



September 5, 2013

Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1601-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically: <http://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 (1601-P)

Dear Administrator Tavenner:

The American Society for Radiation Oncology (ASTRO)¹ 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-P)” published in the *Federal Register* as a proposed rule on July 19, 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 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 proposals that will impact our membership and the patients they serve, including:

- Variety of Problems with the Data Used for Rate-Setting;
- Q1 Conditional Packaging Proposal;
- Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)

¹ ASTRO is the largest radiation oncology society in the world, with 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology, and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly evolving healthcare environment.

(APCs 0066 and 0067);

- Proton Beam Radiation Therapy (APC 0064 and 0067);
- Intraoperative Radiation Therapy (IORT) (APC 0065); and
- Supervision of Hospital Outpatient Therapeutic Services.

Variety of Problems with the Data Used for Rate-setting

In this proposed rule, CMS introduced several significant proposals that would result in a variety of technical changes to the rate-setting methodology used to calculate APC rates. ASTRO has a number of concerns with these proposals.

Problems with Replication

The OPPTS rate-setting methodology is extremely complex. Typically, stakeholders, such as ASTRO, rely on analysts to replicate the CMS methodology as part of their review process. The results are a baseline against which we are able to compare the effects of the proposed policies. There are only a very small number of individuals who have the expertise and hardware capacity to conduct these very specialized analyses. Even in the best scenario, the 60-day comment period is barely sufficient to replicate and analyze results meaningfully. When some of the necessary data is released days or weeks after the posting date of the rule, it is nearly impossible. The volume and complexity of changes in the 2014 proposed rule has required even more time than is typical for the experts to run their replications.

In attempting to replicate the data, there is a general consensus among the analysts in this area that there appear to be potential errors that may have major implications for all of the 2014 OPPTS payment rates. The Virginia-based Moran Company is one of the recognized experts. In a memo to ASTRO, dated August 22, 2013, they stated "...our attempts to replicate the agency's rate-setting methodology, we found numerous issues and inconsistencies which call to question the accuracy and completeness of the CMS published analysis. At minimum, we believe that additional information, clarifications, and potentially corrections are necessary in order to more appropriately document CMS' methodology and allow the public to understand the CMS analysis."² Specifically, they identified issues with:

- Calculation of the geometric mean cost for APC 0634;
- Inconsistent status indicators in CMS published appendices; and
- Treatment of E&M codes and the bypass list.

Note that APC 0634 is newly-proposed for Evaluation & Management services. Any type of calculation error with this APC is of major concern because CMS has proposed to make APC 0634 the base APC in calculating weights of all other APCs. The Moran Company does not believe this is a complete list of issues, but merely those they have been able to identify in the relatively short time available during the comment period. Of significant concern to ASTRO is that these errors have hampered stakeholders' ability to measure the impact of the numerous and complex proposals.

² The Moran Company, "Issues in the CY 2014 Proposed Outpatient Prospective Payment System (OPPTS) Rates-setting Process," August 22, 2013, p.1.

ASTRO urges CMS to delay the conditional packaging proposal (details discussed in the next section of this letter) until issues of potential errors and inconsistencies with the data are resolved.

Q1 Conditional Packaging Proposal

In the 2014 proposed rule, CMS articulates a vision for the direction of the OPSS system. CMS proposes larger payment bundles to maximize hospitals' incentives to provide care in an efficient manner, including a packaging proposal designed to encourage hospitals "to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements." Specifically, CMS proposes to package 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 has significant concerns with the packaging proposal for services assigned status indicator "X." For CY 2014, CMS is proposing 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 proposes 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.

Expansion of Packaging for Radiation Oncology

There are a number of radiation oncology services that have been assigned a Q1 status indicator.

