August 28, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted electronically: http://www.regulations.gov

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015 (1612-P)

Dear Administrator Tavenner:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015" published in the Federal Register as a proposed rule on July 11, 2014.

ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe and make up the radiation therapy treatment teams that are critical in the fight against cancer. These teams often include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers, and they treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

In this letter we address a number of topics that will impact our membership and the patients they serve, including:

- Radiation Treatment Vault;
- Transparency, Modifications to Valuing New, Revised and Potentially Misvalued Codes;
- CPT Codes Identified as Potentially Misvalued Codes (77263, 77334);
- Deletion of G-Codes for Stereotactic Radiosurgery Services (SRS) (77372-77373);
- Substitution for PACs Input (77326-77328);
- Practice Expense Input Correction (+77293);
- Reports of Payments or Other Transfers of Value to Covered Recipients;
- Maintenance Factor Assumption;
- Collection of Data to Validate Physician Fee Schedule PE RVUs;
- Understanding Different Resource Costs among Traditional Office, Facility and Off-Campus Provider-Based Settings;
- Physician Quality Reporting System;
- Physician Compare Website; and
- Physician Value-Based Payment Modifier.

Radiation Treatment Vault

In the CY 2015 proposed MPFS, CMS proposes to remove the radiation treatment vault as a direct practice expense (PE) input from radiation treatment delivery CPT codes 77373, 77402-77416, and 77418. This significant shift in PE policy comes just before CMS will unveil wholesale changes to the radiation treatment delivery code set, representing 50 percent of radiation oncology allowed charges, in the CY 2015 final MPFS. The combination of these two monumental changes to radiation oncology treatment codes is of great concern to ASTRO and the members we serve. Due to the potential enormity of these payment changes facing radiation oncology, ***ASTRO urges CMS to reconsider the proposed radiation treatment vault policy change and delay any final decision until after implementing the radiation oncology coding changes.***

CMS believes that the requirements for the vault reflect building and infrastructure costs (indirect practice expenses), rather than medical equipment costs (direct practice expenses). ASTRO acknowledges the complexity of how to classify the vault. The radiation treatment vault is unlike anything else in medicine, serving a unique medical need that cannot be repurposed for other uses (leases typically require tenants to remove vaults before vacating the property). Each treatment vault is distinct from a medical imaging treatment room, as it is designed and constructed to safely house a specific high-energy radiation treatment machine within its space. A change in treatment machine may require extensive modifications to the vault. The vault must comply with specific federal and state licensing regulations to protect patients, clinic staff, and the public from radiation exposure during the delivery of high-energy radiation therapy. In addition, the Internal Revenue Service rules treat radiation treatment vaults as medical equipment -- separately depreciable from the building itself -- thereby supporting its inclusion as a direct practice expense.

Removing the vault as a direct practice expense accounts for nearly the entire 2015 payment reduction for radiation oncology. On the individual code level, the impact ranges from negative two percent to almost negative 16 percent. In the proposed rule, CMS estimates the aggregate impact of changes to PE RVUs on radiation oncology ranges from negative four percent to negative eight percent, with some stakeholders estimating the impact of the proposed rule on freestanding radiation oncology centers to be negative six percent. It is important to also remember that these 2015 proposed reductions come after five years of cumulative reimbursement cuts to community-based radiation therapy centers totaling approximately 20 percent.

We believe it is premature for the agency to make a determination on removing the vault as a direct practice expense when the agency is scheduled to introduce significant payment rate changes to the radiation treatment delivery code set in the CY 2015 final MPFS. The agency requested these coding and valuation changes in the CY 2013 final MPFS, as part of a review of a series of codes described as having "stand alone procedure time." This list included the radiation therapy codes impacted by the proposed vault policy. Working through the American Medical Association (AMA) CPT Editorial Panel, RVS Update Committee (RUC) and with other stakeholders, ASTRO proposed revisions and updates to these codes so they better reflect the current process of clinical care. The new and revised codes will be published in the 2015 CPT book. The code changes, as noted previously, account for 50 percent of allowed MPFS charges for radiation oncology. The magnitude of these changes represent tremendous uncertainty for the field since the code values will not be known outside the agency until the final 2015 MPFS rule is published in November 2014.

