



September 8, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
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 and Other Revisions to Part B for CY 2016

Dear Acting Administrator Slavitt:

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 and Other Revisions to Part B for CY 2016” published in the Federal Register as a proposed rule on July 15, 2015.

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.

ASTRO has significant concerns with numerous proposed CMS policies related to radiation oncology, which would result in reimbursement cuts of approximately five to seven percent to freestanding radiation oncology clinics—potentially higher for some centers depending on their patient population. The proposed cuts follow on cuts of more than 20 percent to freestanding centers over the last six years. While the radiation oncology community anticipated some payment reductions as a result of the implementation of the new treatment delivery codes, the additional impact of both the equipment utilization rate assumption change and the removal of direct practice expense inputs for image guidance would have a detrimental effect on the ability of many freestanding practices to remain viable. This could limit access to care for cancer patients, particularly in rural and medically underserved areas.

ASTRO, which represents radiation oncology physicians practicing in hospitals and freestanding centers, is very concerned by the timing and application of these disruptive changes. Data from

an ASTRO survey from July 9 through July 20 of the almost 1,400 community-based radiation therapy centers in the U.S. indicates that with reimbursement cuts of five to 10 percent:

- Nearly 30 percent of the practices indicated they may have to close their doors;
- Approximately 62 percent may have to consolidate practice locations; and
- About 41 percent may be forced to discontinue accepting patients covered by Medicare.

The proposed cuts are too deep and too fast for too many freestanding radiation oncology centers to absorb. We urge CMS to work with radiation oncology stakeholders to protect access to radiation therapy services by significantly limiting these proposed cuts and reconsidering several proposed policies.

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

- **Treatment Delivery and Image-Guided Radiation Therapy (IGRT)**
- **Potentially Misvalued Services**
- **Superficial Radiation Treatment Delivery (CPT 77401)**
- **High Dose Radiation (HDR) Brachytherapy**
- **Recommended Items that are not Direct PE Inputs**
 - **New PE Items**
 - **PACS Workstation**
- **Phase-In of Significant RVU Reductions**
- **Target for Relative Value Adjustments for Misvalued Services**
- **Valuation and Code of Global Packages**
- **Medicare Reimbursement for Advance Care Planning**
- **Incident To Billing**
- **Open Payments**
- **Self-Referral**
- **Alternative Payment Models**
- **Merit-Based Incentive Payment System**
- **Physician Quality Reporting System**
- **Physician Compare Website**

Radiation Treatment Delivery and IGRT

Background

Given significant advancements in technology and evolution of the radiation therapy process of care, the CPT Editorial Panel made significant revisions to the radiation treatment delivery code set. In October 2013, the Panel deleted 14 codes (including two Category III codes) and created two new codes to report intensity modulated radiation therapy (IMRT), simple IMRT (77385) and complex IMRT (77386). One new code to report guidance for localization for delivery of radiation therapy (IGRT; 77387) was created, and it was bundled with the two new IMRT codes as they were frequently billed together. The Panel also collapsed multiple codes to report

conventional radiation treatment delivery into three codes, simple (77402), intermediate (77407) and complex (77412).

In January 2014, the Resource Based Relative Value Scale Update Committee (RUC) considered the relative value recommendations for the new treatment delivery, IMRT and IGRT codes (77402, 77407, 77412, 77385, 77386, and 77387). ASTRO developed practice expense recommendations based on survey results from 99 radiation oncologists for the new IMRT and treatment delivery codes. The survey results were reviewed and approved by the RUC Practice Expense Subcommittee. ASTRO also surveyed physician work and practice expenses for CPT Code 77387 *guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed*, which replaced CPT codes 77014, 77421 and 76950 (IGRT codes). The RUC reviewed the surveys of 95 radiation oncologists and determined that a work RVU of 0.58 (3 minutes pre-service, 10 minutes intra-service and 3 minutes post-service) lower than the survey 25th percentile, appropriately accounted for the physician work in the new IGRT code. The RUC considered the work RVUs of the deleted IGRT codes to determine the value of the new IGRT code to maintain budget neutrality. The RUC also noted that the previous treatment delivery codes (77402-77418), which did not include physician work, could be reported on the same date of service when image guidance is performed.

ASTRO also explained that the linear accelerator equipment has changed significantly since the codes were last reviewed by the RUC. Linear accelerators are now capable of delivering all energies in therapeutic use, including IMRT, conventional radiation therapy, and electrons. The previous generations of single low energy linear accelerators (ER009 and ER010) are no longer commercially available. Given this evolution, ASTRO recommended to the RUC, and the RUC accepted, that ER089 is the most appropriate linear accelerator to use for the treatment delivery codes.

The RUC also approved the inclusion of on board imaging (OBI), which is a type of IGRT as a separate piece of equipment, in addition to the costs of the linear accelerator. Image guided radiation therapy (IGRT) technology has evolved from using third party vendor hardware and software to the use of integrated technology. When the new codes were reviewed by the RUC, ASTRO provided invoices detailing the expense associated with OBI and the RUC approved OBI as distinct direct practice expense equipment inputs.

2016 Proposals: Radiation Treatment Delivery

As discussed above, ASTRO has serious concerns with several of the CY2016 proposed CMS polices related to radiation oncology. Below you will find details comments on the following issues:

1. *Image Guidance – Equipment*
2. *Image Guidance – CT Typical*
2. *Image Guidance – Increased Work*
3. *Image Guidance – CPT Code 77014*
4. *Equipment Utilization Rate for Linear Accelerators*
6. *Complex Treatment Delivery*

7. *Other Changes*
8. *Not Direct PE Items*
9. *Radiation Therapy Centers*

1. *Image Guidance – Equipment*

ASTRO believes CMS made inappropriate assumptions related to the image guidance equipment for the new conventional radiation treatment delivery (77402, 77407, 77412) and the IMRT/IGRT codes (77385, 77386, 77387).

