August 29, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted electronically: http://www.regulations.gov

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated with Submitted Data (1613-P)

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; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated with Submitted Data" published in the Federal Register as a proposed rule on July 11, 2014.

ASTRO members are medical professionals practicing 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 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.

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

- Comprehensive APC Policy (SRS and IORT);
- Stereotactic Body Radiation Therapy (SBRT) (77373);
- Proton Beam Therapy (77520-77525);
- Low Dose Rate (LDR) Prostate Brachytherapy Composite APC;
- Proposal to Modify the Current Process for Accepting New and Revised CPT Codes that Are Effective January 1;
- Insert Uteri Tandem/Ovoids (57155); and
- Understanding Different Resource Costs among Traditional Office, Facility and Off-Campus Provider-Based Settings.

Comprehensive APC Policy (SRS and IORT)

The policy for comprehensive APCs (C-APCs) was finalized in the CY 2014 final OPPS rule. Under the C-APC policy, CMS provides a single payment for all services on the claim regardless of the span of the date(s) of service. Conceptually, the C-APC is designed so there is a single primary service on the claim, identified by a status indicator (SI) of J1. All adjunctive services provided to support the delivery of the primary service are included on the claim. The payment is calculated to capture the costs associated with all of these services.

The C-APC advances CMS's desire to establish a single bill for a service rather than individual bills for the components of that service. These new APCs will count all items on the same claim (across multiple days) to be part of the service package and will thus not render separate payment for conditionally packaged codes or other services (with the exception of preventive care) that appear anywhere on the same claim. For CY 2015, these new C-APCS will apply to what had previously been called "device dependent" APCs, as well as a few other types of services.

CMS believes that the C-APCs will improve the validity of payments to more accurately reflect true costs, reduce the administrative burden, and improve transparency for the beneficiary, physicians, and hospitals. For CY 2015, CMS proposes two radiation oncology-related C-APCs: C-APC 0067 for single-session cranial stereotactic radiosurgery (SRS) and C-APC 0648 (Level IV Breast and Skin Surgery) for intraoperative radiation therapy treatment (IORT). For C-APC 0648, CMS reassigned CPT codes 77424 (Io rad tx delivery by x-ray) and 77425 (Io rad tx deliver by elctrn) to C-APC 0648.

Stereotactic Radiosurgery

CMS proposes to rename APC 0067 from "Level II Stereotactic Radiosurgery" to "Single Session Cranial Stereotactic Radiosurgery", which they are proposing as a C-APC. The proposed 2015 payment rate for C-APC 0067 is $9,767.98 in comparison to the 2014 rate of $3,591.65. While this represents an increase of 271.96 percent, it is important to remember the payment includes all adjunctive (or associated) services listed on the claim provided to support the primary service. This new C-APC will contain CPT codes 77371 (SRS multisource) and 77372 (SRS linear based). In addition to the primary SRS service, it includes other related services such as MRI, physics consult, and treatment planning, in addition to the stereotactic radiosurgery procedures.

Intraoperative Radiation Therapy (IORT)

For CY 2015, CMS proposes to assign IORT CPT codes 77424 and 77425 to C-APC 0648 (Level IV Breast and Skin Surgery). CMS's rationale is that IORT is a single session comprehensive service that includes breast surgery combined with a special type of radiation therapy that is delivered inside the surgical cavity but is not technically brachytherapy. The proposed rate for C-APC 0648 is $7,329.67. In CY 2014, IORT services are assigned to APC 0065 with a payment rate of $1,248.28. Again, while this represents a payment increase of 487.18 percent, it is important note that the payment includes the IORT, surgery, and all other adjunctive services listed on the claim provided to support the primary service.

Concerns with C-APC Methodology

ASTRO appreciates the agency's efforts to develop a more accurate payment system. In recent years the OPPS system has moved toward bundled payments, putting pressure on hospitals and physicians to eliminate redundant or inappropriate care and become more efficient. ASTRO supports policies that promote efficiency and the provision of high quality care. However, in this letter we raise a number of questions about the proposed C-APC as it relates to SRS and IORT services. ASTRO urges CMS to delay finalizing APC 0067 and 0068 until these issues are resolved.

