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TARGETING CANCER CARE

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September 5, 2019

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; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

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; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals," published in the Federal Register as a proposed rule on August 9, 2019.

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
- Supervision Policy for Hospital Outpatient Therapeutic Services

- Evaluation of Substantial Clinical Improvement Criterion for Transitional Pass-Through Payments for Devices
- Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

Comprehensive APC (C-APC) Methodology

CMS continues to expand the Comprehensive Ambulatory Payment Classification (C-APC) methodology by proposing two new C-APCs. The proposed new C-APCs include C-APC 5182 *Level 2 Vascular Procedures* and C-APC 5461 *Level 1 Neurostimulator and Related Procedures*. The addition of these new C-APCs increases the total number of C-APCs to 67. 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.

Since the inception of the C-APC methodology, ASTRO has expressed concern regarding the claims data used for rate-setting due to significant variations in clinical practice and billing patterns across the hospitals that submit these claims. **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.** Unfortunately, ASTRO's concerns are now playing out in the proposed Radiation Oncology Alternative Payment Model (RO Model), resulting in undervalued HOPPS-based national case rates for radiation treatment for certain cancer types, including cervical cancer.

In the 2020 HOPPS proposed rule, CMS does not propose to make any modifications to existing radiation oncology C-APCs. **However, ASTRO remains concerned about how the C-APC methodology impacts radiation oncology particularly the delivery of brachytherapy for the treatment of cervical cancer. As described in the attached letter submitted to the Agency on March 19, 2019 this is an issue that remains unresolved. We urge the Agency to explore alternatives to the C-APC methodology so that it appropriately values this life saving service and supports the transition to value-based payments under the finalized RO Model.**

Supervision Policy for Hospital Outpatient Therapeutic Services

In the 2009 HOPPS final rule, CMS clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare in hospitals as well as in provider-based departments of hospitals. In the 2010 HOPPS final rule, CMS clarified that this standard applies to Critical Access Hospitals (CAHs) and small rural hospitals with fewer than 100 beds. In response to concerns expressed by the hospital community, in particular CAHs and small rural hospitals who indicated that they would have difficulty meeting this standard, CMS instructed all Medicare contractors not to evaluate or enforce the supervision requirements for therapeutic services provided to outpatients in CAHs and rural hospitals from January 1, 2010 through December 31, 2010. This non-enforcement policy was extended in 2011, 2012, 2013, and most

recently in 2018 with an expiration of December 31, 2019.

In the 2020 HOPPS proposed rule, CMS is proposing to change the minimum required level of supervision from "direct supervision" to "general supervision" for all hospital outpatient therapeutic services provided by all hospitals and CAHs. This proposal would establish a standard minimum level of supervision for each hospital outpatient service furnished incident to a physician's service.

In the proposed rule, CMS establishes that the agency is not aware of any supervision-related complaints from beneficiaries or providers regarding the quality of care for services furnished since 2010. According to the Agency, the enforcement instructions and legislative actions that have been in place since 2010 created a two-tiered system of physician supervision requirements for hospital outpatient therapeutic services for providers in the Medicare program, "with direct supervision required for most hospital outpatient therapeutic services in most hospital providers, but only general supervision required for most hospital outpatient therapeutic services in CAHs and small rural hospitals with fewer than 100 beds." CMS believes that the direct supervision requirement for hospital outpatient therapeutic services places an additional burden on providers that reduces their flexibility to provide medical care. The Agency is seeking feedback regarding this proposed modification to hospital-based supervision policies.

Currently, direct supervision is required for radiation therapy services provided in the hospital outpatient department. The sophistication and complexity of radiation therapy technology has increased exponentially in the past few decades. As radiation treatments have become more targeted and precise, they have also required increasingly complex equipment and processes. The work of ensuring treatment accuracy and patient safety throughout a prescribed course of treatment has also become more demanding in expertise and attention. Due to the complexity of radiation therapy, radiation oncology providers need to be immediately available during treatment planning and delivery, meaning physically present, interruptible and able to furnish assistance and direction throughout the performance of the procedure. Additionally, the supervising physician must have within his or her State scope of practice and hospital-granted privileges the ability to perform the service or procedure that he or she supervises.

All hospital outpatient diagnostic tests performed in conjunction with radiation therapy must follow the physician supervision requirements as specified for each individual test. The vast majority of image guidance services in radiation therapy involve stereoscopic x-ray or computed tomography guidance, which are subject to the direct supervision requirement.

Finally, the ASTRO Accreditation Program for Excellence (APEx®), which establishes policies and procedures as a Quality Improvement program, recognizes direct supervision as a standard of care for delivering radiation therapy. Radiation therapy utilizes high doses of ionizing radiation. Under General Supervision, the use of therapeutic levels of radiation dose poses an inherent danger and could cause serious harm to patients due to the irreversible nature of radiation treatment delivery.

While ASTRO appreciates concerns regarding the challenges of meeting supervision requirements, particularly for rural radiation oncology clinics, we believe that the current supervision policy should be retained for radiation oncology to protect patients and ensure the continued delivery of safe and high-quality radiation therapy services. ASTRO recommends that all radiation therapy services be exempt from the CMS proposal to apply a minimum required level of General Supervision for hospital outpatient therapeutic services furnished by all hospitals and critical access hospitals (CAHs). Further, it is ASTRO's opinion that a board-certified radiation oncologist is the most qualified physician to perform these services.

Evaluation of Substantial Clinical Improvement Criterion for Transitional Pass-Through Payments for Devices

CMS is seeking comment on the "substantial clinical improvement" criterion for evaluating applications for the OPPS transitional pass-through payment for devices. Existing regulations provide that a new technology is an appropriate candidate for additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available.

