

September 6, 2024

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1809-P P.O. Box 80010 Baltimore, MD 21244–1850

> Re: CMS-1809-P: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Dear Administrator Brooks-LaSure:

The American College of Radiology (ACR), representing over 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services' (CMS) calendar year (CY) 2025 proposed rule on Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs.

The ACR provides comment on the following important issues:

- 1. Proposed APC Placement of Newly Established CPT Codes
- 2. Cardiac Computed Tomography Reimbursement
- 3. Medical Physics Dose Evaluation Code Reimbursement
- 4. Hospital Outpatient Prospective Payment System (HOPPS) Payment for Software as a Service
- 5. Payment Policy for Diagnostic Radiopharmaceuticals
- 6. Virtual Direct Supervision of Diagnostic Services Furnished to Hospital Outpatients
- 7. Coverage Changes for Colorectal Cancer (CRC) Screening Services
- 8. Hospital Outpatient Quality Reporting (OQR) Program Updates
- 9. Provisions Related to Medicaid & CHIP

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102

215-574-3150

ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY 1100 Wayne Ave., Suite 1020 Silver Spring, MD 20910

703-648-8900



Proposed APC Placement of Newly Established CPT Codes

Proposal

CMS proposes to place CPT codes 5X006 through 5X008 to describe MRI-monitored transurethral ultrasound ablation services in the following APCs for CY2025:

CPT Code	Short Descriptor	CY2025 Proposed SI	CY2025 Proposed APC	CY2025 Proposed Payment
5X006	Ins trurl ablt trnsdc thr us	В	*	*
5X007	Ablt trurl prst8 tis thrm us	В	*	*
5X008	Ablt trurl prst8 tis trnsdcr	J1	5376 – Level 6 Urology & Related Services	\$9208.50

*5X006 and 5X007 are packaged into 5X008 as a Comprehensive-APC

ACR Perspective and Comments

The ACR is pleased with the proposed placement for CPT codes 5X006, 5X007, and 5X008 for CY2025 and agrees with CMS's recommendation. The proposed APC placement is appropriate for the work and resources involved in the treatment planning, transducer insertion, and ablation procedures done with an MRI-monitored TULSA system.

Proposal

CMS proposes to place CPT code 6XX01 to describe services for percutaneous radiofrequency ablation of the thyroid in the following APCs for CY2025:

		CY2025	CY2025			
		Proposed	Proposed	CY2025	ACR	ACR
CPT	Short	Status	APC	Proposed	Proposed	Proposed
Code	Descriptor	Indicator	Placement	Payment	APC	Payment
			5072 – Level 2		5073 – Level 3	
6XX01	Abltj 1/+thyr		Excision/		Excision/	
	ndul 1lobe prg	J1	Biopsy/	\$1615.22	Biopsy/	\$2,824.39
	ndut nobe prq		Incision &		Incision &	
			Drainage		Drainage	

ACR Perspective and Comments

The ACR does not agree with CMS's placement of CPT 6XX01 for percutaneous radiofrequency ablation of the thyroid in this rule. The proposed payment rate of \$1615.22

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 **CENTER FOR RESEARCH AND INNOVATION** 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150 ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY 1100 Wayne Ave., Suite 1020 Silver Spring, MD 20910

703-648-8900



does not cover the supplies, resources, and clinical staff needed to provide this service to Medicare beneficiaries. The College recommends that CMS place CPT 6XX01 into APC 5073 (Level 3 Excision/Biopsy/Drainage) with payment rate of \$2,824.39, as it shares more clinical similarity and resource homogeneity with other codes within that APC. Under APC 5073, hospitals would be able to adequately provide this service to their patients.

Proposal

CMS proposes to place CPT codes 7XX00, 7XX02, 7XX03, 7XX04, and 7XX05 to describe magnetic resonance (MR) examination safety procedures in the following APCs for CY2025:

CPT Code	Short Descriptor	CY2025 Proposed Status Indicator	CY2025 Proposed APC Placement	CY2025 Proposed Payment	ACR Proposed APC	ACR Proposed Payment
7XX00	Mr sfty implt&/fb asmt stf 1	S	5731 – Level 1 Minor Procedures	\$24.55	5611 - Level 1 Therapeutic Radiation Treatment Preparation	\$133.40
7XX02	Mr safety deter phys/qhp	S	5521 – Level 1 Imaging without Contrast	\$87.56	5611 - Level 1 Therapeutic Radiation Treatment Preparation	\$133.40
7XX03	Mr sfty med physics xm cstmz	S	5734 – Level 4 Minor Procedures	\$127.99	5612 - Level 2 Therapeutic Radiation Treatment Preparation	\$369.19
7XX04	Mr safety implant elec prepj	S	5731 – Level 1 Minor Procedures	\$24.55	5742 – Level 2 Electronic Analysis of Devices	\$91.87
7XX05	Mr safety implt pos&/immoblj	S	5733 – Level 3 Minor Procedures	\$59.07	5612 - Level 2 Therapeutic Radiation Treatment Preparation	\$369.19

ACR Perspective and Comments

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900

GOVERNMENT RELATIONS 505 Ninth St. N.W.

