AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

September 4, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Proposed Rule; CMS-1809-P

Dear Ms. Brooks-LaSure,

The American Association of Physicists in Medicine (AAPM)[1] is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 22, 2024 *Federal Register* notice regarding proposed changes to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems.

Packaging Policy & Diagnostic Radiopharmaceuticals

CMS packages several categories of non pass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged with the payment for the related procedure or service.

After significant consideration and ongoing engagement from interested parties, CMS is proposing a change to the current policy that packages diagnostic radiopharmaceuticals regardless of their cost. CMS proposes to pay separately for any diagnostic radiopharmaceutical with per day cost greater than $630, which is approximately two times the volume weighted average cost amount currently associated with diagnostic radiopharmaceuticals. Any diagnostic radiopharmaceutical with a per day cost below the threshold would continue to be packaged under the current packaging policy.

The AAPM strongly supports the CMS proposal to unpackage and pay separately for diagnostic radiopharmaceuticals with per day costs exceeding $630.

[1] The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 9,000 medical physicists.

We believe that the proposed policy will reduce financial barriers and improve access to essential diagnostic tests that utilize radiopharmaceuticals.

The AAPM also supports the Society of Nuclear Medicine and Molecular Imaging (SNMMI) recommendation that CMS implement a lower threshold of $550 per day costs, aligning with a 1.75 multiplier, which better identifies high-cost outliers.

In response to CMS' request for input on an alternative per day cost, the SNMMI recommends that CMS adopt a packing threshold amount of $550 using a multiplier of 1.75. A 1.75 multiplier aligns with the current CMS payment methodology used to identify cases with unusually high costs that qualify for additional outlier payments. We believe that a 1.75 multiplier is more appropriate to use for identifying high-cost diagnostic radiopharmaceuticals that would qualify for separate payment.

In addition, CMS proposes to use the Mean Unit Cost (MUC) from Medicare claims data for payment but also seeks input on using Average Sales Price (ASP) data in unique circumstances.

The AAPM supports the Mean Unit Cost payment methodology in 2025 but suggests that Average Sales Price data is more accurate and should be considered for future years.

Proposed APC Assignment of New Magnetic Resonance Examination Safety Procedures

CMS proposes APC assignment for new codes effective January 1, 2025 that describe magnetic resonance (MR) examination safety procedures that capture the work involving patients with implanted medical devices that require access to MR diagnostic procedures (CPT codes 7XX00-7XX05). Patients with implanted medical devices now have expanded access to MR imaging procedures because of international test methods and standards for MR safety and conditional labeling. The conditions of an implanted device can limit anatomical regions eligible for MR imaging, and foreign bodies or implanted medical devices without MR conditional labeling need to be evaluated for suitability of an MR procedure. (See table below.)

CPT Code	SI	2025 Proposed APC Group	2025 Proposed Payment
7XX00 MR safety implant &/fb asmt stf 1	S	5731 Level 1 Minor Procedures	$24.55
7XX01 MR safety implant &/fb asmt stf ea	N		$0.00
7XX02 MR safety deter phys/qhp	S	5521 Level 1 Imaging without Contrast	$87.56
7XX03 MR safety med physics xm cstmz	S	5734 Level 4 Minor Procedures	$127.99
7XX04 MR safety implant elec prepj	S	5731 Level 1 Minor Procedures	$24.55
7XX05 MR safety implant pos &/immoblj	S	5733 Level 3 Minor Procedures	$59.07

The proposed APC assignments and their payment do not reflect the facility costs associated with these procedures. Now that it is possible to perform an MR examination in the presence of some of these devices and implants, it is necessary to appropriately reimburse hospitals for the work performed once a potential contraindication is discovered. We believe it is more appropriate to assign these codes to existing Radiation Therapy APCs.

The AAPM recommends that CPT codes 7XX00 and 7XX02 be assigned to APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation) with status indicator S and a proposed payment rate of $133.40.

The AAPM recommends that CPT codes 7XX03, 7XX04, and 7XX05 be assigned to APC 5612 (Level 2 Therapeutic Radiation Treatment Preparation) with status indicator S and a proposed payment rate of $369.19.

Procedure codes 7XX03, 7XX04, and 7XX05 require additional staff time, MR room time and clinical resources for planning, preparation, and patient positioning.

