



September 5, 2013

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-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 & Other Revisions to Part B for CY 2014 (1600-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 & Other Revisions to Part B for CY 2014” published in the Federal Register as a proposed rule on July 19, 2013.

ASTRO members are medical professionals, who practice 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 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:

- Using OPPS and ASC rates in developing PE RVUs,
- Revising the Medicare Economic Index (MEI),
- Direct PE inputs for Stereotactic Radiosurgery (SRS) services (CPT Codes 77372 and 77373),
- Price adjustment for laser diode,
- Validating RVUs of potentially misvalued codes,
- Medicare coverage of items and services in FDA Investigational Device Exemption (IDE) clinical studies - revision of Medicare coverage,
- Proposed changes to the criterion for satisfactory reporting of individual quality measures via registry for individual eligible professionals for the 2014 PQRS incentive,
- Physician Value Based Payment Modifier; and
- Physician Compare website.

Using OPPS and ASC Rates in Developing PE RVUs

CMS believes that hospitals/facilities incur greater costs than those incurred by practitioners furnishing services in offices and other non-facility settings. They have found that for some services, the total Medicare payment when the service is furnished in the physician office setting exceeds the total Medicare

payment when the service is furnished in a hospital outpatient or ambulatory surgical center. The agency believes this is an inappropriate payment differential. CMS is proposing to cap the physician fee schedule (PFS) freestanding practice expense (PE) RVUs so that the total freestanding payment rate would not be greater than the total Medicare payment for the same service provided in a hospital setting.

There are 211 codes affected by the OPPS/ASC cap to non-facility PE RVUs. The radiation oncology codes impacted by this proposal are listed below.

- 77280, Set radiation therapy field
- 77290, Set radiation therapy field
- 77301, Radiotherapy dose plan IMRT
- 77403, Radiation treatment delivery
- 77404, Radiation treatment delivery
- 77406, Radiation treatment delivery
- 77412, Radiation treatment delivery
- 77413, Radiation treatment delivery
- 77414, Radiation treatment delivery
- 77416, Radiation treatment delivery
- 77422, Neutron beam tx simple
- 77423, Neutron beam tx complex
- 77605, Hyperthermia treatment
- 77610, Hyperthermia treatment
- 77615, Hyperthermia treatment

ASTRO strongly opposes this proposal. We disagree with the general premise of replacing the resource based PE RVU methodology of the Medicare physician fee schedule (PFS) with rates benchmarked to the APC rates from the hospital outpatient prospective payment system. ASTRO understands that there are limitations to the existing practice expense methodology. CMS, working with the AMA/RUC, physician specialty societies, and other collaborators, has spent years developing and revising the current PE methodology. ASTRO is confused why the agency would suddenly dismiss all of the prior and ongoing contributions of so many individuals to build and implement this policy. While ASTRO agrees that a comparison of OPPS and PFS rates might be an appropriate method to identify services for review as potentially misvalued, it simply is not appropriate to assume that it is fair to interchange the rates arbitrarily.

ASTRO also believes this proposal will contribute to the ongoing instability of the Medicare physician payment system. CMS has proposed to cap 15 radiation oncology codes. These codes accounted for about 1.4 million services and \$420 million in practice expense payments (at 2013 PE amounts). The caps would reduce PE payment for these codes by 30 percent, and would reduce total technical component PE payments for radiation oncology by about 11 percent, a very significant one-year reduction in payment. These severe decreases are being imposed after multiple consecutive years of cuts to radiation oncology PE RVUs resulting from the transition to the Physician Practice Information Survey (PPIS) data which occurred from CY 2010-CY 2013. These continued annual cuts cannot help but to impact patient care. In recent years, radiation oncology and other specialties have also experienced uncertainty due to annual SGR cuts. This year-to-year instability is challenging for physicians running practices but it is also problematic for Medicare beneficiaries. For a resource-intensive specialty like radiation oncology, offering a new service and maintaining or expanding existing services requires significant capital as well as hiring and training specialized staff. It is difficult to make such commitments in an unstable reimbursement environment.

Hospital Rate-Setting Methodology Ill-Suited for Freestanding Environment

An analysis of how the OPPS manages costs provides further evidence that the application of an OPPS cap to physician fee schedule rates is problematic and inappropriate. Hospital markups vary substantially across services within a single cost-reporting category. CMS' cost-finding method is limited to applying a single markdown (cost-to-charge ratio or CCR) to all services mapping to any one cost report line (hospital department level). The resulting estimate of cost is too high for services with high markup, and too low for others.

The relevance of this to the proposed OPSS cap is that by construction, OPSS costs should be accurate only down to the level of the cost report line. At the CPT code level, OPSS costs are known to suffer from charge compression (lower markup in high cost items), leading to understatement of cost for high-cost items.