CMS believes that ER089 (updated in the 2013 rule making cycle) included “onboard imaging/image guidance” costs. Therefore, the agency did not include on board imaging as a separate item in the CY2016 proposed direct PE inputs for CPT codes 77385, 77386 or 77387, even though it appeared as a separate item on the PE worksheet included with the RUC recommendations for these codes. CMS is seeking comment on this “*apparent contradiction between technical component billing for image guidance in the context of the inclusion of a single linear accelerator with integrated imaging guidance technology being included for all external beam treatment codes.*” In reviewing the new code structure and the RUC recommendations, the agency said that it “*assume(d) that the CPT editorial panel did not foresee that the RUC would recommend that we develop PE RVUs for all the radiation treatment delivery codes based on the assumption that the same capital equipment is typically used in furnishing the entire range of external beam radiation treatments.*”

CMS’ proposal to ignore the significant capital equipment costs associated with image guidance/on board imaging is disappointing and inappropriate. ASTRO believes CMS may have misinterpreted the complex RUC recommendations for the new treatment delivery/IGRT family of codes. As part of the RUC recommendations, and as stated above, invoices were submitted for on board imaging equipment as a separate line item. CMS direct PE item ER089, the IMRT linear accelerator, does not include the cost of the on board imaging equipment. Without this input, CMS is failing to appropriately account for the expenses associated with this critical component of treatment delivery.

The final RUC recommendations update the CMS equipment type for the conventional radiation treatment delivery codes, 77402, 77407 and 77412. Inputs for the previous linear accelerators described by ER009 and ER010 for the conventional codes were replaced because they are no longer typically used for treatment delivery and are no longer commercially available. ER009 and ER010 were replaced with ER089, which describes the currently-used linear accelerator. In 2012, CMS updated the pricing of the equipment for IMRT (previously 77418). The inputs were updated from ER010 plus MLC ER017 to a newly created “IMRT accelerator” ER089. (*There were other updates made, albeit not related to the linear accelerator.*) The cost of OBI was not included in the \$2,641,783 for ER089, as IGRT was separately reportable with the specific corresponding codes. ASTRO did not submit new invoice pricing for ER089, which is priced at \$2,641,783.

ASTRO also updated the direct practice expense inputs for the new IGRT code (77387). The existing inputs for the IGRT codes (77421, 76950, 77014) were collapsed into one new proposed CMS item “on board imaging (OBI)”. Invoices were submitted for OBI ranging from \$549,219 to \$907,973. Again, these costs are not included in the \$2,641,783 pricing for ER089.

Vendor-produced marketing material indicate that when practices purchase a linear accelerator, it typically has the capacity to operationalize OBI. However, it is important to understand that if a practice purchases a linear accelerator, while it might arrive hardwired for OBI, it will cost significantly more than \$2.6 million dollars for that linear accelerator to have an operational OBI. The manufacturers of the most widely used linear accelerators can provide documentation to CMS demonstrating the price of a linear accelerator with operational OBI is greater than \$3 million. ASTRO urges CMS to reach out to equipment manufacturers to confirm this additional cost.

ASTRO specifically did not recommend updating the ER089 from its current \$2.6 million price so that CMS would appropriately capture the equipment expenses for IGRT billed with the new conventional treatment delivery codes, 77402, 77407 and 77412, as these codes will not be billed frequently with IGRT. We recommend maintaining ER089 at the \$2.6 million price so that when IGRT is performed, adding together ER089 and the separately identified costs for the new OBI equipment items appropriately captures the additional IGRT costs. This ensures that there is no duplication, and that the IGRT expenses are not inappropriately factored into non-IGRT services.

ASTRO urges CMS to include the documented cost of on board image equipment into CPT codes 77385, 77386 and 77387.

CMS also questioned the reason for including ER089 in the direct inputs for CPT Code 77387, stating it was a duplication of capital costs if both ER089 and OBI were included in the equipment. The recommendations included 21 minutes on both the linear accelerator and the OBI. As outlined above, both the linear accelerator and the OBI should be included in the direct practice expense inputs for IGRT codes to account for accurate costs of the service.

2. Image Guidance – CT Typical

In the proposed rule, CMS requested comments on whether CT guidance is typical for image guidance. The agency expressed concern that the new code to report IGRT assumes that CT guidance is typical.

We believe CMS is referring to the vignette used to survey for CPT code 77387. It is important to note that CPT code 77387 is a PC/TC code (*both work and PE were surveyed*). The PC component can be billed with treatment delivery codes (77402, 77407 or 77412) or IMRT codes (77385 or 77386), whenever IGRT is performed. However, the TC component can only be billed when image guidance is performed with the treatment delivery codes 77402, 77407 or 77412. The PC, or physician work, for IGRT is the same whether done with IMRT or conventional treatment delivery. We continue to believe that the surveyed vignette is appropriate and reflects

the typical case treated with 3D conformal radiation and image guidance:

A 67-year-old man presents with Stage III lung cancer will undergo concurrent chemotherapy and 3D conformal radiation. Prior to daily radiation therapy, cone-beam CT image guidance scan is performed and reviewed, and patient’s position is adjusted to localize the primary tumor and the mediastinal nodes accurately before treatment. Surface tracking is performed during treatment delivery to ensure no movement exceeds safe thresholds.

