



December 30, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-FC
P.O. Box 8013
7500 Security Boulevard
Baltimore, MD 21244-8013
Submitted electronically: <http://www.regulations.gov>

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Centers for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015

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 Centers for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015” published in the Federal Register as a final rule on November 13, 2014.

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

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

- Radiation Treatment Vault
- Radiation Therapy Codes
- Isodose Calculations with Isodose Planning Bundle (CPT 77316)
- Radiation Treatment Delivery (CPT Code 77373)
- High Dose Rate Brachytherapy (CPT Codes 77785, 77786, 77787)
- Radiation Therapy Dose Plan (CPT 77300), Teletherapy Isodose Plan Simple (CPT

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

8280 WILLOW OAKS CORPORATE DRIVE • SUITE 500 • FAIRFAX, VA 22031 • 800.962.7876 • 703.502.1550 • FAX: 703.502.7852

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- 77306) and Teletherapy Isodose Plan Complex (77307)
- Hyperthermia (CPT Code 77600)
- 77326-77328 - Substitution for PACS Input
- 77263, 77334 – Identified as potentially misvalued codes
- 77293 PE Input Correction
- Understanding the Different Resource Costs among Traditional Office, Facility and Off-Campus Provider-Based Settings
- Reports of Payments or Other Transfers of Value to Covered Recipients (Open Payments)
- Physician Quality Reporting System
- Physician Compare Website
- Value-Based Payment Modifier

Radiation Treatment Vault

In the 2015 MPFS proposed rule, CMS proposed to refine the way it accounts for the infrastructure costs associated with radiation therapy equipment, specifically to remove the radiation treatment vault as a direct expense when valuing radiation therapy services. After considering public comments, including ASTRO's concern regarding the significant impact such a decision would have combined with the anticipated 2015 radiation oncology coding changes, the agency decided not to finalize this proposal but will reconsider whether the vault is a direct or indirect cost through rulemaking in a future year.

The radiation treatment vault is unlike anything else in medicine, serving a unique medical need that cannot be repurposed for other uses. 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. ***ASTRO applauds CMS for delaying the final decision on how to classify the radiation treatment vault until all the new radiation oncology treatment delivery codes are rolled out in the 2016 proposed MPFS rule. We welcome the opportunity to work with CMS to determine how the vault fits into the overall practice expense methodology.***

Radiation Therapy Codes

(CPT Codes 76950, 77014, 77421, 77387, 77401, 77402, 77403, 77404, 77406, 77407, 77408, 77409, 77411, 77412, 77413, 77414, 77416, 77418, 77385, 77386, 0073T, and 0197T and HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017)

The CPT Editorial Panel revised the radiation therapy code set for CY 2015. The RUC subsequently provided recommendations to CMS for valuing these services. In its comments on the 2015 MPFS proposed rule, ASTRO expressed concern regarding the revaluing of these codes, in addition to CMS's proposal to remove the radiation treatment vault as a direct practice expense, noting that these codes account for the vast majority of Medicare payment for radiation therapy.

In light of the substantial nature of this code revision, CMS is delaying revaluation of these codes until CY 2016. The coding changes involve significant changes in how radiation therapy services and associated image guidance are reported. CMS is maintaining the inputs for radiation therapy codes at the CY 2014 levels. Since the code set has changed and some of the CY 2014 codes were deleted, CMS is creating G-Codes to allow practitioners to continue to report services to CMS in CY 2015 as they did in CY 2014 and for payments to be made in the same way. All payment policies applicable to the CY 2014 CPT codes will apply to the replacement G-Codes.

ASTRO appreciates the Agency's concern regarding the magnitude of the radiation oncology treatment delivery changes and the potential impacts on physicians and their practices. ***We agree with CMS's decision to roll out the radiation oncology treatment delivery changes in the 2016 proposed MPFS. We are however, concerned about the implementation of the G codes and the potential for confusion by Medicare Carriers and private insurers. We believe CMS may need to issue specific coding guidance to Medicare Carriers to avoid denials. We would like to work with the Agency if coding guidance is considered.***

CMS also discussed CPT code 77401 in the final rule. The agency noted that changes to the prefatory text modify the services that are appropriately billed with CPT code 77401, which is used to report superficial radiation therapy. This change effectively means that CPT code 77401 is now bundled with many other procedures supporting superficial radiation therapy. However, the RUC did not review superficial radiation therapy procedures, and therefore, did not assess whether changes in its valuation were appropriate in light of this bundling. The change to the prefatory text prohibits providers from billing for codes that were previously frequently billed in addition to this code, and, as a result, there will be a significant reduction in payments. CMS is interested in information on whether the new code set combined with modifications in prefatory text allows for appropriate reporting of the services associated with superficial radiation and whether the payment continues to reflect the relative resources required to furnish superficial radiation therapy services.

