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September 9, 2022

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Submitted electronically: <http://www.regulations.gov>

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure,

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; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating,” published in the Federal Register as a proposed rule on July 26, 2022.

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 patients with cancer 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:

- 340B
- Comprehensive Ambulatory Payment Classifications (C-APCs)
- Two-Times Rule Exception
- APC Classification of CPT Code 76145, *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report*
- Brachytherapy Sources
- HOPPS Payment for Software as a Service
- Proposed HOPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals
- Health Equity

340B

In the proposed rule, CMS states that it intended to continue the existing policy of paying Average Sales Price (ASP) minus 22.5% for 340B-acquired drugs and biologicals. This was in accordance with the Agency's policy and calculations that were made prior to the Supreme Court decision, *American Hospital Association v. Becerra* (Docket 20-1114). In light of the Supreme Court's decision, CMS acknowledges that it will be required to apply a rate of ASP +6% to drugs and biologicals in the final rule for CY 2023, which will impact the HOPPS conversion factor. Additionally, the Agency states that it will have to evaluate the Court's decision on prior calendar years.

ASTRO appreciates CMS acknowledging the impact of the recent Supreme Court decision and the challenges that it presents. We urge the Agency to provide as much detail as possible in the final rule related to the Conversion Factor modifications that will impact HOPPS payments as a result of the revised policy. Additionally, if the CMS determines that it must revisit prior calendar years, we urge the Agency to provide opportunities for public input regarding how it will carry out retrospective policy changes.

Comprehensive Ambulatory Payment Classifications (C-APCs)

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.

In the 2023 HOPPS proposed rule, this issue remains unresolved, despite the fact that 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, which highly undervalues these services. In 2023, this C-APC category is expected to be reimbursed at a rate of \$4,712.62.

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. This type of cancer in particular disproportionately impacts disadvantaged and minority women, who are less likely to have access to screening services that would allow preventive intervention prior to the emergence of life-threatening invasive cancer. For example, studies show that Black women are less likely to receive appropriate treatment for cervical cancer compared to Whites, and treatment differences have been reported for other minorities as well, including Hispanics and American Indians. Additionally, differences in cervical cancer treatment are likely to be

compounded in rural and other medically underserved areas.¹

ASTRO again urges CMS to consider allowing brachytherapy to be reported through the traditional APC methodology. 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 \$7,039.90 (our own analysis shows that a more accurate reimbursement for brachytherapy for cervical cancer is \$16,693.48).²

Two-Times Rule Exception

CMS established two-times rule criteria within the APC methodology that requires that the highest calculated cost of an individual procedure categorized to any given APC cannot exceed two times the calculated cost of the lowest-costing procedure categorized to that same APC. However, the Agency can exempt any APC from the two-times rule for any of the following reasons:

- Resource homogeneity
- Clinical homogeneity
- Hospital outpatient setting utilization
- Frequency of service (volume)
- Opportunity for upcoding and code fragments

Based on CY 2021 claims data, CMS proposes to apply the two-times rule exception to APC 5611 *Level 1 Therapeutic Radiation Treatment Preparation*. This is in addition to APC 5612 *Level 2 Therapeutic Radiation Treatment Preparation* and APC 5627 *Level 7 Radiation Therapy*, which were on the two-times rule exception list in previous years.

APC 5611 *Level 1 Radiation Therapeutic Radiation Treatment Preparation* includes the following codes, whose mean costs reflect that the APC is now in violation of the two-times rule:

HCPCS Code	Description	Mean Cost	Total Frequency
77331	Special radiation dosimetry	\$104.07	9,272
77399	External radiation dosimetry	\$109.57	5,592
77300	Radiation therapy dose plan	\$121.12	182,930
77332	Radiation treatment aid(s)	\$135.03	32,893
77336	Radiation physics consult	\$146.43	535,687
77333	Radiation treatment aid(s)	\$150.67	7,037
77370	Radiation physics consult	\$205.52	23,630
77280	Set radiation therapy field	\$209.89	84,659
77299	Radiation therapy planning	\$273.70	127

For APC 5611, CMS proposes a payment rate of \$135.80. **ASTRO is concerned with adding this APC to the two-times rule exception list.** The highest-cost service in APC 5611 is radiation therapy planning (77299), and the actual cost of the service is 163% higher than the lowest cost service, 77331 special radiation dosimetry, and 102% higher than the proposed rate for the APC. **This highlights an underlying flaw with the APC methodology: it does not provide an accurate representation of costs for radiation oncology services. Rather than excepting**

¹ Wentzensen N, Clarke MA, Perkins RB. Impact of COVID-19 on cervical cancer screening: Challenges and opportunities to improving resilience and reduce disparities. *Prev Med.* 2021;151:106596. doi:10.1016/j.ypremed.2021.106596, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8241689/>

² https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/C-APC_Methodolgy_Letter.pdf

APC 5611 Level 1 Radiation Therapeutic Radiation Treatment from the two-times rule, CMS should evaluate whether it is appropriate to include these codes in the same APC.