ASTRO believes that the RUC recommendations regarding CPT code 77387 are accurate and requests that CMS implement these recommendations in 2016.

3. Image Guidance – Increased Work Time

CMS also questioned the overall work time associated with new IGRT code 77387, stating that if the recommendations were accurate, “this increase in time and maintenance of total work would suggest a decrease in the overall intensity for image guidance relative to the current codes.” CMS is seeking comment as to the appropriate work time associated with CPT code 77387.

ASTRO is unclear why CMS is asking for comments “as to the appropriate work time associated with CPT code 77387.” ASTRO stands by the survey data and believes the total time of 16 minutes and an RVU of 0.58 are appropriate. The table below outlines the data inputs for all the IGRT codes.

	IWPUT	wRVU	Time
77014	0.050	0.85	17
76950	0.032	0.58	18
77421	0.043	0.39	9
<i>77387 (surveyed code)</i>	<i>0.045</i>	<i>0.58</i>	<i>16</i>

It is also important to note that the RUC compared CPT Code 77387 to 76536 *Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation* (work RVU=0.56), which has identical intra-service time, and determined that 77387 is slightly more intense to perform, accounting for the slightly higher work value. For further support, the RUC compared 77387 to MPC code 93224 *External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional* (work RVU=0.52) and determined that the work for performing 77387 is more intense than 93224, further supporting the higher work value.

ASTRO recommends that CMS accept the RUC recommendations for CPT Code 77387.

4. Image Guidance – CPT Code 77014

CPT Code 77014 *Computed tomography guidance for placement of radiation therapy fields* (work RVU= 0.85) has been used in the past to report CT with simulation and imaging guidance. ASTRO believes that 77014 utilization would drop to negligible levels based on changes made in 2014 to the simulation codes and the new treatment delivery/IGRT codes implemented in 2015 and 2016. In October 2013, when the simulation process description was changed to reflect the use of a CT simulator, the CPT Editorial Panel decided not to delete 77014 as it did the previous IGRT codes, 77421 and 76950, as it was concerned that there would be no valid CPT alternative other than the use of higher valued diagnostic CT codes. The RUC determined that 77014 will be re-reviewed once the new radiation treatment delivery codes go into effect and two years of Medicare data are available to monitor the continued use of 77014.

ASTRO continues to believe that utilization of 77014 will drop to negligible levels, but accepts the decisions of the RUC and CPT to monitor and review this code.

5. Equipment Utilization Rate for Linear Accelerators

CMS is proposing to adjust the equipment utilization rate assumption for the linear accelerator from 50 percent to 70 percent, over two years, based on ER089 (linear accelerator) now being used in a broader range of services. ASTRO believes this change in policy will have a disproportionate impact on lower-volume freestanding centers that serve rural and medically underserved populations, resulting in significant cuts that will jeopardize access to care for cancer patients in these settings.

ASTRO and other stakeholders have reviewed the CMS proposal to change the utilization rate from 50 percent to 70 percent. We believe that such a change, in conjunction with the proposed valuation of the treatment delivery codes, could have a destabilizing effect on access to services, particularly in the freestanding and rural settings. ASTRO urges CMS to maintain the current 50 percent utilization rate. At the very least, CMS should delay the implementation of the equipment utilization assumption change until at least 2017, which allows time to monitor utilization changes that may stem from the implementation of the new treatment delivery codes. Should the agency decide not to delay or forego the implementation of the equipment utilization rate assumption change, we recommend extending the phase-in period to four years to mitigate the significant payment cuts caused by this policy. In addition, if CMS proceeds with any change in the equipment utilization rate assumption, ASTRO urges CMS to modify the proposal for radiation oncology practices that serve medically underserved and rural populations by maintaining the equipment utilization rate assumption of 50 percent.

Furthermore, ASTRO's analysis indicates that CMS has applied the linear accelerator equipment utilization rate assumption change to all equipment items, beyond just the linear accelerator. This is inconsistent with CMS' existing policy which applies a 90 percent equipment utilization rate assumption to advanced diagnostic imaging equipment costing more than one million dollars.

Additionally, this change is inconsistent with the text of the proposed rule and inappropriately magnifies the impact of the adjustment.

*“Therefore, we are proposing to adjust the equipment utilization rate assumption for the **linear accelerator** to account for the significant increase in usage. Instead of applying our default 50 percent assumption, we are proposing to use a 70 percent assumption based on the recognition that **the item** is now being typically used in a significantly broader range of services, and that would increase its overall usage in comparison to the previous assumption.”*

If CMS implements this new policy, ASTRO urges the agency to review the proposed adjustment to ensure that it only applies to the linear accelerator.

6. Complex Treatment Delivery

CMS published estimated PE RVUs for the three new treatment delivery codes.

