September 4, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1589-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations (CMS-1589-P)

Dear Ms. Tavenner:

The American Society for Radiation Oncology (ASTRO)\(^1\) appreciates the opportunity to provide written comments on the “Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations (CMS-1589-P)” published in the *Federal Register* as a proposed rule on July 30, 2012.

ASTRO members are medical professionals, 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 three proposals that will impact our membership and the patients they serve including:

- Intraoperative Radiation Treatment (IORT);
- Proton Beam Therapy; and
- Device Construction for Intensity Modulated Radiation Therapy (IMRT).

\(^{1}\) 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.
Intraoperative Radiation Therapy (IORT) (APC 0412)

The 2012 CPT® code book includes two new codes that describe IORT delivery: 77424 Intraoperative radiation treatment delivery, x-ray, single treatment session and 77425 Intraoperative radiation treatment delivery, electrons, single treatment session. This technology has been around for many years. ASTRO submitted the original CPT code application for the IORT codes and is supportive of the technology and the potential advantages that are provided to a selected subgroup of women with early stage breast cancer and other intrabdominal and head and neck cancers. For CY 2012, CMS assigned status indicator (SI) “N”, items and services packaged into APC rate, to the two new IORT delivery codes. The assignment of SI “N” means there is not a separate payment for the service in the hospital outpatient environment.

CMS is proposing to unpackage both codes and assign them to APC 0412 (IMRT Treatment Delivery). CMS agreed with recommendations from ASTRO and other stakeholders that IORT services are not the typical intraoperative services that are normally packaged into the surgical procedure in the outpatient environment, as they are not integral to or dependent upon the surgical procedure to remove a malignancy that precedes IORT. The 2013 proposed payment rate for APC 0412 is $483.63.

<table>
<thead>
<tr>
<th>HCPCS/ CPT</th>
<th>Short Descriptor (from 2013 file)</th>
<th>2013 APC</th>
<th>2013 Payment Rate</th>
<th>2012 Payment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>77424</td>
<td>Io rad tx delivery by x-ray</td>
<td>0412</td>
<td>$483.63</td>
<td>N/A</td>
</tr>
<tr>
<td>77425</td>
<td>Io rad tx deliver by elctrns</td>
<td>0412</td>
<td>$483.63</td>
<td>N/A</td>
</tr>
<tr>
<td>77469</td>
<td>Io radiation tx management</td>
<td>Not Paid</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

For CY 2013, CMS is also proposing to assign a status indicator “B” to CPT code 77469 (Intraoperative radiation treatment management). Codes with status indicator “B” (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type [12x and 13x]) are not paid under the OPPS. This is consistent with other radiation oncology management codes like 77431 (Radiation therapy management with complete course of therapy consisting of 1 or 2 fractions only) and CPT code 77432 (Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)). ASTRO believes that assignment of status indicator “B” to CPT code 77469 is appropriate.

ASTRO appreciates CMS’ proposal to “unpackage” IORT services for CY2013. However, ASTRO recommends that CPT codes 77424 and 77425 be placed in APC 0313 (Brachytherapy) and not APC 0412 (IMRT Treatment Delivery). The CY 2013 proposed payment for APC 0313 is $685.02. APCs are assigned on the basis of clinical and resource use similarity. ASTRO believes that IORT is more similar to the services assigned to the brachytherapy APC than the IMRT APC. To illustrate our point, the chart that follows lists the services CMS proposes to assign to each APC for CY 2013.
Intraoperative radiation therapy (IORT) is a type of radiation therapy in which radiation is delivered in a single dose at the time of surgery. A concentrated beam of radiation is delivered to cancerous tumors while they are exposed during surgery. Similarly, brachytherapy is a form of radiotherapy where a radiation source is placed inside or next to the area requiring treatment. As these descriptions illustrate, both brachytherapy and IORT target the cancerous tumor from inside the body. In contrast, IMRT, a form of external beam radiation therapy, delivers radiation from outside the body.