CMS requested information on whether the new code set combined with modifications in the prefatory text allows for appropriate reporting of services associated with superficial radiation and whether the payment continues to reflect the relative resources required to furnish superficial

radiation therapy services. *While there have been significant changes to the CPT preamble text, which applies to CPT code 77401, we believe the final language published by CPT is acceptable. We believe the Medicare payment generally reflects the resources used to furnish the service, relative to the other services in the specialty.*

Isodose Calculation with Isodose Planning Bundle (CPT Code 77316)

For CY 2015, the CPT Editorial Panel replaced six CPT codes (77305, 77310, 77315, 77326, 77327, and 77328) with five new CPT codes to bundle basic dosimetry calculation(s) with teletherapy and brachytherapy isodose planning. CMS is establishing the RUC recommended work RVUs for CY 2015 for all of the codes in this family except CPT code 77316.

CMS disagreed with the RUC-recommended crosswalk for CPT code 77316 because they do not believe it is an appropriate match in work. The RUC cross walked CPT code 77318 to CPT code 77307, both of which are complex isodose planning codes in the same family. CMS believes that the RUC should have crosswalked CPT code 77316, a simple isodose planning code, to the corresponding simple isodose planning code in the same family, CPT code 77306. Therefore, for CY 2015 they are establishing an interim final work RVU of 1.40 for CPT code 77316.

Although the surveyed physician times are the same for CPT codes 77306 and 77316, 77306 captures the work of external beam radiation planning for one or two unmodified ports, whereas 77316 is typically used for high dose rate brachytherapy planning with a single channel, which has multiple dwell positions (typically more than four). This represents a significantly higher number of variables that have to be taken into account to create the plan. Thus there is an incremental increase in the amount of physician work for brachytherapy isodose plans. *ASTRO agrees with the relativity recommended by the RUC, whereby the simple brachytherapy isodose plan is slightly greater than the work for the simple isodose plan. As such, we recommend that the Agency establish final work RVUs of 1.50 in 2016 for CPT Code 77316.*

Radiation Treatment Delivery (CPT Code 77373)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code 77373 by refining the equipment time for "pulse oximeter w/printer" (EQ211) and "SRS system, SBRT, six systems, average" (ER083) to conform to established equipment policies. ASTRO has advocated that the times should be maintained at 104 minutes, rather than reduced to 86 minutes as proposed by CMS. After consideration of stakeholder comments, CMS is finalizing the CY 2014 interim final direct PE inputs for CPT code 77373 as established, with the additional refinement of adjusting the equipment times to 104 minutes as noted above. *ASTRO applauds CMS's adjustment in clinical labor time for CPT code 77373.*

High Dose Rate Brachytherapy (CPT Codes 77785, 77786, 77787)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's

recommendations for CPT codes 77785, 77786, and 77787 to remove “Emergency service container – safety kit,” as they consider it an indirect PE. CMS acknowledges that the emergency service container safety kit needs to be readily available during the procedure, and the agency notes that “standby” equipment, or items that are not used in the typical case, are considered indirect costs.

When reviewing the interim final direct PE inputs for these services, CMS noted that the specialty societies conducted a survey of the technicians, which revealed higher procedure times than the current procedure times. However, since the RUC indicated that they did not have “compelling evidence,” the specialty society did not request the higher procedure times. CMS stated that if the specialty society believes that the code is undervalued relative to the expert panel value, and there is no indication that the survey was flawed, the specialty society should recommend the use of the surveyed procedure times. In doing so, the specialty society would give CMS the opportunity to consider the information provided alongside the RUC recommended times. CMS stated that surveys of technicians have the potential to be more accurate, rather than less accurate, than those of physicians, as the technicians do not have incentives to increase the surveyed time. CMS recommended that rather than attempting to insert items that are not standard in the PE methodology, that specialty societies make a strong, data-driven case, for why the survey times are correct.