**Radiation Oncology Services Assigned a Q1 Status Indicator
CY 2014 proposed OPSS Regulations**

Code #	Descriptor	Code #	Descriptor
77280	Set radiation therapy field	77326	Brachytx isodose calc simp
77285	Set radiation therapy field	77327	Brachytx isodose calc interm
77290	Set radiation therapy field	77328	Brachytx isodose plan compl
77295	Set radiation therapy field	77331	Special radiation dosimetry
77300	Radiation therapy dose plan	77332	Radiation treatment aid(s)
77301	Radiotherapy dose plan IMRT	77333	Radiation treatment aid(s)
77305	Teletx isodose plan simple	77334	Radiation treatment aid(s)
77310	Teletx isodose plan intermed	77336	Radiation physics consult
77315	Teletx isodose plan complex	77338	Design mlc device for IMRT
77321	Special teletx port plan	77370	Radiation physics consult

ASTRO strongly opposes this CMS proposal to significantly expand packaging of radiation oncology services. Codes assigned a Q1 status indicator, by definition, should be ancillary services. An ancillary service supports the primary service. In contrast, CMS is proposing to package 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.

The services that may be particularly affected are those that, for the sake of maximizing quality of care for the patient, need to occur in a compressed time cycle (sometimes all occurring on the same day) as may be seen with Stereotactic Body Radiation Therapy (SBRT), Stereotactic Radiosurgery (SRS), and brachytherapy. For example, SRS performed using a Cobalt-60-based system (CPT 77371) is often performed and billed on the same day as the treatment planning code 77295. These two services are equally important steps in the process of care, and there is no option to perform SRS without treatment planning—it is mandatory additional work. Thus, if packaged together without separate payment, there would be substantial under-compensation for the resources expended.

The process of care for radiation oncology is firmly established:

Step 1: consultation with the patient;

Step 2: preparing for treatment (treatment planning and simulation);

Step 3: physics and dosimetry quality assurance review and the creation of treatment devices; and

Step 4: treatment delivery.

Additionally, the physician manages the patient throughout the process of care.

The established steps of the process of care are independent components that build on each other. For example, simulation must occur before dosimetric planning. It is this structure that drives when services are performed and reported; thus providing an inherent efficiency to radiation oncology. ASTRO fears that the packaging proposal could make radiation oncology less efficient, the opposite of what CMS is trying to achieve. For example, if services performed on separate days receive separate payments, but they do not receive separate payments if they are billed on the same day, this could create perverse incentives to deliberately perform services that are typically performed on the same day on separate days. This would make the provision of radiation oncology services less efficient in the hospital outpatient department.

The impact of this proposal on physics services is also of great concern to ASTRO and could have far-reaching implications that we believe are inconsistent with agency intentions. Although physics is a sub-specialty and not an ancillary service, CMS has proposed to package all of the medical physics services as if they were ancillary. By packaging physics services, hospitals will be seriously challenged to ensure that the expenses and reimbursements of this sub-specialty are tracked. Once the hospital administration cannot specifically track the reimbursement performance of a line of services, they are likely to eliminate those services. ASTRO fears that

this proposal could jeopardize the culture of safety that has been built around radiation therapy delivery.

A radiation oncology physicist brings a unique perspective to the clinical team in a radiation oncology program: that of a scientist trained in physics, including radiological physics, and also in clinical, basic medical, and radiobiological sciences. A 2010 article in the *New York Times* described the devastating impact on patients when appropriate standards and safety protocols are not followed.³ Physics and the physicist play a critical role in ensuring that radiation therapy is provided in a safe and effective manner. ASTRO believes the reimbursement system should support the provision of high-quality care. We are concerned that this proposal would make it more challenging for hospitals to maintain important evidence-based quality standards that are critical to providing radiation therapy in a safe manner.

Limited Implementation Timeline

ASTRO believes the timeline to implement the packaging proposal is also very problematic. If implemented in CY 2014, the packaging proposal will require significant administrative, billing, and computer system changes across numerous departments to ensure that costs are appropriately documented and services are appropriately billed. Additionally, staff will need to be trained in any new systems and procedures. Hospitals will also need to determine the impact this proposal could have on revenue streams. The final rule is released on or around November 1st and is effective on January 1st, which gives hospitals only about 60 days to interpret, analyze, plan, and implement these changes.