CPT Code	CPT Descriptor	Proposed CY2016 NF PE RVUS
77402	Radiation Treatment Delivery, Simple	3.84
77407	Radiation Treatment Delivery, Intermediate	6.63
77412	Radiation Treatment Delivery, Complex	5.89

CPT code 77412 *Radiation treatment delivery, complex* has lower proposed PE RVUs than CPT code 77407 *Radiation treatment delivery, intermediate* despite having more direct practice expense inputs. ASTRO believes this is due to an anomaly in the data, as the highest-volume service that went into 77407 was performed almost entirely by dermatologists, which have a higher indirect allocation than radiation oncologists. Therefore, despite the direct cost portion of the RVU being higher for 77412 than 77407, the PE RVUs are projected to be lower. Although this is not an “error” in the data, the outcome is not logical nor appropriate. **ASTRO recommends that the agency work with stakeholders to estimate projected utilization data and integrate that information to determine CY2016 Non Facility PE RVUs for 77412.**

7. Other Changes

In the proposed rule, CMS states that it accepted the RUC recommended values for the new radiation treatment delivery and IGRT codes. However, CMS made significant modifications to the RUC-recommended equipment times for several pieces of equipment in codes 77385, 77386, 77402, 77407 and 77412, saying that the agency “refined equipment time to conform to established policies for highly technical equipment.” The items affected by these changes include:

- Laser, diode ER040
- Vault ER056
- Power conditioner ER102
- Accelerator ER089
- Chiller ER065

ASTRO has several concerns regarding these revisions. While CMS has not issued an explicit threshold or definition for “highly technical equipment,” they have issued the following example:

Highly Technical			Not Highly Technical		
Item	CMS Code	Price	Item	CMS Code	Price
room, CT	EL007	\$1,284,000.00	Light, exam	EQ168	\$1,630.12
accelerator, 6-18 MV	ER010	\$1,832,941.00	Table, exam	EF023	\$1,338.17
gamma camera	ER097	\$600,272.00	Chair, medical	EF009	\$829.03

Based on the criteria CMS has used to date, ASTRO believes that only the linear accelerator would be considered highly technical, but not the Laser Diode (ER040), Vault (ER056), Power Conditioner (ER102), and Chiller (ER065). Furthermore, CMS did not include the two minutes from line 19 of the RUC recommendations “Other Clinical Activity: Dose output and performance verification”. This activity, “*Output measurement for each energy using beam profiler. Mechanical tests of Laser, Collimator, ODI. Safety tests. MLC/collimator Qualitative test,*” is a critical step in the process of care and is certainly performed on the five pieces of equipment listed above.

ASTRO urges CMS not to implement the changes proposed in TABLE 13: CY 2016 Proposed Codes with Direct PE Input Recommendations Accepted with Refinements described above as the proposal inconsistently applies the vague term “highly technical” and fails to account for a key step in the typical process of radiation oncology care.

CMS also deleted EQ139 *intercom* from all the treatment delivery codes. The agency stated that it was an indirect practice expense input and not individually allocable to a particular patient for a particular service. ASTRO disagrees and seeks to clarify that EQ139 is not a general intercom for the department, but rather a direct link for the provider to communicate with the patient during treatment delivery. Additionally, the intercom is installed separately from department-wide communication equipment. **ASTRO urges CMS to include EQ139 intercom in all treatment delivery codes and the minutes should be added back into all of the treatment delivery codes.**

8. *Not Direct PE Items*

CMS stated in the proposed rule that the agency believes the “emergency service container/safety kit” and “service contract” cannot be allocated to individual services or patients. As such, the agency does not include these recommended items as direct PE inputs in the calculation of PE RVUs.

The current PE RVU methodology contains a fixed five percent maintenance factor. As ASTRO has stated in the past, maintenance costs are a significant operating expense in the practice of radiation oncology. Service contracts for sophisticated radiation therapy equipment, most notably linear accelerators, typically includes significant maintenance costs that exceed the five percent allowance in the current PE RVU methodology.

In the CY 2015 MPFS, CMS sought comment regarding reliable data on maintenance costs that vary for equipment and the agency questioned whether the cost formula should be adjusted to include equipment costs that do not vary based on equipment time. In response, ASTRO submitted copies of paid invoices, along with RUC recommendations for the revised treatment delivery family, which demonstrated that the typical service contract for a linear accelerator far surpassed the five percent allocated in the PE methodology.

ASTRO is disappointed that CMS failed to address the RUC’s submission and our repeated requests to modify the CMS PE methodology to account for the significant direct expense of a linear accelerator service contract incurred by radiation oncologists. We urge CMS to update the CMS methodology for ER089 to a 10 percent allowance for allocation of the service contract. While this amount is still below the norm, we believe it better represents actual costs than the current standard.

9.) *Radiation Therapy Centers*

CMS includes “Radiation Therapy Centers” in the impact table produced annually in the proposed and final MPFS. The impact table is often the first place that individuals go to when the rule is produced. However, by including “Radiation Therapy Centers” in the impact table, CMS may inadvertently confuse and mislead the radiation oncology community and the public about the actual impact of the proposed policies. Radiation Therapy Centers are a small and limited number of freestanding centers that are not representative of the larger specialty. **ASTRO urges CMS to omit the reference to “Radiation Therapy Centers” in future rulemaking.**

Potentially Misvalued Services: Review of High Expenditure Services across Specialties with Medicare Allowed Charges of \$10,000,000 or More

CMS is proposing 118 codes listed in Table 8: *Proposed Potentially Misvalued Codes Identified through High Expenditure by Specialty Screen* as potentially misvalued codes, identified using the high expenditure screen under the statutory category, “codes that account for the majority of spending under the PFS.” The list includes CPT codes 77263 *treatment planning*, 77334 *treatment devices* and 77470 *special radiation treatment*.

ASTRO has urged CMS in the past to remove CPT Codes 77263 and 77334 from the list of potentially misvalued codes, as both of these codes have gone through the RUC process and have maintained stable utilization levels in recent years. **While ASTRO supports the agency’s efforts to identify potentially misvalued services, we urge CMS to not re-review codes that were recently RUC-reviewed and maintaining stable utilization patterns, as this puts undue burden on specialty societies.**

Superficial Radiation Treatment Delivery – CPT Code 77401

CMS is seeking recommendations from stakeholders regarding whether it would be appropriate to add physician work for superficial radiation treatment delivery and to remove minutes for the radiation therapists, even though physician work is not included in other external beam radiation treatment services.