APC Classification of CPT Code 76145, Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report

CPT 76145, *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report*, is a new medical physics code that was implemented on January 1, 2021.

CPT 76145 is used to describe the medical physicist's work in performing a patient-specific peak organ dose calculation subsequent to an interventional radiology or interventional cardiology procedure exceeding the facility's established threshold for radiation air kerma from one or more procedures. Typically, the medical physicist will review the request and verify that the institutional review threshold has been exceeded. In addition, the medical physicist will ascertain if adverse skin or other organ injuries have been reported, consistent with typical time-dose response effects. The medical physicist reviews the procedure with the physician and imaging staff.

The work includes a patient-specific calculation and tabulation of the input calculation data for each imaging segment (and sub-segments if there is a significant change in x-ray parameter(s)), resultant organ dose for each segment and total peak organ dose for all segments for the maximally exposed tissue. Further, there is a review of the anticipated tissue response based on time/dose/effect literature. The medical physicist will verify the recorded reference air kerma, entrance skin air kerma, and other relevant radiation parameters input to the calculation by independent radiation exposure measurements in the procedural room using the same equipment and techniques as were used for the clinical procedure.

CMS proposes to maintain assignment of the medical physics code 76145 to APC 5612 *Level 2 Therapeutic Radiation Treatment Preparation* with a 2023 proposed payment of \$365.15. APC 5612 has 10 clinically similar, radiation oncology therapeutic radiation treatment codes. CPT 76145 is not a radiation oncology code used in the treatment of cancer patients. CPT 76145 describes a patient-specific peak organ dose calculation that can be utilized across a broad spectrum of interventional radiology or interventional cardiology services. The dose evaluation service is not provided as part of treatment preparation but after an interventional radiology or interventional cardiology service(s).

The American Association of Physicists in Medicine (AAPM) presented to the Hospital Outpatient Payment (HOP) Advisory Panel on August 22, 2022. Although the Panel did not accept the AAPM's recommendation for reassignment of CPT 76145, the Panel did recognize that this is not a radiation oncology service and remarked on the lack of outpatient claims data for 2021 used for 2023 rate setting. In contrast to the present APC placement of CPT 76145 within HOPPS, CPT 76145 is a technical component only code under the Medicare Physician Fee Schedule with 2022 payment of \$832.97 and a 2023 proposed payment of \$907.65.

ASTRO agrees with the HOP Advisory Panel that CPT 76145 should be assigned to a New Technology APC; however, the recommended payment band may not provide appropriate reimbursement to hospitals. We believe that the current underpayment for the amount of time required for an imaging medical physicist to provide this service may result in hospitals not receiving appropriate payment for the resources used. This could lead to the performing physician not receiving quantitative dose information necessary to predict and prepare the patient for possible effects resulting from multiple high dose procedures.

This imaging medical physics service meets the criteria for assignment to a New Technology APC and we agree that assigning this service to a New Technology APC will allow CMS, in future rulemaking, to gather claims data to price the service and assign it to the APC with services that use similar resources and are clinically comparable.

ASTRO supports the HOP Advisory Panel recommendation that CMS reassign CPT code 76145 *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report to a New Technology APC beginning January 1, 2023. We recommend that CMS reassign CPT 76145 to APC 1510 New Technology Level 10 (\$801-\$900), which more closely aligns reimbursement to the current 2022 and proposed 2023 Medicare Physician Fee Schedule payment rates.*

Brachytherapy Sources

In the 2023 HOPPS proposed rule, CMS is proposing to continue to base the payment rates for brachytherapy sources on the geometric mean costs for each source, which is consistent with the methodology used for other services under HOPPS. Additionally, the Agency will use the costs derived from 2021 claims data to set the proposed 2023 payment rates for brachytherapy sources because that is the claims data used for most other items in the proposed rule.