ASTRO also considered the issue of resource use similarity. There are multiple technologies that can be used to deliver IORT services. ASTRO does believe that there is validity to the proposition to assign IORT to the brachytherapy APC. One of the systems that is currently approved by the FDA for x-ray beam-based IORT was initially approved via the 510(k) mechanism whereby they demonstrated substantial equivalence to HDR brachytherapy devices. The FDA recognized that the technical performance characteristics were essentially identical in terms of the ability to produce a distribution of radiation dose within patients that mimicked HDR brachytherapy. Indeed, the x-ray based IORT systems may be used for the delivery of fractionated breast brachytherapy, typically billed as 0182T which falls under APC 313.

Our comments today reflect the factors we believe CMS should consider when valuing this service in the hospital outpatient environment, pricing it appropriately and avoiding perverse incentives. It is possible that CMS will collect cost data that ultimately indicates that IORT should be placed in a different APC than 0313, especially IORT given with an electron beam system, where there is a higher initial equipment cost and that might not be evenly offset by the typically shorter beam-on time for dose delivery (compared to x-ray based IORT), nevertheless our recommendation today is based on currently available evidence.

**ASTRO is very pleased CMS has proposed to unpack IORT services. We disagree with the proposed assignment of IORT services (CPT codes 77424 and 77425) to APC 0412 IMRT Treatment Delivery. ASTRO believes that IORT is much more similar to brachytherapy services and urges CMS to assign CPT codes 77424 and 77425 to APC 0313 Brachytherapy.**

**Proton Beam Therapy (APCs 0664 and 0667)**
The proposed proton beam therapy payment rates for CY 2013 reflect significant reductions from CY 2012. Based on claims data, for CY 2013 CMS is proposing to reassign CPT code 77522 to APC 0667 and to reassign CPT code 77525 to APC 0664. CMS stated that only three providers bill Medicare for these proton services and their payment rates may fluctuate significantly from year to year. CMS went on to say the estimated cost of APC 0667 decreased
substantially, which is largely attributable to cost changes for CPT code 77523. The claims sample for proton services is small, ranging from 185 claims for 77520 to almost 14,000 claims for 77522. In contrast, the proposed rate for IMRT (CPT code 77418) is based on over 1 million claims. ASTRO is very concerned that CMS is proposing significant payment changes based on such a small number of providers and claims. ASTRO recommends that CPT code 77522 remain in APC 0664 for 2012 and that CPT code 77525 remain in APC 0667 for 2012.

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<table>
<thead>
<tr>
<th>HCPCS/ CPT</th>
<th>Short Descriptor (from 2013 file)</th>
<th>2013 APC</th>
<th>2013 Payment Rate</th>
<th>2012 Payment Rate</th>
<th>% Change in Payment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>77520</td>
<td>Proton trmt simple w/o comp</td>
<td>0664</td>
<td>$450.40</td>
<td>$1,183.77</td>
<td>-61.95%</td>
</tr>
<tr>
<td>77522</td>
<td>Proton trmt simple w/comp</td>
<td>0667</td>
<td>$1,110.23</td>
<td>$1,183.77</td>
<td>-6.21%</td>
</tr>
<tr>
<td>77523</td>
<td>Proton trmt intermediate</td>
<td>0667</td>
<td>$1,110.23</td>
<td>$1,548.54</td>
<td>-28.30%</td>
</tr>
<tr>
<td>77525</td>
<td>Proton treatment complex</td>
<td>0664</td>
<td>$450.40</td>
<td>$1,548.54</td>
<td>-70.91%</td>
</tr>
</tbody>
</table>

**Proposed CY 2013 APC Assignments Create Rank Order Anomaly**

As discussed in the previous section of this letter, APCs are grouped based on clinical and resource use similarities. The proposed proton beam therapy APC assignments are inappropriate, illogical, and create a rank order anomaly in the family. CPT code 77525 represents a complex proton service. Based on the CY 2013 proposed rates, this complex service is now valued less than CPT code 77523 (proton treatment intermediate) and 77525 is now in the same APC as the simple treatment without compensator (CPT code 77520).