Comprehensive APC Methodologies for Surgical Insertion Codes for Brachytherapy

CMS continues to utilize the Comprehensive Ambulatory Payment Classifications (C-APC) payment methodology in CY 2025. 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 Comprehensive APC methodology, the AAPM has commented on concerns around the claims data used for rate setting due to significant variations in clinical practice and billing patterns across the hospitals that submit these claims. We met with CMS staff in February 2018 and in our 2019, 2020, 2021, 2022 and 2023 HOPPS proposed rule comment letters, the AAPM proposed a modified C-APC methodology for the surgical codes related to brachytherapy that mirrors the current CMS payment policy for single-session cranial stereotactic radiosurgery codes 77371 and 77372, which allows separate payment for specified preparation and planning codes. To date, the Agency has not addressed these concerns and the impact on Medicare beneficiary access to brachytherapy in the hospital outpatient setting is evident.

While the AAPM 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.

The AAPM remains concerned that the rates associated with C-APCs do not accurately or fully reflect the services and costs associated with the primary procedure. Given the complexity of coding, serial billing for cancer care, and potentially different sites of service for the initial surgical device insertion and subsequent treatment delivery or other supportive services, the AAPM continues to oppose the current comprehensive APC payment methodology for cancer care. **We urge the Agency to explore alternatives to the C-APC methodology so that it appropriately values this life saving service.**

The current Comprehensive APC payment methodology for brachytherapy does not accurately reflect the true cost of providing the procedures.

AAPM recommends that CMS discontinue the Comprehensive APC payment policy in 2025 for all brachytherapy insertion codes. CMS should revert to status indicator "T" for CPT codes 19296, 19298, 19499, 20555, 31643, 41019, 43241, 55874 55875, 55920, 57155 and 58346.

Alternatively, CMS could continue to pay for "J1" brachytherapy insertion codes under the C-APC payment methodology but exclude and make separate payment for designated preparation and planning services in addition to the C-APC payment (see Attachment A).

New Technology APCs & Biology Guided Radiation Therapy

Services that are assigned to New Technology APCs are typically new services that do not have sufficient outpatient claims to establish an accurate payment for services. New Technology APCs are designated by cost bands which allows CMS to provide appropriate and consistent payment for designated new procedures that are not yet reflected in the claims data. CMS generally retains a procedure in the New Technology APC to which it is initially assigned until it has obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC.

CMS proposes to maintain HCPCS codes C9794 and C9795 for biology guided radiation therapy in APCs 1521 and 1525, respectively, since the codes only became effective on January 1, 2024, and there is no claims data available for either code.

AAPM supports the CMS proposal to maintain HCPCS codes C9794 and C9795 for biology guided radiation therapy in APCs 1521 and 1525, respectively.

Payment Adjustment Policy for Radioisotopes Derived from Non-Highly Enriched Uranium Sources

CMS continues the policy of providing an additional $10 payment for radioisotopes produced by non-highly enriched uranium sources (non-HEU) through December 31, 2025. CMS proposes for CY 2026 that they would replace the add-on payment for radiopharmaceuticals produced without the use of Tc-99m derived from non-HEU sources with an add-on payment of $10 for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99.

AAPM supports the CMS proposal for a $10 add-on payment for radiopharmaceuticals that use Tc-99M derived from domestically produced Mo-99.

Low Volume APC Policy

Beginning in 2022, CMS established a Low Volume APC policy that designates clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims that can be used for rate setting purposes in the claims year used for rate setting for the prospective year (the CY 2023 claims year for this CY 2025 proposed rule) as Low Volume APCs. We agree with CMS that low utilization of services can lead to wide variation in payment rates from year to year, especially as it relates to brachytherapy sources and new procedures and services. Under the proposed Low Volume APC policy, the payment rates for these APCs would be set at the highest amount among the geometric mean, median, or arithmetic mean, calculated using up to four years of data.

AAPM supports continuation of the Low Volume APC policy.

Hospital Outpatient Quality Reporting Program

For the Hospital Outpatient Quality Reporting (OQR) Program measure set, CMS adopted the *Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults* eCQM for voluntary reporting that begins with the CY 2025 reporting period, and mandatory reporting that begins with the CY 2027 reporting period/CY 2029 payment determination.