The Agency recognizes that additional clarity regarding the requirements associated with the "substantial clinical improvement" criterion will help the public better understand how CMS evaluates new technology applications for add-on payments and will provide greater predictability about which applications will meet the criterion. The request for comments is intended to inform future rule making but may result in changes applied to the 2020 HOPPS rules.

ASTRO appreciates CMS' interest in improving the "substantial clinical improvement" criterion for evaluating applications for the OPPS transitional pass-through payment for devices. In the 2019 OPPS proposed rule, ASTRO supported a transitional pass-through payment application submitted by Augmenix, Inc. for SpaceOAR®. We were disappointed that the Agency did not grant pass through payment, despite a randomized clinical trial confirming the biodegradable gel material reduces toxicity for patients treated with radiotherapy for prostate cancer[1]. Furthermore, the benefits documented in the 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

[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.

urinary toxicity.[2] It is ASTRO's opinion, that this evidence demonstrates that SpaceOAR reduces the number of hospitalizations or physician visits and reduces the recovery time associated with rectal toxicity compared to existing technologies, thus demonstrating "substantial clinical improvement".

In the 2019 OPPS final rule, CMS did not grant pass through payment because it did not believe that SpaceOAR® met the "substantial clinical improvement" criterion. This was due to the Agency's request for a "head-to-head" trial of SpaceOAR® versus a comparator. The comparator was a rectal balloon, which is a significantly different device and not an appropriate comparator. A rectal balloon is useful for prostate immobilization, but it does little to protect the rectum from any toxicity associated with the radiation dose. When the rectal balloon is placed in the rectum it displaces the anterior rectal wall pushing it toward the radiation dose, whereas SpaceOAR® does the opposite by protecting the rectum from the radiation dose. It is not possible to do a randomized comparison of two products that are intended for different purposes.

ASTRO urges CMS to reconsider how it determines whether a new technology meets the "substantial clinical improvement criterion". The criterion should recognize that there are new technologies that are not designed to replace existing technologies but rather improve care in ways that have previously not been possible. CMS needs to recognize these types of innovations and truly focus on how they improve patient outcomes over time. Otherwise, the Agency runs the risk of hampering innovation and the potential proliferation of services that benefit patients and ultimately save Medicare money over time due to reduced symptoms management and care needs in the long run. To further refine the Transitional Pass-Through Payment application and review process, ASTRO recommends that CMS establish a panel of clinical experts to provide insights and opinions regarding applications. With so many new technologies and innovative approaches to healthcare delivery, CMS should expand its current review process to involve subject matter experts who can lend their expertise in the evaluation of Transitional Pass-Through Payment applications.

Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services

The 2020 HOPPS proposed rule proposes to establish prior authorization requirements as a condition of Medicare payment for five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation. Section 1833(t)(2)(F) of the Act directs the Secretary to establish a method to control "unnecessary increases in the volume of services" under the OPPS. CMS has determined that some services experienced significant increases in volume. CMS selected these particular procedures because they have both therapeutic and cosmetic indications, and utilization of these services has increased rapidly in recent years.

[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.

Under the proposed prior authorization program, hospital outpatient departments would be required to submit documentation to show that a service meets applicable Medicare coverage, coding and payment rules, prior to furnishing a service and submitting a claim. Claims that had not received a provisional affirmation would be denied. If a prior-authorization request were to receive a non-affirmation decision, providers could resubmit the prior authorization request with additional documentation. Non-affirmation decisions could not be appealed, but a claim denial resulting from a claim submitted without an affirmation decision could be appealed.

Notably, CMS is proposing that providers could be exempt from the prior authorization requirement if they were to achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment. Exempt providers could lose exemption if their rate of non-payable claims becomes higher than 10 percent during a biannual assessment. The proposed rule and regulations do not clarify the process by which CMS would biannually identify the percentage of non-payable claims for exempt providers that are not submitting prior authorization requests.

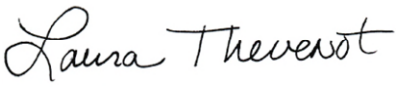
In the 2018 ASTRO Annual Member survey, radiation oncologists named prior authorization as the greatest challenge facing the field. To determine the extent of the burden, ASTRO launched a nationwide survey of radiation oncologists to look at the extent that prior authorization policies have impacted the field. The survey results clearly illustrate that restrictive prior authorization practices cause unnecessary delays and interference in physician-patient care decisions.

According to the survey, 93 percent of radiation oncologists said that their patients experience delays in treatment, 31 percent of whom report average delays of more than five days. Furthermore, 73 percent of radiation oncologists said their patients regularly express concern about the delay caused by prior authorization.

ASTRO is strongly opposed to any expansion of the use of prior authorization. While ASTRO can appreciate the need to monitor and address inappropriate utilization, prior authorization has become a blunt instrument used by private payers and Medicare Advantage plans to prevent patients from accessing care. The use of prior authorization results in delays in care and erodes the value of physician-patient care decision. ASTRO applauds CMS for proposing an exemption criterion based on provider performance if providers achieve a prior authorization provisional affirmation threshold of at least 90 percent during a semiannual assessment. However, CMS should also establish standardized prior authorization protocols, including timely resolution of clinical reviews and clearly articulated decision criteria and rationale in an effort to minimize care delays and encourage effective communication channels between providers and health plans.

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 Bryan Hull, Assistant Director of Health Policy, at (703) 839-7376 or Bryan.Hull@astro.org.

Respectfully,



Laura I. Thevenot
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