When considering the actual medical service described by the various CPT codes, the CY 2013 APC assignments are clearly not appropriate.

- **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.

In proposing the rates for CY 2013, CMS followed standard rate setting procedures. In this instance it is inappropriate, however, since simple 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 appear to show.

ASTRO believes this provides further evidence of the inappropriateness of these proposed APC assignments.
Potential Problems with Claims Data

Of the three providers reporting this service, one started reporting proton therapy in 2010. The chart below summarizes recent claims history for CPT code 77525. From the chart, it is clear that starting in 2010 the frequency of the service increased significantly. In that same year the median cost of the service dropped drastically. There is no logical reason for this sharp drop in median costs. When initially discovered, ASTRO questioned the integrity of that institution’s data and concluded that CMS should carefully review the data, both claims and cost reports, for anomalies.

<table>
<thead>
<tr>
<th>Claims Year</th>
<th>Rule Year</th>
<th>APC</th>
<th>Payment</th>
<th>Single Freq</th>
<th>Total Freq</th>
<th>Median Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>2013p</td>
<td>664</td>
<td>$450.40</td>
<td>1,400</td>
<td>1,591</td>
<td>$477.87</td>
</tr>
<tr>
<td>2010</td>
<td>2012f</td>
<td>667</td>
<td>$1,548.82</td>
<td>1,036</td>
<td>1,378</td>
<td>$477.87</td>
</tr>
<tr>
<td>2009</td>
<td>2011f</td>
<td>0667</td>
<td>$1,349.61</td>
<td>230</td>
<td>320</td>
<td>$1,418.33</td>
</tr>
<tr>
<td>2008</td>
<td>2010f</td>
<td>0667</td>
<td>$1,232.67</td>
<td>483</td>
<td>612</td>
<td>$1,297.42</td>
</tr>
</tbody>
</table>

This speculation was confirmed on August 27, 2012 during the semi-annual meeting of the Advisory Panel on Hospital Outpatient Payment. The Alliance of Dedicated Cancer Centers made a presentation on the CY 2013 proposed rates for proton treatment to the Panel. The Cancer Centers examined the underlying claims and cost report data to uncover why CMS cost estimates for CY 2013 differed from that of past years. The Cancer Centers found that the third provider, who began reporting the proton beam codes in 2010, had been reporting the costs and charges for the proton beam therapy codes to the wrong cost center in their cost reports. This error was confirmed in public comments by the CFO of this provider who was in the audience. This representative also informed the Panel that they have submitted revised claims and cost reports.

The Panel concluded that CMS does not have sufficient data to implement such drastic changes and that the data they did have was now found to be flawed. ASTRO was pleased to see that the Panel recommended that CMS maintain the CY 2012 APC configurations and CY 2012 rates.

ASTRO agrees with the Panel’s conclusion that CMS should not use flawed data to set rates for proton beam therapy services. CMS’ payment systems should be relatively consistent and not have unexpected dramatic swings in payment from year to year. That, coupled with the question of data integrity from one of the institutions and the fact that payment rates for this cancer service are based on only three institutions, supports maintaining the 2012 APC assignments for these services. Since CMS strives to create a stable payment system for providers, it should not implement the proposed proton beam therapy APC 0664 and 0667 reconfigurations for CY 2013 without first resolving the proposed 6.2 - 70.9% payment decreases for these services.
During the Panel meeting several options were considered: maintaining CY 2012 APC configurations and CY 2012 rates, removing the incorrect data from the rate setting methodology and re-running the numbers, and replacing the incorrect data with the corrected data in the rate setting methodology and re-running the numbers.

