ASTRO
TARGETING CANCER CARE

January 27, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–1601–FC, P.O. Box 8013
Baltimore, MD 21244–1850
Submitted electronically via www.regulations.gov

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals (CMS-1601-FC)

Dear Administrator Tavenner:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals (CMS-1601-FC)" published in the Federal Register as a final rule on December 10, 2013.

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

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

- Treatment Delivery Codes Updated in 2015;
- Changes to Packaged Items and Services;
- Stereotactic Radiosurgery (SRS) Services (APCs 0066 and 0067);
- Intraoperative Radiation Therapy (IORT) Related Services (APCs 0028 and 0065);
- Proton Beam Therapy (APCs 0664 and 0667);

- Interstitial Radiation Source Application (APC 0312); and
- Supervision of Hospital Outpatient Therapeutic Services.

Treatment Delivery Codes Updated in 2015

In a response to a request from CMS to review conventional radiation therapy, Intensity Modulated Radiation Therapy (IMRT), and Image Guidance Radiation Therapy (IGRT) CPT codes, ASTRO, working with the CPT Editorial Panel and the RVS Update Committee (RUC) of the American Medical Association (AMA), is in the process of revising and updating these codes. It is anticipated that the new codes will go into effect on January 1, 2015.

The chart below provides a summary of the anticipated changes to these codes.

SERVICES	CY 2014 REPORTING	ANTICIPATED CY 2015 REPORTING
Conventional Radiation Therapy	12 codes stratified by energy and treatment area	3 codes stratified by treatment area
IMRT	1 code	2 codes stratified by complexity with IGRT bundled
Compensator IMRT	1 category III code	No separate code; report using new IMRT code, simple
IGRT	3 separate codes stratified by modality, reported separately when performed	1 code that describes image guidance and tracking; technical portion bundled into IMRT; when performed with IMRT, report only -26
Tracking	1 cat III code	Bundled into new guidance code

ASTRO believes the structure of these new codes better describes the current process of care for these services, including new technology, and it packages together services typically billed at the same time. Clinical practice has evolved significantly since many of these codes were instituted. The new codes will include code descriptors to better demonstrate the degree of complexity for these treatments. These services are performed in the freestanding and hospital outpatient environments and represent a significant portion of all radiation oncology services. Practice expense inputs for these new codes when performed in a freestanding environment will be reviewed by the RUC. ***ASTRO requests a meeting with CMS to provide guidance and data on the appropriate APC placement of these services when they are performed in the hospital outpatient environment.***

Q1 Conditional Packaging Proposal

In the CY 2014 proposed rule, CMS proposed packaging the following seven new categories of supporting items and services into procedural ambulatory payment classification (APC) payments: drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; drugs and biologicals that function as supplies or devices when used

in a surgical procedure; certain clinical diagnostic laboratory tests; procedures described by add-on codes; ancillary services assigned status indicator "X;" diagnostic tests on the bypass list; and device removal procedures. ASTRO is pleased that CMS did not finalize this proposal for CY 2014. As CMS continues to review this issue, ASTRO urges the agency consider concerns that were raised with the original proposal.

For CY 2014, CMS proposed to delete status indicator "X" and assign ancillary services that are currently assigned status indicator "X" to either status indicator "Q1" or "S." CMS defines services that are proposed to be assigned status indicator "Q1" as including many minor diagnostic tests that are generally ancillary to and performed with another service. CMS proposed that ancillary services, which are assigned status indicator "X," should be packaged when they are performed with another service, but should continue to be separately paid when performed alone.

CMS received considerable opposition from ASTRO and others to this proposed packaging proposal. Commenters responded that this category of services is too varied and the services included are not always ancillary to the services into which they would be packaged. ASTRO strongly opposed the packaging of entire steps in the radiation oncology process of care, such as treatment planning, simulation, and physics. ASTRO supports the agency's goal of aligning incentives so that hospitals provide care in a more efficient manner, but the services identified by CMS are not ancillary. Rather, these services are independent components in the process of care for radiation therapy services.

While CMS will not finalize this proposal for CY 2014, the agency will conduct a reexamination of this group of services to determine which services are best described as ancillary services and should be packaged on that basis, as well as which services should either be packaged under a different policy or separately paid in the hospital outpatient prospective payment system (OPPS). The agency may review the services assigned status indicator ''X'' (ancillary services) to determine which may be appropriate for packaging as ancillary services in the OPPS in future years. ***ASTRO supports CMS' decision not to finalize this proposed packaging policy.***

Stereotactic Radiosurgery (SRS) Services (APCs 0066 and 0067)

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

Historically, ASTRO has believed it is not necessary to distinguish between robotic and non-robotic linac-based SRS through the HCPCS G-codes, and therefore we agree with CMS's decision. ***ASTRO is pleased that CMS is replacing the four existing SRS HCPCS G-codes G0173, G0251, G0339, and G0340 with the SRS/SBRT CPT codes 77372 and 77373.***

The chart below illustrates the crosswalks from the G-codes used in CY 2013 to the CPT codes that will be used in CY 2014.

2013 CPT Code	Descriptor	2013 APC	2013 Payment	2014 CPT Code	Descriptor	2014 APC	2014 Payment
77371	SRS multisource	0127	$3,300.64* ---------- $7,910.51*	77371	SRS multisource	0067	$3,591.65
G0173	Linear acc stereo radsur com	0067	$3,300.64	77372	SRS linear based	0067	$3,591.65
G0251	Linear acc based stero radio	0065	$978.25	77373	SBRT delivery	0066	$1,921.3
G0339	Robot lin-radsurg com, first	0067	$3,300.64				
G0340	Robot lin-radsurg fractx 2-5	0066	$2,354.79				

*Under section 634 of the ATRA of 2012, effective April 1, 2013, payment to rural hospitals, rural referral centers, and sole community hospitals for CPT code 77371 is $7,910.51. Payment to most hospital outpatient facilities is $3,300.64.

