December 30, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1656-P
P.O. Box 8013, 7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically: http://www.regulations.gov

**Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (HER) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program**

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (HER) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program” (HOPPS), published in the Federal Register as a proposed rule on July 14, 2016.

ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers. They treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services. In this letter we address a number of topics that will impact our membership and the patients they serve, including:

- Comprehensive APCs
- Therapeutic Radiation Treatment Preparation
- Advisory Panel on Hospital Outpatient Payment
Composite APC (C-APC) Methodology

CMS’ Comprehensive-Ambulatory Payment Classification (C-APC) methodology packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the HOPPS at the claim level. ASTRO remains concerned that the one-size-fits-all C-APC methodology is poorly suited and inappropriate for radiation oncology services. Radiation oncology essentially requires component coding to account for the multiple steps encompassing the process of care (consultation; preparing for treatment; medical radiation physics, dosimetry, treatment devices and special services; radiation treatment delivery; radiation treatment management; and follow-up care management). The existing C-APC methodology does not consider the multiple steps involved in radiation therapy and needs to be properly addressed.

C-APC 5627 - Level 7 Radiation Therapy (SRS & IORT)

CMS will continue the policy for the payment of Stereotactic Radiosurgery (SRS) treatment as described in the 2016 HOPPS final rule. This policy removes claims reporting for planning and preparation services for SRS treatment from the geometric mean cost calculation for the 2017 payment rate for C-APC 5627 and pays separately for the planning and preparation services. In 2015, the C-APC reimbursement rate was $9,769. This policy change resulted in a 25 percent decline between 2015 and 2016 rates. The continuation of the policy results in a continued decline of 31 percent from the 2015 rate.

For 2018, CMS will examine the claims for cranial single session SRS patients and evaluate the services reported with modifier “CT” (Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification [C-APC] procedure). They will consider in future rulemaking whether repackaging all adjunctive services (planning, preparation, and imaging, among others) back into cranial single session SRS is appropriate in order to preserve the integrity of the C-APC policy and the HOPPS as a prospective payment system.

ASTRO remains concerned that this policy decision does not address the fundamental issues associated with different practice patterns involving multisource Cobalt-60-based SRS (77371) and linear accelerator-based (77372) SRS, which is evident in HOPPS claims data. Additionally, the SRS claims are also contaminated with charges for CPT Code 77373 Fractionated Stereotactic Body Radiation Therapy (SBRT). Patients being treated for brain metastases (with SRS) may concurrently or consecutively be treated for a primary lung cancer (with SBRT). The CMS/HOPPS C-APC methodology is not designed to differentiate which charges are linked to which major procedure, as such, the methodology does not appropriately capture charges for these services.

CMS proposed assigning CPT Codes 77424 and 77425, intraoperative radiation treatment (IORT) delivery, to C-APC 5093 Level 3 Breast/Lymphatic Surgery and Related Procedures. This would have resulted in an 11 percent reduction in reimbursement. ASTRO urged CMS not to finalize this proposal, as IORT is not clinically similar to the breast procedures included in C-APC 5093. In the final rule, CMS is assigning the IORT codes to APC 5627 Level 7 Radiation
Therapy, based on the fact that the codes are radiation oncology codes and their geometric mean costs are similar to the SRS codes. CMS notes that if planning and preparation and imaging services are repacked into the SRS codes, this could cause the geometric mean cost for the SRS codes to increase such that it may no longer be appropriate to group the IORT codes with SRS in the same C-APC.

ASTRO appreciates CMS’ recognition of the importance of grouping clinically similar codes in the same APC. However, we are concerned that anticipated changes in C-APC assignment in the future could lead to significant fluctuations in reimbursement.

C-APCs 5113, 5165, 5302, 5341 and 5414 - Brachytherapy Insertion

In the proposed rule, ASTRO expressed concern that claims for several of the brachytherapy device/insertion codes (CPT codes 57155, 20555, 31643, 41019, 43241, 55920, and 58346) often did not contain a brachytherapy treatment delivery code. As a result, brachytherapy delivery charges are underrepresented in rate setting under the C-APC methodology. A correctly coded claim should always include an insertion and treatment delivery code combination. It was suggested that CMS adopt a composite APC methodology for CPT code 57155 similar to the composite methodology for LDR prostate brachytherapy services.