Another problem is that unlike hospitals, physician practices will not be able to make up their losses with profits from another service. For example, the technical component of CPT codes 77301 (IMRT Planning) is valued at \$1594.32 in the MPFS 2013 and CPT 77295 (3D Planning) at \$219.11. Under the OPSS 2013, they are both in APC 0310 with a payment rate of \$984.49. While hospitals can make up for losses on one service with profits from another, physicians will have no opportunity to make up their losses because CMS does not propose to increase payments where the PFS is lower than the APC rate. This will have a devastating effect on these key radiation oncology dosimetric planning codes.

This provides further evidence that the OPSS cap policy is inappropriate for the freestanding environment and that CMS should not finalize this policy.

Addressing CMS' Concerns with Physician Fee Schedule PE Data

In the rule, CMS describes its inability to validate PE data. CMS states, "Currently, we have little means to validate whether the information is accurate or reflects typical resource costs. Furthermore, in the case of certain direct costs, like the price of high-cost disposable supplies and expensive capital equipment, even voluntary information has been very difficult to obtain. In some cases the PE RVUs are based upon single price quotes or one paid invoice." ASTRO disagrees. Each list of resources needed to provide services in the physician office is collected using standardized processes, carefully examined by a cross-specialty panel, and is typically submitted with invoices for expensive equipment and supplies. CMS participates in all deliberations and makes final decisions on the practice expense values.

If CMS is dissatisfied with the quality or robustness of the data it is receiving, ASTRO is committed to working with the agency to find a solution. ASTRO believes that working to improve the current system, which relies on a validated methodology backed by years of evidence is more appropriate than replacing it with APC rates, where there is no evidence that the true costs of providing the individual services in the office setting are captured accurately.

For example, we believe the collection of invoices is one area, with some minor adjustments to the process, where ASTRO and other specialty societies would be able to improve the data it provides. For more than a decade ASTRO has submitted paid invoices along with our practice expense recommendations. Although specialty societies, like ASTRO, put requests out to their membership for help with pricing, these members are often very uncomfortable sending such confidential information to specialty society staff. Also, while important identifying information is redacted, we are required to leave some identification (i.e. State) for validation purposes. These invoices are distributed to all RUC meeting participants and included as public information on the CMS site. Stakeholders in the marketplace are often able to identify the practice through this process, which has major implications to price negotiations and service lines in local markets. We believe once protections are put into place to protect confidential information, physicians would be more likely to help their societies supply this important information.

Another flaw is a failure to differentiate services that have had a comprehensive PE review which have been accepted by both the RUC and CMS within the last three years or codes which are undergoing a comprehensive review. For example, CPT code 77301 Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications was just reviewed and approved at the May 2013 RUC meeting. This was the third RUC review of practice expense since

2010. The simulation codes CPT 77280, 77285, 77290 and 77295 have also just been reviewed at the January 2013 RUC meeting. During the RUC process, specialty societies invest significant time and resources into generating direct practice expense inputs, which are then, reviewed line-by-line by the RUC and their Practice Expense Subcommittee. Additionally, throughout the process—prior to, during, and after the RUC meetings—CMS staff expends great efforts to review the submissions. These exhaustive reviews of inputs during the RUC evaluation process are more accurate than the OPSS rates that average high and low services within a single APC.

ASTRO strongly encourages CMS to work with specialty societies and the AMA/RUC to improve upon the process for pricing data collection and better protect this confidential information.

In addition to disagreeing with the premise of the proposed policy, ASTRO believes there are significant problems with how CMS plans to implement it.

Benchmarking to 2013 APC Rates

A major flaw ASTRO has identified in the proposal is that the cap that would apply to 2014 PFS rates is based on a comparison to 2013 OPSS and ASC rates. This flawed approach fails to account for anticipated payment updates of 1.8 percent for the OPSS and 0.9 percent for the ASC payment rates as well as any APC weight changes that CMS has proposed. In some cases, these will result in significant disparities between the OPSS/ASC cap and the actual rate paid in these settings in 2014. APC rates from CY 2013 to CY 2014 for radiation oncology services impacted by this cap have increased significantly. For example, CPT code 77403, Radiation treatment delivery, would be paid \$95.50 under the PFS in 2014, well below the level to which the APC rate is actually increasing in 2014 (\$120.16). In another example, CPT code 77301, Radiotherapy dose plan IMRT, would be paid \$984.49 under the PFS in 2014, whereas the APC rate is proposed at \$1879.06 in 2014.

In addition, it is important to note that APC rates are based on claims data from two years prior. Therefore, CY 2014 rates are based on CY 2012 cost data. Benchmarking the PFS rates to CY 2013 OPSS rates which is based on CY 2011 cost data is an unacceptable and inappropriate lag.

ASTRO opposes the cap proposal, but believes that if CMS were to implement this plan, it should benchmark the PFS rates to CY 2014 OPSS rates.

Four of the radiation oncology codes would not be capped at the 2014 OPSS proposed rule rates. Those codes are:

- 77280, Set radiation therapy field
- 77290, Set radiation therapy field
- 77301, Radiotherapy dose plan IMRT
- 77406, Radiation treatment delivery

ASTRO recommends that CMS should exempt them from the proposed policy, rather than reduce the reimbursement in CY 2014, only to raise it back up again in CY 2015.