This is not a reasonable timeline. A two-year timeline seems much more appropriate. For example, ASTRO believes that the packaging proposal in its current form has an appropriate level of detail for the public to analyze, investigate, discuss, and comment on for a full regulatory cycle (one year). After this one-year review period, CMS could then publish a thorough proposal with greater analytical detail on implementation and potential impact in the proposed rule for CY 2015 and have the typical 60-day comment period, finalizing the proposal in the CY 2015 final rule.

ASTRO recommends this packaging proposal be studied further before implementation. CMS should publish their packaging analysis so that stakeholders can analyze the components of these new packaged/bundled rates. ASTRO also proposes, at minimum, a two-year implementation timeline.

Impact on Bypass List

It is generally desirable to use the data from as many claims as possible to recalibrate the APC relative payment weights, including those claims for multiple procedures. Single procedure claims are used in rate-setting. As CMS has for several years, they are proposing to continue to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to “pseudo” single procedure claims. Through bypassing specified codes that CMS believes do not have significant packaged costs, they are able to use more data from multiple

³ Bogdanich, Walt. “Radiation Offers New Cures, and Ways to Do Harm.” *New York Times* 23 Jan 2010. Web 2 Sept. 2013.

procedure claims. CMS is proposing to remove from the bypass list the codes that they are proposing to conditionally or unconditionally package in the CY 2014 OPPTS. The following radiation oncology codes are proposed to be removed from the bypass list:

Radiation Oncology Services Proposed to Be Removed From the Bypass List
CY 2014 proposed OPPTS Regulations

Code #	Descriptor	Code #	Descriptor
77300	Radiation therapy dose plan	77327	Brachytx isodose calc interm
77301	Radiotherapy dose plan imrt	77331	Special radiation dosimetry
77305	Teletx isodose plan simple	77336	Radiation physics consult
77310	Teletx isodose plan intermed	77338	Design mlc device for imrt
77315	Teletx isodose plan complex	77370	Radiation physics consult

CMS is also proposing a number of other technical changes related to how costs are calculated for codes on the bypass list.

ASTRO is very concerned with the changes to the bypass list. ASTRO urges CMS to publish the direct impact on rate-setting and the number of usable claims affected by these bypass list changes. Without this information, it is not possible to fully understand the impact of the packaging proposal.

Packaging of Imaging Services Proposal

On a related issue, CMS is contemplating a proposal for CY 2015 that would conditionally package all imaging services with any associated surgical procedures. Imaging services not provided with a surgical procedure would continue to be separately paid according to either a standard clinical APC or a composite APC. CMS is requesting public comments on this potential CY 2015 proposal.

While ASTRO appreciates the request for input, similar to the Q1 packaging proposal, ASTRO believes there is not enough information available to appropriately comment. ***ASTRO requests CMS provide additional details on this proposal so ASTRO can provide meaningful comments.***

Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) 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 G-codes that are priced 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 that it is no longer necessary to distinguish between robotic and non-robotic linac-based SRS through the HCPCS G-codes.

CMS is proposing to replace the four existing SRS HCPCS G-codes G0173, G0251, G0339, and

G0340 with the SRS/SBRT CPT codes 77372 and 77373. CMS believes that utilizing all of the CPT codes for stereotactic radiation treatments (77371, 77372, and 77373) will more accurately capture the distinctions between the various SRS/SBRT procedures.