- *Potential misalignment between hospital billing practices and C-APC policy*: Under the C-APC policy there is a single payment rate for the primary service and all adjunctive services listed on the claim. An underlying assumption of this policy is that the hospital is reporting all services related to the primary service on a single claim.
  This assumption does not necessarily apply to radiation therapy services. ASTRO has found that the protocol for billing for radiation therapy services varies considerably by hospital. Many hospitals bill monthly, others weekly, and a small number bill daily. ASTRO is concerned that current hospital billing practices are not consistent with the proposed C-APC policy. This lack of alignment will make it nearly impossible for CMS to establish accurate rates for services. Even with hospitals that bill on a monthly basis, if the service started at the end of the month and then continued to the beginning of the following month, services could be split into multiple claims. Additionally, these claims may include other services not related to the primary service. These unrelated services could be eligible for separate payment under the OPPS system, but if listed on a claim with a C-APC, they would be inappropriately bundled into the primary service and would not receive separate payment.

  ASTRO has significant concerns about the misalignment between hospital billing practices and the C-APC policy. We believe it hinders CMS from providing accurate payments for services and it causes uncertainty and confusion for providers on appropriate billing protocols. The proposal is administratively burdensome as it would require hospitals to completely overhaul existing billing protocols or develop distinct billing protocols for certain services reported to a specific payer.

- *Lack of transparency in the establishment of proposed CY 2015 C-APC rates*: Typically, CMS has provided clear straightforward information on the data used to calculate payment rates in the OPPS environment. In its addendum to the OPPS rule, CMS provides aggregate claims data on individual HCPCS codes, crosswalks of which HCPCS codes are assigned to an APC, and in the case of composite APCs, the specific codes used to calculate that rate. In the case of the C-APCs 0067 and 0648, there seems to be a significant absence of this data. CMS did not provide information on what services were packaged into the C-APC and used to calculate the proposed rate. Nor was any information provided on the criteria used to determine which services were considered adjunctive to the primary service. ASTRO urges CMS to provide more detail on the methodology used to develop C-APC rates.

ASTRO appreciates CMS' attempt to refine the OPPS in order to develop accurate payment rates. However, we believe that a more thorough analysis of this proposal must be conducted prior to its implementation. ASTRO urges CMS to address the concerns raised by ASTRO and other stakeholders before finalizing this proposal.

Stereotactic Body Radiation Therapy (SBRT) (77373)

In 2001, CMS began using G-codes for Stereotactic Radiosurgery (SRS) in the hospital outpatient environment. G-codes distinguish between robotic and non-robotic methods of delivery. After reviewing the current literature, CMS concluded it was no longer necessary to make this distinction. As a result, in CY 2014, CMS discontinued the use of G-codes G0173 (Linear acc stereo radsur com), G0251 (Linear acc based stero radio), G0339 (Robot lin-radsurg com, first), and G0340 (Robt lin-radsurg fractx 2-5) and established APC rates for CPT codes 77372 (SRS multisource) and 77373 (SBRT delivery). ASTRO supported this decision.

In order to establish a payment rate for CPT code 77373, which was assigned to APC 0066, CMS cross walked claims data from G-codes G0251, G0339, and G0340. In our comments on the CY 2014 final

OPPS rule, ASTRO stated that we understood that by including the G-codes, CMS was ensuring that historical claims data was incorporated into the proposed CY 2014 rates. While we agreed with the concept, ASTRO had and continues to have major concerns with how the rate for APC 0066 was calculated.
ASTRO does not believe that G0251 should be used for rate setting for CPT code 77373, 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. ***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. ASTRO requests CMS remove claims data for G-code G0251 from rate setting for CPT code 77373.***

Proton Beam Therapy (77520-77525)
In CY 2014, 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).

CPT Code 77520
For CY 2015, CMS is proposing changes to the APC configuration for proton services. The agency proposes to reassign CPT code 77520 from APC 0664 to APC 0412 (Level III Radiation Therapy). This reassignment will correct a violation of the two times rule within APC 0664 (Level I Proton Beam Radiation Therapy).

