

September 6, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-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 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model

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 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model” published in the Federal Register as a proposed rule on July 15, 2016.

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.

The proposed rule updates the payment policies, payment rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule (MPFS) effective January 1, 2017. After years of significant instability in payments for radiation oncology services provided under the MPFS, ASTRO is pleased that CMS is proposing little to no change in overall payments for the specialty. However, we are greatly concerned with CMS’ decision not to accept the RUC recommendations for radiation therapy treatment devices. The following letter addresses this and several other issues of interest including the following:

- Valuation of Specific Codes
 - Radiation Treatment Devices – CPT Codes 77332, 77333, & 77334

- Special Radiation Treatment – CPT Code 77470
- Interstitial Radiation Source Codes – CPT Codes 77778 and 77790
- Radiation Treatment Delivery, IMRT and IGRT G Codes
- Moderate Sedation
- Methodology for Proposing Work RVUs
- Potentially Misvalued Codes
 - PACS Workstation
 - Validating RVUs of Potentially Misvalued Codes
- Collecting Data on Resources Used in Furnishing Global Services

Valuation of Specific Codes

Radiation Treatment Devices – CPT Codes 77332, 77333 & 77334

In 2015, CPT code 77334 *Treatment devices, design and construction; complex* was identified by CMS as a potentially misvalued service through a high expenditure services' screen. ASTRO surveyed the code set and presented the revalued codes to the American Medical Association's Relative Value Update Committee (RUC) at the panel's January 2016 meeting. The RUC recommended the retention of the existing RVUs for Radiation Treatment Device code set. CMS rejected the RUC recommended values for this code set.

CMS is proposing to value CPT code 77332 *Treatment devices, design and construction; simple* based on a crosswalk with the value of CPT code 93287 *Peri-procedural device evaluation (in person)*. CMS proposes to use this crosswalk because CPT code 93287 has identical intraservice time, similar total time, and a similar level of intensity. The Agency further supports this valuation proposal with the inclusion of CPT code 97760 *Orthotic(s) management and training*. Both have a work RVU of 0.45.

CMS proposes establishing a work RVU of 0.45 for CPT Code 77332 and retaining the incremental increase for CPT codes 77333 and 77334 reflecting the increase in work value. The chart below depicts the RUC RVU recommendation compared with the CMS RVU recommendation.

CPT Code	CPT Descriptor	Global Period	RUC Recom	CMS Recom	CMS Crosswalk	
77332 (f)	Treatment devices, design and construction; simple (simple block, simple bolus)	XXX	0.54	0.45	93287 & 97760	Peri-procedural device evaluation (in person) & Orthotic(s) management and training
77333 (f)	Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus)	XXX	0.84	0.75		<i>incremental methodology</i>
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)	XXX	1.24	1.15		<i>incremental methodology</i>

CMS states in the proposed rule that a 34 percent reduction in total time is not reflected in the recommended RVUs, thus the Agency believes that the recommended RVUs overstate the work involved. ASTRO disagrees and believes this is inaccurate for the following reasons: The RUC survey times and the existing times are nearly identical for 77332 and are identical for 77333. Finally, the RUC survey times are greater than the existing times for 77334.

Comparison of RUC survey times and existing times

	RUC survey total time	Existing time
77332	25 minutes (5, 15, 5)	28 minutes
77333	33 minutes (8, 20, 5)	33 minutes
77334	45 minutes (10, 30, 5)	35 minutes

The treatment device codes are XXX global periods and do not have standard pre or post service packages. Therefore, ASTRO chose to recommend no pre time and minimal post time. The recommended/existing values along with the refined/surveyed RUC times yield reasonable and appropriate intensities for these services.

	wRVU	IWPUT	Total Time	Pre	Intra	Post
77332	0.54	0.032	18		15	3
99212	0.48	0.034	16	2	10	4
77333	0.84	0.036	25		20	5
77334	1.24	0.038	35		30	5
77470	2.09	0.040	55		50	5
77300	0.62	0.041	15		15	
77295	4.29	0.042	112	7	90	15
77301	7.99	0.050	195	30	130	35
99213	0.97	0.053	23	3	15	5

There is no data to support CMS' proposed arbitrary crosswalk to CPT 93278, which results in a reduction to the value of 77332, and corresponding reduction in values for the intermediate (77333) and complex (77334) codes. The RUC surveyed time for CPT Code 77334 is greater and the RUC recommended time is identical – yet CMS is inappropriately reducing the RVUs for the intermediate and complex codes simply because they reduced 77332.

ASTRO strongly opposes the modified work RVU recommendations for the treatment device codes and urges CMS to implement the RUC approved values (existing values), which are overwhelmingly supported by the RUC survey data and the descriptions of work submitted by ASTRO.

Special Radiation Treatment – CPT Code 77470

CMS also identified CPT Code 77470 *Special Radiation Treatment* for reevaluation through the high expenditure services' screen. The Agency is approving the RUC recommended work RVU value of 2.03. However, CMS expressed concern that the description of the service and the vignette used for the RUC recommendation describes different and unrelated treatments being performed by the physician and clinical staff for a typical patient. According to the Agency, this represents a discrepancy between the work RVUs and the PE RVUs. CMS is seeking additional information that will address this disparity to help determine appropriate PE inputs. Specifically, the Agency is seeking feedback on whether the issue can be addressed through the establishment of two G-Codes: one G code that describes the physician work portion of the service and another G code that describes the PE portion.

Medicare data shows ICD-9 Code 162 *Malignant Neo Trachea/Bronchus/Lung* to be the typical patient for CPT code 77470. The following vignette was used for the RUC physician work survey: *A 68-year-old male with stage IIIA non-small cell lung cancer will be treated with chemo/radiotherapy preoperatively.* The description of physician work describes the work done for a typical 77470 patient.

ASTRO believes that CMS may be questioning whether the description of clinical labor on the practice expense side is for a lung special procedure. The clinical description of labor submitted and presented describes what the radiation oncologist typically does in a lung case that requires the delivery of a special procedure. There may be some confusion regarding the use of the term 'treatment device'. Although that term also appears in CPT codes (77332-77334), those codes describe the design and construction of treatment devices. It is important to note that the treatment device codes were surveyed and presented at the same meeting. The work involved is not the same.

ASTRO is confused by the Agency's recommendation to create two new G-Codes. The CPT descriptor is accurate and represents the typical patient in the Medicare database and what was surveyed and presented on both the work and PE side. ASTRO sees no purpose for the use of a G-code to describe this service.

The direct practice expense inputs include clinical labor and no supplies or equipment. When the code is used for another diagnosis the resource consumption would be the same and does not pose any issues. We note the typical claim is for a -26 Professional Fee. If the Agency is suggesting that there should be multiple CPT Codes for every possible diagnosis for the use of this code, ASTRO would not support that approach. That is simply not how CPT 77470 works or is applied in the delivery of care.

ASTRO urges CMS to finalize the work and practice expense RUC recommendation for CPT code 77470 without modification.

Interstitial Radiation Source Codes – CPT Codes 77778 and 77790

As part of the 75 percent reported together screen, the RUC identified that CPT code 77778, *Interstitial radiation source application, complex*, as being reported with CPT code 77790, *Supervision, handling, loading of radiation source*. In February 2015, the CPT Editorial Panel deleted interstitial radiation source codes 77776, 77777 and revised interstitial radiation source code incorporating supervision and handling of brachytherapy sources, 77790, into 77778. In April 2015, CPT code 77778 was revalued to include supervision and handling of brachytherapy sources previously reported with CPT code 77790, *Supervision and handling, loading of radiation source*.

In the final 2016 MPFS, CMS established an interim final value for CPT code 77790 *Supervision, handling, loading of radiation source* without a work RVU as recommended by the RUC. CMS chose not to use the RUC recommended work RVU of 8.78 to establish the interim final values for CPT code 77778 *Interstitial radiation source application; complex*. The agency established a work RVU of 8.00 as an interim final value for CPT code 77778 based the 25th percentile RUC survey result. In the proposed 2017 MPFS, CMS proposes to finalize the work RVU for CPT code 77778 at 8.0.

ASTRO continues to believe that CMS inappropriately reduced the work RVUs for CPT Code 77778 from 8.78 to 8.00. The intra service work for the code (at the time of survey) was 8.42 for the intra portion of the procedure. The comparable work RVU for the procedure is 10.93 (0.78 +8.42+0.67+1.05). The specialty made the recommendation of 8.78, which reflects a 20 percent savings for bundling the two procedures.

There is work in supervising the ordering of the isotope. That work is performed by the physician and the RUC survey demonstrated this clearly. The RUC questioned whether supervising the ordering of the isotope should be in the pre time, so it was agreed to remove it from the pre time. All parties agreed the 8.78 was an appropriate reflection of the physician work involved.

The work associated with the procedure has not changed. The surveyed times are greater than the existing times. There is no appropriate rationale to reduce the value beyond the discount the RUC had already recommended for the procedure.

CMS continues to ask about the pre time. ASTRO believes this is a deflection to support the inappropriate reduction of work RVUs. CMS performed calculations using the ASTRO spreadsheet that was submitted to the RUC, rather than the final spreadsheet that was officially submitted to CMS. The Agency multiplied 35 minutes by an IWPUT of 0.076 and then backed out the RVU value that was recommended by the RUC.