CY 2013		CY 2014	
HCPCS Code # 2013	Descriptor	HCPCS Code # 2014	Descriptor
77371	SRS multisource	77371	SRS multisource
G0173	Linear acc stereo radsur com	77372	SRS linear based
G0251	Linear acc based stero radio	77373	SBRT delivery
G0339 ⁴	Robot lin-radsurg com, first		
G0340	Robt lin-radsurg fractx 2-5		

ASTRO agrees with CMS that it is not necessary to distinguish between robotic and non-robotic linac-based SRS through the HCPCS G-codes. Historically, this has been the society’s position. ***ASTRO urges CMS to finalize the proposal to replace the four existing SRS HCPCS G-codes G0173, G0251, G0339, and G0340 with the SRS/SBRT CPT codes 77372 and 77373.***

On August 29, 2013, just nine days before public comments were due; CMS posted corrected data files on its website. The SRS and SBRT codes were significantly impacted by these revised files. In fact, while ASTRO appreciates the agency’s efforts to provide stakeholders and the general public with the most accurate information, it is very difficult to conduct a meaningful analysis within such a limited timeframe. Nevertheless, our analysis below is based on this corrected data.

APC 0066 - Level I Stereotactic Radiosurgery

For CY 2014, CPT code 77373 has been assigned to APC 0066. Rate-setting for CY 2014 was based on 2012 claims data from 77373, G0251, G0339, and G0340. Since CPT code 77373 was not reported in the OPSS environment in CY 2012, the bulk of the data comes from the G-codes.

HCPCS Code	SI	APC	Payment Rate	Single Freq.	Total Freq.	Min. Cost	Max. Cost	Median Cost	Geometric Mean Cost
77373	S	0066	\$2,047.86	5	5	\$2,082.12	\$4,927.71	\$2,082.12	\$2,505.82
G0251	S	0066	\$2,047.86	13229	13883	\$212.62	\$7,200.70	\$1,066.43	\$1,106.48
G0339	S	0066	\$2,047.86	8957	9877	\$616.31	\$25,700.23	\$4,131.18	\$3,999.87
G0340	S	0066	\$2,047.86	24269	24501	\$448.81	\$11,595.54	\$2,287.90	\$2,347.38

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 believes that G-codes G0339 and G0340 are the only appropriate codes to be used for rate-

⁴ Although not reflected in the above table (in order to avoid confusion), single session cranial cases currently billed with HCPCS code G0339 would be billed with CPT code 77372 beginning in CY 2014. Any other reporting of HCPCS code G0339 (other than single session cranial cases) would be reported with CPT code 77373 beginning in CY 2014.

setting for APC 0066.

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

ASTRO has more serious concerns regarding the inclusion of G-code G0251, which 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 which 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 similar complex clinical situations. An ablative dose of radiation is administered to an extra-cranial target for the purpose of achieving complete tumor eradication. The treatment involves a resource-intensive combination of patient immobilization, management of breathing-related motion, and near real-time image guidance to ensure precise target relocalization. This level of precision is necessary since there would be a high risk of serious complication with an error of even a few millimeters. Often SBRT patients have limited, if any, other options. The applications of SBRT for lung cancer grew out of the fact that patients with early stage, yet medically inoperable, lung cancer had fairly poor outcomes with conventional radiation therapy; with SBRT, however, rates of survivorship approximately doubled. ASTRO is very concerned that if this important therapy is not accurately valued, access to SBRT for Medicare beneficiaries, particularly lung cancer patients with limited options, may be negatively impacted.

On the other hand, 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 that are not amenable to fully aggressive, high-dose single fraction radiosurgery due to large size; consequently, the treatment is divided into multiple smaller doses, risks associated with small positional errors are greatly reduced, and the clinical goal is more likely palliative rather than curative. Therefore, we do not believe G0251 is clinically homogenous in comparison to SBRT, and as such, not appropriate to be used for inclusion in the same APC. Furthermore, there is obvious resource inhomogeneity in the sense that including G0251 into the same APC would violate the two times rule given that its mean cost (\$1106) is less than half of the mean costs for the G0339 and G0340 codes, which more appropriately represent the cost of SBRT. ASTRO recommends designating a separate APC for G0251 given its clinical and resource utilization differences from the other treatments.