ASTRO recognizes that CMS must determine how the vault fits into the overall practice expense methodology; however, radiation oncology stakeholders cannot adequately assess and comment on the

vault proposal without the essential, significant context of the revised treatment delivery code values. As reflected in the reduced PE RVUs for the services published in Addendum B of this proposed rule, the implications of this decision are significant for radiation therapy providers and their patients. Continued ratcheting down of Medicare reimbursement rates has destabilized the provision of radiation oncology services in the physician office setting in recent years. We are very concerned that further reductions could have an impact on patients' access to high quality radiation therapy.

ASTRO supports the agency's efforts to determine accurate payment rates, but these efforts should be fair and fully transparent, in keeping with the agency's intentions for revaluations and new codes beginning in CY 2016. Before making a decision on the vault, the agency should consider the totality of variables impacting radiation oncology payments in 2015 and provide complete transparency and meaningful opportunity for public comment. ***Therefore, ASTRO strongly urges the agency to take the most reasonable and balanced approach by delaying any final decision on the vault until after implementing the 2015 radiation oncology coding changes.***

Transparency, Modifications to Valuing New, Revised and Potentially Misvalued Codes

In the current MPFS process, CMS issues interim final RVUs for all revaluations and new codes in the final rule and makes payment based upon those values during the calendar year. Although the code valuations are interim and open for comment, providers and other stakeholders have limited time to prepare for, or provide, public comment before the values are implemented. The current process lacks transparency and severely limits opportunities for public input. ASTRO is very pleased the agency recommended a modified process in this proposed rule.

CMS proposes to modify the process by including in the proposed rule values for all codes for which CMS has complete RUC recommendations by January 15 of the preceding year. ASTRO supports a modification to the current process; however, ASTRO strongly believes that CMS should implement this process immediately and requests the agency to immediately release the CY 2015 interim values for the new/revised radiation oncology treatment delivery codes.

As discussed earlier in this letter, the restructured codes represent over 50 percent of Medicare allowed charges for radiation oncology. The proposed changes will have an enormous impact on radiation oncology providers and patients across the nation. Radiation oncology providers need time to review, analyze and prepare for these changes. Additionally, releasing the codes now would allow for sufficient time to provide CMS with critical feedback. ***ASTRO strongly urges CMS to immediately release CY 2015 interim values for the new and revised radiation treatment delivery codes.***

In this proposed rule, CMS proposes to include proposed values for all services for which the agency has a RUC recommendation by January 15, 2015, in the CY 2016 proposed rule. For codes where CMS does not receive a RUC recommendation by January 15th of a year, CMS would delay revaluing the codes for one year (or until they receive the RUC recommendation for the code) and include proposed values in the following year's rule. CMS proposes to adopt coding policies and payment rates that conform, to the extent possible, to the policies and rates in place for the previous year.

The current valuation will be applied to those codes for which there is no change in the CPT code. For those codes that are revalued, revised or deleted, CMS proposes to create G-codes to describe the predecessor codes. For new codes that describe completely new services, CMS proposes to work with the RUC to ensure recommendations are received in time to include proposed values in the proposed rule. If RUC recommendations are not received in time and CMS determines it is in the public interest to use a new code, CMS proposes to establish values for the code's initial year using the current policy of

considering RUC recommendations if available for the final rule and proposing interim final values. CMS also notes that when it would not be appropriate to establish interim final values, CMS would have contractors price the code for the initial year.

The MPFS and CPT/RUC process of the American Medical Association (AMA) are interdependent. ASTRO appreciates CMS's efforts to address the potential lack of alignment between the timelines of the two processes. However, the agency's reliance on G-codes represents an administrative burden to both providers and CMS. The AMA has proposed an alternative timeline that deserves the agency's consideration. The AMA proposal would retain the current meeting infrastructure for both CPT and the RUC, while shifting the workflow to accommodate the review of commonly performed services to the May CPT/October RUC and October CPT/January RUC meetings. Under this proposal, the February CPT meeting would predominantly address editorial changes, clinical lab payment schedule services, and new technology services, with expected low volume. The April RUC meeting would replace the formerly lighter September RUC meeting agenda and would be utilized to review the low volume new technology services and discuss methodological and process issues. The AMA believe that CMS should be able to publish consideration of the low volume new technology codes in the final rule as interim values, as these changes would have minimal impact on the other services on the MPFS. The AMA proposes to submit RUC recommendations to CMS within one month of each meeting (each November and February for new, revised and potentially misvalued codes; and each May for low volume new technology).