Suite 910 Washington, DC 20004 202-223-1670

CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102

215-574-3150

ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY



CPT codes 7XX00, 7XX02, 7XX03, 7XX04, and 7XX05 are newly established codes for CY 2025 to report magnetic resonance (MR) examination safety procedures. 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. In 2018, CMS released a Decision Memo with a national coverage determination (NCD) allowing coverage of MRI for patients with cardiovascular implanted electronic devices (CIEDs) that lack FDA labeling specific to use in an MRI environment under specified conditions, including additional qualified personnel supervision and pre-/post-MRI interrogation and programming of the device. Technological advancements in both the MRI scanner and in the design and testing of implants for MR safety have enabled many new implants to come to market with FDA-approved labeling specific to use in an MRI environment. However, now that it has become possible to perform an MRI 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.

The ACR recommends that codes 7XX00 and 7XX02 be placed in APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation) with status indicator S and payment rate of \$133.40. Codes 7XX03 and 7XX05 require additional staff time and clinical resources for planning, preparation, and positioning, so we believe they are most appropriately placed in APC 5612 (Level 2 Therapeutic Radiation Treatment Preparation) with status indicator S and a payment rate of \$369.19. 7XX04 involves interrogation and programming of an implanted device to protect the device and patient against interactions with the MRI scanner; we recommend placing 7XX04 in APC 5742 (Level 2 Electronic Analysis of Devices) with status indicator S and payment rate of \$91.87.

Cardiac Computed Tomography Reimbursement

Proposal

The three codes used to describe cardiac CT studies (75572, 75573, 75574) are proposed to be placed in APC 5571 with a reimbursement rate of \$175.75 under the current HOPPS methodology. CMS proposed a change in this proposed rule with a potential reclassification into a new and higher Ambulatory Payment Classification (APC). CMS is seeking feedback to determine whether 50% or more of hospital outpatient departments are using, have attempted to use, or would use a cardiology revenue code for CCTA tests, if allowed. CMS will also be reviewing the latest available claims data before finalizing APC placements of these codes.

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150

		CY2025 Proposed	CY2025	CY2025	ACR	ACR
СРТ	Short	Status	Proposed	Proposed	Proposed	Proposed
Code	Descriptor	Indicator	APC	Payment	APC	Payment
	Ct hrt w/3d		5571 – Level 1		5572 – Level 2	
75572	image	S	Imaging with	\$175.75	Imaging with	\$373.77
	indgo		Contrast		Contrast	
	Ot brt of atrus		5571 – Level 1		5572 – Level 2	
75573	Ct hrt c+ strux	S	Imaging with	\$175.75	Imaging with	\$373.77
	cgen hrt ds		Contrast		Contrast	
	Ct angio hrt		5571 – Level 1		5572 – Level 2	
75574	w/3d image	S	Imaging with	\$175.75	Imaging with	\$373.77
	woumage		Contrast		Contrast	

ACR Perspective and Comments

CMS has acknowledged concerns raised by stakeholders regarding the insufficiency of current payment rates for CCTA codes, which have declined since 2017, and if no changes are made, will continue to decrease again for the seventh year in a row. The ACR does not agree with the placement of cardiac CT codes 75572, 75573, and 75574 into APC 5571 for CY 2025 under the current HOPPS methodology.

In December 2023, CMS removed the coding edit restriction in a transmittal stating, "[CMS] identified an outdated return-to-provider (RTP) HCPCS-to revenue code edit that resulted in certain claims submissions being limited to specific revenue codes for CPT codes 75572, 75573 and 75574. These claims were returned to the providers for resubmission. The outdated edit has been removed." This restriction had previously precluded hospitals and practices from using the cardiology revenue code (048X), which maps to the cardiology cost center (03140). The removal of this restriction would potentially lead to higher payment rates, allowing hospitals to bill for cardiac CT services using the most appropriate revenue code for CY 2024. This point was reaffirmed by CMS in its recent study, highlighting that if 50% or more hospital outpatient departments (HOPDs) bill with the cardiology revenue code (048X), the GMC would significantly increase, leading to a higher ambulatory payment classification APC assignment (from APC 5571 to APC 5572).

Irrespective of the revenue code utilized, the cost to the system or practice remains high, given that facilities must compensate for advanced scanners, specialized resources and highly trained personnel, in addition to extra work that comes with a CCTA, regardless of the reader's specialty (radiologist or cardiologist).

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150

Cardiac CT exams involve higher risk patients and require more time, highly trained technologists who reformat non-orthogonal projections, administration of vasoactive medications, and close monitoring of patients during and after the procedure. The need for all these resources is vastly different from other contrast-enhanced imaging studies in 5571 which are less resource intensive and may only take a fraction of the time. Moreover, this test has been shown to be highly cost-effective in evaluating acute chest pain in the emergency setting by reducing hospital admissions and precluding the need for costlier interventional procedures. APC misassignment will only serve to stunt further adoption. **Cardiac CT codes 75572, 75573, and 75574 should be reassigned to APC 5572 with payment rate \$373.77 to ensure beneficiary access to guideline-driven care and eliminate health inequities in cardiac care.**

We urge CMS to consider the significant cost implications and the critical nature of CCTA services in the final decision-making process. Adequate reimbursement is essential to ensure that facilities can continue to provide high-quality cardiac imaging services to patients. Thank you for the opportunity to provide input, and we hope CMS considers this feedback in revising the payment methodology for CY 2025.

Hospital Outpatient Prospective Payment System (HOPPS) Payment for Software as a Service (SaaS)

Proposal

For CY 2025, CMS proposes to place SaaS codes in the following APCs:

CPT Code	Short Descriptor	CY20 25 PR SI	CY2025 Proposed APC Placement	CY2025 Proposed Payment
0625T	Auto quan c plaq cptr alys	S	1511 – New Technology Level 11	\$950.50
0648T	Quan mr tis wo mri 1orgn	S	1504 – New Technology Level 4	\$250.50
0649T	Quan mr tiss w/mri 1orgn	S	1504 – New Technology Level 4	\$250.50
0721T	Quan ct tiss charac w/o ct	S	1508 – New Technology Level 8	\$650.50
0722T	Quan ct tiss charac w/ct	S	1508 – New Technology Level 8	\$650.50

Software as a Service (SaaS) CY 2025 Proposed APC Placements and Payment Rates

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150 ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY



0723T	Qmrcp w/o dx mri sm anat ses	S	1511 – New Technology Level 11	\$950.50
0724T	Qmrcp w/dx mri same anatomy	S	1511 – New Technology Level 11	\$950.50

ACR Perspective and Comments

The ACR supports the broad use of SaaS codes at an appropriate reimbursement rate so they may be adopted and utilized more widely by clinicians. The ACR believes CMS should allow adequate time for appropriate claims data to accrue before reassigning SaaS codes to new APCs. Refinements and exclusions based on low claims volumes should be applied consistently throughout the current fee schedule and across years. This would allow for more stability within the HOPPS with constantly emerging AI technologies.

The College believes CMS should clarify in the HOPPS final rule that the SaaS codes were designed by The American Medical Association (AMA) Current Procedural Technology (CPT) to be vendor neutral, and that these codes do not belong to any single vendor or represent any single vendor's services. To focus on a single commercial platform for a code is not accurate and confuses the applicability, limiting adoption of other tools for which the code was intended. By removing the current language that these codes are "associated with" a specific service, we anticipate an increase in claims, allowing CMS to gain a more accurate understanding of the actual costs associated with these services.

Payment Policy for Diagnostic Radiopharmaceuticals

Proposal

CMS proposes to pay separately for diagnostic radiopharmaceuticals with per day costs above a threshold of \$630, which is approximately two times the volume weighted average cost amount currently associated with diagnostic radiopharmaceuticals. CMS also proposes to update the \$630 threshold in CY 2026 and subsequent years by the Producer Price Index (PPI) for Pharmaceutical Preparations. CMS proposes to pay separately for payable diagnostic radiopharmaceuticals based on their Mean Unit Cost (MUC) derived from OPPS claims and is seeking comments on the use of Average Sales Price (ASP) for payment in future years.

ACR Perspective and Comments

We appreciate CMS' engagement with stakeholders on this topic in past years and the opportunity to comment on this important issue. **The College supports CMS's proposal for separate payment of diagnostic radiopharmaceuticals with the proposed per day costs above a threshold of \$630.** Separate payment is appropriate for advanced diagnostic radiopharmaceuticals because they are often not interchangeable with lower-cost, older

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 **CENTER FOR RESEARCH AND INNOVATION** 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150

ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY



diagnostic radiopharmaceuticals. In some instances, patients have no comparable diagnostic option to these advanced diagnostic radiopharmaceuticals, which may result in physicians prescribing less effective alternatives and a resulting inaccurate diagnosis or treatment plan.