ASTRO believes that CMS did not appropriately map all the SBRT data for this code transition. As such, ASTRO recommends that CMS further analyze the SBRT claims and recalculate the mean/payment rates for this series of services. Specifically, ASTRO recommends excluding costs for G0251 in determining a cost for APC 0066 and suggests that G0251 should be included in a different APC.

APC 0067 - Level II Stereotactic Radiosurgery

For CY 2014, CPT codes 77371 and 77372 have been assigned to APC 0067. Rate-setting for CY 2014 was based on 2012 claims data from 77371 and G0173. While CPT code 77372 has been in existence for several years, it has not been used for paying hospitals under OPPTS. Instead, single fraction cranial radiosurgery using the linear accelerator based technology has been reimbursed with the G-code G0173.

These complex services, with multiple components are being impacted by two different proposed policies. At the same time as CMS is proposing new reporting rules and changes to the APC, these services will potentially be impacted by the proposed packaging policy. The impact of these multiple changes in coding and payment policy on these critical services is not clear. Instability in the payment rates could make it very difficult for hospitals to provide these important services.

ASTRO recommends that CMS should examine its methodology used for rate-setting for the SRS codes. We are also very concerned about the potential implications for packaging other services with the treatment delivery of SRS.

Proton Beam Radiation Therapy (APCs 0664 and 0667)

In CY 2013 the four proton delivery CPT codes are assigned to two separate APCs.

CY 2013 OPPTS Proton Delivery APC Configuration

APC	CY 2013 Rate	CPT Codes
0064 – Level I Proton Beam Radiation	\$1,131.61	77520 - Proton trmt simple w/o comp
		77522 - Proton trmt simple w/comp
0067 – Level II Proton Beam Radiation	\$682.36	77523 - Proton trmt intermediate
		77524 - Proton trmt complex

This rank-order anomaly, where simple proton radiation is priced higher than the more complex proton radiation, is due to flawed data that was used in the CY 2013 rate-setting process. For CY 2014, CMS proposes to collapse all four codes into a single APC with a payment rate of \$984.24. CY 2012 claims data was used to set rates for CY 2014. Based on this updated data, CMS has identified a violation of the two times rule for APC 0064, as the cost of the highest cost item or service within the APC group is more than double the cost of the lowest cost item or service within that same group.

CY 2014 Proposed OPPTS Proton Delivery Cost Data

HCPSCS Code#	2014 APC	2014 Prop Rate	Single Freq.	Total Freq.	Min. Cost	Max. Cost	Median Cost	Geometric Mean Cost
77520	0667	\$988.24	217	218	\$361.61	\$750.37	\$388.15	\$446.24
77522	0667	\$988.24	10647	11260	\$537.74	\$1,567.94	\$874.08	\$895.39
77523	0667	\$988.24	6628	7104	\$790.57	\$1,975.33	\$1,265.35	\$1,206.04
77525	0667	\$988.24	436	547	\$879.80	2,769.32	\$1,214.54	\$1,192.79

The actual medical services described by the various CPT codes are as follows:

- Simple proton treatment delivery is to a single treatment area utilizing a single non-tangential/oblique port, custom block with compensation (77522) and without compensation (77520).
- Intermediate proton treatment delivery (77523) is to one or more treatment areas utilizing two or more ports or one or more tangential/oblique ports, with custom blocks and compensators.
- Complex proton treatment delivery (77525) is to one or more treatment areas utilizing two or more ports per treatment area with matching or patching fields and/or multiple isocenters, with custom blocks and compensators.

ASTRO does not agree with CMS's proposal to place all four proton beam therapy codes into a single APC since there are significant clinical and resource differences between simple, intermediate, and complex proton beam therapy services. The new proposed payment rate does not reflect the resources used for the more complex treatment codes.

