

September 11, 2017

Ms. Seema Verma
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

Dear Administrator Verma,

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,” published in the Federal Register as a proposed rule on July 20, 2017.

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 APC Methodology
 - C-APC 5627 - Level 7 Radiation Therapy
 - C-APCs 5113, 5165, 5302, 5341, and 5414 - Brachytherapy Insertion
 - Composite APC 8001 LDR Prostate Brachytherapy
- APC 5625 Level 5 Radiation Therapy – Proton Therapy
- Expansion of Excepted Off-Campus Provider Based Department Services
- Enforcement Instruction for Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals
- Ambulatory Surgical Center (ASC) Payment Reform
- OP-33: External Beam Radiotherapy for Bone Metastases (NQF# 1822)

Comprehensive 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 continues to have great concern that the one-size-fits-all C-APC methodology is poorly suited and wholly inappropriate for radiation oncology services. Radiation oncology essentially requires component coding to account for several steps in 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). Cancer treatment is complex, as patients are often treated concurrently with different modalities of radiation therapy for different disease sites. CMS' C-APC methodology does not account for this complexity and fails to capture appropriately coded claims, resulting in distorted data leading to inaccurate payment rates that will jeopardize access to certain radiation therapy services if continued and expanded.

Hospital billing practices vary greatly in terms of submitting radiation oncology services. They can bill services daily, weekly, monthly or a variety of other algorithms they have established internally. The site of service often varies for part of the treatment, with patients receiving steps of their treatment in the hospital outpatient, office and/or ASC setting. The radiation services are also reported through multiple hospital service lines. For example, the surgery department might report a part of the service while the radiation department reports another part of the service. These reporting complexities do not lend themselves to the "per claim" C-APC methodology. Denying claims for all radiation oncology services and conducting retrospective analysis in order to establish appropriate cost data/payments will cause an undue burden on the hospitals and patients.

The current C-APC HOPPS rate setting methodologies provide an inaccurate representation of costs for radiation oncology services. Several of these issues were highlighted in ASTRO's 2015, 2016 and 2017 proposed and final rule comments. We appreciate that the Agency has chosen not to expand this flawed methodology for 2018. However, ASTRO has serious concerns with the current CMS methodology for calculating HOPPS payment rates for radiation oncology services. Below are some highlights:

1. Using the traditional APC methodology for radiation oncology services.

ASTRO recognizes that the Agency is moving away from traditional APC methodology toward more bundled services. However, the complexity of radiation therapy claims (planning and preparation procedures, varying patterns in time prior to 'major' treatments, the potential for multiple treatment sites, site of service inconsistencies, etc) suggest that separate traditional APCs may be the most accurate way to pay for these services in HOPPS. *(Note: If CMS reverts to traditional APC methodology for radiation oncology services, the Agency will need to expand the bypass list again to ensure appropriately coded claims are used in rate setting.)*

2. Creating a modified C-APC methodology for radiation oncology services.

If CMS continues the use of C-APC methodology for radiation oncology services, the Agency must revise the methodology to adequately capture appropriately coded claims and mitigate major distortions in data. CMS may need to establish a variety of edits to (1) exclude inappropriate services and (2) capture appropriate services in rate setting because the current methodology does not achieve this goal. The Agency will also need to consider how to appropriately identify and reimburse other codes reflected in the radiation therapy process of care (planning, physics, etc).

3. Modifying the complexity adjustment methodology for radiation oncology services.

CMS only considers J1 codes in the complexity adjustment formulas. However, Radiation treatment delivery codes are assigned a status indicator S and not considered for a complexity adjustment. Radiation oncology services should not be considered “ancillary” in the complexity adjustment methodology. Further highlighting the flaw in the current C-APC methodology is the issue of twice-a-day (BID) radiation treatments. They are not considered for a complexity adjustment, which further distorts the data creating payments that do not truly recognize the actual costs.

