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TARGETING CANCER CARE

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December 2, 2019

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

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

Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots.

Dear Administrator Verma:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the "Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots," final rule as published in the Federal Register on November 12, 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 several topics that will impact our membership and the patients they serve, including:

- Supervision Policy for Hospital Outpatient Therapeutic Services
- Comprehensive APC Methodology

Supervision Policy for Hospital Outpatient Therapeutic Services

ASTRO is both concerned and very disappointed that CMS finalized its proposal to change the minimum required level of supervision for all hospital outpatient therapeutic services provided by all hospitals from a combination of "direct supervision" and "general supervision," depending on the service provided, to a broad "general supervision" policy. In the final rule, CMS defines general supervision as "when the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure." Not requiring physician presence during the delivery of radiation therapy services has the potential to endanger patients due to the irreversible nature of radiation therapy. Just as one would expect a surgeon to be present for an operation, ASTRO expects the radiation oncologist to be present for radiation treatments as situations arise requiring expert opinion and problem solving.

According to the Agency, this new policy establishes a standard minimum level of supervision for each hospital outpatient service furnished incident to a physician's service. CMS further emphasizes that providers have the flexibility to establish what they believe is the appropriate level of physician supervision for these procedures, which may be higher than the requirements for general supervision. CMS asserts that the previous supervision paradigm -- which established a two-tiered system in which direct supervision is required for most hospital therapeutic services but allowed an exception for services conducted at critical access hospitals and at hospitals with 100 or fewer beds to be delivered under general supervision -- placed an additional burden on providers that reduced their flexibility to provide medical care.

In our comment letter on the proposed rule, ASTRO urged the Agency to retain the current supervision policy for radiation oncology to protect patients and ensure the continued delivery of safe and high-quality radiation therapy services. The sophistication and complexity of radiation therapy technology has increased exponentially in the past few decades, requiring complex processes that lead to more targeted and precise treatments. The work of ensuring treatment accuracy and patient safety throughout a prescribed course of treatment has 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."[1]

ASTRO opposes the finalized HOPPS supervision rule policy change and is disappointed that CMS chose to disregard ASTRO's and patient groups' specific concerns. According to a September 27, 2019 comment letter on the HOPPS proposed rule, the Cancer Leadership Council wrote, "As patients receiving these services and health care professionals providing them, we believe that radiation therapy services – increasingly targeted and precise and requiring complex equipment and processes – should be subject to direct supervision. This means that

[1] ASTRO Comments on 2020 HOPPS Proposed Rule, September 5, 2019

radiation oncology providers should be present during treatment planning and delivery, able to furnish assistance and direction throughout the performance of the procedure. We understand that this issue requires evaluating and balancing issues of access, quality, and safety. In our analysis, direct supervision of radiation oncology services is in the best interest of patients."

It remains ASTRO's position that a board-certified/board-eligible radiation oncologist is the ONLY clinically appropriate physician to supervise radiation treatments. We remain very concerned that the new general supervision policy will have a negative impact on the quality of patient care. ASTRO has urged radiation oncologists to work with hospital administrators and compliance officers to retain existing supervision standards for radiation therapy services. We continue to believe that these standards are in the best interest of patients and that they should be applied nationwide, rather than on an ad hoc basis. We urge the Agency to reconsider its position.

Comprehensive APC (C-APC) Methodology

CMS continues to expand the Comprehensive Ambulatory Payment Classification (C-APC) methodology in the 2020 Hospital Outpatient Prospective Payment System (HOPPS) final rule by finalizing two new C-APCs. Conceptually, the C-APC is designed so there is a single primary service on the claim, identified by the status indicator (SI) of "J1". When a HCPCS code is indicated by an SI of J1, all other HCPCS codes on the bill are considered packaged in the J1 payment and all adjunctive services provided to support the delivery of the primary service are included on the claim.

For several years, ASTRO has provided the Agency with a comprehensive analysis detailing how the methodology used to create C-APCs lacks the appropriate charge capture mechanisms and how it grossly undervalues cancer treatments, particularly brachytherapy. In previous letters, we have described the radiation oncology 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) and how component coding is more appropriate to capture these services.[2] ASTRO is concerned that despite our previous comments regarding the methodology, CMS continues to move forward with the inappropriate application of the C-APC methodology to radiation oncology services.

In the 2020 HOPPS final rule, CMS reassigned CPT codes 57155 *Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy* and 58346 *Insertion of Heyman capsules for clinical brachytherapy* from C-APC 5414 *Level 4 Gynecologic Procedures* to C-APC 5415 *Level 5 Gynecologic Procedures*. In our 2019 HOPPS comment letter, ASTRO provided the Agency with an analysis of the actual cost of cervical brachytherapy treatment. In our analysis, we determined that the 2019 Medicare HOPPS payment for cervical brachytherapy treatment was $13,731.51 less than the average cost for the brachytherapy portion of the treatment; and $40,000 less than the average cost for brachytherapy and external beam radiation therapy (partial treatment).

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[2] ASTRO Comments on 2019 HOPPS Final Rule, December 3, 2018

While ASTRO appreciates that the Agency has finalized increases in the reimbursement rate for these specific services, we remain concerned with the C-APC methodology's impact on radiation oncology. Although both HCPCS codes 57155 and 58346 are finalized to experience increases in reimbursement from $2,361 in 2019 to $4,271 in 2020, this increase still does not adequately account for the actual cost of treatment delivery for these services. The 2020 Medicare HOPPS payment for cervical brachytherapy treatment is still $11,821.51 less than the average cost for the brachytherapy portion of the treatment; and $38,000 less than the average cost for brachytherapy and external beam radiation therapy (partial treatment).

ASTRO is disappointed by this and will continue to educate CMS on the impact that the C-APC methodology has on radiation oncology services. **ASTRO continues to urge CMS to consider allowing brachytherapy to be reported through the traditional APC methodology. If CMS insists on the continued use of the C-APC methodology, we recommend that the Agency move brachytherapy for cervical cancer treatment to C-APC 5416 Level 6 Gynecologic Procedures. This C-APC is reimbursed at $6,703, which more closely reflects the actual cost of treatment delivery for brachytherapy.**

Thank you for the opportunity to comment on this final 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
Chief Executive Officer