ASTRO supports the AMA proposal as it is the most reasonable plan to transition the MPFS to a more transparent system that allows for maximum public input. Additionally, one of the strengths of the AMA plan is that it reduces the reliance on G-codes. ASTRO does not believe G-codes represent a practical solution for addressing the need for a replacement code when the old CPT code has been deleted and a new one is not yet available due to the lack of alignment between the two processes. ***ASTRO recommends that CMS consider favorably the alternative proposal submitted by the AMA.***

Finally, CMS proposes to eliminate the Refinement Panel process used by the agency to consider comments on interim relative values. For nearly two decades, stakeholders considered the CMS Refinement Panel Process as an appeals process. CMS organized and composed the Refinement Panel, which consisted of members from the primary care organizations, contractor medical directors, a specialty related to the commenter and the commenting specialty.

The elimination of the Refinement Panel concerns ASTRO as it effectively eliminates an appeals process. Medicare providers and beneficiaries have the opportunity to pursue an appeals process when disputing claims and/or denials of coverage. Additionally, appeals processes exist for many other CMS initiatives, such as the Physician Quality Reporting System (PQRS). The appeals process is an important cornerstone of the Medicare program. ***While the Refinement Panel may no longer be appropriate in this modified process, ASTRO believes there is still a need for some sort of appeals process. ASTRO urges CMS to establish a fair and reasonable appeals process available to all stakeholders.***

CPT Codes Identified as Potentially Misvalued Codes (77263, 77334)

CMS is required by law to identify and review potentially misvalued codes. For CY 2015, CMS identified the top twenty codes by specialty, then they excluded codes that had been identified previously, had less than $10 million in allowed charges, or described anesthesia or evaluation and management services. A total of 65 codes, including two radiation oncology services, were identified through this filter:

- 77263 Radiation therapy planning and
- 77334 Radiation treatment aid(s).

CMS requests that codes identified through this process be reviewed for both work and practice expense RVUs. ASTRO has conducted a thorough review of the history of these codes and available claims data, and we believe these codes are appropriately valued and should be removed from the list of potentially misvalued codes.

CPT code 77263 describes complex clinical treatment planning. Treatment planning requires the radiation oncologist to understand the natural history of the patient's disease process, conceptualize the extent of the disease relative to adjacent normal anatomical structures and integrate the patient's overall medical condition and associated comorbidities to formulate a plan of therapy. This code has gone through the RUC process and contains recommendations based on a robust sample size. According to available Medicare claims data, the service is typically billed alone. Therefore, there is no risk of failing to account for efficiency or overlap in physician time or practice expense inputs that may occur with codes that are billed together. Additionally, the utilization has remained stable for 15 years and the site of service has remained the same. We also note that this is a professional code and does not have direct practice expense inputs assigned to it. Based on this review, ASTRO has not found any evidence that necessitates a further review of this code. ***ASTRO urges CMS to remove CPT code 77263 from the list of potentially misvalued codes.***

CPT code 77334 describes the design and construction of a custom fabricated device, specifically designed for a patient and not reusable for any other patient during that course of therapy (e.g. thermoplastic immobilization device or custom-formed vacuum cushions). Similar to CPT code 77263, CPT code 77334 has been through a robust RUC survey process and is not typically billed with other services. We also found that utilization has actually decreased in recent years. ***Based on this evidence, we believe the code is appropriately valued. ASTRO urges CMS to remove CPT code 77334 from the list of potentially misvalued codes.***

Deletion of G-Codes for Stereotactic Radiosurgery Services (SRS) (77372-77373)

In the MPFS, Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) services furnished using robotic methods are billed using contractor-priced G-codes:

- G0339 (Image-guided robotic linear accelerator based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment) and
- G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment).

Based on comments received in the CY 2014 cycle, including those from ASTRO, CMS concluded that the PE RVUs for the CPT codes accurately captured the resources utilized for robotic SRS and SBRT services. For CY 2015, CMS proposes to recognize only the CPT codes for payment of SRS and SBRT services and delete the G-codes used to report robotic delivery of SRS and SBRT. The practical implication of this policy change is that freestanding centers will no longer be able to report the G0339 and G0340, and these centers would instead report CPT code 77372 or 77373.