Direct Expenses Exceed Proposed Payment Rates

Several high volume radiation oncology codes are impacted by this cap and we believe the payment rates for these codes would only partially cover the costs of direct practice expense inputs (labor, supplies, and equipment), let alone indirect practice expense costs.

For the radiation oncology codes impacted by the cap proposal, ASTRO compared the costs of their direct practice expense inputs¹ published with the proposed rule to the 2013 APC rates at which they have been capped. We found several examples where the APC rate only partially covers the cost of direct practice expense inputs listed in the agency’s own practice expense file.

77412, Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; up to 5 MeV

77413, Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6-10 MeV

77414, Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 11-19 MeV

77416, Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 20 MeV or greater

A series of treatment delivery CPT codes (77412, 77413, 77414, and 77416) are experiencing cuts under this proposal. These services are key treatments for breast cancer and other sites. Cuts at this level would be devastating and unsustainable for community based cancer centers. The chart below demonstrates the proposed rates would only cover 68 to 76 percent of direct practice expense inputs for these services.

CPT Code	Descriptor	Labor Cost	Supply Cost	Equipment Cost	2013 Payment	2014 Total Cost*	2014 Proposed Rate	Percent of Cost Covered by 2014 Proposed Payment
77412	Radiation treatment delivery	\$ 12.50	\$ 2.39	\$ 232.06	\$ 240.20	\$ 246.95	\$ 188.67	76.40%
77413	Radiation treatment delivery	\$ 12.50	\$ 2.39	\$ 232.06	\$ 231.36	\$ 246.95	\$ 188.67	76.40%
77414	Radiation treatment delivery	\$ 12.50	\$ 2.39	\$ 263.18	\$ 260.28	\$ 278.07	\$ 188.67	67.85%
77416	Radiation treatment delivery	\$ 12.50	\$ 2.39	\$ 263.18	\$ 259.94	\$ 278.07	\$ 188.67	67.85%

It is worth noting that the treatment delivery codes were identified for review in the 2013 final Medicare physician fee schedule. At the agency’s request, ASTRO is spending significant time and resources to review these codes and they were addressed in a CPT code change application discussed at the June 2013 CPT meeting. The issue was tabled and is once again on the agenda for the October 2013 CPT meeting.

ASTRO urges CMS to follow the established process for reviewing potentially misvalued codes and not finalize the OPFS cap proposal.

Revising the Medicare Economic Index (MEI)

The Medicare Economic Index (MEI) is a measure of practice cost inflation that was developed in 1975 as a way to estimate annual changes in physicians’ operating costs and earning levels. The MEI is a fixed-weight input price index, with an adjustment for the change in economy-wide, private nonfarm

¹ CMS; CY 2014 Proposed Rule, Medicare Physician Fee Schedule (1600-P); Direct Practice Expense Inputs Used To Create Resource-Based Practice Expense Relative Value Units File (July 19, 2013)

business multifactor productivity. This index is comprised of two broad categories: (1) physicians' own time; and (2) physicians' practice expense (PE). MEI impacts the annual SGR update as well as the calculation of PE RVUs.

CMS is proposing revisions to the calculation of the MEI. The changes are in response to recommendations by a Technical Advisory Panel that met during CY 2012. There were numerous changes to cost categories and the weights assigned to them. These proposed changes led to revised RVUs based on new weights for work (increased to 50.866%), PE (decreased to 44.839%), and malpractice (unchanged at 4.295%). This change has positive impacts for some specialties (i.e. nurse anesthetists, anesthesiology, emergency medicine) and negative impacts for others (i.e. radiation oncology (-2%) and radiation therapy centers (-5%)). Below are examples of some of the radiation oncology impacts:

CPT Code	CPT Descriptor	MEI Impact
77295	Set radiation therapy field	-6.6%
77336	Radiation physics consult	-6.8%
77412	Radiation treatment delivery	-6.7%

In recent years, there have been multiple changes to the practice expense (PE) methodology that have reduced PE values for radiation oncology. While we understand these changes are attempts by the agency to more accurately measure resources utilized, we do not believe that the results reflect the true cost of running a technology-intensive practice like radiation oncology. RVUs should reflect the relative cost of physician work, practice expense, and professional liability. ASTRO realizes the agency is concerned about perverse market incentives that could influence medical decision-making. ASTRO is sympathetic to this concern but we do not believe that RVUs should be manipulated to solve this problem. Rather RVUs should reflect the relative resources used in providing a service in the current market.

We strongly urge the agency to consider alternative methodologies for offsetting the MEI changes, to mitigate the redistribution of RVUs. ASTRO recommends postponing the MEI changes until an alternative methodology can be fully vetted.