CMS is finalizing the CY 2014 interim final direct PE inputs for CPT codes 77785, 77786, and 77787 as established. *ASTRO is currently working with the CPT Editorial Panel and the RUC on these issues. Updated recommendations will be forwarded to CMS for consideration in CY 2016. ASTRO is concerned by CMS’s assertion that physicians are providing inflated survey times. ASTRO believes that physicians and other health care professionals are honest in their survey, and we are concerned that CMS would make this statement.*

Radiation Therapy Dose Plan (CPT 77300), Teletherapy Isodose Plan Simple (CPT 77306) and Teletherapy Isodose Plan Complex (77307)

CMS eliminated the RUC recommendation of five minutes on the record and verify computer system (ED011) for CPT codes 77300, 77306 and 77307. In the final rule, CMS justified rejecting the minutes because ED011 was not previously included in these services and rationale for including ED011 was not provided.

ASTRO recommended adding the record and verify system to the inputs for CPT Codes 77300, 77306 and 77307 when these codes were submitted and presented at the April 2014 RUC meeting. The five record and verify minutes were included on the practice expense summary of the recommendation form, the practice expense spreadsheet and discussed during the presentation. This is an additional step/change in technology since the codes were last valued and an integral part of the three procedures. Once all of the calculations are completed and accepted, the CMD/MP will verify correct monitor units (or time) in the R&V system, print/pdf and archive all

calculation records and approve monitor unit (time) setting in R&V system. This is a necessary step in the current process of care.

ASTRO urges CMS to approve the five minutes of time on the record and verify computer system (ED011) for CPT Codes 77300, 77306 and 77307 and update the direct practice expense inputs before January 1, 2015.

Hyperthermia (CPT Code 77600)

In establishing interim final direct PE inputs for CY 2014, CMS refined the RUC's recommendations for CPT code 77600 by refining the time allocated to equipment item "hyperthermia system, ultrasound, external" (ER035) and removing the time associated with clinical labor task "clean scope," among other refinements. CMS continues to believe that the time allocated to this equipment item is appropriate. As such, they are finalizing the CY 2014 interim final direct PE inputs for CPT code 77600 as established.

ASTRO urges CMS to maintain the time associated with the clinical labor task "clean scope" for CPT code 77600. The time included in this line item relates to the cleaning of the equipment used in hyperthermia (i.e. ultrasound probe, hyperthermia applicator) – not specifically a 'scope'. The probes must be cleaned after the procedure before they are used on a subsequent patient.

77326-77328 - Substitution for PACS Input

CMS finalized its decision to use the computer desktop, w-monitor (ED021), priced at \$2,501 as a proxy for the Picture Archiving and Communication System (PACS). CMS justifies its decision based on the lack of evidence to indicate the resource costs are any different. CMS had asked for invoices or suggestions for a more appropriate proxy in the 2015 proposed rule.

ASTRO is disappointed with CMS's decision and encourages the agency to continue working with stakeholders to ensure that digital inputs are identified and integrated into the CMS database along with appropriate invoices.

77263, 77334 – Identified as potentially misvalued codes

CMS confirmed its use of the high expenditure screen as an effective method for identifying services that are either over or under valued. However, CMS did not finalize the codes identified through the high expenditure screen as potentially misvalued. CMS notes that at an unspecified future date they will re-run the high expenditure screen and propose a specific set of codes to be reviewed.

ASTRO is pleased with CMS's decision. ASTRO urges CMS to reconsider the effectiveness of the high expenditure screen, especially when considering CPT codes that have undergone a robust RUC review and revaluation.

77293 PE Input Correction

CMS is finalizing the assignment of clinical labor type L152A to code 77293 to correct a clerical error made in the 2014 final MPFS. *ASTRO appreciates CMS's decision to assign the appropriate clinical labor type to CPT Code 77293.*

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

CMS finalized its decision 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 new 2-digit modifier that will be added to the HCPCS annual file as of January 1, 2015, with the label "PO," the short descriptor "Serv/proc off-campus pbd," and the long descriptor "Services, procedures and/or surgeries furnished at off-campus provider-based outpatient departments." Compliance with the new HCPCS modifier will be voluntary for 2015 and mandatory beginning in 2016.

With respect to professional claims, CMS will request two new place of service (POS) codes to replace POS 22 (Hospital Outpatient) through the POS Workgroup, one of which will identify off-campus provider-based departments. CMS indicated in the final rule that it does not expect the new codes to be available prior to July 1, 2015.