In the final HOPPS, CMS did not modify the methodology for these brachytherapy insertion codes. The Agency stated that it is the hospitals’ responsibility to code correctly. CMS said they will continue examine the claims for these brachytherapy insertion codes and determine if any future adjustment to the methodology (or possibly code edits) would be appropriate.

Similar to the scenario described above for gynecologic brachytherapy (using CPT Code 57155), other insertion codes used to prepare for radiation treatment delivery (CPT codes 20555, 31643, 41019, 43241, 55920, 58346, etc) yield similar problems. ASTRO is disappointed in CMS’ response as it is clear that the C-APCs don’t appropriately capture the charges for these radiation oncology services.

C-APCs 5092 Level 2 Breast/Lymphatic Surgery and Related Procedures

CMS finalized its proposal to reassign CPT Code 19298 Placement of radiotherapy afterloading brachytherapy catheters into the breast for interstitial radioelement application following partial mastectomy, includes image guidance to newly converted C-APC 5092 for 2017. CMS rejected comments requesting that CPT Code 19298 stay in the APC 5093 Level 3 APC because the geometric mean cost for code decreased from approximately $6,269 in 2016 to approximately $5,128 for 2017. CMS does not believe that the CY 2017 geometric mean cost supports continued assignment to APC 5093. The decision results in a 42 percent lower payment for 19298.

ASTRO is disappointed in the significant reduction in reimbursement that CPT 19298 will experience due to a change in C-APC assignments. As mentioned previously, changes in C-APC assignment and the resulting fluctuations in reimbursement create significant instability that CMS should make an effort to address.
Ambulatory Payment Classifications (APCs)

APC 5625 Level 5 Radiation Therapy - Proton Therapy
In the final rule, CMS decreased the reimbursement rate for APC 5625 by 13.6 percent. This was an unanticipated reduction in reimbursement as the proposed rule indicated that the Agency was considering a 3 percent reduction. Upon further analysis, it has been determined that charges for CPT code 77522 Proton Treatment, simple with compensation have declined resulting in a lower geometric mean cost for the APC. As a result, the APC will be reimbursed at $994 in 2017, compared to $1,151 in 2016. ASTRO has concerns with the wide variation between proposed and finalized values, as it can impact access to care.

Therapeutic Radiation Treatment Preparation APCs 5611, 5612 and 5613
CMS finalized its proposal to move CPT code 77370 Radiation physics consult, along with CPT codes 77280 Set radiation therapy field and 77333 Radiation treatment aid(s), from APC 5612 Level 2 Therapeutic Radiation Treatment Delivery to APC 5611 Level 1 Therapeutic Radiation Treatment Preparation, thus combining Level 1 and Level 2 services. According to the agency, the geometric mean costs between Levels 1 and 2 are not significant and combining the two levels promotes resource homogeneity. As a result, payment will decrease from $167 in 2016 to $117 in 2017, a 30 percent decrease in reimbursement.

CMS finalized reassignment of CPT codes 77295 Three-Dimensional Radiotherapy Plan and 77301 Intensity Modulated Radiotherapy Plan to APC 5613 Level 3 Therapeutic Radiation Treatment Preparation. In proposed rule comments, ASTRO expressed concern that the significant costs associated with the simulation services bundled into CPT Code 77301 are not appropriately reflected in the 2015 and 2016 data. CMS was urged to create a new Level 4 Therapeutic Radiation Treatment Preparation APC and assign CPT Code 77301 to the new APC.

In the final rule, CMS acknowledged ASTRO’s concerns about CPT Code 77301 but declined to move the code to a new APC to account for costs associated with simulation. The Agency said that it will wait to analyze claims data before making any changes to the APC assignment. ASTRO believes this omission is costing physicians $500 for every IMRT plan in the hospital setting.

