

September 11, 2017

Ms. Seema Verma
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 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

Dear Administrator Verma:

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 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program” published in the Federal Register as a proposed rule on July 21, 2017.

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, 2018. 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 and we urge the agency to maintain this vital stability in future rulemaking.

The following letter addresses this and several other issues of interest, including the following:

- CMS Approach to RUC Recommended Values
 - Radiation Oncology Conventional Treatment Delivery, IMRT & IGRT Codes
- Valuation of Specific Codes
 - Radiation Treatment Planning – CPT Codes 77261, 77262, & 77263

- Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed - CPT Code 55X87
 - Superficial Radiation Treatment Planning and Management Related Services – GRRR1
- 2018 Identification and Review of Potentially Misvalued Services
 - Technical Corrections for CY 2018 CMS Time File
 - Separate Payment for High Cost Medical Supplies
 - Pre-service Clinical Labor for 0-Day and 10-Day Global Services
 - Obtain Vital Signs Clinical Labor
 - Calculation of Malpractice RVUs
 - Proposed Payment Rates under the MPFS Schedule for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital
 - MACRA Patient Relationship Categories and Codes
 - CMS Request for Information on Flexibilities and Efficiencies
 - 2018 MPFS Proposed Rule Quality Provisions

CMS Approach to RUC Recommended Values

In the 2018 MPFS proposed rule, CMS is adopting a new, two prong strategy for valuing new, revised, and potentially misvalued codes. First, CMS proposes to adopt the Relative Value Update Committee (RUC) recommended work values as CMS values for almost all services. Second, CMS provides alternative valuations, rather than proposing actual CMS refined substitute values, for all services for which CMS has concerns regarding the RUC recommended work/time values.

Given the relative nature of the MPFS and CMS' obligation to ensure that the RVUs reflect relative resource use, the Agency has included descriptions of potential alternative approaches it might have considered in developing work RVUs that differ from the RUC recommended values. CMS seeks comment on both the RUC-recommended values as well as proposed alternatives. Below are ASTRO's comments on the RUC values as well as the proposed alternative values.

ASTRO is pleased with the shift in CMS' approach to reviewing RUC recommendations. We agree with the Agency's recognition that the majority of practitioners paid under the Physician Fee Schedule (PFS), though not necessarily those in any particular specialty, would prefer CMS rely more heavily on RUC recommended values in establishing payment rates under the MPFS. ASTRO echoes the RUC's consistent reassurance that concerns regarding changes in time (for example) are already considered, and either incorporated or dismissed, as part of the development of recommended values.

In addition, ASTRO appreciates the Agency for recognizing the value of the CPT/RUC process, and urges application of this approach when addressing the radiation treatment delivery, IMRT and IGRT codes that were not valued in 2015.

Radiation Oncology Conventional Treatment Delivery, IMRT and IGRT Codes

When ASTRO revised the treatment delivery codes in 2013, we did so to ensure that the codes and their values represent the current process of care and technology, and we were mindful of CMS' concerns that Intensity Modulated Radiation Therapy (IMRT) treatment for prostate cancer was overvalued and overutilized. Additionally, the Agency urged ASTRO to create a modality-agnostic image guidance code. Therefore, we rewrote the conventional treatment delivery codes based on technology, instead of energy; we split the IMRT code to account for differences in complexity; and we bundled image guidance in with the treatment delivery codes, where it is typically used (IMRT) and consciously chose not to bundle image guidance where it is not commonly used. Finally, we described all forms of image guidance in a single code, regardless of technology.

A great amount of volunteer time and effort was expended to develop the treatment delivery codes—and with good reason, as this group of codes represents about half of all radiation oncology spending under the fee schedule. A good faith effort was made to put forth recommendations that, we believe and the RUC confirmed, were accurate and reasonable. We have met with Agency officials multiple times since the decision was made not to accept the RUC recommended values for the treatment delivery and Image Guided Radiation Therapy (IGRT) codes, most recently on March 16, 2017.

ASTRO remains committed to the RUC-recommended values for the conventional radiation therapy, IMRT and IGRT codes. After considering a variety of options to address concerns about the IMRT codes, we believe all other options would be worse and potentially subject to abuse.

ASTRO understands CMS' concern about the apparent rank order anomaly between complex conventional radiation therapy when used with IGRT and simple IMRT; however, we disagree that this is evidence of inappropriate valuation of the conventional radiation therapy code set or the IGRT Code. It is reasonable to believe that the work and resource used for the types of cases requiring complex conventional radiation therapy services **with** image guidance are greater than those required for simple IMRT treatment.

Finally, current Medicare utilization data demonstrates that CT is the most commonly used IGRT technology, confirming ASTRO's RUC recommendation. ASTRO recognizes that the recommendations for this new set of codes represents an overall cost savings to Medicare. As such, we believe it is within the purview of the specialty to make recommendations for allocation of resources within the family. A detailed budget neutrality calculation was submitted with the recommendations and we are happy to work with the Agency to prepare an updated calculation.