For 66 years, the AAPM is and has been a leading scientific and professional organization for continual improvements and assurance of the highest quality imaging and dose-image optimization for the safety and benefit of patient care. Based on our broad expertise and deep track record, the **AAPM remains concerned regarding this quality measure as currently developed. In summary, this quality**

measure lacks national consensus of stakeholders and practitioners and has significant scientific limitations that will impact its safety and practical value. These limitations will decrease the measure's overall likelihood of clinical impact and may even negatively impact image quality, patient safety, and patient outcomes. Further, this measure would disproportionately burden hospitals serving a low-income population (e.g., rural and inner-city hospitals) due to their older equipment and lack of in-house medical physicists.

Given that CMS has paused implementation of the Appropriate Use Criteria for Advanced Diagnostic Imaging, we believe that a quality measure that addresses excessive CT radiation dose is important; however, the science behind this specific proposed quality measure is lacking. **AAPM advocates for the development of national consensus metrics, with input from scientific, manufacturing, and standards stakeholders, towards scientific, meaningful, and practical assessment and tracking of CT dose and image quality.**

Additional Details

While efforts to enhance consistency of CT practice are noble and include initiatives by AAPM and others nationally and worldwide, this measure has significant limitations that impact its scientific and practical value. These limitations include non-consensus, non-standardized, and gross under-representation of image quality, improper estimation of radiation risk (in terms of dose length product (DLP) adjusted by patient size, not the actual patient dose and explicitly prohibited by the AAPM standard), over-simplified stratification of CT categories, and substantial oversimplified representation of implementation in practice, including not addressing the implementation challenges. We also believe that even attempting to implement this measure would cause excessive burden for medical physics and radiological technologist staff without any clear benefit.

The AAPM strongly agrees that efforts need to be continually applied to ensure patients receive high quality diagnostic imaging, optimized CT dose, and consistency across facilities while considering differing technologies and practices. The non-profit entities of the AAPM, the American College of Radiology (ACR), and Image Wisely and Image Gently Alliances have spent decades working towards this goal and continue to do so through many initiatives. Among them, the non-profit ACR CT Dose Index Registry (DIR; https://www.acr.org/Practice-Management-Quality-Informatics/Registries/Dose-Index-Registry, established in 2011) has the significant stature of implementing a dose registry that enables facilities to compare dose indices nationally, to ensure the highest quality imaging with lowest possible dose. The ACR CT DIR implementation incorporates the expert, consensus opinions of the medical imaging community.

Analysis and Concerns

AAPM's significant concerns about this eCQM and its adoption in the 2025 HOPPS proposed rule are based on detailed reviews by leading AAPM experts on this topic and broad consensus across multiple committees of experts that we have conducted over the past year. This position stems from six major concerns about the proposed measure:

1) *Unscientific characterization of CT scan risk:* The measure is based on risk estimation approaches and their uncertainties that are not reflective of the consensus of the scientific community. At the present time, epidemiological evidence supporting increased cancer incidence or mortality from radiation doses below 100 mSv is inconclusive.[2] Given the lack of scientific consensus about potential risks from low doses of radiation, predictions of hypothetical cancer incidence and mortality from the use of diagnostic imaging are highly speculative. The

[2] https://www.aapm.org/org/policies/details.asp?id=2548

AAPM, and other radiation protection organizations, specifically discourages these predictions of hypothetical harm.

2) *Inactionability of the measure to enable targeted change to improve practice*: It is not clear how the measure can be practically used to improve imaging practice and how a facility can achieve compliance, given the wide variety of factors and technologies involved. For instance, estimation of patient size for CT dose estimation remains an evolving challenge due the wide range of body habitus. In addition, the measure uses size-adjusted DLP to characterize radiation exposure, but there is no established and accepted method for adjusting DLP by patient size.

3) *Inadequate addressing of the complexity of CT categorization:* The measure does not address the magnitude of the complexity of CT categorization (e.g., body, adult, dynamic, etc.) nor does it suggest means to overcome it given that even current standards are lacking in the uniform characterization of protocols. The CT categorization scheme in this measure inadequately addresses criteria such as the reason for the scan, CT reconstruction parameters, and patient size. Inaccurate classification of data can lead to significant errors in the resulting aggregated data, leading to erroneous conclusions negatively impacting patient care.

   For example, one reference cited to support the proposed measure has an accompanying editorial highlighting the proposed approach's limitations [Mahesh M. Benchmarking CT Radiation Doses Based on Clinical Indications: Is Subjective Image Quality Enough? Radiology. 2022; 302:2, 390-391]. The editorial and stated limitations are not addressed in the eCQM proposal.

