September 28, 2020

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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

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; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals” published in the Federal Register as a proposed rule on August 12, 2020.

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, ASTRO seeks to provide input on the policy change proposals that will impact our membership and the patients they serve, including:

- **Comprehensive Ambulatory Payment Classifications (C-APCs)**
- **APC Placement of Medical Physics Dose Evaluation (CPT code 7615X)**
- **Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services**
Comprehensive Ambulatory Payment Classifications (C-APCs)

In the 2021 HOPPS proposed rule, CMS indicates its continued commitment to the Comprehensive Ambulatory Payment Classifications (C-APC) methodology by proposing two new C-APCs. These new C-APCs include C-APC 5378 Level 8 Urology and Related Services and C-APC 5465 Level 5 Neurostimulator and Related Procedures, increasing the total number of C-APCs to 69. 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 our concerns that the policy is poorly suited and wholly inappropriate for the accurate reflection of costs associated with the component coding aspects of 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). In addition, ASTRO has expressed our concerns regarding the claims data and charge capture mechanisms used for rate-setting due to the complexities associated with treating cancer and significant variations in clinical practice and billing patterns across the hospitals that submit these claims. **ASTRO reiterates that the C-APC methodology does not account for this complexity and fails to capture appropriately coded claims, resulting in distorted data. If continued and further expanded, ASTRO is concerned that this could lead to inaccurate payment rates that will jeopardize access to certain radiation therapy services.**

In February 2018, ASTRO met with CMS officials to specifically discuss the impact of the C-APC policy on brachytherapy services. At that time, we supplied the Agency with a detailed analysis specific to the treatment of cervical cancer that we believe verified how the C-APC methodology severely underpays for costs associated with the treatment of cervical cancer. Those concerns were again shared with CMS in response to the 2019 HOPPS final rule where we supplied our analysis through comments and expressed our disappointment that the Agency did not recognize these concerns.

In the 2020 HOPPS final rule, CMS applied modest increases by reassigning two brachytherapy codes, CPT code 57155 Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy and CPT code 58346 Insertion of Heyman capsules for clinical brachytherapy from C-APC 5414 Level 4 Gynecologic Procedures to C-APC 5415 Level 5 Gynecologic Procedures, increasing their reimbursement rates from $2,361 to $4,271. However, these increases still did not adequately account for the actual cost of treatment delivery for these services.

In the 2021 HOPPS proposed rule, this issue remains unresolved, although ASTRO has continuously urged the Agency to explore alternatives to its C-APC policy. CMS continues to assign CPT codes 57155 and 58346 to C-APC 5415. In 2021, this C-APC category is expected to be reimbursed at a rate of $4,491. **ASTRO continues to be concerned about how the C-**
APC methodology impacts radiation oncology, particularly the delivery of brachytherapy for the treatment of cervical cancer and urges CMS to consider allowing brachytherapy to be reported through the traditional APC methodology.

ASTRO supports CMS policies that promote efficiency and the provision of high-quality care but the C-APC methodology by design is not equipped to accurately capture the complexities of radiation oncology services, particularly brachytherapy. **If CMS is committed to the C-APC methodology we recommend that the Agency move brachytherapy for cervical cancer treatment to C-APC 5416 Level 6 Gynecologic Procedures, which is expected to be reimbursed at a rate of $6,930.**

**APC Placement of Medical Physics Dose Evaluation (CPT code 7615X)**

CMS proposed placing CPT code 7615X in APC 5611 Level 1 - Therapeutic Radiation Treatment Preparation. APC 5611 currently has nine, clinically similar radiation oncology therapeutic radiation treatment codes. Newly created CPT code 7615X is not a radiation oncology code, rather a service that will be performed in interventional radiology or interventional cardiology.

ASTRO believes that CPT Code 7615X is better suited in APC 5724 - Level 4 Diagnostic Tests and Related Services. APC 5724 currently has 17 services, with a range of clinical variability (urology, neurology, internal medicine, radiology, dermatology, allergy, etc). The resource consumption in APC 5724 more closely aligns with the resources used to perform CPT code 7615X. **As such, ASTRO urges CMS to place CPT code 7615X in APC 5724 for 2021.**

**Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process**

In the 2020 HOPPS final rule, CMS established 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 determined that some services experienced significant increases in volume. CMS selected these procedures specifically because they have both therapeutic and cosmetic indications, and utilization of these services has increased rapidly in recent years.

In the 2021 HOPPS proposed rule, CMS proposes to apply prior authorization requirements to include two new categories of services, cervical fusion with disc removal and implanted spinal neurostimulators. The Agency states that the proposed addition of these service categories is consistent with their vested authority under section 1833(t)(2)(F) and is based an unnecessary increase in the volume of these services. Services contained in these two categories would be subject to prior authorization for dates of service on or after July 1, 2021.

Under the prior authorization program, hospital outpatient departments are 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. 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.

While ASTRO appreciates the need to curb the delivery of services that may not be medically necessary, we are concerned about CMS’ decision to expand the use of prior authorization as a method for addressing the issue. ASTRO believes that the use of prior authorization results in delays in care and erodes the value of physician-patient decision making process. Burdensome prior authorization policies have become a blunt instrument used by private payers and Medicare Advantage plans to prevent patients from accessing care.

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 better understand the extent that prior authorization policies have impacted the field. The survey results clearly illustrate that restrictive prior authorization practices cause unnecessary delays in care and interfere with the physician-patient decision making process. According to the survey, 93 percent of radiation oncologists said that their patients experience delays in treatment, 31 percent 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.

While ASTRO can appreciate the need to monitor increases and address inappropriate utilization, we strongly oppose the use of prior authorization as a tool to address this issue. We urge the Agency to consider alternative methods for reducing the delivery of services that are not medically necessary.

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
Chief Executive Officer