To that end, ASTRO has made a good faith effort to address CMS' concerns. We believe it is time to focus on creating a fair and predictable payment foundation for this code set to avoid undermining the development of value-based alternative payment models for radiation oncology.

As the Agency may know, ASTRO has been working collaboratively on a radiation oncology APM (RO-APM) with the Center for Medicare and Medicaid Office of Innovation (CMMI). The RO-APM is a guidelines adherence based model that features a common payment framework that applies to the five primary disease sites, including: breast, lung, prostate, colorectal and head and neck, as well as two secondary disease sites: bone metastases and brain metastases. This model is highly consistent with Quality Payment Program's (QPP) recommended characteristics for an Advanced APM. It includes requirements that physicians assume accountability for controlling the total cost of Medicare spending related to the condition, in this case the treatment of cancer, as well as the total cost of Medicare spending on all services the patient receives during the episode of care.

2018 Valuation of Specific Codes

For 2018, CMS is applying its new strategy for valuing new, revised and potentially misvalued codes. As previously mentioned, a significant amount of physician, volunteer and specialty society time is committed to the development of the RUC recommendations. We believe that the CPT/RUC process is rigorous and results in fair and equitable valuation of services.

Radiation Therapy Planning (CPT Codes 77261-77263)

CPT Code 77263 *Therapeutic radiology treatment planning; complex* was identified in a High-Expenditure Services Screen in the 2016 MPFS Final Rule. The Clinical Treatment Planning code set, CPT Codes 77261-263, were reviewed and revalued by the RUC in April 2016. In the 2018 MPFS proposed rule, CMS agrees with the RUC recommended work RVUs; however, the Agency expresses concerns with the recommended values given the decreases in service times as recommended by the RUC and reflected in the survey data compared to current values.

The Agency is concerned that despite a 15-minute decrease in intra-service time, the RUC did not recommend a corresponding decrease in work RVUs. As an alternative, CMS proposes a RVU value of 2.60 based on a crosswalk to CPT code 96111 *Developmental testing, includes assessment of motor, language, social, adaptive, and/or cognitive functioning by standardized developmental instruments) with interpretation and report*, which has similar intra-service and total time to the RUC recommended values for CPT code 77263.

The Agency proposes using a ratio of the two RVU valuations for CPT codes 96111 and 77263 ($2.60 \text{ RVUs} / 3.14 \text{ RVUs} = 0.83$) to determine the values for CPT codes 77261 and 77262. The ratio of 0.83 is multiplied by the RUC-recommended RVU value for the remaining treatment planning codes to achieve the CMS proposed alternative value. CMS seeks comments on the proposed alternative RVU values for the radiation oncology treatment planning codes. The chart below depicts the RUC-recommended values, as well as the CMS proposed alternative values.

Radiation Therapy Planning RUC Value vs. CMS Alternative

CPT Code	CPT Descriptor	Global Period	RUC Recom RVU Value	CMS Proposed CPT Crosswalk	CPT Descriptor	RVU Value
77263	Therapeutic radiology treatment planning; complex	XXX	3.14	96111	Developmental testing, includes assessment of motor, language, social, adaptive, and/or cognitive functioning by standardized developmental instruments with interpretation and report	2.60
77262	Therapeutic radiology treatment planning; intermediate	XXX	2.00		0.83 X 2.00 = 1.66	1.66
77261	Therapeutic radiology treatment planning; simple	XXX	1.30		0.83 X 1.30 = 1.08	1.08

The use of direct crosswalks based only on time comparison or ratios of time inappropriately discounts the variation in technical skill, judgment, and risk inherent to procedures. The Radiation Therapy Treatment Planning Codes (CPT codes 77261-77263) describe the physician work involved in integrating the patient's overall medical condition and extent of disease in the formulation of a plan of therapy for the patient. Clinical treatment planning includes analysis of the diagnosis, treatment site, target anatomical structures (e.g., primary and regional lymph nodes or primary site only), identification of any organs at risk in or adjacent to the treatment fields, intent of treatment, special tests interpreted, modality and interaction with chemotherapy and technique contemplated (e.g., conventional, three-dimensional, IMRT, SRS, SBRT or brachytherapy).

CPT Code 96111 *Developmental testing, includes assessment of motor, language, social, adaptive and/or cognitive functioning by standardized developmental instruments with interpretation and report*, is commonly used for evaluating individuals with suspected developmental disorders. CPT code 96111 describes evaluation, interpretation and reporting. It

does not include treatment planning. As such, the crosswalk to CPT Code 96111 is inappropriate. It is also important to note that CPT code 96111 is billed with an E&M code greater than 50 percent of the time (see below). The treatment planning codes are NOT billed with an E&M.