4. Exacerbating distorted claims data for radiation oncology services.

ASTRO is concerned that when CMS chooses to maintain flawed methodologies, it leads to contaminated data, resulting in inaccurate payment rates for radiation oncology services. CMS’ current methodologies are distorting radiation oncology claims data and contributing to the erosion of the specialty. While we can appreciate CMS’ desire to implement methodologies that can be widely adapted to the house of medicine, it is clear that radiation oncology services have complexities that are being inappropriately ignored

C-APC 5627 - Level 7 Radiation Therapy

C-APC 5627 is a clear example of how the C-APC methodology can be dysfunctional for radiation oncology. CMS is required, by statute, to pay CPT code 77371 *Stereotactic Radiosurgery (SRS), Multi-source Cobalt-60 Based* and CPT Code 77372 *Stereotactic Radiosurgery, Linear Accelerator Based* at the same HOPPS rate. However, the Agency is not required to use a C-APC methodology to calculate that rate.

The practice patterns for multisource Cobalt-60-based SRS (77371) vs linear accelerator-based (77372) SRS are dramatically different, which is evident in HOPPS claims data. Specifically, there are significant differences in the amount of time between planning and preparation and treatment delivery depending on whether Cobalt-60 based SRS (77371) or linear accelerator-based (77372) SRS is used for treatment. The mean number of days between SRS treatment delivery and the 10 planning and preparation codes identified by CMS range from 0.17-4.32 for 77371 and 1.43-22.00 for 77372. This explains why more than 15 percent of the 77372 claims don’t include planning and preparation charges, resulting in an error in the geometric mean calculation and an inappropriately low geometric mean for 77372.

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 be concurrently or consecutively treated for an anatomically distinct site of oligometastatic disease 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.

In the 2018 HOPPS proposed rule, CMS proposes to 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 the 10 planning and preparation services for SRS treatment from the geometric mean cost calculation for the 2018 payment rate for C-APC 5627 *Level 7 Radiation Therapy* and pays separately for the planning and preparation services.

In the 2017 HOPPS final rule, CMS finalized the requirement that providers append a “CP” modifier to claims for cranial single session SRS patients. Based on preliminary data collected with modifier “CP”, CMS had identified additional services that are adjunctive to the primary “J1” SRS treatment service and reported on a different claim outside of the 10 SRS planning and preparation codes that were removed from SRS C-APC cost calculations. The analysis also demonstrates that the modifier was not always appended correctly. The “CP” modifier is set to expire at the end of 2018.

For 2018, CMS is proposing to continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of SRS treatment. The Agency believes this will allow for additional claims data analysis that will determine if repackaging all adjunctive services (planning, preparation, and imaging, among others) back into cranial single session SRS is appropriate in future rule making.

In 2017, CMS added CPT Codes 77424 and 77425 *Intraoperative Radiation Therapy* to APC 5627. The Agency proposes to maintain these codes in this C-APC again for 2018.

The proposed payment rate is set at \$7,335 for 2018, compared to the 2017 payment rate of \$7,456. This is a 1.6 percent decline in payment. Since the 2016 policy was implemented, the APC has experienced a 25 percent overall reduction in payment.

ASTRO remains concerned that the C-APC methodology does not account for the variation in care delivered to patients receiving treatment for cancer in multiple sites, as described above. ASTRO urges the Agency to abandon this effort and recommends that the Agency work with stakeholders to develop a more appropriate methodology for radiation oncology.

ASTRO continues to believe that the issues associated with C-APC 5627 will not be resolved as a result of CMS’ decision to make separate payment for the 10 planning and preparation services. We believe hospitals are not appropriately coding for SRS and SBRT

services. The continued use of the modifier will not help CMS achieve clean claims for SRS services.

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

In the 2017 HOPPS final rule, CMS finalized six new C-APCs that described procedures for inserting brachytherapy catheters/needles and other related brachytherapy procedures, such as the insertion of tandem and/or ovoids and the insertion of Heyman capsules. In written comments, ASTRO expressed concern that claims for several of the brachytherapy device/insertion codes (CPT Codes 57155, 20555, 31643, 41019, 43241, 55920, and 58346) did not contain a brachytherapy treatment delivery code (CPT Codes 77750 through 77799). As a result, brachytherapy delivery charges are underrepresented in rate setting under the C-APC methodology. In response to ASTRO’s concerns, CMS stated that the Agency would continue to examine the claims for these brachytherapy insertion codes and determine if any future adjustment to the methodology (or possibly code edits) would be appropriate.