For CY 2015, the CPT Editorial Panel changed the prefatory text to clarify the services that are appropriately billed with CPT code 77401, which is used to report superficial radiation therapy. Physician work is typically not included in external beam treatment delivery codes because these services can be performed by a technician. As such, ASTRO does not believe it is appropriate to include physician work in CPT code 77401. **Any modifications made to the value of the code should be evaluated through the CPT/RUC process established for this purpose. ASTRO believes that would be the appropriate forum for making such determinations.**

CMS is also proposing to update the equipment item ER045 “orthovoltage radiotherapy system” by renaming it “SRT-100 superficial radiation therapy system” and updating the price from \$140,000 to \$216,000, on the basis of the submitted invoices. **ASTRO supports CMS’ proposal to update the price of ER045 “orthovoltage radiotherapy system” from \$140,000 to \$216,000. However, we recommend that ER045 be renamed “superficial radiation therapy system” to avoid naming a proprietary commercial system (one of several superficial radiation therapy systems in the marketplace) in the CMS database.**

High Dose Radiation (HDR) Brachytherapy

CMS is proposing to accept the RUC recommendations for the recently revised family of High Dose Rate (HDR) brachytherapy codes (7778A-E). The codes and the accepted physician work recommendations are included in Table 11: *CY2016 Proposed Work RVUs for New, Revised and Potentially Misvalued Codes*. The table does not include CPT code 7778A, however it is displayed in Addendum B with the RUC recommended physician work value of 1.05 RVUs.

Table 11 – CY 2016 Proposed Work RVUs for New, Revised and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
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7778B ...	formed. Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter over 2.0 cm and 2 or more channels, or multiple lesions.	NEW	1.4	1.4	No.
7778C ...	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel.	NEW	1.95	1.95	No.
7778D ...	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2–12 channels.	NEW	3.8	3.8	No.
7778E ...	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels.	NEW	5.4	5.4	No.

CMS is also proposing to accept the RUC recommended PE inputs for the five new HDR codes without refinement. CMS included the new HDR codes in Table 12 “CY2016 Proposed Codes with Direct PE Input Recommendations without Refinement.” **ASTRO appreciates CMS’ decision to accept the AMA RUC recommendations for High Dose Radiation Brachytherapy.**

New Practice Expense Items

CMS received invoices for several new supply and equipment items for CY 2016, including some radiation oncology items, and accepted the majority of these items and added them to the direct PE input database. However, CMS said it continues to have concerns when only one invoice is provided as documentation. They also continue to have concerns that discounts are being applied in the market, but not reflected in the invoices. When CMS has a particular concern about a new item/invoice, it is detailed in the appropriate section.

Invoices Received for New Direct PE Inputs*

CPT Code	Item Name	CMS Code	Avg. Price	No. of Invoices	Estimated non-Facility allowed services for HCPCS codes using this item
77385, 77386, 77402, 77407, 77412	Power Conditioner	ER102	\$26,400	2	2,198,441
7778A, 7778B, 7778C, 7778D, 7778E	Brachytherapy Treatment Vault	ES052	\$175,000	1	24,936

*Table 9 – Proposed 2016 MPFS Rule

ASTRO appreciates CMS’ proposal to accept the invoice prices for the new PE equipment and supply items. We share CMS’ concern regarding reliance on a limited number of invoices for these decisions. **ASTRO urges the Agency to work with stakeholders to develop a pathway to submit pricing information that will protect the companies and their customers. Publishing copies of paid invoices, even when redacted, on the public website does not afford the appropriate protection.**

PACS Workstation

PE Inputs for Digital Imaging Services

In the 2015 final rule, CMS finalized its proposal to create a new equipment item as a proxy for the Picture Archiving and Communication System (PACS) workstation as a direct expense. CMS used the current price associated with ED021 (computer, desktop, with monitor) to price the new item, ED050 (PACS Workstation Proxy) at \$2,501. In the proposed 2016 MPFS, CMS proposes to price the PACS workstation at \$5,557 for CY 2016. ASTRO appreciates CMS' willingness to work with specialty societies to collect costs data that better reflects the resources used to provide these services. However, we do not believe the updated price captures the full amount for the PACS workstation. It appears that CMS did not include the costs associated with the "Rad (professional) Workstation." **ASTRO requests that CMS update the pricing further, to include all the costs associated with the PACS.**

Clinical Labor Tasks Associated with Digital Imaging Services

CMS is proposing to establish standard times for clinical labor tasks associated with digital imaging for purposes of reviewing individual services at present, and for possible broad-based standardization in the future. CMS is proposing the following tasks/times:

- Availability of prior images confirmed: 2 minutes
- Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocolled by radiologist: 2 minutes
- Technologist QC's images in the PACs, checking for all images, reformats, and dose page: 2 minutes
- Review examination with interpreting MD: 2 minutes
- Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue: 1 minute.