CPT Code 1	CPT Code 2	Percent Billed Together
96111	99203	2%
96111	99205	2%
96111	99212	2%
96111	99213	6%
96111	99214	30%
96111	99215	12%
TOTAL		54%

The RUC compared CPT Code 77261 with key reference service CPT Code 77306 *Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)* (work RVU= 1.40, intra time= 30 minutes) and agreed that while the two services have comparable physician work, the reference code has more intra-service time and should be valued higher. The RUC also reviewed CPT Codes 77334 *Treatment devices, design and construction; complex* (irregular blocks, special shields, compensators, wedges, molds or casts) (work RVU= 1.24, intra time= 35 minutes) and 77768 *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* (work RVU= 1.40, intra time= 35 minutes) and agreed both services offer reasonable comparisons to the recommended value.

The RUC compared CPT Code 77262 with two key reference services CPT Codes 77317 *Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)* (work RVU= 1.83, intra time= 50 minutes) and 77307 *Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)* (work RVU= 2.90, intra time= 80 minutes) and agreed that both these reference codes provide appropriate brackets around the recommended value. The RUC also reviewed CPT Code 77770 *Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel* (work RVU= 1.95, intra time= 45 minutes) and agreed that both services have comparable physician time and work and should be valued similarly.

The RUC compared CPT Code 77263 with CPT Code 77307 *Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)* (work RVU= 2.90, intra time= 80 minutes) and agreed that while both services have analogous physician work, with

similar total time, the surveyed code is a more intense procedure and should be correctly valued higher. In addition, the RUC reviewed several recently RUC reviewed services with identical intra-service time to validate the recommended work value across a broad spectrum of services: CPT Code 38241 *Hematopoietic progenitor cell (HPC); autologous transplantation* (work RVU= 3.00), 90792 *Psychiatric diagnostic evaluation with medical services* (work RVU= 3.25) and 94012 *Measurement of spirometric forced expiratory flows, before and after bronchodilator, in an infant or child through 2 years of age* (work RVU= 3.10).

When CPT Code 77263 was last surveyed during the third five-year review (2005) total time was surveyed for this XXX code (not specifically pre, intra and post), making it inappropriate to compare only intra times from the existing input to the surveyed time. It is important to note that the TOTAL time for the recent survey was significantly higher than the existing time and that the recommended (after package) time is also higher, further justifying the RUC recommendation of current value.

We believe that the RUC undertook a rigorous and valid analysis to ensure the accuracy of the recommended values. ASTRO urges CMS to accept the RUC recommended values for the Radiation Therapy Treatment Planning codes.

CPT Code 55X87 Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed

In 2016, the CPT Editorial Panel deleted CPT Category III code 0438T and created new CPT Code 55X87 *Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed*. The RUC recommended an RVU value of 3.03 at its January 2017 meeting. In the proposed 2018 MPFS, CMS proposes to accept the RUC-recommended value.

However, the Agency expresses concern regarding the decrease in pre-service time (30 minutes) compared to the current pre-service time. To account for this change in time, CMS proposes an alternative methodology, which involves calculating the intra-service time ratio between the key reference code (CPT code 49411), which has an intra-service time of 40 minutes, and the RUC-recommended intra-service time (30 minutes) and multiplying that against the work RVU for CPT code 49411 (3.57), which would have resulted in a work RVU of 2.68. A work RVU of 2.68 would have been further supported by a bracket of two crosswalk codes, CPT code 65779 *Placement of amniotic membrane on the ocular surface; single layer, sutured*, which has a work RVU of 2.50; and CPT code 43252 *Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy*, which has a work RVU of 2.96. Compared with CPT code 55X87, these codes have identical intra-service and similar total times. CMS seeks comments on whether the alternative values of these codes should be considered.

CMS is proposing a minor modification to the equipment time to conform with changes in the clinical labor formula as a result of the revaluation of the code. This results in a two-minute increase in each of the associated equipment times.

ASTRO does not agree with the Agency's position that there is a decrease in pre-service time (30 minutes) compared to the current pre-service time. The current code is a Category III code (0438T), which has not been surveyed. There are no current physician time inputs in the database. The Agency may be referring to the discrepancy between surveyed pre times and package pre times. The surveyed pre time was 55 minutes. The application of pre time packages reduces that to 25 minutes. The use of pre time packages is a long-standing policy of the RUC. CMS also typically accepts and supports this methodology.

The RUC reviewed the survey results from 175 urologists and radiation oncologists and determined that a work RVU recommendation of 3.03 was appropriate and supported by the 25th percentile of the survey. Of the 175 survey respondents, 65 had performed the procedure in the last year, which exceeds the survey threshold; these responses were combined with the 110 other respondents who had not performed the procedure in the last year but likely had contributed to the initial clinical trial. ASTRO and the American Urological Association (AUA) confirmed that the final recommendation of the 25th percentile reflected the combined survey. The specialty societies also clarified that ultrasound is performed continuously throughout the procedure. Further, it was confirmed that the description of intra-service work is correct, in that after the ultrasound probe is placed and anesthesia is conducted, hydrodissection is the initial step in the procedure. Once the hydrodissection is completed, the syringe is removed but the needle is intact; at that time, the biodegradable material is prepped. It is never prepped prior to the procedure but is done after the hydrodissection, which is why it is included in the intra-service time.