SRS and SBRT are precise and effective types of radiation therapy that use concentrated radiation beams in high doses to destroy tumors in difficult and hard to reach areas, such as the brain or spine, and other sites within the body. These forms of treatment are high-value services that achieve tumor eradication expediently and non-invasively. Many providers have been reporting G-codes for SRS and SBRT services, relying on established contractor negotiated rates when billing for these services. Several ASTRO members have reported concerns that previous reimbursement reductions have forced several freestanding SRS/SBRT centers to close, and other centers are concerned that the transition to CPT codes

could result in further limiting access to SRS and SBRT services in the physician office setting. ***In light of the potential significant impact of this change on reimbursement for an effective treatment for a high-risk population of cancer patients, ASTRO urges CMS to closely monitor the impact of this policy change on access to SRS and SBRT services.***

Substitution for PACs Input (77326-77328)

The health care arena has been experiencing a significant transition from film to digital imaging. To capture the impact of these changes on the MPFS, the RUC has provided recommendations to CMS regarding the PE inputs for digital imaging services. Specifically, the RUC recommended that CMS remove a list of supply and equipment items associated with film technology since these items are no longer a typical resource input. The RUC also recommended including the Picture Archiving and Communication System (PACS) equipment for these imaging services since these items are now typically used in furnishing imaging services. However, since CMS did not receive any invoices for the PACS system, it proposes to allocate minutes for a desktop computer (ED021) as a proxy for the PACS workstation. There are 56 codes impacted by this proposal to use a desktop computer as a direct PE input proxy for the PACS workstation, including three radiation oncology services (CPT codes 77326-77328 Brachytx isodose calc).

ASTRO appreciates the agency's recognition that PE inputs reflect the most current process of care, but we do not believe the desktop computer is an appropriate or accurate proxy for the PACS workstation. A PACS workstation provides efficient storage and convenient access to images from multiple modalities. The architecture of the current PACS workstation has evolved tremendously from the early days. Today, a PACS workstation is able to provide a single access point to archive, backup, and retrieve images taken from multiple imaging modalities. A desktop computer is not comparable to the sophistication required of a PACS workstation. ***ASTRO opposes this proposal, and we urge CMS to work with stakeholders to obtain documentation of the current price of a PACS workstation.***

Additionally, CMS requested comments on whether the computer workstation, which they propose to use as a proxy for the PACS workstation, is the appropriate input for the CPT codes 77326-77328, or whether an alternative input is a more appropriate reflection of direct PE costs. The RUC submitted recommendations to CMS for CPT codes 77326-77328, effective January 1, 2015. Recommendations include time for the following equipment:

- Computer workstation, brachytherapy treatment planning (ED017);
- Radiation Therapy dosimetry software (Argus QC) (ED055); and
- Printer, laser, paper (ED032).

ASTRO believes allocating time on a PACS system is appropriate. ASTRO recommends that CMS allocate time on the PACS/computer workstation in addition to the three items listed above.

Practice Expense Input Correction (+77293)

Due to a clerical error, CMS entered the incorrect clinical labor type for CPT code 77293 (Respiratory Motion Management Simulation). CMS assigned L052A (Audiologist) instead of L152A (Medical Physicist), which has a higher cost per minute. CMS is proposing a correction to the clinical labor type for this service, which will have a positive impact on the code. ***We appreciate the agency's proposal to correct this error. ASTRO recommends CMS finalize this proposal and correct the labor type assigned to CPT code +77293.***

Reports of Payments or Other Transfers of Value to Covered Recipients

In its proposed rule, CMS seeks to revise the current regulations implementing the Physician Payment Sunshine Act, now referred to as the Open Payments program. Currently, payments to physician faculty and attendees at accredited continuing education programs are not reported to CMS, even when the event receives industry support. In the final rule on the Open Payments program, CMS created a special rule for continuing education programs, exempting payments that are made in support of an event when 1) it is accredited or certified by one of five bodies (including the Accreditation Council for Continuing Medical Education (ACCME)); 2) the manufacturer does not pay the physician directly; and 3) the manufacturer does not select the physician or provide a distinct, identifiable set of individuals to be considered as speakers.

CMS proposes to remove this special rule for continuing education and instead rely on another exception – the exception for indirect payments – to exclude industry support for educational events from reporting. The agency's primary rationale is to avoid an appearance of endorsing certain continuing educational events over others. ASTRO does not believe that the indirect payment exception should be used to evaluate continuing education support. ***ASTRO opposes this change and urges CMS to maintain the special treatment for continuing education contained in the existing rule.***

As a direct provider of accredited continuing educational programs and a leader in the professional and educational development for the radiation oncology community, ASTRO follows strict policies to avoid commercial influence on its educational content. ASTRO complies with the *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*, which were promulgated by ACCME and adopted by the US continuing medical education (CME) credit systems currently named in the regulations. These standards provide the framework for independent continuing education and distinguish rigorous continuing education from promotional sessions sponsored by manufacturers.