ASTRO is committed to working with CMS to understand the growth in hospital-based practices and their impact on Medicare payments. We appreciate CMS's recognition of the significant impact the application of a HCPCS modifier will have on current hospital bill system practices. *However, ASTRO remains concerned that both the hospital and professional claims modifiers will be administratively burdensome.*

Reports of Payments or Other Transfers of Value to Covered Recipients (Open Payments)

CMS eliminated the special regulation implementing the Physician Payment Sunshine Act (now referred to as the Open Payments program) relating to manufacturer support for continuing education. Under the existing regulations, payments are exempt from reporting under Open Payments when manufacturers provide financial support for physician speakers at continuing education events if 1) the payments supported a continuing education event that is accredited or certified by one of five bodies; 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.

ASTRO is a direct provider of continuing educational programs and a leader in the professional and educational development of the radiation oncology community. As such, ASTRO advocated for maintaining the existing exception, which relies on strict requirements for independent

continuing education and provided clear guidance that physician faculty receiving compensation would not be reported under the Open Payments program.

In the final rule, CMS stated that “[w]hen an applicable manufacturer or applicable GPO provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting” under the exception for indirect payments to physicians. Furthermore, CMS stated that general subsidies for attendees would not require reporting.

While we are disappointed that CMS eliminated the explicit exception for continuing education, we are encouraged that CMS’s intention, as clarified in the final rule, is that payments to speakers and tuition subsidies for attendees will not be reportable under the Open Payment program if the manufacturer does not direct the payment to go to a specific physician.

Physician Quality Reporting System (PQRS)

Oncology Measures Group

ASTRO thanks 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. However, the agency has modified the Oncology Measures Group by removing measure #194 Oncology: Cancer Stage Documented. Documenting cancer stage is a critical component in determining treatment options for patients with cancer. ***ASTRO urges the agency to reconsider its decision and replace #194 Oncology: Cancer Stage Documented in the Oncology Measures Group in future rulemaking, as it is important for ensuring that cancer patients receive high-quality care.***

Criteria for Satisfactory Reporting for the 2017 PQRS Payment Adjustment

The agency initially proposed modifying the individual measures requirement for the 2017 payment adjustment so that at least two of the nine individual measures would qualify as cross-cutting measures. ASTRO appreciates the agency reducing the requirement from two cross-cutting measures to one cross-cutting measure. We would like to reiterate our concern that the nine-measure requirement is burdensome for radiation oncology and other specialties because it is difficult to find nine existing measures applicable to radiation oncologists and spread across the various domains. ***Until more meaningful measures are included, we encourage the agency to explore less burdensome options for eligible professionals who have a limited selection of measures available for reporting.***

Proposed Changes to Reporting Mechanisms for PQRS Quality Measures

For 2015, CMS has removed the claims-based reporting option for three measures often reported by radiation oncologists: #102 Prostate Cancer: Avoidance of overuse of bone scan for staging low risk prostate cancer patients; #104 Prostate Cancer: Adjuvant hormonal therapy for high risk prostate cancer patients; and #194 Oncology: Cancer stage documented. As mentioned above, there are very few measures available to radiation oncologists, and by removing the claims-based reporting option for these measures, the number of measures available becomes even more limited. ASTRO believes that the claims-based reporting mechanism should still be an option for providers who elect to participate using the claims-based method due to practice, administrative, or financial limitations. However, since the agency has decided it will eliminate claims-based reporting in future rulemaking, ***ASTRO encourages the agency to continue a phased-in approach to eliminate claims-based reporting, which will provide physicians with opportunity to adapt accordingly.***

Proposed Changes to the Requirements for Qualified Clinical Data Registries (QCDRs)

For 2015 participation and beyond, CMS finalized modifications to the reporting requirements for participation in PQRS through a QCDR. Providers who participate in PQRS through a QCDR will have to ensure that at least one of the nine measures is a cross-cutting measure, and that at least two of the nine measures are outcome measures, or, in lieu of two outcome measures, one outcome measure and one other type of measure: a resource use measure, a patient experience of care measure, an efficiency/appropriate use measure, or a safety measure. Thus, QCDRs must also possess at least one cross-cutting measure, and either two outcome measures or one outcome measure and one other type of measure as described above.