The RUC recommends 25 minutes pre-service time, 30 minutes intra-service time, and 15 minutes post-service time (total time 70 minutes). The RUC agreed to add five minutes of positioning time above the standard package to account for positioning the patient in the dorsal lithotomy position. The RUC compared the surveyed code to the top key reference service, 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* (work RVU = 3.57, intra-service time of 40 minutes, total time 75 minutes), and noted that both services have similar physician IWP/UT (0.074 and 0.071 respectively) with the surveyed code being higher due to the shorter intra-service work time. The RUC noted that the second key reference service, CPT Code 55876 *Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple*, (work RVU = 1.73 and intra-service time of 20 minutes) requires 10 minutes less intra-service time and is less complex and intense, thus the surveyed code is appropriately valued higher.

For additional support, the RUC compared the surveyed code to CPT code 44389 *Colonoscopy through stoma; with biopsy, single or multiple* (work RVU = 3.02, intra-service time of 30 minutes, total time 65 minutes) and also considered CPT code 50386 *Removal (via snare/capture) of internally dwelling ureteral stent via transurethral approach, without use of cystoscopy, including radiological supervision and interpretation* (work RVU = 3.05, intra-service time of 30 minutes, total time 80 minutes). **The RUC recommends a work RVU of 3.03 for CPT code**

55X87. ASTRO urges CMS to accept the RUC recommended valuation of 3.03 RVUs for CPT Code 558X7.

Practice Expense

According to CMS, “Endocavity balloon invoice price of \$399.00 for ten devices was inadvertently included in the PE spreadsheet, rather than \$39.90 for one device. The Agency proposes to modify the price of the “endocavity balloon” to \$39.90.” ASTRO agrees that the pricing of one balloon is \$39.90. That price (\$399/10) was noted on line 103 of the submitted spreadsheet to the RUC and subsequently the Agency.

CMS questions whether the invoice price of \$29,999 for existing equipment item EQ250 Portable Ultrasound Unit includes probes. EQ250 ultrasound unit, portable (\$29,999) does not include an intracavitary probe, the probe necessary to perform this procedure. Both the portable unit and the intracavitary probe should be recognized as direct practice expense inputs for this procedure.

GRRR1 Superficial Radiation Treatment Planning and Management Related Services

At a February 2014 CPT meeting, the CPT Editorial Panel considered and ruled out potential reporting of other radiation therapy services with CPT Code 77401 *Radiation Treatment Delivery, Superficial and/or Ortho Voltage, per day*. The Panel determined that a physician evaluation and management code could be reported, when performed, if CPT Code 77401 was billed alone. Superficial Radiation Treatment (SRT) vendor representatives sought reconsideration of this decision at the Panel’s May 2014 meeting, but rather than revise its decision, the CPT Panel confirmed guidance that limits the reporting of other radiation therapy services with CPT Code 77401.

In the 2015 MPFS, CMS finalized language limiting the codes that could be reported with CPT Code 77401 *Radiation Treatment Delivery, Superficial and/or Ortho Voltage, per day* or superficial radiation therapy (SRT) delivery. In the 2016 MPFS, CMS asked for stakeholder feedback regarding the physician work associated with SRT. Stakeholder comments revealed significant differences of opinion regarding the physician work associated with CPT Code 77401, which is why the issue remains unresolved.

In the 2018 MPFS, CMS is proposing to make separate payment for the professional planning and management associated with SRT using HCPCS code *GRRR1 Superficial Radiation Treatment Planning and Management Related Services, including but not limited to, when performed, clinical treatment planning (e.g., 77261, 77262, 77263), therapeutic radiology simulation-aided field setting (e.g., 77280, 77285, 77290, 77293), basic radiation dosimetry calculation (i.e., 77300), treatment devices (e.g., 77332, 77333, 77334), isodose planning (e.g., 77306, 77307, 77316, 77318), radiation treatment management (e.g., 77427, 77431, 77432, 77435, 77469, 77470, 77499), and associated evaluation and management per course of treatment*. The Agency intends to use this code to describe the range of professional services

associated with a course of SRT, including services similar to those not otherwise separately reportable under CPT guidance and the NCCI manual.

To value this code, CMS is including physician work and any work time associated with radiation management-related services that are typical for a course of SRT. CPT Code 77261 *Therapeutic radiology treatment planning; simple*, CPT Code 77280 *Therapeutic radiology simulation-aided field setting; simple*, CPT Code 77300 *Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician*, CPT Code 77306 *Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)*, CPT Code 77332 *Treatment devices, design and construction; simple (simple block, simple bolus)*, and CPT Code 77427 *Radiation treatment management, 5 treatments*. The Agency is proposing a work RVU of 7.93 for HCPCS code GRRR1.

To develop the proposed direct PE inputs for this code, CMS is proposing to use the RUC recommended direct PE inputs from the aforementioned codes with several adjustments. The Agency proposes to apply the staff type “RN/LPN/MTA” for all of the clinical labor inputs for this code because the Agency believes that the typical office performing SRT will be staffed with this labor type, rather than radiation therapists. CMS seeks comments as to the appropriateness of the staff type “RN/LPN/MTA” for this SRT-related service. Some stakeholders have suggested that many services related to SRT are personally performed by the billing practitioner rather than by clinical staff.

CMS is proposing to remove the supply items "gown, patient" and "pillow case" that are associated with CPT code 77280, as these items are included in the minimum multi-specialty visit pack that is associated with CPT code 77427. The Agency is not proposing to include the equipment items “radiation virtual simulation system,” “room, CT” and “PACS Workstation Proxy” that are associated with CPT code 77280, as the Agency does not believe that a typical office furnishing SRT uses this kind of equipment.

CMS proposes to include additional time for the capital equipment used in delivering SRT in the proposed direct PE inputs. For “radiation dose therapy plan,” the Agency proposes to apply the clinical labor time that is associated with CPT code 77300 to HCPCS code GRRR1 for purposes of developing a proposed value, but it seeks comments as to whether the clinical staff would typically perform the radiation dose therapy planning for this service, or if the physician would perform this and/or other tasks, and, in the case of the latter, what the appropriate physician time would be. Likewise, CMS is soliciting comment as to whether the clinical labor associated with the teletherapy isodose plan would be performed by the physician. The Agency is proposing to assign 14 minutes each to the equipment items “radiation therapy dosimetry software (Argus QC)”, “computer workstation”, and “3D teletherapy treatment planning” as these are the times assigned to these equipment items for CPT code 77300.

ASTRO disagrees with CMS’ proposed G-code to account for the work associated with the

delivery of SRT. It is not clear as to whether this G-Code is billed once per course of treatment, once per lesion, or once per day. This lack of detail could lead to unintended consequences, such as over utilization of the code. A particular concern is that the proposed code does not explicitly make clear the role of the Qualified Medical Physicist (QMP) in the delivery of this bundled service. It is crucial that any course of treatment involving external beam radiation therapy be subject to a quality management process provided by the QMP. It is for these reasons that ASTRO cannot support the establishment of a bundled code, rather we believe that more effort should be made to establish G-codes that are specific to each aspect in the delivery of SRT.

ASTRO has provided guidance in previous comment letters recommending that this issue be addressed through the CPT/RUC process. However, in light of CMS' desire to address this issue through the NPRM, ASTRO supports the establishment of three G-Codes to account for the planning, devices and management related to SRT. We urge CMS to establish a series of three G-Codes based on crosswalks to existing codes. While we believe the work associated with the SRT steps below is not currently described by existing CPT codes, we believe the resources associated with the existing CPT codes below more closely approximates the resources used in these steps of the SRT process of care. Below is a chart depicting the proposed crosswalk:

G-Code Description	Crosswalk Code	RVU Value
GRRR1 – SRT Treatment Planning	77261 – Therapeutic Radiation Treatment Planning; Simple	1.30
GRRR2 – SRT Treatment Device	77332 – Treatment Devices; Simple	0.45
GRRR3 – SRT Treatment Management	99213 Office or Other Outpatient Visit for the Evaluation and Management of an Established Patient	0.97

Technical Corrections for CY 2018 CMS Time File

For CPT code 77767 *Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter up to 2.0 cm or 1 channel*, the CY2016 NPRM time file included the RUC recommended pre-, intra- and post-times, though incorrectly summed the total time (listed as CPT dummy code number 7778A). This error appears to have carried forward. There is no mention of time refinement in text for CY2016 final rule.

CPT Code	CY2018 CMS Time File Total Time	2017 RUC Database Total Time	Difference in Total Time
77767	22	32	-10

ASTRO recommends that the erroneous times for this service be corrected in the CY2018 CMS Time file for the CY2018 Final Rule.

Separate Payment for High Cost Medical Supplies

There are 33 supply items that CMS has priced in excess of \$1,000 and bundled into the practice expense RVU of various CPT codes. The pricing of these supplies should be based on a transparent process, where items are annually reviewed and updated. **ASTRO urges CMS to separately identify and pay for high cost disposable supplies using distinct J codes, rather than bundle supplies into the service described by the CPT codes, so that these expenses may be monitored more closely and paid appropriately.**

CY 2018 Identification and Review of Potentially Misvalued Services

CMS is not proposing a new screen for CY 2018. CMS continues to believe that it is important to prioritize codes for review under the misvalued code initiative. As a result, the Agency is seeking public comment on the best approach for developing screens, as well as what new screens they might consider. They will consider these comments for future rulemaking.

While ASTRO supports the agency's efforts to identify potentially misvalued services, we urge the Agency to pursue this in collaboration with the American Medical Association, as well as the CPT/RUC panels. We would also 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.

Pre-service Clinical Labor for 0-Day and 10-Day Global Services

CMS is seeking comment specifically on whether the standard pre-service clinical labor time of 0 minutes should be consistently applied for 0-day and 10-day global codes in future rulemaking.