Since reporting began under the Open Payments program, physicians and continuing education providers have relied on the clear cut determination that, when continuing educational events comply with CMS's regulations, both faculty and attendees will be exempt from reporting. The "indirect payment" exception will not have the same effect because it requires that a manufacturer is "unaware" of the identity of the physician benefiting from a payment. Unaware is defined to mean that the manufacturer does not know the identity of the physician receiving the compensation during the reporting year or by the end of the second quarter of the following reporting year. Because it relies on the knowledge of multiple people over a period of up to 15 months, the indirect compensation exception is much less clear cut and creates uncertainty for physicians and entities providing CME activities.

Additionally, the nature of the planning and execution of CME activities may also make it ill-suited for the indirect payment exception. ASTRO's educational programs feature faculty who are experts in the field. Manufacturers working in the field and therefore supporting educational programming may learn the names of faculty or even of attendees who received tuition subsidies or awards. Even though they had no influence over ASTRO's programming, under the indirect compensation exception's awareness standard, they would need to report data about those physicians. ASTRO's continuing educational programs meet strict standards to prevent commercial influence, and we do not believe physicians speaking at or attending these events should be reported under the Open Payments program. If CMS seeks to recognize additional continuing education providers, as it indicated in the proposed rule, we urge it to require educational programing to meet the *Standards for Commercial Support: Standards to Ensure Independence in CME Activities* or to work through the Joint Accreditation, an inter-professional coalition of accreditors of continuing education in the health professions.

ASTRO urges CMS to delay public release of data
ASTRO's physician members are struggling with the registration process required to review and dispute payments that have been reported about them by manufacturers through the Open Payments program. On September 30, the first reports (covering the period from August 1 to December 31, 2013) are scheduled to be made public. Physicians have had very little time to access and review this information. Registration in the program is a complex, two-part process which has been reported to take longer than the one hour CMS originally estimated physicians would spend reviewing reports in the program's first year. CMS has been candid about problems with the system, making some modifications to the registration process, temporarily taking the database down due to "data integrity issues" and delaying release of about one-third of submitted records because they contain intermingled data. While CMS gave physicians additional time to review information to make up for time the system was down, ***ASTRO urges the agency to delay public release of Open Payments data by at least six months. This would give physicians more time to register in the system, review their data and dispute any potentially inaccurate reports before they are made public. It would also allow CMS to identify and correct additional problems and correct some of the problems associated with the registration process.***

Maintenance Factor Assumption
The current PE RVU Methodology contains a fixed five percent maintenance factor. In the CY 2015 MPFS, CMS reports hearing from stakeholders that the maintenance factor should be variable and recognize usage fees and per-use equipment costs as direct costs. CMS seeks comment regarding reliable data on maintenance costs that vary for equipment and whether the cost formula should be adjusted to include equipment costs that do not vary based on equipment time.

ASTRO is committed to making the PE RVU methodology as transparent and accurate as possible. Maintenance costs are a significant operating expense in the practice of radiation oncology. Service contracts for radiation therapy equipment, such as linear accelerators, typically include maintenance and exceed the five percent allowance in the current PE RVU methodology. ***ASTRO supports a revision to the PE RVU methodology that accounts for the variation in maintenance costs. We look forward to an opportunity to work with CMS on the development of an appropriate methodology that accounts for this expense.***

Collection of Data to Validate Physician Fee Schedule PE RVUs
In the CY 2014 MPFS, CMS proposed to use OPPS rates in developing PE RVUs. CMS did not include this concept in the final 2014 MPFS. In the 2015 MPFS, CMS states that "a comparison of OPPS payment amounts to PFS payment amounts for particular procedures is not the most appropriate or effective approach to ensuring that MPFS payment rates are based on accurate cost assumptions." ASTRO applauds CMS' decision not to use OPPS Rates in validating or developing PE RVUs.

CMS continues to seek ways of collecting better and updated resource data from physician practices, including those that are provider based, and other non-facility entities paid through the MPFS. Section 220 of PAMA provides CMS with the authority to use alternative approaches to establish practice expense relative values, including the use of data from suppliers and providers of services. CMS seeks recommendations on the best approach for using various forms of data, including hospital outpatient cost data, in validating or potentially setting relative value cost assumptions within PE methodology.

ASTRO remains concerned with CMS's assertion that invoices for medical supplies and equipment are difficult to obtain. The CPT-RUC process collects each list of resources needed to provide services in the physician office using a standardized process, carefully examined by a cross-specialty panel, and

typically submitted with invoices for equipment and supplies. CMS actively participates in all deliberations and makes final decisions on the practice expense values.

Understanding Different Resource Costs among Traditional Office, Facility and Off-Campus Provider-Based Settings

In the CY 2015 MPFS, CMS seeks to understand the growing trend in hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments. CMS is specifically interested in how this trend affects payment under PFS and beneficiary cost sharing. CMS questions the validity of PE resource data as more physician practices become provider-based and whether certain outpatient services should be paid at PFS rates rather than at OPPS rates.

CMS is proposing to create a HCPCS modifier to be reported with every code for physician and hospital services furnished in an off-campus provider-based department of a hospital. The modifier would be reported on the CMS-1500 claim form for physicians' services and the UB-04 (CMS form 1450) for hospital outpatient claims. CMS anticipates that the collection of this data will allow the agency to begin to assess the accuracy of PE data, including both the service-level direct PE inputs and the specialty-level indirect PE information used to value PFS services.

ASTRO is committed to working with CMS to understand the growth in provider-based practices and their impact on Medicare payments. ***ASTRO is concerned that the proposed modifier would be administratively burdensome. Additionally, the application of a modifier will be difficult to enforce and CMS may not get full compliance leading to a potentially inaccurate analysis.***

Physician Quality Reporting System

The Physician Quality Reporting System (PQRS) is a pay-for-reporting program that uses a combination of payment adjustments to promote reporting of quality measures information. Beginning with CY 2015 participation, a negative two percent penalty will be implemented for failure to participate in PQRS.

Oncology Measures Group

ASTRO would like to thank CMS for renewing the Oncology Measures Group for the 2015 PQRS reporting period and for maintaining the minimum 20-patient reporting requirement for the measures group. There has been increased participation in the PQRS program by radiation oncologists using the Oncology Measures Group option, and renewing the measures group will help encourage continued participation.

The agency proposes modifying the Oncology Measures Group by removing measure #194 Oncology: Cancer Stage Documented from the measures group. ASTRO believes measure #194 should be retained. Documenting cancer stage is a critical component in determining treatment options for patients with cancer. Though critically important, this measure was developed because cancer stage is not always documented in the medical record. ***ASTRO urges the agency to retain measure #194 Oncology: Cancer Stage Documented from the Oncology Measures Group as it is critical in ensuring that cancer patients receive high-quality care.***

Proposed Criteria for the Satisfactory Reporting for Individual Eligible Professionals for the 2017 PQRS Payment Adjustment

In the CY 2014 final MPFS, CMS finalized the requirement that eligible professionals reporting individual measures via claims, qualified registries, or qualified clinical data registries, must report a minimum of nine measures, covering three National Quality Strategy (NQS) domains, and report each measure for at least 50 percent of patients to which each measure applies. The agency proposes modifying

this requirement for the 2017 to require that at least two of those nine measures must be cross-cutting measures.

ASTRO supports CMS in its goal to emphasize quality improvement activities through the NQS domains and cross-cutting measures. However, we are concerned that requiring providers to report on two cross-cutting measures may put some radiation oncologists at greater risk for experiencing a negative two percent payment adjustment. Radiation oncologists will only have one individual measures reporting option available to avoid this payment adjustment. Currently, providers have two individual measures reporting options available to avoid the 2016 payment adjustment: 1) they may report nine measures covering at least three NQS domains, and report each measure for at least 50 percent of applicable patients for a 12-month reporting period; OR 2) they may report three quality measures covering at least one NQS domain, and report each measure for 50 percent of applicable patients for a 12-month reporting period. We believe this alternative option should also be made available for the 2017 payment adjustment.