4) *Inadequate assessment of noise:* Use of "global noise" can misrepresent the quality of an exam and does not account for the diversity of influences on noise in a CT image, such as differences in CT technologies or new reconstruction methods that may dramatically alter noise. Further, noise does not have a singular value in a CT exam.

5) *Inadequate assessment of image quality:* Image quality is affected by a myriad of factors including resolution and contrast, as well as the intended purpose of the exam. A singular representation of image quality via global noise is a gross simplification of image quality, leading to misrepresentation of image quality that detracts from patient care. By example, a CT image protocol may be purposefully designed that yields higher noise to best address a particular diagnostic imaging task. A recent study by leading CT experts presented at the Radiological Society of North America 2022 annual meeting clearly documents that CT noise is only a tertiary consideration of image quality as judged by leading radiologists (Gress et al. Ranking the Relative Importance of Image Quality Features in CT by Consensus Survey, RSNA 2022 – the refereed paper is currently under review by *Radiology*).

6) *Emphasis on dose reduction instead of dose optimization:* We appreciate inclusion of both radiation dose and image quality as factors in the eCQM as a balance; however, the eCQM incorrectly emphasizes dose reduction, instead of dose *optimization*, for the imaging task at hand. Individualization and optimization of care and safety should be the goal, not dose minimization. Minimizing doses can lead to patients being underexposed, resulting in reduced image quality, potentially missed or delayed diagnosis, and even repeat scans thereby ultimately increasing dose to the patient.

We thank you for this opportunity to submit our comments and request that CMS carefully consider these issues for the final rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (561) 631-0677.

Sincerely,

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President, American Association of Physicists in Medicine

Michele S. Ferenci

Michele S. Ferenci, PhD
Chair, Professional Economics Committee

ATTACHMENT A

The AAPM identified a list of twenty-eight (28) codes proposed for separate payment in addition to the C-APC payment for the brachytherapy insertion codes (CPT 19296, 19298, 19499, 20555, 31643, 41019, 43241, 55874, 55875, 55920, 57155, 58346) effective January 1, 2022 (see below). Not all planning and preparation codes would be utilized for each brachytherapy insertion procedure code listed above. This C-APC modified policy mirrors the current CMS payment policy for single-session cranial stereotactic radiosurgery codes 77371 and 77372, which allows separate payment for specified preparation and planning codes.

- 10035 Placement of soft tissue localization device (egg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including image guidance; first lesion
- 32553 Placement of interstitial devices for radiation therapy guidance (egg fiducial markers, dosimeter), percutaneous, intra-thoracic, single or multiple
- 49411 Placement of interstitial devices for radiation therapy guidance (egg fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvis (except prostate), and/or retroperitoneum, single or multiple
- 55874 Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance
- 55876 Placement of interstitial device(s) for radiation therapy guidance, prostate, single or multiple
- 76000 Fluoroscopy, up to 1 hour physician or other qualified health care professional time
- 76872 Ultrasound, transrectal
- 76873 Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning
- 77280 Therapeutic radiology simulation-aided field setting; simple
- 77285 Therapeutic radiology simulation-aided field setting; intermediate
- 77290 Therapeutic radiology simulation-aided field setting; complex
- 77295 3-dimensional radiotherapy plan, including dose-volume histograms
- 77300 Basic radiation dosimetry calculation
- 77301 Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
- 77306 Teletherapy isodose plan; simple, include basic dosimetry calculation(s)
- 77307 Teletherapy isodose plan; complex, include basic dosimetry calculation(s)
- 77316 Brachytherapy isodose plan; simple, include basic dosimetry calculation(s)
- 77317 Brachytherapy isodose plan; intermediate, include basic dosimetry calculation(s)
- 77318 Brachytherapy isodose plan; complex, include basic dosimetry calculation(s)
- 77321 Special teletherapy port plan
- 77331 Special dosimetry, only when prescribed by treating physician
- 77332 Treatment devices; simple
- 77333 Treatment devices; intermediate
- 77334 Treatment devices; complex
- 77336 Continuing medical physics consultation
- 77338 Multi-leaf collimator devices for IMRT
- 77370 Special medical radiation physics consultation
- C9728 Placement of interstitial devices for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach); abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple