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TARGETING CANCER CARE

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Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013, 7500 Security Boulevard
Baltimore, MD 21244-1850

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

Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Administrator Verma,

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the "Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model," published in the Federal Register as a proposed rule on July 31, 2018.

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
- New Device Pass-Through Application - SpaceOAR®
- Method to Control Unnecessary Increases in Volume of Outpatient Services
- Expansion of Excepted Off-Campus Provider Based Department Services
- OP-33: External Beam Radiotherapy for Bone Metastases (NQF# 1822)

Comprehensive APC (C-APC) Methodology

CMS continues to expand the Comprehensive Ambulatory Payment Classification (C-APC) methodology by proposing new C-APCs for ear, nose, and throat (ENT) services and vascular procedures. The addition of these new C-APCs increases the total number of C-APCs to 65. 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 the status indicator (SI) of "J1". All adjunctive services provided to support the delivery of the primary service are included on the claim.

While ASTRO supports policies that promote efficiency and the provision of high quality care, we have long expressed concern that the C-APC methodology lacks the appropriate charge capture mechanisms to accurately reflect the services associated with the C-APC. Most recently we met with CMS officials in February 2018 to discuss the impact of the methodology on brachytherapy services. A follow up letter was supplied to the Agency in March detailing specific issues and providing an example of how the methodology underpaid for costs associated with the treatment of cervical cancer.

As discussed during our February meeting with CMS, ASTRO, in collaboration with the American College of Radiology, the American Brachytherapy Society and the American Academy of Physicists in Medicine, have committed significant time and resources to the analysis of the C-APC methodology and its impact on radiation oncology reimbursement. **ASTRO is disappointed that CMS did not acknowledge our concerns articulated in the March 2018 letter in the proposed HOPPS rule and urges the Agency to strongly consider these issues. Radiation oncology requires component coding to account for the multiple steps that comprise 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, combined with other specialty modalities, and often at different sites of service. The 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.

New Device Pass-Through Application - SpaceOAR®

Augmenix, Inc. submitted an application for a new device category for transitional pass-through payment for the SpaceOAR® system. SpaceOAR® is a polyethylene glycol hydrogel spacer that temporarily positions the anterior rectal wall away from the prostate to reduce the radiation delivered to the anterior rectum during prostate cancer radiation therapy.

CMS establishes specific criteria for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries. However, based on the evidence submitted, CMS does not believe that it has sufficient evidence that

SpaceOAR® provides a substantial clinical improvement over other products. The Agency seeks comments on whether the SpaceOAR® system meets the substantial clinical improvement criterion.

ASTRO supports the establishment of a pass-through payment for SpaceOAR®. A recent randomized clinical trial has shown that the biodegradable gel material reduces toxicity for patients treated with radiotherapy for prostate cancer[1]. Specifically, this Level I clinical data demonstrates greater than 70 percent reductions in acute rectal pain and chronic rectal complications and improved bowel quality of life scores for patients treated with a rectal spacer versus those patients treated without a spacer. Based on published clinical outcomes data from this pivotal trial, the perirectal hydrogel spacer provides physicians with an option to help ensure patients are provided with the best clinical outcomes with the fewest adverse effects.

The benefits documented in this initial report were confirmed with a subsequent report of the same trial, with a median follow-up period of 3 years. At 3 years, more men in the control group than in the spacer group had experienced a decline in bowel quality of life (41 percent versus 14 percent). Additionally, the control group were more likely to experience large declines in bowel quality of life (21 percent versus 5 percent). Use of rectal spacer resulted in a sustained 75 percent reduction in any rectal toxicity persisting at 3 years, as well as significant reductions in urinary toxicity.[2]

In addition to meeting criteria for pass-through payment, SpaceOAR® must meet specific criteria for CMS to establish a new category of devices. Currently, there is not an existing pass-through category that describes SpaceOAR®. Augmenix recommended "Absorbable perirectal spacer" as a category descriptor in its application. The criteria for establishing a new category of devices, requires that the device is not appropriately described by any other category; and that it has an average cost that is not insignificant relative to the payment amount for the procedure or service with which the device is associated by demonstrating. **Based on the analysis provided in the proposed rule, ASTRO believes that SpaceOAR® has met these criteria and supports the establishment of "Absorbable perirectal spacer" category descriptor.**

<u>Method to Control Unnecessary Increases in Volume of Outpatient Services</u>

In 2017, CMS implemented section 603 of the Bipartisan Budget Act of 2015. The Agency established "excepted" off-campus provider-based departments (PBDs) as those departments that billed for items and services under HOPPS prior to November 2, 2015. PBDs who were billing for items and services under HOPPS after that date were considered "non-excepted" off-campus

[1] Mariados N, Sylvester J, Shah D, et al: Hydrogel spacer prospective multicenter randomized controlled pivotal trial: dosimetric and clinical effects of perirectal spacer application in men undergoing prostate image guided intensity modulated radiation therapy. Int J Radiat Oncol Biol Phys 92:971-977, 2015.