ASTRO understands that, by including the G-codes, CMS is ensuring that historical claims data is incorporated into the proposed CY 2014 rates. While we agree with the concept, ASTRO does have some concerns with how the crosswalk is being implemented. ASTRO does not believe that G0251 should be used for rate setting, as it is typically used for fractionated cranial SRS (not for SBRT). There are major differences in the clinical application, methodology, and resource utilization between fractionated cranial SRS and SBRT, and it would be inappropriate to group them in the same APC.

SBRT is a radiation therapy approach that delivers ultra-high-dose radiation to a target within the body, in either a single treatment session or up to approximately five treatment sessions. It is used for the curative management of medically inoperable lung cancer and other complex clinical situations. In contrast, fractionated cranial SRS involves a less resource-intensive technique and has a vastly different clinical focus. The typical patient has one or more brain metastases not amenable to fully aggressive, high-dose single fraction radiosurgery due to the large size of tumor; consequently, the treatment is divided into multiple smaller doses, which greatly reduces the risks associated with small positional errors, and the clinical goal is more likely palliative than curative. ***Therefore, ASTRO does not believe G0251 is clinically homogenous in comparison to SBRT, and as such, is not appropriate for inclusion in the same APC.***

We also believe it is inappropriate to use CPT code 77373 since it was not reported in the OPPS environment in CY 2012. There are only five claims reported, and the accuracy of this data is unclear because it was typically not reported in the OPPS environment.

ASTRO believes that CMS did not appropriately map all the SBRT data for this code transition. ASTRO requests CMS explore further options for setting rates for these services.

Intraoperative Radiation Therapy (IORT) Related Services (APCs 0028 and 0065)

CMS is not finalizing its proposal to delete HCPCS code C9726 for CY2014. They are designating HCPCS code C9726 as an add-on code for payment with CPT Codes 77424 and 77425 -- the primary procedures that involve the intraoperative placement of the applicator into the breast -- consistent with the agency's policy to package add-on codes for CY2014. CMS is revising the code descriptor for HCPCS code C9726 to read: "Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure." The agency is assigning CPT Codes 77424 and 77425 to APC 0065 for CY2014, which has a final geometric mean cost of $1,253 and an APC Payment Rate of $1,248.

ASTRO is concerned with the integrity of the data used to set rates for these IORT services. The number of useable claims in the OPPS for this service is minimal, and it is therefore difficult to maintain stable rates from year-to-year with such limited data. ASTRO also encourages CMS to ensure no payment incentives exist based solely on technology selected.

Proton Beam Therapy (APCs 0664 and 0667)

APC 0664 (Level I Proton Beam Radiation Therapy) includes two procedures: CPT code 77520 (Proton treatment delivery; simple, without compensation) and CPT code 77522 (Proton treatment delivery; simple, with compensation). APC 0667 (Level II Proton Beam Radiation Therapy) also includes two procedures: CPT code 77523 (Proton treatment delivery, intermediate) and CPT code 77525 (Proton treatment delivery, complex).

The payment rates for proton beam radiation therapy services are set annually based on claims data according to the standard OPPS rate-setting methodology. CMS initially proposed to delete APC 0664 and reassign CPT codes 77520 and 77522 to APC 0667 because the agency determined a violation of the two-times rule in APC 0664. A two-times rules violation occurs when the cost of the highest cost significant item or service within an APC group is more than two times greater than the cost of the lowest cost significant item or service within that same group. Using the additional final rule claims data in accordance with the standard OPPS ratesetting methodology, CMS determined that the number of claims for CPT code 77520 is not significant, and, therefore, the two-times rule does not apply within APC 0664 for CY 2014. Instead, CMS will continue the current APC configuration and include simple proton delivery in a separate APC from intermediate and complex proton delivery.

There are significant clinical and resource differences between simple, intermediate, and complex proton beam therapy services and it would not be appropriate to place all three services into a single APC. ***ASTRO is pleased with this decision and thanks the agency for reconsidering this issue. We remain concerned with the instability and unpredictability of***

Medicare payments for proton therapy. The unique nature of this service, and the limited number of sites performing these procedures, continue to raise questions about the statistical reliability of the agency's data. ASTRO recommends that CMS continue to closely monitor this situation and give special consideration to alternative methods for valuing these services.

Supervision of Hospital Outpatient Therapeutic Services

On March 15, 2010, CMS instructed all Medicare contractors not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in critical access hospitals (CAHs) from January 1, 2010 through December 31, 2010. This non-enforcement policy was extended in 2011, 2012, and 2013. CMS notes in this final rule that the non-enforcement instruction for the supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals expires at the end of CY 2013.

The Medicare physician supervision requirements for radiation therapy services in the hospital outpatient environment are of great importance to our membership. ASTRO's mission is to advance the practice of radiation oncology by promoting excellence in patient care, with a strong emphasis on quality and patient safety. ASTRO supports the CMS position that outpatient radiation therapy services must be furnished in hospitals under direct supervision. It is ASTRO's view that the radiation oncologist is always considered the clinically appropriate provider to supervise radiation therapy services.

ASTRO members practice across the country, including rural locations, and we recognize the challenges they face to meet the Medicare supervision requirements. ASTRO urges the agency to closely monitor patient access to radiation therapy in rural areas, and work with stakeholders to ensure that Medicare patients in rural and underserved areas have access to radiation oncology treatments.

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Sheila Madhani, Assistant Director of Medicare Policy at 703-839-7372 or sheilam@astro.org.

Respectfully,

Laura Thevenot

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