ASTRO believes the tasks outlined in Table 5 "Clinical Labor Tasks Associated with Digital Technology" of the proposed rule reflect the PE Subcommittee's film/digital workgroup recommendations. We recommend that CMS generalize the staff types in the tasks (i.e. technologist to clinical staff, radiologist to physician). **ASTRO urges CMS to work with the Relative Value Update Committee (RUC) and specialty societies before adjusting the existing times for current codes.**

Phase-in of Significant RVU Reductions

On April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was enacted. The Act states that the applicable adjustments in work, PE, and malpractice RVUs shall be phased-in over a two-year period when the RVU reduction for a code is estimated to be equal to or greater than 20 percent. CMS is proposing to consider a 19 percent reduction as the maximum one-year reduction. Any remaining reduction, greater than 19 percent, would be phased in during the second year. CMS believes that this approach is more equitable for codes with significant reductions, but that are less than 20 percent.

Front-loading the reductions in the first year (*20 percent the first year, remaining changes in the*

subsequent year) does not fully embrace the spirit of the requirement. **ASTRO urges CMS to consider a 50/50 approach that will lead to a more equitable payment system and allow physicians more time to make changes in their practices to accommodate for the reductions.**

Target for Relative Value Adjustments for Misvalued Services

In the Protecting Access to Medicare Act of 2014 (PAMA), Congress set a target for adjustments to misvalued codes in the fee schedule for calendar years 2017 through 2020, with a target amount of 0.5 percent of the estimated expenditures under the PFS for each of those four years. Subsequently, the Achieving a Better Life Experience Act of 2014 (ABLE) accelerated the application of the target by specifying it would apply for calendar years 2016 through 2018, and increasing the target to 1 percent for 2016. If the net reductions in misvalued codes in 2016 are not equal to or greater than 1 percent of the estimated expenditures under the fee schedule, a reduction equal to the percentage difference between 1 percent and the estimated net reduction in expenditures resulting from misvalued code reductions must be made to all PFS services.

In this proposed rule, CMS is proposing a methodology for the implementation of this provision, which includes how net reductions in misvalued codes would be calculated. Based on that methodology, CMS has identified changes that achieve 0.25 percent in net reductions. However, CMS could make further misvalued code changes in the final rule to move closer to the statutory goal of 1 percent based on public comment and new recommendations.

ASTRO is concerned with how the agency will operationalize this policy. The language in the proposed rule did not specifically outline at what steps in the CMS methodology adjustments would be taken. ASTRO is also concerned with how CMS plans to track and project savings from misvalued services. ASTRO would also like CMS to further discuss how they will address issues related to new technology, and new codes (that are really a restructuring of old services).

Global Packages

In the 2015 MPFS, CMS finalized a policy to transition all 10-day and 90-day global codes to 0-day global codes. MACRA prohibits the Secretary from implementing this policy but it does not prevent the Secretary from revaluing specific surgical services as misvalued codes or assigning values to new or revised codes for surgical services.

CMS is seeking guidance on how to determine the number and level of post-operative evaluation and management visits furnished during the current post-operative period and how to revalue the individual components of the global surgical package, including the procedure and the pre- and post-operative care. CMS is interested in using this input to develop a proposed approach for the collection of this information in future rulemaking.

ASTRO appreciates that the proposal last year to deconstruct the global periods was not implemented and that this initiative is being further analyzed before changes are being made. ASTRO supports the efforts to ensure that appropriate resources are allocated to reimburse for services provided in the post-operative period. However, ASTRO does not support any pathway that will create massive disruptions (i.e. use of modifiers) to our physicians' practices. We still

believe that if CMS has specific concerns that there are too many post-operative visits assigned to particular codes, then they should nominate those particular services as potentially misvalued and work through the RUC process to resurvey those codes.

Reimbursement for Advanced Care Planning

In the proposed rule, CMS proposes to establish separate payment rates and codes for advanced care planning services provided to Medicare beneficiaries by physicians and other practitioners. While Medicare currently allows payment for these services for patients during initial enrollment, CMS proposes to establish separate payment for advance care planning codes, which will give beneficiaries and practitioners more flexibility to utilize these planning sessions at the most appropriate time for patients and their families.

ASTRO supports CMS' proposal to establish payment rates and codes for advance care planning services. Radiation therapy can play an important role in palliative care by improving the quality of life of cancer patients at the end-of-life. Evidence suggests that radiation therapy is extremely effective in relieving pain for patients with metastatic cancer. Additionally, the proposal compliments a provision in the ASTRO-supported Care Planning Act of 2015 introduced by Senators Warner and Isakson in June. The bill seeks to allow Medicare to cover advanced illness planning services for eligible individuals within a twelve month period, giving the Secretary flexibility to establish frequency limitations. Payment for advance care planning is an important step towards identifying patient goals and providing patients and their families with appropriate care and support at the end-of-life.

Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements

CMS proposes to revise the requirements for "incident to" billing. The agency proposes to require the physician supervising auxiliary personnel to be the same physician who bills for the services. CMS believes this will ensure that the services are in fact integral, although incidental, to the physician's professional services. CMS also proposes to explicitly prohibit auxiliary personnel from providing incident to services if they have been excluded from Medicare, Medicaid and other federally funded health care programs or if they have had their enrollment revoked. Currently, auxiliary personnel who fall into these categories are prohibited from providing services; the change clarifies that they also cannot provide services incident to a physician or other professional.

ASTRO supports efforts to prohibit auxiliary personnel from providing services if they have already been excluded from federal health care programs. However, we are concerned that this provision may have unintended consequences in large practices or in settings, such as radiation oncology, where patients are treated over an extended period of time. Specifically, the proposed revision may present a problem for practices in which a physician may require the assistance of another physician to supervise patient treatment while they are unavailable for acceptable circumstances, such as illness or vacation. **ASTRO urges CMS to consider the unintended consequences of this provision before making this proposed change.**

Self-Referral

In the 2016 proposed rule, CMS proposes a new exception for timeshare arrangements between a hospital or physician organization and a physician that will allow the physician to use office, equipment, personnel, supplies or other services on a periodic basis. Timeshare arrangements have typically been used to increase access to specialty care in rural and underserved areas that cannot support full-time physician services. This new exception would prohibit arrangements involving advanced imaging equipment, radiation therapy equipment or clinical or pathology laboratory equipment.