[2] Hamstra, D.A. et al: Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial. Int J Radiation Oncol Biol Phys, 97:5:976-985, 2017.

PBDs. Non-excepted PBDs have been subjected to a MPFS Relativity Adjuster since 2017 that effectively reduces the HOPPS payment rate for services delivered in these settings.

In the 2019 HOPPS proposed rule, CMS continues to express concern regarding the continued growth in Medicare expenditures for hospital outpatient services paid under the HOPPS. While changes required by section 603 of the Bipartisan Budget Act of 2015 address some of the Agency's concerns related to shifts in sites of care and overutilization in the hospital outpatient setting, CMS remains concerned that the majority of hospital outpatient departments continue to receive full HOPPS payment. Full HOPPS payment is often higher than payment for a similar service furnished in a physician office setting.

To address this issue, CMS is proposing to cap the HOPPS payment at the MPFS rate for clinic visits as described by G0463, regardless of whether the PBD delivering the service met the "excepted" status as implemented in 2017. The Agency is also interested in other methods, including the use of prior authorization, to control unnecessary increases in volume for outpatient services.

ASTRO appreciates CMS' interest in addressing unnecessary growth in services delivered in the off-campus PBD setting. However, we strongly urge the Agency to consider the potential downsides of increasing the requirement for prior authorization. In our members experience, prior authorization has become an administrative burden that often delays the time to proper care for patients, thus lowering the quality of care.

Radiation oncologists increasingly are restricted from exercising their clinical judgment in what is in the best interest of the patient; yet they are held accountable for the outcomes of treatments where decisions have been taken out of their hands by Radiation Oncology Benefit Managers (ROBMs). Radiation oncologists regularly report that ROBMs fail to provide approvals in a timely and transparent manner, instead frequently practicing "denial-by-delay" that can exacerbate patient anxiety and lead to physicians and their patients abandoning recommended treatments. **ASTRO opposes expansion of prior authorization in Medicare.**

ASTRO also disagrees with the general premise of benchmarking the resource based PE RVU methodology of the Medicare physician fee schedule (PFS) with the APC rates from the hospital outpatient prospective payment system. ASTRO understands that there are limitations to the existing practice expense methodology. CMS, working with the AMA/RUC, physician specialty societies, and other collaborators, has spent years developing and revising the current PE methodology. While ASTRO agrees that a comparison of OPPS and PFS rates might be an appropriate method to identify services for review as potentially misvalued, it simply is not appropriate to assume that it is fair to interchange the rates arbitrarily.

<u>Expansion of Excepted Services at Off-Campus Provider-Based Departments (PBDs)</u>

In the 2017 and 2018 HOPPS rules, CMS proposed but did not finalize limitations on service line expansion for excepted off-campus PBDs. In the 2019 HOPPS proposed rule, the Agency proposes to pay new services at the MPFS rate.

Thus, the Agency is proposing that, effective January 1, 2019, excepted items and services include only those items and services from the same clinical family that were furnished and billed prior to November 2, 2015. CMS is also proposing that if an excepted off-campus PBD furnishes a new item or service from the same clinical family of services from which it furnished a service prior to November 2, 2015, this would not be treated as a service expansion and would be paid under HOPPS. However, if an excepted off-campus PBD furnished items or services from a new clinical family of services, these items and services would be paid under the MPFS because they are no longer considered excepted items or services. **ASTRO urges the agency to consider the potential impact of this proposal on rural settings or underserved settings without access to these services. Consideration should be given to retaining the HOPPS payments for those excepted off-campus PDBs in rural settings or underserved communities that seek to expand services outside of the existing clinical family, so they may be able to provide a service to the community that would otherwise not exist.**

Hospital Outpatient Quality Reporting Program (OQR)

The Hospital Outpatient Quality Reporting (OQR) Program is a pay-for-reporting program for services rendered in the hospital outpatient setting. The program requires hospital outpatient facilities to meet quality reporting requirements or receive a reduction of 2 percentage points from their annual payment update, if they fail to meet the requirements. In the 2019 HOPPS proposed rule, CMS is proposing changes to payment determinations, measure removal policies, clarification on topped out measures, and updates to participation status for the Hospital Outpatient Quality Reporting (OQR) program. The Agency is also proposing the removal of one measure beginning in 2020 and nine measures effective January 1, 2021.

CMS proposes to retain the use of OP-33: External Beam Radiotherapy (EBRT) for Bone Metastases, which 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 difficultly 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 Health Services Advisory group (HSAG) indicated that significantly more questions were received regarding OP-33 than any other measure. Overall, we believe the burden outweighs the value.

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, HSAG, Mathematica and those reporting on the measure. More recently, ASTRO has chosen not to seek NQF re-endorsement for OP-33 because of the prescriptive nature of the fractionation schemes and the burden of reporting the measure.

Considering the complexity and burden, we are concerned about the negative unforeseen effects that 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 OPPS/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 Thevenot

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