In the 2022 HOPPS final rule, CMS established a Low Volume APC policy for brachytherapy APCs (also for New Technology APCs and clinical APCs—it is universal). For those APCs with fewer than 100 single claims that can be used for rate setting purposes in the existing claims year, CMS uses up to four years of claims data to establish a payment rate for each item or service, which is a similar methodology that the Agency applies to low volume services assigned to New Technology APCs. Further, the Agency calculates the cost based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost.

CMS is proposing to designate 4 brachytherapy APCs as Low Volume APCs for CY 2023 (See Table 24 below). *Brachytherapy, non-stranded, Gold-198*, did not meet the claims threshold for the CY 2023 proposed rule as it had zero claims available for ratesetting. **ASTRO is concerned that proposing an APC payment without any claims data sets a troubling precedent. The Agency should further consider how to handle situations where there are no claims data available in order to avoid publishing inappropriately low payment rates.**

Table 24: Cost Statistics for Proposed Low Volume APCs Using Comprehensive (HOPPS) Ratesetting Methodology for CY 2023

APC	APC Description	CY 2021 Claims Available for Ratesetting	Geometric Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	CY 2023 Proposed APC Cost
2632	Iodine I-125 sodium iodide	9	\$141.23	\$31.74	\$44.35	\$37.26	\$44.35
2635	Brachytx, non-str, HA, P-103	26	\$125.24	\$34.04	\$51.09	\$42.77	\$51.09
2636	Brachy linear, nonstr, P-103	0	---*	\$49.65	\$53.38	\$38.80	\$53.38
2645	Brachytx, non-str, Gold-198	14	\$144.37	\$184.49	\$377.65	\$141.18	\$377.65

*For this proposed rule, there are no CY 2021 claims that contain the HCPCS code assigned to APC 2636 (HCPCS code C2636) that are available for CY 2023 HOPPS/ASC rate setting.

HOPPS Payment for Software as a Service

Algorithm-driven services that assist practitioners in making clinical assessments can include clinical decision support software, clinical risk modeling, and computer aided detection (CAD). CMS refers to these technologies as software as a service (SaaS). For CY 2023, CMS is seeking comments on the specific payment approach it might use for these services under the HOPPS as SaaS-type technology becomes more widespread. CMS is concerned about the potential for bias in algorithms and predictive modeling and is seeking comments on how it can encourage software developers to prevent or mitigate the possibility of bias in new applications of this technology.

ASTRO appreciates CMS' interest in seeking stakeholder input regarding appropriate payment approaches for SaaS. We recognize that many of the current examples of SaaS involve diagnostic imaging and appreciate that the Agency recognizes the importance of separate and distinct payments, sometimes through add-on payments, for these services. As has been previously discussed, ASTRO has long been concerned regarding the CMS packaging methodology that does not recognize component coding or the complexity of some services. **We encourage CMS to pursue future code development and valuation through the American Medical Association (AMA) CPT/RUC process, which allows for transparency and dialogue with involved stakeholders.**

At its September 2021 meeting, the AMA CPT Editorial Panel issued guidance for classifying various artificial intelligence/augmented intelligence (AI) applications. The guidance divides the work associated with the use of AI enabled medical services and/or procedures into one of three categories: assistive, augmentative, or autonomous.

The assistive category involves technology that detects clinically relevant data without analysis or generated conclusions that inform the physician or other qualified health professional's (QHP) decision making. The augmentative category involves technology that analyzes and/or quantifies data in a clinically meaningful way that requires the physician or QHP to interpret and report. Finally, autonomous category involves technology that automatically interprets data and independently generates clinically meaningful conclusions without concurrent physician or QHP involvement.

AI, SaaS, and Software as a Medical Device (SaMD) should not be viewed as "operating in the background" simultaneously for patients. Some types of AI, SaaS, and SaMD should be paid separately because of the added value they provide for a specific patient's condition, while other types may not need to be paid separately. Furthermore, AI, SaaS, and SaMD may be unique to a specific service and patient diagnosis, warranting an approach to value PE on a case-by-case basis. CMS should also consider the different business models through which AI, SaaS, and SaMD are made available to hospitals, physicians, and other providers, including (1) a subscription model where the customer pays a monthly fee independent of the number of uses; (2) a per-click model where the customer pays each time the AI is used; (3) a yearly fee; (4) a licensing model; and (5) an add-on payment to a piece of capital equipment. The contractor should analyze how and when these models are used and how they can be incorporated Medicare's payment systems.