ASTRO does not believe the standard pre-service clinical labor time of zero minutes should be consistently applied to 0-day and 10-day global codes. We recommend establishing package options, potentially based on BETOS categories (i.e. minor procedure, major procedure) verses a single standard. We believe the RUC should create a workgroup to discuss practice expense pre service time packages.

Calculation of Malpractice RVUs

CMS collects malpractice insurance premium data from all 50 states, the District of Columbia and Puerto Rico in order to update the Malpractice RVUs for each specialty. Rate filings must

be available from at least 35 states to establish the minimum amount of premium data necessary to establish a malpractice RVU rate.

CMS crosswalks specialties for which there is not sufficient premium data to similar specialties, in order to establish a malpractice RVU. Data for radiation oncology was only available based on 23 states' worth of premium rate filings data. CMS is proposing to cross walk the risk factor for diagnostic radiology to the radiation oncology Malpractices RVU. This would provide radiation oncology with a risk factor of 2.82 for application in the calculation of a Malpractice RVU for the specialty. CMS seeks comments on the calculation of MP RVUs for 2018.

While ASTRO supports the temporary crosswalk to diagnostic radiology for the calculation of malpractice RVUs for the specialty, we are concerned that CMS was unable to collect radiation oncology specific malpractice data from at least 35 states. In 2015, when a similar analysis was performed, radiation oncology malpractice data was collected from 41 states. It seems odd that data could not be collected from at least 35 states, given the number of radiation oncology practices across the country. **ASTRO urges CMS to reevaluate the process for collecting this data, so that more accurate information is available in the future.**

Proposed Payment Rates under the MPFS Schedule for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

In the 2017 Hospital Outpatient Prospective Payment System final rule, CMS finalized new MPFS payment amounts for nonexcepted items and services furnished by nonexcepted provider based departments (PBDs) that bill under the Hospital Outpatient Prospective Payment System. Nonexcepted items and services, as well as nonexcepted providers, are those items and services that are rendered by providers in provider based-departments, that are billed under the HOPPS after November 2, 2015.

The Agency adopted payment rates for these items and services that were based on a 50 percent reduction, also known as the Physician Fee Schedule (PFS) Relativity Adjuster, to the OPFS payment rates for 2017. At the time, CMS stated that the application of the adjuster would be a transitional policy until more precise data became available.

CMS recognizes that the comparison between the OPFS and MPFS rates for other services varies greatly, and that there are other factors, including the specific mix of services furnished by non-excepted PBDs, policies related to packaging of codes under OPFS, and payment adjustments like Multiple Procedure Payment Reductions (MPPRs) and bundling under the PFS that rely on empirical information about whether or not codes are billed on the same day, that contribute to the differences in aggregate payment amounts for a broader range of services. However, for 2018, the Agency again proposes the application of a PFS Relativity Adjuster prior to studying the CY 2017 claims data that might allow them to consider and incorporate many more factors, including the ones stated above.

CMS prepared an analysis comparing 2016 Hospital Outpatient Prospective Payment System (HOPPS) payment rates with 2016 MPFS payment rates and provided a chart detailing the difference in payment for technical services in the top hospital billed codes in the 2018 proposed

rule. Most codes listed indicated that the MPFS payment rate was lower than the HOPPS rate. CPT Code 77386 *Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex* was listed at an estimated MPFS payment amount of \$347.30 compared to a \$505.51 HOPPS payment rate. However, CPT Code 77412 *Radiation Treatment Delivery* was listed as an outlier with the MPFS rate exceeding the HOPPS rate by 38 percent. The variation in radiation oncology code payments demonstrates the complexity of this exercise.

CMS is concerned that the current 50 percent PFS Relativity Adjuster is too small, resulting in greater overall payments to hospitals for non-excepted services furnished by PBDs. For 2018, the Agency proposes to reduce the PFS Relativity Adjuster to 25 percent of HOPPS payment rates. CMS came to this proposed adjustment by performing a code level comparison of the services most commonly billed in the office-campus PBD setting under HOPPS, which is HCPCS code G0463 *Hospital Outpatient Clinic Visit for Assessment and Management of a Patient*. The Agency seeks comment on this proposal and whether a 40 percent PFS Relativity Adjuster should be considered as an alternative

ASTRO urges CMS to retain the 50 percent PFS Relativity Adjuster for another year. The Agency's proposal to reduce the PFS Relativity Adjuster to 25 percent will create instability in the market, potentially creating situations where services are no longer provided due to such a significant reduction in reimbursement. **We urge the Agency to retain the 50 percent PFS Relativity Adjuster for 2018 until data is collected that will allow for the development of a more precise payment methodology.**

Coding Consistency for Radiation Oncology Services

In 2014, major revisions were made to the conventional treatment delivery, intensity modulated radiation treatment (IMRT) delivery and image guided radiation therapy (IGRT) codes. In 2015, CMS declined to assign values in the MPFS to the new conventional radiation treatment delivery, IMRT and IGRT codes. In place of the new codes, CMS created HCPCS G-codes to report many of these services effective January 1, 2015. However, the new conventional radiation treatment delivery, IMRT and IGRT codes were assigned to Ambulatory Payment Classifications (APCs) under the HOPPS. This distinct difference in code classification by payment system will remain in place through 2018, due to the passage of the ASTRO-supported Patient Access and Medicare Protection Act of 2015, which freezes the MPFS payments.