Additionally, the nine measures requirement is a burdensome requirement for specialties, such as radiation oncology, to meet because it is difficult to find nine existing measures that are applicable to the practice of radiation oncology and spread across the various domains. ASTRO is currently working collaboratively with other stakeholders to develop cross-cutting oncology measures that could apply to radiation oncologists. Until more meaningful measures are included in the program, we believe there should be a less burdensome option available for eligible professionals who have a limited selection of reportable measures. ***ASTRO strongly recommends that the agency renew the individual measures reporting option that would allow eligible professionals to report on three quality measures covering at least one NQS domain, and report each measure for at least 50 percent of applicable patients to avoid the 2017 payment adjustment.***

Proposed Changes to Reporting Mechanisms for PQRS Quality Measures
CMS proposes removing the claims-based reporting option for a significant number of quality measures, including measures commonly reported by radiation oncologists. As mentioned above, there are very few measures available to radiation oncologists, and by removing the claims reporting option, the number of measures becomes even more limited for providers who elect to participate using the claims-based method due to practice, administrative, or financial limitations. ***ASTRO believes that the claims-based reporting mechanism should still be an option, but should this mechanism be eliminated, ASTRO encourages the agency to eliminate it for CY 2016 participation and beyond, to provide providers with adequate notice to adapt accordingly.***

Proposed Changes to the Requirements for Qualified Clinical Data Registries
In the CY 2014 final MPFS, CMS finalized the addition of QCDRs as a new PQRS reporting mechanism for 2014 and beyond. QCDRs are CMS-approved entities whose participants can meet the criteria for satisfactory participation in PQRS if they report on at least nine measures covering three NQS domains for at least 50 percent of their patients. Currently for PQRS participation, QCDR participants must report on at least one outcome measure. For 2015 and beyond, CMS proposes to modify this requirement so that at least three of the nine measures are outcomes measures.

Thus, QCDRs would be required to report on at least nine measures covering three NQS domains for at least 50 percent of their patients, and at least three of those nine measures would have to be outcome measures. If three outcome measures are not available, then QCDRs may report on at least two outcome measures and at least one of the following types of measures: resource use; patient experience of care; or efficiency/appropriate use. While we understand the value and importance of outcome measures for

measuring the quality of care, we reiterate our concern regarding the deficiency of specialty-specific measures, and even more so of specialty-specific outcome measures.

ASTRO is also concerned about the lack of stability in the program and the difficulties this causes for QCDRs currently in development. ASTRO recently launched the National Radiation Oncology Registry (NROR), the first of its kind for radiation oncology. In the near future, ASTRO plans to have the NROR certified as a QCDR. However, constant changes in the program requirements may set back registry certification. ***ASTRO believes that consistency and stability in the program requirements, at least in the beginning, are necessary to encourage and allow more quality and meaningful registries currently in the early stages of development to become QCDRs, and therefore, the number of outcome measures should remain unchanged.***

In the CY 2014 proposed MPFS, CMS proposed the requirement that QCDRs must publicly report quality measures data. This proposal was not finalized due to the lack of clarification about this requirement. CMS renews this proposal for CY 2015 by proposing to make public the titles and descriptions of measures reported for PQRS purposes, as well as the performance results for each measure. QCDRs would have the flexibility to select how they make this information public, but it must be made public by April 30 the year after the participation year, and must be continuously updated thereafter.

ASTRO supports transparency. However, we are concerned that posting raw performance data for these measures may lead to confusion and even mislead the public if it is not reported with the appropriate context. ASTRO believes it is critical to link claims data with quality measures data to derive the most utility for quality improvement purposes. The ability to marry claims data with clinical data would provide beneficiaries with a more meaningful and complete picture to help them make more effective and informed health care decisions. Furthermore, we believe that CMS should be consistent and uniform in publicly posting PQRS participation data and should make this information available on the Physician Compare website.

Physician Compare Website

The Physician Compare website was established to provide the public with information on Medicare physicians and healthcare providers, including their participation and performance in PQRS and the EHR Incentive Programs.

In addition to indicating if providers are successfully participating in PQRS, CMS proposes to also indicate if providers earned the additional 0.5 percent 2014 PQRS incentive for meeting Maintenance of Certification (MOC) requirements “more frequently” than is required to maintain board certification. The agency also proposes to report all provider-level measures reported for 2015 PQRS in 2016, if technically feasible. CMS proposes to create and post composite scores and benchmarks by grouping measures based on PQRS measures groups, including the Oncology Measures Group, if a statistically viable composite score can be constructed with 2015 data.

ASTRO supports the posting of performance data. Physician Compare is an important tool for providing Medicare beneficiaries with comparable information on quality and patient measures. In order to maximize the full utility that Physician Compare has to offer, the focus should be on the quality, value, and usefulness of the information being provided to beneficiaries, to help them make educated health care decisions. The focus should not be on quantity, as too much information can be overwhelming and counterproductive. ***ASTRO recommends CMS work closely with stakeholders (specialty societies and***

physicians) before posting additional data on the Physician Compare site so that the information is presented in a clear, concise, and helpful manner.