The AMA AI taxonomy could serve as a starting point for establishing a comprehensive framework for how AI and SaaS can be covered across Medicare's benefit categories if patients are to benefit from the wide variety of digital advances in health care delivery and providers are to be encouraged to incorporate these advances into their practices. This framework should include principles that apply across Medicare's benefit categories. Finally, CMS should consider solutions that can be applied consistently across all services in a benefit category that would provide appropriate coverage and reimbursement for new technology across all payment systems. Finally, CMS should consider how the New Technology APC, including the application process could be consistently used for SaaS and AI, and how they could also be used within the Physician Fee Schedule to recognize appropriate payment.

Health Equity

Similar to proposals put forth in the Agency's other proposed rules, CMS is seeking input on ways to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable. One approach being considered to measure equity across CMS programs is the expansion of efforts to report quality measure results stratified by patient social risk factors and demographic variables.

ASTRO supports the stratification of quality measure results by race and ethnicity, but also encourages CMS to consider stratification by patient residency in rural versus urban locations. These indicators lend themselves to demonstrating whether a hospital or other healthcare settings may provide healthcare services to an underserved population that is at higher risk for experiencing healthcare disparities.

As for the collection of additional demographic data, the collection of a minimum set of demographic data elements such as race, ethnicity, sex, sexual orientation, gender identity, primary language, tribal membership, and disability status can be valuable to better understanding the patient population served. However, these indicators can be further enhanced through the collection of additional data points such as employment status, education level, insurance status, income level, and distance from provider, which may further inform whether a patient needs additional social and financial supports to ensure they are able to initiate and complete care.

The collection of demographic data and stratification of quality measures can be used to better understand quality measures performance across different patient populations. It will allow for more granular analysis to determine whether interventions that are in place to improve quality are successful for some populations but not for others. Thus, this will inform the need for modifications or changes to quality measures that can be designed to truly drive quality improvement across all patient populations.

Additionally, this data could be used to establish a Hospital Equity Score. Hospital Equity Scores can synthesize reported metrics to better inform decision making for addressing healthcare disparities, but it could be taken one step further and applied to patients seeking care in these facilities by ensuring that they have access to social and financial supports necessary to access and complete medical treatment. **ASTRO supports the concept of developing beneficiary-specific equity scores to identify those patient populations that require wrap around services, such as nutritional counseling, access to healthy food, transportation, housing, etc.** A health equity score can then be further used to tie community need to additional reimbursement that supports the delivery of specific services that are supportive of patients who experience health inequities.

While ASTRO is supportive of efforts to collect better data points for informing improved patient care and outcomes, we continue to urge the Agency to consider the burden—on hospitals, practices and patients—associated with collecting this data. Not only are time and money needed to upgrade software and implement new programming, but also hospitals and other healthcare settings will require staff to collect data and manage the related programming. CMS cannot meaningfully address the healthcare equity gap without investing in the resources necessary to reach our nation's most vulnerable populations.

Many physicians are frustrated with the existing Certified Electronic Health Records Technology (CEHRT) requirements associated with the Promoting Interoperability programs. Clinicians do not have any control over the electronic health records (EHR) products issued by vendors, yet they are penalized for not achieving CEHRT status. More data submission requirements require a stronger reporting framework, more commonly applied standards, and changes to workflow, for which there is currently no funding. Additionally, these changes cannot be made overnight, they take time to implement. For example, the Cures Update Edition is set for 2023, yet only Cerner has made adequate upgrades to meet these new requirements. CMS needs to provide adequate time for vendors to prepare and implement upgrade requirements.

Additionally, vendors must be held accountable for the upgrades required to CEHRT systems to ensure improved care coordination and patient access. Hospitals and physicians should not shoulder the burden of meeting these

requirements nor should they bear the costs associated with system upgrades. As previously stated, CMS needs to invest in the technological and social resources necessary to improve patient care across all populations. As COVID-19 has demonstrated, a “one-size-fits-all” approach has left many Americans behind. Therefore, the way to achieve health equity will be to target high risk populations with the social support and resources necessary to ensure they are able to achieve better health outcomes.

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 Adam Greathouse, Assistant Director, Health Policy, at (703) 839-7376 or Adam.Greathouse@astro.org.

Respectfully,



Laura I. Thevenot
Chief Executive Officer



Laura Dawson, MD, FASTRO
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