Because the radiation oncology G-codes are not recognized under the HOPPS, CMS is proposing that those nonexcepted items and services denoted by the radiation oncology G-codes that are provided by nonexcepted off-campus PBDs continue to be billed as G-codes with an appended PN modifier. The PFS Relativity Modifier would not apply to these codes and the payment amount would be set to reflect the technical component rate for the G-Codes under the MPFS. ASTRO appreciates CMS' recognition of the Radiation Oncology G-Codes in the MPFS.

Application of Supervision Rules

CMS confirms in the 2018 MPFS proposed rule that supervision rules that apply to hospitals will also apply to nonexcepted off-campus PBDs that furnish nonexcepted items and services.

Direct supervision is required for radiation therapy services provided in the hospital outpatient department. In general and per Medicare regulations, either a physician or a non-physician practitioner may directly supervise hospital outpatient therapeutic services. However, the supervising physician or non-physician practitioner must have within his or her State scope of practice and hospital-granted privileges the ability to perform the service or procedure that he or she supervises. As it specifically pertains to radiation therapy services, many states (as well as hospital privilege guidelines) are likely to limit a non-physician practitioner's scope of practice such that he or she would not be able to serve as a supervisor. The supervisory responsibility is more than the capacity to respond to an emergency. **It is ASTRO's opinion that a board-certified/board-eligible Radiation Oncologist is the clinically appropriate physician to supervise radiation treatments. ASTRO appreciates the Agency's clarification that this policy also applies in nonexcepted off-campus PBDs.**

2019 and Future Years

For 2019 and for future years, CMS intends to examine the claims data in order to determine not only the appropriate PFS Relativity Adjuster(s), but also to determine whether additional adjustments to the methodology are appropriate – especially with the goal of attaining site neutral payments to promote a level playing field under Medicare between physician office settings and nonexcepted off-campus PBD settings, without regard to the kinds of services furnished by particular off-campus PBDs. The Agency seeks comments on potential changes to their methodology that would better account for these specialty-specific patterns.

ASTRO appreciates CMS' desire to achieve an appropriate payment system for off-campus PBDs. We would urge the Agency to do this in an open and transparent manner. It is important for CMS to collaborate with specialties so that it may fully understand the distinct differences in resource costs between off-campus PBDs and HOPPS settings. As an example, the significant fixed costs associated with operating a radiation oncology clinic can be spread throughout a hospital outpatient system. Those fixed costs are the same in off-campus PBDs but they can't be spread across a broader system, so appropriate consideration must be given to ensure that those services are appropriately reimbursed so they remain accessible in the communities they serve.

MACRA Patient Relationship Categories and Codes

The Medicare and CHIP Reauthorization Act (MACRA) requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of physician or applicable practitioner with a patient at the time of care delivery.

MACRA requires CMS to post a list of patient relationship categories and codes by November 1 of each year, beginning in 2018. In preparation for posting the first list by November 1, 2018, CMS seeks comments on the following proposed list of patient relationship categories and codes:

- Continuous/Broad Services

- Continuous/Focused Services
- Episodic/Broad Services
- Episodic/Focused Services
- Only as ordered by another clinician

The Agency is also seeking comment on the application of the following modifiers denoting the new patient relationship categories and codes:

No.	Proposed HCPCS Modifier	Patient Relationship Categories
1x	X1	Continuous/Broad Services
2x	X2	Continuous/Focused Services
3x	X3	Episodic/Broad Services
4x	X4	Episodic/Focused Services
5x	X5	Only as ordered by another clinician

CMS proposes that initially, modifier reporting would be optional and not a condition of payment. This would allow physicians time to incorporate the application of the modifier into their regular practice routine.

ASTRO believes that the Patient Relationship Categories capture the majority of patient relationships for clinicians furnishing care to Medicare beneficiaries. In particular, ASTRO believes that radiation oncologists would fall into the categories of Episodic/Focused or Continuous/Focused based on the diagnosis, comorbidities, and disease progression of a particular patient. However, it is important for CMS to understand that the role of the radiation oncologist, as well as other clinicians, may change during a course of care. Radiation oncologists are involved in many complex diagnoses indicating a need for multidisciplinary and complex care, and, as a result, the physician may vacillate between these two categories over a period of time. ASTRO urges CMS to understand that attribution for these patient categories may be difficult due to these changes, and urges CMS to consider the effects and complexity of attribution when categories may shift based on changes in clinical indications for individual patients.

ASTRO appreciates that CMS plans to initially make the application of the modifier optional. Allowing for a period of technical assistance and education regarding the use of the modifiers will be critical to the success of the program. This will aid providers in correctly identifying and submitting correctly coded HCPCS modifiers on Medicare claims.