**ASTRO recommends that CMS work with all three providers reporting proton beam services in the OPPS environment and come to a solution that is based on accurate data and that is technically possible to implement in time for the release of the CY 2013 final rule. If it is not technically feasible to use the corrected data from the third provider, ASTRO believes the most reasonable alternative would be to use data from the remaining two providers in setting rates for proton beam therapy in the hospital outpatient setting for CY 2013.**

CMS followed standard rate setting procedures when developing the proposed rates for proton beam therapy. This recent experiences illustrates that this may not always be appropriate.

**ASTRO recommends CMS to consider exception policies to standard rate setting procedures when significant swings in payment result when rates are based on either a small number of providers or a small number of claims.**

**Device Construction for Intensity Modulated Radiation Therapy (IMRT)**

CPT code 77338 (Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan) was first established in CY 2010, and CY 2012 was the first year that claims data was available for rate setting. Based on claims data, in the 2012 final rule CMS reassigned CPT code 77338 from APC 0310 to APC 0305. The CY 2012 payment of $263.83 represented a 72% decrease from the 2011 rate. For CY 2013, CMS proposes to maintain the assignment of CPT Code 77338 to APC 0305.

<table>
<thead>
<tr>
<th>HCPCS/CPT</th>
<th>Short Descriptor (from 2013 file)</th>
<th>2013 APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>77338</td>
<td>Design mlc device for IMRT</td>
<td>0305</td>
</tr>
</tbody>
</table>

**Concerns with Claims Data for CPT Code 77338**

ASTRO provided extensive comments to CMS for the 2012 outpatient rules (proposed and final) outlining concerns with the provider data for this service. The Society believes the data indicates that providers are not coding appropriately for the service, resulting in flawed claims data. For example, in the data provided with both the proposed and final rules, the estimated cost for CPT code 77334, which represents the cost of a single device, was greater than the estimated cost for CPT code 77338, which represents the cost of all devices in a single IMRT plan of treatment. While CMS acknowledged that this was peculiar, they still finalized the proposal which assigned the APC placement of CPT code 77338 based on CY 2010 claims data.

We also noted previously that approximately 25% of claims for CPT code 77338 were not used in rate setting because CPT code 77418 likely was billed on the same day. In the CY2013
proposed rule, CMS is proposing to bypass 480 HCPCS codes (identified in Addendum N) for CY 2013 and 77338 is one of the newly added codes to the bypass list. While adding CPT code 77338 to the bypass list does increase the number of claims that can be used for rate setting, it does not resolve the issue of flawed claims data since we believe that providers are not coding appropriately.

Comparison to CPT Code 77334 (Radiation treatment aid)
For CY 2011, CMS developed a simulated cost for one unit of CPT code 77338 by using the frequency information they acquired from an internal study and the median cost of one unit of CPT code 77334 (Radiation treatment aid). CMS assumed that if a total of eight devices were typically furnished across two treatments, then approximately four devices were furnished for each treatment (results from CMS internal study). CMS assumed that the cost of each device for IMRT would be approximately the same as a single unit of CPT code 77334 because one unit of CPT code 77334 represents one device. Therefore, CMS estimated that the cost of the devices reported by one unit of CPT code 77338 would be approximately $792 (four devices at an estimated per device cost of $198 each). For CY2013 the median cost for CPT code 77334 is $230. Based on CMS prior methodology, the appropriate simulated cost for CPT code 77338 would be $920.

ASTRO recommends that CMS use their previous simulated methodology for CPT code 77338 and assign CPT code 77338 to APC 0310 (Level III Therapeutic Radiation Treatment Preparation) for 2013. The CY 2013 proposed APC rate for APC 0310 is $984.86. The simulated cost lines up with the medians for the other radiation oncology codes in APC 310 for CY2013.

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, ASTRO Health Policy Department at (703) 839-7372 or sheilam@astro.org.

Respectfully,

Laura I. Thevenot
Chief Executive Officer