Direct PE Inputs for Stereotactic Radiosurgery (SRS) Services (CPT Codes 77372 and 77373)

Since 2001, Medicare has used HCPCS G-codes, in addition to the CPT codes, for stereotactic radiosurgery (SRS) to distinguish between robotic and non-robotic methods of delivery. In the hospital outpatient setting there are four G-codes that are priced to distinguish between robotic and non-robotic SRS. In the freestanding setting, CMS has priced two CPT codes that do not distinguish between robotic and non-robotic. The two G-codes that describe robotic SRS are carrier priced in the freestanding setting. After reviewing the current literature, CMS believes it is no longer necessary to distinguish between robotic and non-robotic linac-based SRS through the HCPCS G-codes.

For CY 2014, CMS is not proposing to replace the contractor-priced G-codes for PFS payment. Instead, they are seeking comment on whether the direct PE inputs for the existing CPT codes (77372, SRS linear based and 77373, SBRT delivery) for PFS payment would continue to accurately estimate the resources used in furnishing typical SRS delivery were there no coding distinction between robotic and non-robotic methods of delivery.

ASTRO appreciates the opportunity to comment on this issue prior to implementation. We support this proposal and agree that using the CPT codes, instead of the G-codes, to describe all SRS and SBRT

treatments is appropriate. All SRS and SBRT treatments, including robotic treatments, are appropriately captured with CPT codes 77372 and 77373. These codes have been recently reviewed by the AMA/RUC. CPT code 77372 was reviewed in April 2013 and CPT code 77373 was reviewed in January 2013. As part of this review of direct PE inputs, all technologies, including those with robotic functionality, were incorporated. In addition, equipment invoices for all these technologies were included with the AMA/RUC's submission to CMS. The price for the SRS system, CMS equipment code ER083, is the result of weighting six different treatment systems.

ASTRO supports the proposal to delete the G-codes describing stereotactic body radiation therapy and using CPT codes 77372 and 77373 to report all SBRT services. ASTRO believes that the direct PE inputs approved by the RUC for CPT codes 77372 and 77373 accurately reflect the typical resources used when furnishing these services in the office setting.

Price Adjustment for Laser Diode

In the 2013 final PFS, CMS updated several pieces of equipment related to IMRT. ASTRO and other stakeholders noted a discrepancy between the language in the regulations and the price listed in the direct practice expense input equipment file for the laser diode. The language in the rule stated the price was updated from \$7,678 to \$18,160; however, the equipment file still listed the price of the laser diode as \$7,678. In the 2014 proposed rule, CMS has fixed this error.

ASTRO appreciates the agency's response to the comments from ASTRO and other stakeholders by fixing this error.

Validating RVUs of Potentially Misvalued Codes

The Affordable Care Act (ACA) requires Medicare to develop validation mechanisms for the relative value units (RVUs) assigned to services paid under the physician fee schedule. Currently, CMS assigns values to services based on a review of recommendations made by the AMA/RUC. To address the ACA requirement, CMS has contracted with two consulting companies, the RAND Corporation and the Urban Institute, to validate the current model for valuing services.

During a 2-year project, the RAND Corporation will use available data to build a validation model to predict work RVUs and the individual components of work RVUs: time and intensity. The model design will be informed by the statistical methodologies and the approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and AMA RUC processes. RAND will use a representative set of CMS-provided codes to test the model. RAND will consult with a technical expert panel on model design issues and the test results.

Given the central role of time in establishing work RVUs and the concerns that have been raised about the current time values, a key focus of the Urban Institute project is validating time. Data will be collected from several practices for services selected by the contractor. This data will then be used to develop time estimates. The Urban Institute will use a variety of approaches to develop what it terms as "objective time estimates." These time estimates will then be compared to the current time values used in calculating work RVUs for the Medicare physician fee schedule. The project team will convene groups of physicians from a range of specialties to review the new time data and their potential implications for work and the ratio of work to time.

ASTRO supports efforts to enhance the robustness of Medicare physician fee schedule data. Historically, on such projects CMS has collaborated with the physician community which has contributed data, analyzed or commented on data being used by the agency, and provided feedback on various initiatives

and programs. We believe this collaboration has been beneficial for the agency, beneficiaries, and providers and should continue as part of the agency's efforts to validate RVUs.

ASTRO encourages the agency to keep the physician community informed and engaged as these two contracts move forward. The physician community can be an important partner to help CMS understand the data in a more meaningful manner. ASTRO would like to hear more about how the two contracts will operationalize their scope of work. We would like more information on how CMS will report the findings and ultimately address issues. ASTRO encourages CMS to keep open lines of communication with the physician community.

Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies--Revision of Medicare Coverage

On September 8, 1995, the FDA and CMS entered into an interagency agreement in which the FDA agreed to categorize investigational device exemptions (IDEs) for purposes of Medicare coverage into two categories: (1) Category A devices were described as experimental/investigational; and (2) Category B devices were described as non-experimental/investigational devices. Under current Medicare policy, coverage is available for the costs of routine items and services in Category A IDE studies and trials. Medicare covers the costs of Category B devices as well as the costs of routine items and services in Category B IDE studies and trials.

CMS has proposed to establish criteria that ensure studies and trials of Category A devices conform to appropriate scientific and ethical standards. Based on its rulemaking authority in section 1871 of the Act, CMS has also proposed to extend these same criteria to Category B studies and trials. Lastly, there is a proposal for a review to address the current problems with inconsistent coverage decisions and variable scrutiny of IDE devices across local Medicare contractors. ASTRO appreciates the agency's efforts to establish criteria, efficiency, and consistency for the decision-making process for coverage of Category A and Category B IDEs. However, ASTRO has concerns about some of these proposals.

The agency proposed thirteen standards (criteria) that Category A IDE studies must meet in order to be covered. ASTRO supports the agency's consideration of ethical values and patient safety in the establishment of these standards, and we believe that it is important to have a minimum threshold determining device safety and efficacy. However, some of the standards present hurdles to innovation of valuable devices that could improve the efficacy and safety of radiation treatments provided to cancer patients. The standards could impose a monetary burden on entities that may not have the capital to meet all the proposed requirements. Thus, these standards may prevent the trials and studies of devices based on monetary limitations, instead of the merits of devices.

ASTRO recommends creating less restrictive standards that are phased-in to prevent regulatory and monetary obstacles to innovation and access to care.

Additionally, the requirement that results of the trials and studies must be made public within 24 months of the end of the data collection is a significant concern for ASTRO. For radiation oncology, 24 months is not a sufficient amount of time to publicly report accurate, valuable, and useful data as journals in the field require studies and papers to report data well beyond 24 months. We are also concerned about the feasibility of having a full report made public within three years.

ASTRO recommends revising the required public reporting of trial results to 36 months instead of 24 months and that a full report of the outcomes should be made public no later than five years after the end of data collection.

ASTRO understands the agency's reasoning for proposing that CMS make IDE coverage decisions centrally. However, we believe that this would significantly delay the approval process and take away the expertise provided by stakeholders currently provided through the local coverage process. If the process is centralized, then CMS would bear the totality of decision-making responsibilities that is currently spread across the nation. We are concerned that the process will become more burdensome when only one entity is handling all coverage decisions. We believe this would result in the whole process becoming lengthier, further delaying advancements of innovative devices.

ASTRO recommends that CMS should not finalize the proposal to make coverage decisions centrally. Additionally, ASTRO urges CMS provide ample opportunity for input from stakeholders, like ASTRO, that can provide valuable insight into the coverage decision-making process.

Proposed Changes to the Criterion for Satisfactory Reporting of Individual Quality Measures via Registry for Individual Eligible Professionals for the 2014 PQRS Incentive The Physician Quality Reporting System and Qualified Clinical Data Registries

The Physician Quality Reporting System (PQRS), as set forth in section 1848(a), (k), and (m) of the Social Security Act, is a quality reporting program that uses a combination of incentive payments and payment penalties to promote reporting of quality measures information. The regulation governing PQRS is located at 42 CFR 414.90.

Oncology Measures Group

ASTRO would like to thank CMS for renewing the Oncology Measures Group for the 2014 reporting period and for maintaining the minimum 20 patient reporting requirement for participation in PQRS using a measures group.

Additionally, ASTRO supports the proposal of modifying the minimum amount of measures that may be included in a PQRS measures group from four to six, and modifying the definition of a measures group at § 414.90(b) to reflect this new requirement.

Proposed Criteria for Individual Measures Reported via Claims, Registry, or Qualified Clinical Data Registries

It has been proposed that eligible professionals, who opt to report individual measures via claims, a qualified registry, or a qualified clinical data registry, generally must report a minimum of nine quality measures that cover at least three National Quality Strategy (NQS) domains. ASTRO supports CMS in its goal to emphasize quality improvement activities in the domains specified by the NQS. However, we believe that nine measures is too great a leap forward given that the NQS domains requirement is new and has not been the framework guiding measure development. The requirement for nine quality measures is, especially for specialties like radiation oncology, difficult to meet because it has hard to find nine existing measures that are spread across the various domains. As the quality enterprise shifts in the direction of the NQS, we will shift measure development priorities accordingly but we believe this requirement, as proposed, is premature.

ASTRO proposes that the requirement should be decreased to four measures in the beginning and increased to nine in the future. ASTRO also believes that instead of three NQS domains, the measures should only cover two NQS domains at the outset and expanded to three in the future.

Requests for Comments on the PQRS Reporting Period and Submission Deadlines

CMS stated that it has received many comments and concerns regarding the two-year gap between the reporting period and the adjustment year. Many have requested that the reporting periods occur closer to the year in which the adjustment is applied. However, CMS states that it is operationally infeasible to create a twelve-month reporting period for the PQRS payment adjustment any later than two years prior to the adjustment year “and still avoid retroactive payment or the reprocessing of claims.” CMS asked for comments on the following questions:

1. Should CMS consider establishing a reporting period that occurs close to the adjustment year for certain reporting mechanisms (registry, EHR)?
2. Should the reporting periods be structured as twelve-month reporting periods occurring in one calendar year or multiple years?
3. What should be the length of time for the reporting period?
4. How often should quality measures data be collected?

ASTRO agrees with the comments and concerns that CMS has received on creating a reporting period that occurs closer to the corresponding adjustment year. We believe that, for quality improvement activities such as this, performance feedback is needed in a timely fashion for it to be actionable. ASTRO acknowledges that there are operational hurdles that prevent the creation of a twelve-month reporting period any later than two years prior to the adjustment year.

ASTRO proposes that the reporting period should be shortened to six months, occurring in a single calendar year. The reporting period would ideally be from January through June.

This would allow for successful collection of data in the first half of a calendar year, with the submission of the data to CMS at the end of the reporting period (early July). The remaining six months of the calendar year would provide CMS (and registries) with sufficient time to analyze the data and to provide valuable feedback reports to providers. Since providers will receive their reports before the start of the next reporting period, they will have time to assess their performance and develop an action plan for improving their performance in the next reporting period, which will consequently result in higher quality of care. Additionally, creating a reporting period that is closer to the corresponding adjustment year could incentivize providers to participate in PQRS because a penalty for lack of participation would occur in the near future.

Proposed Changes to Reporting Mechanisms under PQRS

Currently, the reporting mechanisms available under PQRS are: claims, qualified PQRS registry, EHR systems, qualified EHR Data Submission Vendor, administrative claims, and the GPRO web-interface. CMS has proposed including two new reporting mechanisms: certified vendor reporting mechanism for reporting Clinician Group Consumer Assessment of Healthcare Providers and Systems (CG CAHPS) measures for group practices of twenty-five or more eligible professionals; and qualified clinical data registries. CMS has also proposed eliminating the claims-based reporting mechanism for the 2019 reporting year. Although the claims-based reporting mechanism is the most-used mechanism, it is also the mechanism with the most errors and burdensome because of the G-code analysis required. ASTRO supports the addition of the two new reporting mechanisms.

ASTRO believes that the claims-based reporting mechanism should still be an option for providers, but should it be decided that this mechanism be eliminated, ASTRO appreciates timely notification and for phasing out of the claims-based reporting mechanism.

Proposed Definition and Criteria for Qualified Clinical Data Registries

Section 601(b)(1) of the American Taxpayer Relief Act of 2012, amending section 1848(m)(3)(D) of the Act, allows eligible professionals to be treated as satisfactorily submitting data on quality measures for the purposes of PQRS if the eligible professionals are satisfactorily participating in a qualified clinical data registry (QCDR). Additionally, section 1848(m)(3)(E) of the Act, as added by section 601(b)(1) of the American Taxpayer Relief Act of 2012, authorizes the Secretary to define a qualified clinical data registry under PQRS.

After the comments it received in response to its February 7, 2013 Request for Information titled “Medicare Program; Request for Information on the Use of Clinical Quality Measures (CQMs) Reported Under the Physician Quality Reporting System (PQRS), the Electronic Health Record (EHR) Incentive Program, and Other Reporting Programs,” CMS agrees that QCDRs should serve roles that foster quality improvement in addition to data collection and submission. With this in mind, ASTRO would like to stress that, although QCDRs are defined under PQRS, they should be thought of as distinct and separate entities that exist apart from PQRS. The criteria and characteristics that have been proposed for the purposes of PQRS should not be *the* criteria and characteristics for QCDRs. Nothing in these proposed regulations should impede QCDRs’ ability to effectively and successfully perform their other quality improvement roles.

It has been proposed that, for the purposes of PQRS, a QCDR should be defined as a “CMS-approved entity (such as a registry, certification board, collaborative, etc.) that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care furnished to patients.” In addition to this, a QCDR, for the purposes of PQRS, must be able to perform four key functions. One of these is that QCDRs must provide quarterly performance reports to providers.

ASTRO is a strong supporter of providing timely feedback performance reports to providers, but we believe that the reports should be provided at the end of the ASTRO-recommended six-month reporting period, from January through June (see above), rather than quarterly.

This would allow QCDRs to provide participants with meaningful feedback reports that participants could review and use to help them prepare for the next reporting period. Additionally, this would reduce an administrative burden for QCDRs.

Lastly, ASTRO would like to note and clarify that the additional four key functions are *only* for those QCDRs that seek to, on behalf of their eligible providers, submit quality measures data to CMS for the purposes of PQRS, and that these four key functions are not required for an entity to be qualified as a QCDR, generally.

CMS has proposed several requirements an entity must meet in order to serve as a QCDR. To ensure that it is well-established, the entity must: 1) be in existence January 1st the year prior to which it seeks to become a QCDR; 2) have at least 100 participants by January 1st the year prior to which it seeks to become a QCDR; and 3) it must not be owned or managed by an individual, locally-owned, single-specialty group. ASTRO is in support of these requirements and agrees with CMS that a QCDR should have adequate time for ensuring that it is adopting practices that truly foster the improvement of quality care, be robust in technical capabilities, and is sufficiently larger in size than a traditional PQRS qualified registry. However, ASTRO seeks clarification on the 100-participants requirement: whether the number of participants is determined by the number of NPIs participating in the QCDR or by the number of business associate agreements a QCDR has? Additionally, ASTRO believes that requiring the entity to

have 100 participants January 1st the year before it seeks to become a qualified clinical data registry will be a roadblock preventing a broad range of QCDRs to be approved for the 2014 reporting year.

Instead, ASTRO proposes that the entity should be required to have 100 participants by January 1st of the reporting year in which it seeks qualification, or six months prior to January 1st of the year in which seeks qualification.

Another requirement is that QCDRs must possess a method to benchmark the quality of care measures an eligible professional provides with that of other eligible professionals performing same or similar functions.

ASTRO supports the proposal that benchmarks be provided at the provider level, but believes that in some cases assessment at the entity level would be more appropriate, and so that language should be modified accordingly. ASTRO would like to note that CMS has not proposed the unit of analysis for these benchmarks reports. Would QCDRs have the option to establish national or regional benchmarks, or would QCDRs be required to establish both national and regional benchmarks?

CMS has also proposed several requirements pertaining to transmission of quality measures data to CMS. While ASTRO generally supports these requirements and believes that, for the purposes of PQRS, these requirements are necessary, we believe that some of the requirements should be clarified and modified as follows:

CMS seeks, upon request and for oversight purposes, access to the QCDR's database to review beneficiary data on which submissions to CMS are based or provide to CMS a copy of the actual data.

CMS should clarify whether this would be patient-level or provider-level data.

If patient-level data, is the QCDR expected to have identified or de-identified patient data according to HIPAA standards?

Additionally, for this requirement, as well as for the requirement that the QCDR make samples of patient-level data available to CMS for audit purposes, ASTRO believes that CMS should only have access to that data which is being submitted to CMS for the purposes of PQRS and/or the EHR Incentive Program.

Since CMS agrees that QCDRs should "serve additional roles that foster quality improvement in addition to the collection and submission of quality measures data," it is likely that the QCDR will have separate data in addition to what it submits to CMS for PQRS and/or the EHR Incentive Program.

Another criterion for QCDRs is that they must be able to, on behalf of their participants, report to CMS a minimum of nine measures that cover at least three NQS domains. Again, ASTRO reiterates its support of CMS's goal to emphasize quality improvement activities across various domains. However, many QCDRs are still in the early stages of development, and the focus at this time should be developing valuable and meaningful QCDRs that have the infrastructure to embed quality improvement programs into their daily practices.

It has been proposed that if a QCDR submits inaccurate data, it will be disqualified and it must go through the qualification process again.

ASTRO would also urge CMS to develop an appeal process (for both the initial qualification process and for the audit process) if an entity believes it has been wrongly disqualified.

CMS has also proposed the requirement that QCDRs must self-nominate every year. ASTRO believes that this would be an unnecessary burden. The self-nomination process is onerous, so having to go through it every year would mean that this process would be the primary focus of the QCDR for a good portion of the year.

Instead, ASTRO believes that QCDRs should be required to self-nominate every two years.

Physician Compare Website

CMS was required by section 10331(a)(1) of the Affordable Care Act to develop a Physician Compare website with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other eligible professionals who participate in PQRS. CMS launched a redesigned and updated Physician Compare website on June 27, 2013. CMS says the recently-launched website consists of a bolstered underlying database, better search functions, and increased information—including satisfactory reporting to quality programs—on professionals' profile pages.

CMS has proposed to increase reporting in 2014 to include all quality measures for group practices participating in 2014 PQRS GPRO and ACOs participating in the Medicare Shared Savings Program, quality measures organized by registries and EHR reporting mechanisms, more patient-experience measures for group practices and ACOs, and more measures for individual eligible professionals. A 30-day review period will be provided to providers before publication of the quality data on Physician Compare. CMS has asked for comments on potential proposals to post performance from patient experience measures for individual EPs, expanding the reporting of measures developed by specialty societies, and including non-governmental quality measures on Physician Compare. Lastly, there has been a proposal to publicly report a number of individual measures reported by individual EPs in line with measures currently reported by groups through the GPRO web interface.

ASTRO supports the posting of performance data and continuing development of Physician Compare into a valuable and vital resource for Medicare beneficiaries. We believe that Physician Compare is an important tool for providing beneficiaries with comparable information on quality and patient measures. However, because Physician Compare is such an important resource, and in order to maximize the full utility it has to offer, it is critical that the information on the site is accurate. The selection of the measures data that will be posted should be done so methodologically, taking into account several factors. These factors would include, among other things, the diversity of the specialties and subspecialties, as well as considering which measures would be most useful to beneficiaries when they are using Physician Compare to select a provider. 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. To help decide what data should be posted on Physician Compare, ASTRO believes that it is important for CMS to work collaboratively and have continued open dialogue with specialty societies.

ASTRO recommends that prior to any information being added to the site, all providers, not just those in groups and ACOs, should be provided with a 30-day review period to ensure that their information is correct and up-to-date.

Physician Value Based Payment Modifier

Beginning January 1, 2015, the Secretary is required to apply a value-based payment modifier to specific physicians and groups of physicians the Secretary determines are appropriate. In addition, the Secretary

is required to apply the payment modifier to all physicians and groups of physicians, no later than January 1, 2017. In the CY 2013 PFS final rule, CMS finalized policies to calculate the value-based payment modifier using the quality-tiering approach. Quality-tiering requires the creation of quality and cost composites for each group of physicians subject to the value-based payment modifier. In 2013, the modifier applied to physician groups of 100 or more.

In the 2014 proposed rule, CMS made a number of additions and refinements. ASTRO's comments on some of the more significant proposals follow.

Group Size

CMS proposes to apply the value-based payment modifier in CY 2016 to groups of physicians with 10 or more eligible professionals. CMS estimates that this proposal will cause approximately 17,000 groups (TINs) and nearly 60 percent of physicians to be affected by the modifier in CY 2016.

ASTRO appreciates that the agency is staggering the participation of physicians into the program. While it is logical for CMS to begin with the larger practices, it does concern us that the program will have limited exposure during its development phase to specialties that typically have smaller practice, such as radiation oncology.

ASTRO recommends that CMS analyze potential participants in the program by specialty and determine if there are is an absence of certain specialties.

As noted in previous comment letters, ASTRO continues to be concerned with the numerous incentive/penalty programs that physicians will face by the year 2017 (i.e. PQRS, meaningful use, value-based payment modifier), creating a significant burden on practices managing these multiple programs. Participation requirements change from year to year with the final participation regulations released two months before they become effective. This leaves limited time to develop the necessary internal systems or processes needed to satisfactorily implement the program.

Application of Downward Adjustment

CMS proposed that groups of physicians with between 10 and 99 eligible professionals would only be subject to upward or neutral adjustments, and groups of physicians with 100 or more eligible professionals would be subject to upward, neutral, or downward adjustments.

This proposal appears to ensure that during the first year that the value based modifier would apply to a practice, the practice would not be at risk for a penalty.

ASTRO supports this model and encourages CMS to continue this policy as more physicians from smaller practices enter the program. Since smaller practices may have a more difficult time adjusting to the value based modifier, ASTRO encourages CMS to consider if the period where a practice is not at risk for a penalty should be longer for smaller practices. For example, practices of nine or less could have two years to adjust to the program.

Calculation of the Value Based Modifier

The value based modifier is composed of a quality of care composite and a cost composite. To establish the quality composite, CMS creates a standardized score for each quality measure reported through the PQRS reporting mechanism, as well as three outcome measures. Based on the national priorities, measures are classified into one of the six domains: clinical care, patient experience, population/community health, patient safety, care coordination and efficiency. These domains are then

equally weighted to form a quality care composite. When a domain does not contain a quality measure, the remaining domains would be equally weighted to form the quality of care composite.

To create the cost composite, CMS uses five measures of total per capita costs for beneficiaries attributed to the group practice. CMS creates a standardized score for each measure and then classifies each measure's standardized score into one of two domains: total per capita costs for all attributed beneficiaries or total per capita costs for all attributed beneficiaries with specific conditions. Within each cost domain, each measure is equally weighted. If one of the domains contains no measures, the remaining domain is weighted at 100 percent.

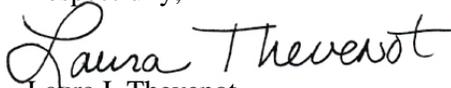
Each group's quality and cost composites are classified into high, average, and low depending upon whether the composites are one or more standard deviations above or below the mean. CMS compares the group's quality of care composite classification with the cost composite classification to determine the value-based payment modifier adjustment.

While these explanations are helpful in understanding the implementation of the value based payment modifier on a very broad level, this general description provides limited insight into how this methodology would apply to different specialties, practices, and patient populations. ASTRO urges CMS to provide examples of the application of the modifier using real de-identified data. For example, in the final rule, CMS could calculate the value based payment modifier for a small pool of physicians in a variety of specialties, practice types, and geographic locations using real de-identified claims and quality data. The results of such an analysis could help CMS better understand the strengths and weakness of the proposed methodology. If this analysis was publically released, individual specialties could identify areas where the methodology is incompatible with the specialty and fails to accurately measure quality and costs.

ASTRO urges CMS to identify ways of explaining and testing the value based modifier in a method that is transparent, accessible, and can provide robust results.

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 Sheila Madhani, Assistant Director of Medicare Policy, ASTRO Government Relations Department at (703) 839-7372 or sheilam@astro.org.

Respectfully,



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