In the 2018 HOPPS proposed rule, CMS announced that the Agency analyzed claims that included brachytherapy insertion codes assigned to status indicator “J1” and that received payment through a C-APC. The analysis validated ASTRO’s concerns and as a result, the Agency proposes to address the issue by establishing a code edit that requires a brachytherapy treatment code when a brachytherapy insertion code is billed.

The brachytherapy insertion codes that will be required to be billed with a brachytherapy treatment code are listed below:

Proposed Brachytherapy Insertion Procedures Assigned to Status Indicator “J1”

HCPCS CODE	Long Descriptor
19296	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy
19298	Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, including image guidance
19499	Unlisted procedure, breast
20555	Placement of needles or catheters into the muscle and/or soft tissue for subsequent interstitial radioelement application (at the time of or subsequent to the procedure)
31643	Bronchoscopy, rigid, or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application
41019	Placement of needles, catheters, or other device(s) into the head and/or neck

	region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube catheter
55875	Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy
55920	Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy
58346	Insertion of Heyman capsules for clinical brachytherapy

ASTRO is pleased with CMS' efforts to capture more correctly coded claims to establish payment rates for radiation services. However, we believe the code edits as proposed need further analysis and updates before they can be implemented.

For example, there are several clinically appropriate pathways for breast brachytherapy catheter insertion and treatment deliveries. After a patient undergoes her partial mastectomy, in some cases she may have her catheter placed during the same session, but in most cases, she will await the results from pathology before she undergoes the catheter placement. The hospital that performed the mastectomy often will not be the site of service where the catheter will be placed. The patient might go to a non-facility setting to get the catheter inserted (no general anesthesia, no hospital co-pay, smaller setting, etc). Or, she might go back to the hospital for the catheter placement, but to a freestanding cancer center for the radiation treatment. (In our claims analysis, we determined that many of the hospitals that performed the mastectomy actually did not even have a brachytherapy service line in their hospital). If a C-APC is established that has both the insertion and the treatment, and it is not 'typical' for both to be performed by the same facility, then the payment will not reflect the actual resources used by the facility.

Another example is prostate brachytherapy. CPT Code 55875 *Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy* can be used with either low dose rate brachytherapy (LDR) or high dose rate brachytherapy (HDR). Prostate LDR brachytherapy has one treatment session. Prostate HDR brachytherapy has multiples sessions, often with two sessions per day. If a C-APC is established that has the prostate insertion and both LDR and HDR, the payment will not reflect the actual resources used by the facility.

Another example is gynecologic brachytherapy. CPT code 57155 *Insertion of Uterine Tandem and/or Vaginal Ovoids for clinical brachytherapy* is used for the treatment of cervical cancer, which is often done two or three times a week over the course of two to three weeks, thus resulting in several appropriate code combinations. If a C-APC is established that has CPT Code 57155 and treatment delivery, how will the multiple, subsequent treatment delivery sessions be handled? How many will be used for rate setting?

CPT Codes 43241 and 19499 are two codes included in the proposed list of brachytherapy insertion procedures assigned to status indicator "J1" that are not used exclusively for

brachytherapy. For example, only 3 percent of the CPT Code 43241 HOPPS Medicare claims included a treatment delivery code. If a C-APC is established that has both the insertion and a treatment (for these two services), and it is not “typical” for both to be performed, then the payment will not reflect the actual resources used by the facility.

For these reasons, ASTRO does not support the CMS proposed mandatory code edit for brachytherapy insertion procedures. ASTRO recommends that CMS discontinue the Comprehensive APC payment policy for all brachytherapy insertion codes identified by CMS in the 2018 proposed rule. Specifically, CMS should discontinue “J1” designation and revert to status indicator “T” for CPT codes 19296, 19298, 19499, 20555, 31643, 41019, 43241, 55920, 57155 and 58346, which will allow for separate payment for insertion codes and treatment delivery codes.

ASTRO also recommends that CMS continue the Composite APC payment methodology in 2018 for APC 8001 Low Dose Rate Prostate Brachytherapy Composite. The current payment policy supports more accurate coding and packaging when the brachytherapy insertion code (CPT 55875) is provided on the same claim as the brachytherapy treatment delivery code (CPT 77778). CMS should revert to status indicator “Q3” for CPT code 55875.