ASTRO supports the proposal to exclude radiation therapy equipment from the proposed timeshare arrangement exception and commends the agency for its commitment to ensuring that patients are protected from abusive self-referral practices. ASTRO believes this proposal is consistent with the agency's efforts to end self-referral abuse under the in-office ancillary services exception.

In addition, ASTRO commends the Administration for proposing to close self-referral law's in-office ancillary services exception in its last three budget proposals. Closing this loophole will provide billions of dollars in savings to the Medicare program and it will bridge the gap between the current fee-for-service system and the new payment system by ensuring that clinical decisions are not unduly influenced by financial gain. ASTRO continues to urge Congress to pass legislation that clarifies that only truly integrated, multispecialty group practices participating in robust alternative payment models (APMs), as described in the Medicare and CHIP Reauthorization Act (MACRA), would not be impacted by narrowing the exception. ASTRO believes that this is another way to encourage additional physicians to make the important move towards practicing within an APM.

Alternative Payment Models

MACRA included a section on promoting APMs that introduced a framework for promoting and developing APMs, as well as for providing incentive payments for eligible professionals who participate in APMs. In the proposed 2016 MPFS, CMS stated that it would issue "Requests for Information" (RFI) regarding provisions for developing APMs.

ASTRO looks forward to reviewing the CMS RFI regarding APMs when it is published. ASTRO has established a payment reform workgroup and is actively working to develop meaningful and viable alternative payment models in cancer care. **ASTRO looks forward to continuing to discuss these APMs with the agency and urges CMS to work with specialty societies on the development and implementation of models.**

Merit-Based Incentive Payment System (MIPS)

MACRA established the Merit-Based Incentive Payment System (MIPS). Beginning in 2018 (for the 2019 payment adjustment year), Physician Quality Reporting System (PQRS), value-based payment modifier (VM), and Meaningful Use programs will be consolidated and replaced by MIPS. CMS does not propose specifications for MIPS in the proposed rule, but does seek comments on several provisions of MACRA and MIPS.

Low-Volume Threshold

Under MACRA, providers may be excluded from MIPS if: they participate in an APM; they are first-time Medicare enrollees; or if they fall below a low-volume threshold. CMS is considering three qualifiers for low-volume threshold: minimum number of Medicare patients seen, minimum number of services provided, and minimum amount of allowed charges billed by the provider. The agency is seeking feedback on which qualifier or combination of the three qualifiers should be used to establish the low-volume threshold.

Radiation oncology is a unique specialty that utilizes highly advanced and sophisticated technology to provide radiation therapy to cancer patients. The use and cost of these sophisticated and expensive technologies are factored into the charges for radiation therapy services. In addition to the technology, radiation therapy charges also include the value, time, and work of others who are critical members of the specialized radiation therapy team, including medical physicists, dosimetrists, radiation therapy technicians, nurses, and other health professionals. ASTRO is concerned that establishing a low-volume threshold on the charges billed would be ineffective and subject some providers to the MIPS program who may otherwise be excluded if evaluated on more equal footing with other specialties. Thus, ASTRO urges CMS to establish a low-volume threshold based off a minimum number of patients seen or number of services provided, which would be a less skewed and a more standardized evaluation method.

Furthermore, a low-volume threshold using either the minimum volumes of patients or services provided would be more appropriate based on the finding and analysis of the existing quality programs. As the agency has experience with the PQRS program, and more so with the Value-Based Payment Modifier (VM) program, setting a minimum number of cases improves the reliability of measures' data. For the quality measures to be included in the composite score for the VM, the agency has determined that there must be a minimum of 20 cases for each measure for it to be statistically valid. ASTRO urges CMS to carry this policy over to the MIPS program, rather than test out new policies that could add more confusion and create more roadblocks to a new and developing program.

Given the complexity of reimbursement for radiation oncology, ASTRO believes that the low-volume threshold should not be based on the number of billings. Instead, a more appropriate and effective low-volume threshold would be based on a minimum number of Medicare patients seen or minimum number of services provided, or some combination thereof.

Clinical Practice Improvement Activities

MACRA establishes four performance categories under MIPS. One of these four categories is provider performance in Clinical Practice Improvement (CPI) activities, which consists of several subcategories, including participation in alternative payment models and care coordination activities. CMS is seeking feedback and comments on additional activities that can be identified as CPI activities for this MIPS performance category. ASTRO believes that the following three subcategories should be added to the list of CPI activities for MIPS: Maintenance of Certification activities, such as MOC Part IV Practice Quality Improvement (PQI)

requirements; participation in practice accreditation programs; and participation in patient safety organizations (PSO) designed as incident learning systems.

ASTRO's Practice Accreditation Program

ASTRO recently launched APEX, its new practice accreditation program. APEX, or Accreditation Program for Excellence, was created to ensure the accountability of radiation therapy practices by objectively assessing the radiation oncology care team, policies and procedures, and the facility itself. Accredited facilities have in place the systems, personnel, and policies and procedures necessary to provide high quality and safe patient care. ASTRO's APEX program is organized around five pillars: the process of care; the radiation oncology team; safety; quality management; and patient-centered care.