ASTRO has supported the historical groupings of the proton therapy CPT codes based upon the homogeneity of the services. Having said that, given the relative geometric mean of CPT 77520, we believe that the reassignment of CPT 77520 to APC 0412 would be appropriate. While there are significant differences (especially in the clinical nature of the services) between CPT 77520 and the other codes that are packaged into APC 0412, the relative geometric mean for APC 0412 is a reasonable reflection of the relative geometric mean for simple proton beam treatment. ***ASTRO supports the reassignment of CPT code 77520 from APC 0664 to APC 0412 and encourages CMS to finalize this proposal.***

CPT Codes 77522, 77523, 77525
CMS is also proposing to reassign CPT code 77522 from APC 0664 to proposed newly renamed APC 0667 (Level IV Radiation Therapy). CMS is proposing to delete APC 0664 for CY 2015 and rename existing APC 0667 to "Level IV Radiation Therapy" (instead of using the existing title of "Level II Proton Beam Radiation Therapy"). In conjunction with this proposed change, CMS is proposing to reassign the following three services to proposed newly renamed APC 0667 for CY 2015: CPT codes 77522, 77523, and 77525.

ASTRO does not believe reassigning CPT code 77522 into APC 0667 along with CPT codes 77523 and 77522 is appropriate. ASTRO recommends that CMS maintain CPT code 77522 in APC 0664. We make this recommendation on the basis of both resource use and clinical similarity. We believe that there are significant differences in the clinical nature and resource intensity of the codes. We are concerned that the current CMS proposal would result in inappropriate groupings of services. ***ASTRO recommends CMS maintain the current assignment of CPT code 77522 to APC 0664.***

ASTRO fully supports the on-going inclusion of intermediate and complex proton treatment into APC 0667. Significantly, the geometric mean cost, resources and clinical nature of these services are relatively

similar. Notably, under our recommendation, the geometric mean for the CPT codes within APC 0667 would range by less than 2 percent. ***ASTRO agrees with the CMS proposal to assign CPT codes 77523 and 77525 into APC 0667 and urges CMS to finalize this proposal.***

Low Dose Rate (LDR) Prostate Brachytherapy Composite APC 8001

In the hospital outpatient setting, CMS provides a single payment, known as a composite APC, for Low Dose Rate (LDR) prostate brachytherapy when CPT codes 55875 (Transperi needle place pros) and 77778 (Apply interstit radiat compl) are furnished in a single hospital encounter. CMS bases the payment for composite APC 8001 (LDR Prostate Brachytherapy Composite) on the geometric mean cost derived from claims for the same date of service that contain both CPT codes 55875 and 77778. For CY 2015, CMS is proposing a rate of $3,504.02, in comparison to the 2014 rate of $3,884.64. This represents an almost 10 percent decrease for APC 8001 in 2015.

ASTRO is very concerned about this proposed payment rate reduction. Significant year to year swings in payment can be very problematic for providers. It is also notable that the 2015 rate is based on just 379 claims (2013 claims data). In comparison, the 2014 rate was based on 1,487 claims. Small data sets, like this one, can be much more vulnerable to outliers. ***ASTRO urges CMS to identify the reasons for this drop in claims volume. We also request CMS to monitor this APC closely. If the volume of the claims data for this composite APC continues to drop, alternative rate setting methods may need to be explored.***

Proposal to Modify the Current Process for Accepting New and Revised CPT Codes that Are Effective January 1

CMS is proposing to modify the process they use to recognize new and revised CPT codes. In the current OPPS process, CMS issues interim APC rates for all revaluations and new codes in the final rule, and makes payment based upon those values during the calendar year covered in the final rule. Although the code valuations are interim and open for comment, providers and other stakeholders have limited time to prepare for or provide public comment before the values are implemented. The current process lacks transparency and severely limits opportunities for public input. ASTRO is very pleased the agency recommended a modified process in this proposed rule.

In conjunction with the proposals presented in the CY 2015 MPFS proposed rule to revise the process used to address new, revised, and potentially misvalued codes under the MPFS, CMS is proposing to include in the OPPS proposed rule proposed APC and status indicator assignments for the new and revised CPT codes that are effective January 1. CMS proposes to modify the process by including in the proposed rule values for all codes for which CMS has complete RUC recommendations by January 15 of the preceding year. In some instances, when timely data is not received and CPT codes are no longer available, CMS will establish G-codes.