Finally, if CMS reverts to traditional APCs, thus allowing for separate payment for these services, ASTRO strongly urges the Agency to review the bypass list methodology and ensure that appropriate radiation oncology codes are included on the bypass list.

APC 5625 Level 5 Radiation Therapy - Proton Therapy

In the 2018 HOPPS proposed rule, CMS proposes to decrease the reimbursement rate for APC 5625 by 5 percent. This reduction comes one year after the APC suffered a 14 percent payment rate reduction due to lower charges than anticipated for CPT code 77522 *Proton Treatment, simple with compensation*.

While CPT Code 77522 did not experience a significant reduction in charges, the code did experience a 20 percent decline in claims, from 8,260 in 2015 to 6,710 in 2016. CPT Code 77523 *Proton Treatment, Intermediate* experienced an 8 percent decline in geometric cost between 2015 and 2016, from \$1,022 to \$935. These year to year fluctuations in claims and geometric mean cost are creating instability. **This is particularly concerning given the significant fixed costs associated with operating proton therapy facilities. This kind of instability can impact access to care for patients should these facilities no longer be able to provide services. ASTRO remains concerned regarding the continued decline in reimbursement for proton therapy services.**

Expansion of Excepted Off-Campus Provider Based Department Services

In the 2017 HOPPS final rule, CMS did not finalize its proposal to limit service line expansion for excepted off-campus provider based departments (PBDs). Excepted off-campus PBDs are

those departments that billed for items and services under HOPPS prior to November 2, 2015. In the 2018 HOPPS proposed rule, the Agency seeks to continue this policy for another year as it continues to monitor claims data for changes in billing patterns and utilization.

For CY 2018, CMS is proposing to revise the PFS Relativity Adjuster for nonexcepted items and services furnished by nonexcepted off-campus PBDs to be 25 percent of the OPPS payment rate. Nonexcepted off-campus PBDs are those departments that bill for items and services under HOPPS after November 2, 2015. In the 2017 final rule, CMS applied a PFS Relativity Adjuster of 50 percent to the rates of these practices. ASTRO urges CMS to retain the 50 percent PFS Relativity Adjuster for another year. The Agency's proposal to reduce the PFS Relativity Adjuster to 25 percent will create instability in the market, potentially creating situations where services are no longer provided due to such a significant reduction in reimbursement. **We urge the Agency to retain the 50 percent PFS Relativity Adjuster for 2018 until data is collected that will allow for the development of a more precise payment methodology.**

Enforcement Instruction for Supervision of Outpatient Therapeutic Services in Critical Access Hospitals (CAHs) and Certain Small Rural Hospitals

In the 2009 HOPPS final rule, CMS finalized supervision requirements in hospital outpatient settings. Specifically, the Agency requires the direct supervision of hospital outpatient therapeutic services covered by Medicare that are furnished in hospitals, as well as in provider-based departments (PBDs) of hospitals. In 2010, CMS confirmed that this standard also applied to Critical Access Hospitals (CAHs). That same year, in response to concerns expressed by CAHs and small rural hospitals regarding their ability to meet the requirement, CMS issued a notice of nonenforcement to Medicare administrative contractors. This nonenforcement policy was amended to include rural hospitals with fewer than 100 beds and was extended through 2013. Separate Congressional legislative action extended nonenforcement through December 2016.

Stakeholders have petitioned CMS to continue the nonenforcement policy, and CMS noted that radiation oncology is a critical specialty service where it is particularly difficult to furnish direct supervision. In the 2018 HOPPS proposed rule, CMS seeks to reinstate the nonenforcement of direct supervision enforcement instruction for outpatient therapeutic services for CAHs and small rural hospitals with 100 or fewer beds for 2018 and 2019. The agency said this will allow CAHs and small rural hospitals more time to comply with the supervision requirements for outpatient therapeutic services and give all parties time to submit specific services to be evaluated by the Advisory Panel on Hospital Outpatient Payment for recommended change in supervision level.

