritizes the following types of measures: outcome measures, patient experience measures, care coordination measures, and appropriate and resource use measures.

ASTRO supports measure development under these various domains and priorities. However, we urge the agency to not establish minimum reporting requirements for the types of measures or domains similar to what exists in the current quality programs. Offering a robust set of measures, varying in types and domains, without restrictions or limitations on reporting requirements, would allow providers to select the measures that would meet the needs of their specific practices. Allowing providers to tailor their measures, instead of mandating blanket reporting of general measures, would truly contribute toward improving the quality of care because providers will be able to better assess and work on those areas that may need improvement in their practices.

Furthermore, ASTRO encourages CMS to work with specialties on converting Choosing Wisely recommendations into measures, not only for the efficiency and cost reduction domain, as mentioned in the MDP, but also for the clinical care and safety domains. ASTRO has released 10 Choosing Wisely recommendations for radiation oncology treatments that are commonly ordered but may not be always appropriate or necessary. Converting these recommendations into measures would help determine and address underuse, overuse, and appropriate use of resources in these clinical areas, as well as ensure the delivery of safe care. Additionally, creating measures from Choosing Wisely will allow for the implementation of more specialty-specific and applicable measures in MIPS and APMs. Thus, ASTRO strongly commends the agency's decision to use Choosing Wisely recommendations as a foundation for developing measures.

Gap Analysis
The MDP will consider measure gaps in the different quality domains identified above, and will take into consideration gap analyses and recommendations identified by the MAP and other stakeholders. The Agency's goal is to address true gaps in performance by providers, and to look closely at where there is variation in care and an opportunity for improvement. ASTRO reiterates our support and commends the Agency's focus on developing more clinically relevant quality measures applicable to all specialties and subspecialties. As mentioned above, one of the goals of ASTRO's Measures Blueprint is to identify and address gaps in care and variation in treatment that align with this MACRA requirement. The lack of specialty-specific measures is a criticism

of the existing measures set, and we believe that this is an opportunity for CMS and ASTRO to work together to help address critical gaps for radiation oncology as we progress with the implementation of MIPS and APMs.

Applicability of Measures Across Healthcare Settings
MACRA requires the MDP to consider the applicability of measures across healthcare settings. CMS outlines several methods for achieving applicability of measures across and ASTRO supports this goal. Radiation oncologists practice in freestanding centers as well as hospital outpatient departments. ASTRO is exploring and hopes to develop measures that are applicable to radiation oncologists regardless of their practice setting.

Clinical Practice Improvement Activities
MACRA further requires the MDP to consider clinical practice improvement activities (CPIAs) for identifying existing gap areas and areas for possible future measure development. As part of this requirement, CMS will review CPIA submissions and evaluate whether the activity can be further developed into a quality measure within the CPIA subcategories. As we mentioned in our November 16, 2015 MACRA RFI comments, ASTRO recommends adding and developing measures from the following three subcategories to the list of CPI activities for MIPS: Maintenance of Certification (MOC) activities, such as MOC Part IV Practice Quality Improvement (PQI) requirements; participation in practice accreditation programs; and participation in patient safety organizations (PSO) designed as incident learning systems.

ASTRO's Practice Accreditation Program
The ASTRO Accreditation Program for Excellence (APEx®), was created to ensure the accountability of radiation therapy practices by objectively assessing the radiation oncology care team, policies and procedures, and the facility itself. ASTRO's APMs for the treatment of early stage breast cancer and the palliative treatment of bone metastases both include APEx accreditation as a standard quality measure. To achieve accreditation, facilities must demonstrate they have in place the systems, personnel, and policies and procedures necessary to provide high quality and safe patient care. The ASTRO APEx program is organized around five pillars: the process of care; the radiation oncology team; safety; quality management; and patient-centered care. The program consists of 16 standards derived from white papers and consensus practice guidance on practice for radiation oncology and contains measures that could be adopted into MIPS, as well as other APMs. For example, the implantable cardiac device screening evidence indicator under APEx ensures that breast and lung cancer patients have been screened for implantable cardiac devices prior to radiation therapy. Furthermore, some of the measures are cross-specialty and would also further aid in tracking utilization and appropriate use. With this underlying focus on a culture of quality and safety, as well as patient-centered care, we believe measures from accreditation programs like APEx would represent an ideal subcategory for CPI activities and quality measures.