ASTRO has reviewed the revised timeline for the OPPS new/revised CPT codes. We appreciate the agency's move toward greater transparency and the publication of values in proposed rules, instead of final rule. However, ASTRO believes the agency needs to further refine the process. We are concerned that the creation of temporary G-codes for services where timely information was not received will contaminate claims data and create confusion for the hospitals and physicians. ***ASTRO urges CMS to include the values in the proposed rules (instead of the final rules) for the following calendar year, while not implementing the alternative G-code pathway.***

CY 2015 New/Revised Radiation Oncology CPT Codes

As discussed in our CY 2015 proposed MPFS comment letter, the agency is scheduled to introduce significant payment rate changes to the radiation treatment delivery codes in CY 2015. The agency

requested these coding and valuation changes in the CY 2013 final MPFS, as part of a review of a series of codes described as having "stand alone procedure time." This list included the radiation therapy codes impacted by the proposed vault policy. Working through the American Medical Association (AMA) CPT Editorial Panel, RVS Update Committee (RUC) and with other stakeholders, ASTRO proposed revisions and updates to these codes so they better reflect the current process of clinical care. The new and revised codes will be published in the 2015 CPT book. The proposed changes will have an enormous impact on radiation oncology providers and patients across the nation. ASTRO strongly urges CMS to immediately release CY 2015 interim APC values for the new and revised radiation treatment delivery codes. Radiation oncology providers need time to review, analyze and prepare for these changes. Additionally, releasing the codes now would allow for sufficient time to provide CMS with critical feedback.

In April of 2014, ASTRO met with CMS officials and provided recommendations on APC assignments for the new and revised treatment delivery codes. ASTRO continues to support these recommendations and is available to provide further clarification or guidance if needed.

ASTRO supports a modification to the current process; however, ASTRO strongly believes that CMS should implement this process immediately and requests the agency to immediately release the CY 2015 interim APC values for the new/revised radiation oncology treatment delivery codes. We stand ready to assist the Agency with any questions regarding the clinical use of the new/revised codes and questions regarding our recommendations on APC assignments for these new/revised codes.

Insert Uteri Tandem/Ovoids (57155)

CPT code 57155 (Insert uteri tandem/ovoids) is a therapeutic procedure that describes the insertion of tandems or ovoids for LDR and HDR brachytherapy. CMS is proposing to move CPT code 57155 from APC 0193 (Level IV Female Reproductive Procedures) to APC 0192 (Level III Female Reproductive Procedures) for CY 2015.

Over the past several years, this service has bounced between APC 0192 and 0193, experiencing significant payment fluctuations. This proposed change in APC for CY 2015 has resulted in another drastic change in the payment for the service. The 2015 proposed payment rate for CPT code 57155 is $500.77 in comparison to the 2014 payment rate of $1,375.20. This represents a payment reduction of 63 percent. ***ASTRO recommends CMS examine APCs 0192, 0193 and 0202 (Level V Female Reproductive Procedures) to confirm that the assignment and distribution provides the best stability for those services assigned to these APCs.***

Understanding Different Resource Costs Among Traditional Office, Facility and Off-Campus Provider-Based Settings

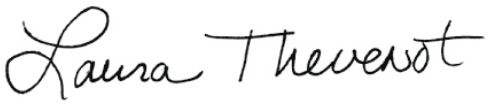
In the CY 2015 MPFS, CMS seeks to understand the growing trend in hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments. CMS is specifically interested in how this trend affects payment under PFS and beneficiary cost sharing. CMS questions the validity of PE resource data as more physician practices become provider-based and whether certain outpatient services should be paid at PFS rates rather than at OPPS rates.

CMS is proposing to create a HCPCS modifier to be reported with every code for physician and hospital services furnished in an off-campus provider-based department of a hospital. The modifier would be reported on the CMS-1500 claim form for physicians' services and the UB-04 (CMS form 1450) for hospital outpatient claims. CMS anticipates that the collection of this data will allow the agency to begin to assess the accuracy of PE data, including both the service-level direct PE inputs and the specialty-level indirect PE information used to value PFS services.

ASTRO is committed to working with CMS to understand the growth in provider-based practices and their impact on Medicare payments. ***ASTRO is concerned that the proposed modifier would be administratively burdensome. Additionally, the application of a modifier will be difficult to enforce and CMS may not get full compliance leading to a potentially inaccurate analysis.***

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 Anne Hubbard, Assistant Director of Health Policy, at (703) 839-7394 or anneh@astro.org.

Respectfully,



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