It is ASTRO's opinion that a board-certified/board-eligible Radiation Oncologist is the clinically appropriate physician to supervise radiation treatments. The delivery of radiation therapy treatments involves a significant amount of clinical expertise that is not available outside the field of radiation oncology. ASTRO appreciates concerns regarding coverage issues in rural parts of the country. However, rather than exempt these areas from existing supervision requirements, we would like CMS to consider ways of incentivizing the practice of radiation oncology in these areas.

Health Professional Shortage Areas (HPSA) are designations made by the Health Resources and Services Administration (HRSA) to indicate shortages in three healthcare domains: primary care, dental and mental health. The Secretary of Health and Human Services reviews criteria set forth by states and accepts applications for potential HPSA regions. Cancer care is not one of the healthcare domains that can be determined as having a health professional shortage. However, cancer is the second leading cause of death in the United States. Facilitating the prevention, health maintenance and curing of cancer in rural or underserved areas is paramount to defeating the disease and providing the best care for that patient population.

There are several key benefits to an HPSA designation. First, an HPSA designation incentivizes payments for physician services provided in these areas. Secondly, the Federal Area Health Education Center program focuses efforts on patient education in HPSAs, increasing wellness in the patient population. Third, placement of federally employed and/or service-obligated health professionals is prioritized for HPSAs, including these health professionals in the National Health Service Corps. This qualifies them for scholarship and loan repayment programs. Overall, an HPSA designation can help increase the number of physicians in an area, which can help improve access to much needed services.

Though currently HPSA designations are reserved for primary care, dental and mental health practices, parameters for HPSA designations regarding cancer treatment centers could benefit many of the aging, rural populations across the US that don't necessarily have easy access to the life-saving therapies provided by radiation oncologists. **ASTRO would like to work with CMS and HRSA to establish a Cancer HPSA to ensure access to cancer care, including radiation therapy services, and adequate supervision in Critical Access Hospitals and small rural hospitals.**

OP-33: External Beam Radiotherapy for Bone Metastases (NQF# 1822)

Since the inclusion of measure OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF# 1822) into the Hospital Outpatient Quality Reporting (HOQR) Program in 2016, concerns have been raised from multiple stakeholders including CMS, Health Services Advisory Group (HSAG), Mathematica and those reporting on the measure. This measure was designed for quality monitoring at a physician level to assess guideline compliance for EBRT 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 radiation (CPT 77402, 77407, 77412). The feasibility and validity testing for the measure was done in the context of physician reporting using the radiation planning codes, and has not been retested for validity and reliability for the coding changes to the radiation delivery codes.

This modification to OP-33 has created significant complications with measurement. For example, a patient's initially prescribed fractionation scheme may need to be altered based on a patient's illness or their own personal reasons. Since the measure specifications are based on the delivery of radiation, instead of the originally intended prescription of treatment, more complicated measure exclusions were required. Additionally, upon integration into the HOQR

Program, the CMS contractor and ASTRO received numerous questions regarding the number and location of the bone metastases. With the coding changes to radiation delivery, the administration of EBRT to different anatomic sites are to be considered separate cases for OP-33. Since there is no way to determine the different anatomic site until detailed review of the patient's record is complete, sampling is a significant concern. Compounded with the extensive number of exclusions requiring clinical input, hospitals have difficulty determining if the HOQR sample size requirements for this measure are met. OP-33 has become overly difficult to report. In addition to the complexity of reporting, substantial administrative burden is placed on facilities, CMS contractors, and ASTRO. A representative from HSAG indicated that significantly more questions were received regarding OP-33 than any other measure. Overall, we believe the burden outweighs the value.

Considering the complexity and burden, we are concerned about the negative unforeseen effects that may arise from the continued reporting of this measure. ASTRO believes that measure removal criteria number seven (collection or public reporting of a measure leads to negative unintended consequences), finalized in the 2013 OP/ACS Final Rule, is met. As such, ASTRO urges CMS to remove this measure from the HOQR program.

ASTRO believes 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 for 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 address published gaps in care and are supported by many guidelines, including National Comprehensive Cancer Network. We suggest CMS consider one or both of these measures for the HOQR.

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, Director of Health Policy, at 703-839-7394 or anne.hubbard@astro.org.

Respectfully,



Laura I. Thevenot

Chief Executive Officer