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, the lack of specialty-specific outcome measures. ASTRO appreciates the flexibility provided for the cross-cutting measures and the reduction in the outcome measures from three to two, but ASTRO remains concerned about the lack of stability in the program and the difficulties constant changes cause for QCDRs in development. ASTRO recently launched the National Radiation Oncology Registry (NROR), the first of its kind for radiation oncology and is considering seeking certification as a QCDR. ***ASTRO encourages the agency to consider more consistency and stability in the program requirements to encourage and allow more registries to become QCDRs.***

CMS also finalized its proposal to publicly report the titles and descriptions of measures reported for PQRS purposes, as well as the performance results for each measure. This data will be reported on Physician Compare, but QCDRs may also post the information elsewhere. ASTRO supports transparency and thanks the agency for maintaining uniformity by making this information available on Physician Compare. However, ASTRO is concerned that posting raw performance data for these measures may lead to confusion and mislead beneficiaries. ASTRO

believes it is critical to link claims data with quality measures data to derive the most utility for quality improvement purposes and to provide beneficiaries with a more meaningful and complete picture to help them make more effective and informed decisions.

Physician Compare Website

CMS finalized proposals to report all quality program performance on CMS's Physician Compare, including satisfactory participation in PQRS and the EHR Incentive Programs and whether the provider earned an additional PQRS Maintenance of Certification (MOC) incentive. Additionally, in 2016, CMS will publicly report all individual measures' data reported by providers for the 2015 PQRS program; this will include performance data and the reporting mechanism. However, a minimum of 20 patients is required for the measures to be publicly reported. Providers will have a 30-day review period prior to the information becoming public on their Physician Compare profile page. ***ASTRO supports the posting of performance data and strongly urges CMS to work closely with stakeholders (specialty societies and physicians) on posting the information in a clear, concise, accurate, and helpful manner.***

Additionally, ASTRO appreciates the agency not finalizing its proposal to create and post composite scores and benchmarks by grouping measures based on PQRS measures groups, including oncology measures. As discussed above, there are a limited set of specialty specific measures, and we believe that additional time is needed until more measures and performance data become available to establish meaningful composite scores and benchmarks.

Value-Based Payment Modifier (VM)

Payment Adjustment

CMS modified its proposal to double the VM payment risk, increasing it to -4.0 percent, and to apply the quality-tiering methodology to all providers, beginning January 1, 2017. The maximum -4.0 percent adjustment will apply to groups of 10 or more eligible providers (EPs), and a -2.0 percent payment adjustment will be applied to solo practitioners and groups of two to nine EPs who fall in Category 2. Solo practitioners and groups of two to nine EPs in Category 1 will be subject to an upward or neutral adjustment; they will not be subject a negative downward adjustment. ASTRO supports the agency's decision to apply only an upward or neutral payment adjustment for first-year providers, allowing them an opportunity to become familiar with the program. ***However, given the complexity of the program and the numerous other penalties providers may be subjected to in other programs (e.g., PQRS and the EHR Incentive Program), ASTRO encourages CMS to extend this flexibility in future rulemaking.***

Quality-Tiering Methodology

CMS eliminated the pre-step in the current attribution methodology, resulting in a two-step attribution methodology. Step 1 assigns beneficiaries to the group practice whose primary care physicians, nurse practitioners, physician assistants, and certified nurse specialists provide the plurality of primary care services. Beneficiaries that are unassigned in Step 1 will be assigned

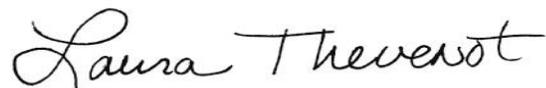
under Step 2 to groups whose non-primary care providers together provide the plurality of primary care services. Furthermore, Medicare FFS beneficiaries who are newly enrolled in Medicare during the performance year and are enrolled in both Part A and Part B will be included in the VM. Part-year beneficiaries enrolled in a Part C plan, and those enrolled in only Part A or Part B for part of the performance year and both Part A and Part B for the remainder of the year will continue to be excluded.

CMS also finalized the policy that a group or solo practitioner must have at least 20 patients for each of the cost and PQRS measures that are used to calculate the cost and quality composite scores. If the 20 patient minimum thresholds are not met for either, then an “average” score will be assigned for the cost and/or the quality composite score(s).

ASTRO appreciates the clarification of the 20-patient minimum requirement to earn a “high” or “low” score for the cost and quality composite scores. However, ASTRO encourages CMS to include measures and performance data reported as part of measures groups, including the Oncology Measures Group, in the quality composite scores. Additionally, ASTRO seeks further guidance and instruction on how specialists, including radiation oncologists, will be impacted and evaluated under the value-based payment modifier.

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
Chief Executive Officer