ASTRO's RO-ILS: Radiation Oncology Incident Learning System®
ASTRO and the American Association of Physicists in Medicine (AAPM) sponsor RO-ILS: Radiation Oncology Incident Learning System®, which is a national incident learning system

partnered with a patient safety organization designed to improve the clinical practice of radiation oncology. The mission of RO-ILS is to facilitate safer and higher quality radiation oncology care by providing a secure and non-punitive environment. This system allows providers to learn from actual and potential 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. In turn, they receive reports on their institutions, as well as aggregate national data on reported events. Knowledge from this program may help inform measure development and other quality initiatives within ASTRO.

Consideration for Electronic Specifications
As part of the measure development process, MACRA requires consideration regarding whether the measures can be electronically specified. Specifications for electronic clinical quality measures would be derived from a set of electronically captured data elements and realistic clinical workflow. Stakeholders would aid in the testing and evaluation of the data elements, workflow, and measure specifications. The process for developing electronic specifications is difficult and burdensome for specialties, and ASTRO encourages CMS to recognize the resource use and costs required for developing electronic specifications.

Challenges in Quality Measure Development and Potential Strategic Approaches
Engaging Patients in the Measure Development Process
Challenges with patient engagement include recruiting patients; patients and caregivers needing additional support and orientation to participate fully; and patients may feel intimidated when surrounded by subject matter experts and highly technical discussions. ASTRO understands the importance of engaging patients in the measures development process. The patient engagement component is built into ASTRO's Measures Blueprint so that measures are reviewed by patient advocacy groups during the development process.

Reducing Provider Burden of Data Collection for Measure Reporting
To reduce the administrative burden to providers, CMS aims to collect data already part of the existing clinical workflow and collecting data from electronic health records. Furthermore, CMS will continue to promote the development of measures that are aligned across payers and settings by ensuring collaboration between private and public measure developers. ASTRO is a strong supporter of the need for developing and reporting quality measures, and encourages the agency to explore and promote opportunities and avenues that would decrease the reporting burden for providers. The less burdensome it is for providers to report quality measures using their existing workflows and electronic health records, the greater the chances of meaningful provider participation in MIPS and APMs and the ability of the agency to truly measure and increase the quality of care provided.

Shortening the Time Frame for Measure Development
CMS solicits comments on how to efficiently move proposed non-consensus, evidence-based measures through the peer-reviewed process. CMS has decreased the measure development time frame by incorporating Lean principles, which allow for a more timely and efficient process for measure development. ASTRO supports this alternative to the NQF endorsement process and

incorporation of Lean principles. We encourage the agency to work with specialties to ensure that this requirement does not unnecessarily further delay implementation of valuable measures.

Streamlining Data Acquisition for Measure Testing
Currently, measure developers are responsible for negotiating data use and business associate agreements with providers to access clinical data to support measure testing. CMS aims to alleviate this burden by leveraging broader data sources and forming the National Testing Collaborative (NTC). The NTC would explore opportunities to implement overarching agreements with clinical data registries, repository vendors, health plans, and provider groups to make data more accessible and less costly. ASTRO strongly supports CMS's efforts to reduce the burden of testing and validating measures, and creating a more streamlined process for measure evaluation.

Identifying and Developing Meaningful Outcome Measures
Outcome measures are a high priority under MACRA regulations. As highlighted in the MDP, there are two key challenges related to outcome measures: the identification of meaningful outcomes, and the development of risk-adjustment models. ASTRO is currently exploring options for outcomes that can be validly and reliably measured for cancer patients, but we agree with the agency that this is indeed a challenge. We believe that increased coordination and sharing of knowledge and best practices will help facilitate this process and promote the development of outcome measures. However, until that time, ASTRO urges the Agency to allocate sufficient time to develop valuable and relevant outcome measures.

ASTRO appreciates the opportunity to provide comments on the Measure Development Plan for MIPS and APMs. We look forward to continued opportunities to work with CMS, as well as other stakeholders to ensure that the programs achieve MACRA's vision of improving the quality of patient care while reducing costs and improving patient outcomes. Questions regarding ASTRO's comments can be submitted to Priya Lamba, Manager of Medicare Policy at priya.lamba@astro.org, or 703-839-7396.

Sincerely,

Laura Thevenot

Laura Thevenot
Chief Executive Officer