CMS Request for Information on Flexibilities and Efficiencies

In the 2018 MPFS proposed rule, CMS seeks recommendations for reducing unnecessary burdens for clinicians, other providers and patients and their families. The Agency states its commitment to increasing quality of care, lowering costs to improve program integrity and make the health care system more effective, simple and accessible. Further, CMS invites public comment on ideas for regulatory, subregulatory, policy, practice and procedural changes to accomplish this goal.

ASTRO appreciates CMS' interest in learning more about ways to reduce unnecessary burdens for clinicians, patients and their families. We agree that reducing these types of burdens results in higher quality care and a more efficient health care system. ASTRO believes there are several areas that CMS must address, including:

MIPS Participation Requirements

We refer the agency to ASTRO's comments on the Quality Payment Program proposed rule for 2018ⁱ. In general, ASTRO urges CMS to recognize that burdensome reporting requirements take away from patient care. We understand that it is important to collect data to determine the quality of patient care delivery, but we disagree with requirements that are onerous and distract from patient care. As an example, the Agency is exploring full year reporting for the MIPS Quality performance category beginning in 2018. Because much of this reporting requires manual input of data, we believe it is unnecessarily burdensome and would urge the Agency to reduce the burden to a 90-day reporting period similar to that of the Advancing Care Information and Improvement Activities performance categories.

We would urge the Agency to make MIPS scoring easier so that physicians can create a business plan that accounts for the reporting requirements. The current scoring methodology is complex and difficult to understand. A more straightforward scoring methodology could be incorporated into practice operations and business plans, yielding greater success for participants. Additionally, **ASTRO urges CMS to work collaboratively with specialty societies in the development of measures.** We believe that this type of collaborative work can yield measures that utilize the most recent clinical guidelines that ensure the most appropriate care pathways.

Further, we would urge the Agency to reconsider requirements that specific types of EHRs be purchased for data reporting. For many practices, the requirements to purchase specific EHRs and then the required frequent upgrades are costly and burdensome. **ASTRO urges the Agency to work with EHR vendors to ensure that their technology can meet reporting requirements. Currently, physicians are penalized if reporting requirements aren't met. This is unfair insofar as they are at the mercy of the products available from EHR vendors.** It would seem more appropriate for CMS to work directly with EHR vendors to ensure that their technology is able to meet CMS designated reporting requirements.

Radiation Oncology Benefit Management (ROBM) Companies

ASTRO believes that it is time for CMS to step in to control the growth of Radiation Oncology Benefit Management (ROBMs) particularly in the Medicare Advantage market. ROBMs that operate on behalf of Medicare Advantage Plans should be required to acknowledge the National and Local Coverage Determinations issued by CMS. These coverage policies are adhered to by the various Medicare Administrative Contractors and they should be adhered to by Medicare Advantage plans.

ASTRO endorses professionally developed and vetted clinical practice guidelines, appropriateness of care criteria and consensus-based model policies developed in a transparent manner with peer review and input as the foundation for clinical decision making. However, too often physicians face overly restrictive ROBM guidelines that oversimplify the process of individual patient management and abrogate the professional judgments that are often only possible within the private boundaries of a direct patient-doctor relationship.

ASTRO has received numerous complaints regarding ROBMs due to increases in denials and delays in preauthorization, treatment or payment. These activities have often caused distressing delays in care for cancer patients, as well as increased costs for providers and their practice staff who must navigate tedious authorization processes. ASTRO members have shared specific accounts of delays in treatment and payment and inadequate peer-to-peer reviews of contested cases. We urge CMS to reign in this activity through its authority to regulate Medicare Advantage plans, as ROBM activity is increasingly burdensome and ultimately jeopardizes the quality of cancer care.

2018 MPFS Proposed Rule Quality Provisions

CMS recognizes in the 2018 MPFS proposed rule the challenges that many eligible professionals face in reporting on PQRS measures. While the Agency proposes not to collect any additional data for the 2016 reporting period, it plans to modify the criteria used to determine successful participation in 2016 PQRS. Therefore, the Agency proposes revisiting the previously finalized PQRS policy to have 2018 PQRS payment adjustments assessed based on satisfactory reporting criteria that are more consistent with the beginning of MIPS.

The Agency proposes to lower the PQRS reporting criteria from 9 measures across 3 domains, where applicable, to 6 measures with no domain or cross-cutting measure requirement for participants who submitted individual measures. While the PQRS and the MIPS are separate programs, **ASTRO believes that this modification would allow for greater continuity between the final year of the PQRS and the beginning of the MIPS.** This would apply to data submitted using claims, a qualified registry, qualified clinical data registry (QCDR), direct EHR reporting, or an EHR data submissions vendor product. CMS believes this proposal will result in fewer negative payment adjustments and no additional burden for eligible physicians. CMS proposes no changes to participants who utilize a measures group, such as the Oncology Measures Group, for reporting.

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,

A handwritten signature in black ink that reads "Laura Thevenot". The signature is written in a cursive, flowing style.

Laura I. Thevenot
Chief Executive Officer