For example, a complex treatment for a pediatric patient with medulloblastoma is a lengthy procedure. It typically involves general anesthesia for the patient and a resource-intensive treatment session in which there can be numerous intra-session table position adjustments and apposition of multiple individual treatment beams. These steps require personnel time and equipment utilization that greatly exceeds what is involved in a simple treatment that might involve only one table position adjustment and a single beam of treatment. ASTRO requests that CMS strongly consider retaining at least two levels of proton therapy treatment delivery to account for the wide differences in resource intensity among the types of treatment commonly given.

In proposing the rates for CY 2014, CMS followed standard rate-setting procedures. In this instance, it is inappropriate; however, since simple, intermediate, and complex proton beam therapy services are not clinically homogenous. Therefore, they should *not* be placed in the same APC, despite what the cost data appears to show.

ASTRO remains concerned with the instability and unpredictability of the CMS payments for proton therapy. The unique nature of this service, and the limited number of sites performing the procedures, continue to raise questions about the statistical reliability of the agency's data.

ASTRO does not agree with CMS's proposal to place all four proton beam therapy codes into a single APC since there are significant clinical and resource differences between simple, intermediate, and complex proton beam therapy services. The new proposed payment rate does not reflect the resources used for the more complex treatment codes. ASTRO also recommends that CMS continue to explore alternative payment methodologies for proton services in the OPPTS setting.

Intraoperative Radiation Therapy (IORT) Related Services

CMS is proposing to delete HCPCS code C9726 (Placement and removal (if performed) of applicator into breast for radiation therapy) effective January 1, 2014. In 2013, if reported, this code was eligible for separate payment. This will impact IORT delivery services.

In 2012 two IORT delivery codes were established.

- CPT code 77424 (IORT delivery, x-ray, single treatment session); and
- CPT code 77425 (IORT delivery, electrons, single treatment session).

According to CMS, CPT codes 77424 and 77425 “describe the placement and removal (if performed) of an applicator into the breast for radiation therapy, as well as the delivery of radiation therapy when performed intraoperatively.” CMS, therefore, believes HCPCS code C9726 is no longer required, and CMS is proposing to delete HCPCS code C9726, effective January 1, 2014. Under this proposal, hospitals would report the costs of the services that were previously reported with HCPCS code C9726, as well as the delivery of radiation therapy when performed intraoperatively with CPT code 77424 or 77425.

ASTRO is concerned with the integrity of the data used to set rates for these IORT services. The number of useable claims in the OPSS for this service is very minimal (0 for 77424 and 5 for 77425). It is 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.

Supervision of Hospital Outpatient Therapeutic Services
Enforcement Instruction for Supervision of Outpatient Therapeutic Services in CAHs and Certain Small Rural Hospitals

On March 15, 2010, CMS instructed all Medicare contractors not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs from January 1, 2010 through December 31, 2010. This non-enforcement policy was extended in 2011, 2012, and 2013. CMS notes in this proposed rule that it expects to allow the non-enforcement instruction for the supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals to expire 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. If CMS allows the non-enforcement policy to expire at the end of CY 2013, as indicated in the proposed rule, ASTRO urges the agency to closely monitor patient access to radiation therapy in rural areas. We encourage CMS to continue to work with stakeholders to ensure that Medicare patients in rural and underserved areas are not inappropriately excluded from receiving crucial radiation oncology treatments.

On a related supervision issue, CMS generally defers to hospitals to ensure that the state scope-of-practice and other state rules relating to healthcare delivery are followed, such that these services are performed only by qualified personnel in accordance with all applicable laws and regulations. CMS is proposing to revise the existing regulations to explicitly require that individuals who perform hospital or CAH outpatient therapeutic services must do so in compliance with applicable state laws and regulations as a condition of payment under Medicare Part B. ASTRO appreciates the agency's efforts to reduce the administrative burden on hospitals by explicitly aligning Medicare regulations with state laws. It is ASTRO's interpretation of this policy that it does not in any way impact the agency's supervision policy for hospital outpatient therapeutic services.

If this policy is finalized, ASTRO requests CMS to confirm this understanding.

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,

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