The program consists of 16 standards derived from evidence-based consensus statements on practice for radiation oncology. With this underlying focus on a culture of quality and safety, as well as patient-centered care, we believe that this would be an ideal subcategory for CPI activities.

ASTRO recommends that providers who practice at an accredited facility under the APEX program should be given credit for participating in a CPI activity under MIPS.

ASTRO's Radiation Oncology Incident Learning System (RO-ILS)

In 2014, ASTRO and AAPM launched RO-ILS a patient safety organization to improve the clinical practice of radiation oncology. The mission of RO-ILS is to facilitate safer and higher quality radiation oncology care by providing a secure and non-punitive environment to report adverse events. This allows providers to learn from actual and potential adverse events that could occur in radiation therapy, and improve the quality and safety of patient care. Participants are not only able to track and analyze internal incidents, but they are also contributing to a national database. In turn, they receive reports on their institutions, as well as aggregate national data on reported events.

ASTRO recommends that participation in reporting systems like ASTRO and AAPM's RO-ILS should satisfy the CPI activities category required by MIPS.

Physician Quality Reporting System (PQRS)

PQRS is a pay-for-reporting program that penalizes providers for failing to report quality measures data on Medicare Part B fee-for-service (FFS) patients. Beginning with CY 2015 participation, bonuses were no longer offered and a negative two percent penalty was implemented for failure to participate in PQRS. To avoid the 2018 PQRS payment adjustment, providers must report either a measures group or individual measures for a 12-month reporting period in 2016.

Oncology Measures Group

ASTRO appreciates CMS' decision to renew the Oncology Measures Group for the 2016 PQRS reporting period. Each year, ASTRO sees increased participation among radiation oncologists using the Oncology Measures Group reporting option. Renewing the measures

group and keeping the reporting requirements constant encourages this continued increase in participation.

Additionally, ASTRO strongly supports the agency's decision to maintain stability in PQRS and the other quality reporting programs, including the value-based payment modifier. We believe this steadiness will allow for a smoother and less confusing transition to the MIPS as it develops in the next few years.

Collecting Additional Patient Data

The Affordable Care Act creates a goal for CMS to establish a mechanism to collect provider reported data on race, ethnicity, sex, primary language, and disability status. CMS intends to collect this data through PQRS reporting mechanisms, and seeks comments on phasing-in the collection of these data elements, and the obstacles providers may face in collecting and reporting them.

ASTRO understands the importance of this goal, but we do not believe that CMS needs to create new and separate requirements to collect this data through PQRS reporting mechanisms. **Collection of this demographic data is already required under the Electronic Health Records (EHR) Incentive program (Meaningful Use). As CMS begins to develop the MIPS program, ASTRO urges the agency to consider allowing providers to report demographic data using the reporting mechanism that best suits their practice (e.g., this data could be reported through a registry, quality clinical data registry (QCDR), or EHR systems under Meaningful Use).**

Physician Compare Website

Physician Compare is a CMS website that provides beneficiaries with information on Medicare providers, including their practice locations and contact information, along with their participation and performance in the PQRS and Meaningful Use programs.

Quality Benchmarks and Quality Programs Participation

CMS proposes to continue to expand the information on providers reported on the Physician Compare website, including all quality measures and performance data reported as part of the PQRS program. The agency proposes to only publicly report those measures with a minimum sample size of twenty patients, and to adopt the Achievable Benchmark of Care (ABC™) methodology. The ABC™ methodology will be used to derive benchmarks for quality measures and assign providers a star rating comparing their performance to the benchmarks.

CMS also proposes to publicly report whether providers and group practices receive an upward adjustment under the Value-Based Payment Modifier (VM), indicating that the provider or groups achieved high quality care at a low cost, high quality care at an average cost, or average quality care at a low cost.

ASTRO questions the need for providing benchmarks and quality program participation information on providers' profiles at a time when all the programs are in flux and there will be significant changes in the near future. Each year, program requirements have changed for PQRS,

Meaningful Use, and for the VM program. There is a lack of consistency that is necessary for conveying the meaning and value of providers' participation in these complex programs. While we understand the importance of providing beneficiaries with this information, we believe it would be more meaningful when there is more stability in program requirements and after the implementation of MIPS.

ASTRO believes that CMS should delay reporting quality benchmarks and information on participation in the different quality reporting programs until after MIPS has been implemented and there is sufficient data to report.

Reporting Utilization and Open Payments Data

CMS proposes to include Open Payments Data on individual providers' profile pages within the Physician Compare website. Although this data is already available on CMS' website, the agency believes making this information available on Physician Compare will increase consumers' ability to find and evaluate the information. The proposed rule also includes a proposal to include more detailed information on the VM (quality and cost measures information), as well as utilization data derived from Medicare Part B claims on services and procedures in the Physician Compare downloadable database.

It is unclear to ASTRO why it is necessary to repost the utilization data on the Physician Compare website. This information is already available on separate CMS websites, dedicated respectively to Open Payment data and Medicare claims data. We believe that it is unnecessary to post the data in two locations. As the agency states in the proposed rule, the information is useful to the health care industry and health care researchers and stakeholders, who are knowledgeable of and have already accessed the CMS websites where this data is posted. ASTRO believes that there is already an abundance of information on the Physician Compare website, and that adding this data may not be helpful to beneficiaries who are trying to make educated health care decisions.

ASTRO does not believe there is a need to report and make available on Physician Compare claims and utilization data and information that is already available on a different CMS websites.

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

Respectfully,



Laura I. Thevenot
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