CPT Code 77778 describes brachytherapy, which is an efficient and cost effective treatment for prostate cancer¹. Despite this evidence, use of this particular therapy continues to decline in correlation with reimbursement levels. There is pre work associated with the ordering of the isotope and there is pre work associated with the brachytherapy procedure (evaluation, positioning and Scrub, Dress and Wait). The specialty outlined the work associated with all four steps.

ASTRO strongly urges CMS to assign the RUC recommended RVUs of 8.78 for CPT Code 77778.

Radiation Treatment Delivery, IMRT and IGRT G Codes

In the final 2016 MPFS, CMS did not finalize its proposal to implement the new set of conventional radiation treatment delivery, IMRT or IGRT codes. The agency decided to retain the 2015 G-codes and values for another year. In December 2015, Congress passed and the President signed into law the Patient Access and Medicare Protection Act (PAMPA). PAMPA freezes the Treatment Delivery, IMRT and IGRT G Codes and the associated “definitions, units, and inputs for such services” for 2017 and 2018.²

The proposed non-facility (NF) practice expense (PE) RVUs for G 6011 *Radiation Treatment Delivery* are 8.09 for 2017, a 10 percent decrease from the current 9.03 NF PE RVUs. The direct practice expense inputs (i.e. clinical labor, supplies, equipment) have not changed from the current inputs, which is supported in the CMS-1654-P_PUF files. CMS did not provide any written explanation explaining the decrease, which we believe is inconsistent with the PAMPA legislation. We note that G6011 is used by various specialties (i.e. radiation oncology, hematology, medical oncology, etc).

ASTRO believes that PAMPA effectively freezes the PE RVUs for G 6011 in 2017. We seek clarification from the Agency regarding the proposed decrease.

Moderate Sedation

In prior rulemaking, CMS noted that practice patterns for certain endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures even

¹ Orio III PF, Nguyen PL, Buzurovic I, Cail DW, Chen Y-W, Prostate brachytherapy case volumes by academic and non-academic practices: Implications for future residency training, *International Journal of Radiation Oncology Biology Physics* (2016), doi: 10.1016/j.ijrobp.2016.07.013.

² Patient Access and Medicare Protection Act of 2015. Public Law 114-115. 129 Stat. 3131. 28 December 2015. <https://www.congress.gov/bill/114th-congress/senate-bill/2425/text/pl>

though payment for sedation services was automatically included in payment to the physician furnishing the primary procedure. To address this issue, separate CPT codes for reporting moderate sedation were developed and valued by the CPT and RUC. In the 2017 proposed MPFS, CMS is proposing values for the new CPT moderate sedation codes. The Agency is also proposing to back out the proposed value of moderate sedation from existing CPT codes, including the following eight services reported by radiation oncologists:

CPT Code 19298 – *Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes image guidance.*

CPT Code 49411 – *Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple*

CPT Code 57155 – *Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy*

CPT Code 77371 – *Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of one session; multi-source Cobalt 60 based*

CPT Code 77600 – *Hyperthermia, externally generated; superficial (ie, heating to a depth of 4 cm or less)*

CPT Code 77605 - *Hyperthermia, externally generated; deep (ie, heating to depths greater than 4 cm)*

CPT Code 77610 – *Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators*

CPT Code 77615 - *Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators*

ASTRO supports a two-tiered work RVU adjustment based on pre-service time package assignments (1B vs 2B). Therefore, ASTRO supports removing 0.10 work RVUs from CPT Code 49411 and 0.19 work RVUs from CPT Code 57155 to account for moderate sedation. However, the other codes listed above were not valued with moderate sedation, and we do not support a work RVU adjustment for those codes.

CPT Code 19298

At the time of the RUC valuation for CPT code 19298 “under appropriate anesthesia” or “anesthesia needs are discussed with patients” was included in the SOR. The pre time package associated with CPT code 19298 was assigned retrospectively as a proxy, but it was not valued with moderate sedation. With regard to practice expense, a moderate sedation pack did not exist at the time of submission and we have confirmed that none of the components of the modern day moderate sedation pack were included at the time of submission. The moderate sedation pack

was added retrospectively. **ASTRO concedes it is appropriate for the Agency to remove the practice expense moderate sedation pack but does not agree with the Agency's proposal to back out 0.25 work RVUs for moderate sedation.**

CPT Code 77371

CPT Code 77371 is a PE only code. However, there are no direct practice expense inputs associated with the code. This code should not be included on Table 22.

Hyperthermia CPT Codes 77600-77615

The pre time packages associated with the Hyperthermia code set were assigned as proxies in a retrospective exercise in April 2015. They were **not** originally valued with moderate sedation. No moderate sedation packages are in the PE inputs. ASTRO does not support the Agency's proposal to remove work RVUs (wRVU) to account for moderate sedation for the hyperthermia codes.