Hospital Outpatient Quality Reporting (HOQR) Program

Penalty Adjustments
CMS finalized penalty adjustments for hospitals that fail to meet the reporting requirements of the Hospital Outpatient Quality Reporting (HOQR) Program. Hospitals will continue to be subject to a further reduction of 2.0 percentage points to the Outpatient Department (OPD) fee schedule increase factor. However, CMS will use a reduced OPD fee schedule update factor of -0.45 percent (that is, the proposed OPD fee schedule increase factor of 1.55 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2017 of $73.411 for hospitals that fail to meet the Hospital OQR requirements (a difference of -1.498 in the conversion factor relative to hospitals that met the requirements).
OP-33: External Beam Radiotherapy for Bone Metastases (NQF# 1822)

In the 2016 final HOPPS rule, CMS finalized its proposal to add OP-33: External Beam Radiotherapy for Bone Metastases (NQF# 1822) to the HOQR Program beginning with the 2018 payment determination. This measure was designed for quality monitoring at a physician level to assess guideline compliance for external beam radiation therapy for the treatment of bone metastases. Since the radiation planning codes are physician services (CPT 77261, 77262, 77263) and are not billed at the hospital level, the coding to support this measure in the HOQR was changed to delivery of the dose. This modification to OP-33 has created complications with measurement and the measure is a very significant administrative burden to the facilities. The feasibility and validity testing for the measure was done in the context of physician reporting and has not been re-examined since these coding changes were made. Additionally, the burden on ASTRO to support and maintain this measure is beyond our capacity at this time. Due to these changes, ASTRO believes the measure has become overly complex, and its use should be discontinued until it is revalidated. As such, ASTRO urges CMS to remove this measure from the HOQR program.

ASTRO does believe that there are cancer care measures that could be incorporated into the HOQR that are appropriate to be measured at the hospital outpatient department level. For example, the Commission on Cancer reports on two measures related to referral to radiation therapy both post-breast conserving surgery (NQF 0219) and post-mastectomy (MASTRT). Because these are measures about referrals for appropriate care, we believe they are well suited to the HOQR program. Additionally, these measures are supported by many guidelines, including NCCN. Finally, there have several publications that speak to this gap in care. We would respectfully suggest CMS consider one or both of these measures for the HOQR.

Electronic Health Records Incentive Program (Meaningful Use)

Reduced Reporting Period

CMS finalized its proposal to reduce the 2016 reporting period from a full calendar year to a 90-day reporting period for new and returning Meaningful Use participants. ASTRO applauds this decision as it responds to concerns expressed by ASTRO and other stakeholders regarding the challenges of preparing for Stage 3 and the implementation of 2015 Edition Certified EHR Technology (CHERT), as well as the transition to the Merit-Based Incentive Payment System.

CMS also finalized its proposal to establish a 90-day reporting for Clinical Quality Measures (CQMs). CQMs can either be reported electronically or by attestation. CQM reporting can be for a different 90-day period than for the Meaningful Use objectives and measures. This is also consistent with ASTRO recommendations and we appreciate the Agency’s recognition of our concerns.
CY 2017 New Participants and Hardship Exception Application

CMS finalized its proposal to require that providers, who have not successfully demonstrated Meaningful Use in the past, attest to the Modified Stage 2 objectives and measures for 2017. These providers are exempt from reporting and attesting to Stage 3 of the Meaningful Use program, and will have to attest to the Modified Stage 2 by October 1, 2017.

Furthermore, providers who have not successfully demonstrated Meaningful Use in previous years, but who intend to attest to Meaningful Use in 2017 and transition to the MIPS Advancing Care Information objectives and measures, may apply for a new hardship exception. These providers will be required to submit their hardship application by October 1, 2017, explaining why participating in both Meaningful Use and reporting the Advancing Care Information category in 2017 will result in a significant hardship. This hardship exception will allow providers to avoid the 2018 Meaningful Use payment adjustment.

ASTRO appreciates these efforts to recognize the varied levels of CHERT readiness within the practitioner community.

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialog with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Anne Hubbard, Director of Health Policy, at 703-839-7394 or anne.hubbard@astro.org.

Respectfully,

Laura I. Thevenot
Chief Executive Officer