Physician Value-Based Payment Modifier

The Value-Based Payment Modifier (VM) program rewards providers and groups for providing high-quality, low-cost care. The VM uses a budget neutral, quality-tiering methodology under which providers and groups are subject to a payment adjustment based on their quality performance in comparison to their peers. The VM will be applied to groups of 100 or more providers in 2015, to groups of 10 or more providers in 2016, and to solo practitioners and groups of two or more providers in 2017.

Payment Adjustment

In the CY 2015 proposed rule, CMS proposes to double the VM payment risk, increasing it to four percent , and to apply the quality-tiering methodology to all Category 1 providers (groups that have self-nominated/registered for the PQRS system or have elected the PQRS Administrative Claims option), beginning January 1, 2017. This includes physicians and non-physicians, who are solo practitioners or in groups of two or more EPs that meet the criteria for satisfactory reporting or participation in 2015 PQRS. Under the proposal, these individual providers and groups will either receive an upward (up to 4.0x), neutral (0), or downward (up to -4.0 percent) payment adjustment. Providers who care for high-risk beneficiaries will have the opportunity to earn an additional 1.0x payment adjustment. CMS proposes to calculate preliminary payment adjustment factors, "x," prior to the payment adjustment year. Final payment adjustment factors will be determined after the end of the performance period and will be based on the aggregate amount of downward payment adjustments.

CMS proposes that solo practitioners and groups of two to nine EPs in Category 1 will only be subject to an upward or neutral payment adjustment; they will not be subject to a downward adjustment until 2018. Groups and individual providers who are not in Category 1 will fall in Category 2, and will automatically be subject to the 2017 VM downward adjustment of negative four percent. ***ASTRO supports the proposal to only apply an upward or neutral payment adjustment for first-year providers to help introduce them to the program. However, given the complexity of the program and to allow smaller practices more time to adjust to the value-based payment modifier, ASTRO encourages CMS to consider further delaying the downward payment adjustment for, at minimum, an additional year.***

Quality-Tiering Methodology

The quality-tiering methodology requires the development of quality and cost composites. CMS proposes calculating the quality composites using performance rates for PQRS quality measures, and also the performance rates on three additional VM program outcome measures. CMS proposes calculating the cost composite using the performance rates for VM program's five standardized and risk-adjusted annual per capita cost measures.

The three additional outcomes measures CMS proposes to include follow: 1) composite of rates of potentially preventable hospitable admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; 2) composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia; and 3) rates of an all-cause hospital readmissions measure. Measures groups are an important alternative to individual measures and allow for increased participation in the program. As previously mentioned, due to the lack of applicable individual measures, many radiation oncologists have begun reporting the Oncology Measures Group. ***ASTRO urges the agency to include measures and performance data reported as part of measures group, including the Oncology Measures Group, in the quality composite scores. Additionally, should failure to meet certain threshold requirements for either the quality or cost composite result in an automatic "average" score, ASTRO***

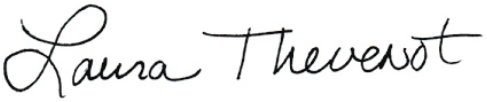
urges the agency to provide clearer guidance on when this is the case and more insight on how this will affect the overall payment adjustment for those providers.

Attribution Methodology
The current attribution methodology includes a pre-step of identifying all beneficiaries who have had at least one primary care service provided by a provider in the group. The beneficiaries are attributed to groups through two-steps: 1) beneficiaries are assigned to the group practice whose primary care physicians provided the plurality of primary care services; and if beneficiaries were unassigned after step one, then 2) they were assigned to groups whose non-primary care providers together provided the plurality of primary care services. CMS proposes to eliminate the pre-step in the current attribution methodology, and to expand step one to include primary care services provided by nurse practitioners, physician assistants, and certified nurse specialists in addition to primary care physicians. Step two would remain the same.

While ASTRO appreciates the clarification on the attribution methodology, it is still unclear how beneficiaries will be attributed to specialists like radiation oncologists. ***ASTRO asks the agency to provide clearer guidance and instructions on how specialists will be impacted and evaluated under the value-based payment modifier, as well as how beneficiaries will be attributed to specialists.***

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Anne Hubbard, Assistant Director of Health Policy, at (703) 839-7394 or anneh@astro.org.

Respectfully,



Laura I. Thevenot
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