ASTRO requests that CMS not remove wRVUs from CPT Codes 19298, 77371, 77600, 77605, 77610 or 77615 as they were never valued with moderate sedation.

Methodology for Proposing Work RVUs

In conjunction with CMS' review of recommended code values for CY 2017, the Agency conducted a preliminary analysis of the relationship between changes in time and changes in work RVUs for 2014 and 2015. The Agency looked at services for which there were no coding changes to simplify the analysis. The intent of this preliminary analysis was to examine commenters' beliefs that CMS is only considering time, and not intensity, when making refinements to RUC recommended work values.

In an effort to address concerns regarding how best to account for changes in time and intensity in improving the accuracy of work RVUs, CMS is interested in receiving comments on whether there are alternatives when it is evident that the survey data and/or the RUC recommendation regarding the overall work RVU do not reflect changes in the resource costs of time for codes describing MPFS services. CMS is also seeking comments on potential alternatives, including the application of the reverse building block methodology, to make the adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services.

The Omnibus Budget Reconciliation Act of 1989 replaced the historical charge-based fee schedule with the existing Resource-Based Relative Value Scale (RBRVS). The RBRVS allows for the determination of the relative values of physician services. The work component includes the "portion of the resources used in furnishing the service that reflects the physician time and intensity in furnishing the service."³

³ Omnibus Budget Reconciliation Act of 1989. Public Law 101-239. December 19, 1989.
<https://www.govtrack.us/congress/bills/101/hr3299>

ASTRO is concerned that CMS is repeatedly ignoring intensity discussions and picking arbitrary crosswalks to justify lowering work RVU values. If CMS continues to require resurvey and then takes the survey results at the 25th percentile (or below), then specialties will continue to see a systematic reduction in work RVUs that is not supported or based on data. This trend prevents the process from living up to the letter of the law for which it was created and is unsustainable over the long term.

Potentially Misvalued Codes

PACS Workstation

A picture archiving and communication system (PACS) allows providers to capture, store, view and share all types of images internally and externally. Based on an analysis of submitted invoices, CMS proposes to set the price of a professional Picture Archiving and Communication System (PACS) workstation (ED053) at \$14,617. The agency is not proposing a change to the current technical PACS workstation (ED050), which is currently set at \$5,557.

CMS proposes to add the professional PACS workstation to many CPT codes in the 70000 series that use the current technical PACS workstation and include the professional work associated with the professional PACS workstation. The Agency proposes to exclude the professional PACS workstation from the Radiation Therapy section (77261 through 77799). CMS seeks comment on the application of the professional PACS workstation to CPT codes in the 70000 series.

Radiation oncology services use all the key components of a PACS system. ASTRO encourages the Agency to consider using the professional PACS system ED053 on a case-by-case basis for certain radiation oncology services.

Collecting Data on Resources Used in Furnishing Global Services

CMS is proposing that any practitioner who furnishes a procedure that is a 10- or 90-day global report the pre- and post-operative services furnished on a claim. CMS is proposing the following codes be used for reporting on claims the services actually furnished but not paid separately because they are part of global packages. No separate payment would be made for these codes. They are seeking public comment on all aspects of these codes, including the nature of the services described, the time increment, and any other areas of interest to stakeholders.

TABLE 9: Proposed Global Service Codes

Inpatient	GXXX1	Inpatient visit, typical, per 10 minutes, included in surgical package
	GXXX2	Inpatient visit, complex, per 10 minutes, included in surgical package
	GXXX3	Inpatient visit, critical illness, per 10 minutes, included in surgical package
Office or Other Outpatient	GXXX4	Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package
	GXXX5	Office or other outpatient visit, typical, per 10 minutes, included in surgical package
	GXXX6	Office or other outpatient visit, complex, per 10 minutes, included in surgical package
Via Phone or Internet	GXXX7	Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package
	GXXX8	Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package

The Medicare and CHIP Reauthorization Act (MACRA). MACRA requires CMS to develop and implement a process to gather and analyze a subset of necessary data on pre- and post-operative visits and other services furnished during global surgical periods other than the surgical procedure itself.

ASTRO believes the Agency’s proposal to require all physicians to report newly created G-codes in ten minutes increments for all pre and post operative work related to 090 and 010 day services far surpasses the spirit of MACRA. ASTRO supports the collection of data (pre- and post-operative work related to 090 and 010 day services) outside the claims reporting system from a subset of high volume/broadly representative services and providers, rather than from all providers who may be rendering these services. Additionally, requiring physicians to bill the new codes in ten minute increments will be administratively burdensome. We urge the Agency to consider a more reasonable approach to data reporting. ASTRO is confident that the CMS proposal, as outlined in the 2017 MFS Proposed Rule, will undoubtedly yield flawed data by which CMS will make payment policy. CMS must move forward with the data collection for global services in a transparent way with providers.

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
 Chief Executive Officer