The ACR supports the use of MUC as a reasonable alternative methodology for payment of radiopharmaceuticals without a currently reported ASP payment rate. We note that hospital outpatient claims data for certain products is limited and could result in fluctuations in payment from the average acquisition costs. We recommend that CMS allow separate payment based on the ASP methodology in CY 2025 where available, in CY 2026, and in future years. Using ASP could improve payment accuracy by applying an already established methodology used for separate payment of therapeutic radiopharmaceuticals. We are also strongly supportive of CMS' continued dialogue with manufacturers to understand some of the unique challenges associated with meeting the reporting requirements for ASP. In conclusion, we strongly support the proposal for separate payment for advanced diagnostic radiopharmaceuticals.

Virtual Direct Supervision of Diagnostic Services Furnished to Hospital Outpatients

Proposal

In the March 31, 2020 COVID-19 IFC, CMS changed the definition of "direct supervision" during the PHE for COVID-19 as it pertains to supervision of diagnostic tests, incident to services including some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using two-way, real-time audio/video technology, instead of requiring their physical presence. CMS has previously extended the virtual supervision flexibility through rulemaking. CMS acknowledged the utilization of this flexibility and recognized that many practitioners have stressed the importance of maintaining it. However, CMS continues to seek additional information regarding potential patient safety and quality of care concerns. CMS noted that an immediate reversion to the pre-PHE definition of direct supervision would prohibit virtual direct supervision, which may present a barrier to access to many services, such as incident-to services. CMS also recognizes that physicians and/or other supervising practitioners would need time to reorganize their practice patterns established during the PHE to reimplement the pre-PHE approach to direct supervision without the use of audio/video technology. CMS is extending this flexibility for all services on a temporary basis only. CMS is proposing to continue to define direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2025.

ACR Perspective and Comments

The ACR previously commented¹ in support of CMS's decision to revise regulatory text to

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 **CENTER FOR RESEARCH AND INNOVATION** 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150

¹ https://www.acr.org/-/media/ACR/Files/Advocacy/AIA/091323-ACR-24-MPFS-PR-Comment-Letter-Final.pdf

allow the virtual presence of the physician (or other practitioner) through audio/video realtime communications technology (excluding audio-only) through December 31, 2024. As previously stated, the ACR supports our previous comments that CMS make permanent the rule that allows virtual direct supervision of level 2 diagnostic tests via real time audio/video communications. *The ACR is supportive of CMS's decision to extend this flexibility through 2025. Additionally, the ACR continues to believe that allowing remote direct supervision for level 2 diagnostic tests will ensure patients have access to timely and safe diagnostic imaging.* The ACR recognizes that flexibility is necessary for those practices that deliver care to rural or underserved populations who may experience access to care issues.

Contrast Material Administration

In 2022, the ACR aligned the <u>ACR–SPR Practice Parameter for The Use of Intravascular</u> <u>Contrast Media</u>² to comply with the <u>ACR Manual on Contrast Media</u>. The Drugs and Contrast Media Committee has now updated their <u>statement</u>³ on the supervision of contrast material administration. The committee statement was designed to afford facilities with latitude in their operations while upholding safety standards. In instances where a physician offers direct oversight for the study, whether on-site or remotely, the requirement for direct supervision is deemed fulfilled. Our primary concern is ensuring a qualified individual capable of managing contrast reactions is present on-site; these individuals may include Nurse Practitioners, Registered Nurses, or other qualified personnel. Recognizing the substantial variability in institutional protocols and local regulations, including state laws and policies, we deliberately abstained from delineating specific professional designations for personnel providing oversight of contrast management. As long as individuals possess the competencies outlined in the contrast statement, they may render the service on-site, provided they adhere to pertinent local statutes and regulations.

Onsite Personnel to Ensure Patient Safety

The ACR supports CMS's prioritization of patient safety. To ensure patient safety, the ACR believes there should be onsite personnel who would be, in the unlikely event of an adverse contrast reaction, able to appropriately handle contrast reactions. The ACR chose to focus on qualifications and training of the individuals providing the oversight as opposed to the specific credentials for the onsite personnel to account for differences in state and local regulations and in anticipation of possible future changes in scope of practice. In the "Statement from Drugs and Contrast Media Committee on Supervision of Contrast Material Administration,"

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 **CENTER FOR RESEARCH AND INNOVATION** 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150

² https://www.acr.org/-/media/ACR/Files/Practice-Parameters/IVCM.pdf

³ <u>https://www.acr.org/-/media/ACR/Files/Clinical-Resources/FINAL_Statement-from-Drugs-and-Contrast-Media-Committee-on-Supervision-of-Contrast-Administration.pdf</u>



the ACR outlines those qualifications for on-site personnel during virtual direct supervision of level 2 diagnostic tests.

Radiologist Led Teams

To ensure quality in diagnostic imaging, it is essential that the supervising professional be able to assess the quality of an image relative to the capability of the equipment and diagnostic demands, ensure diagnostic quality, and minimize unnecessary radiation exposure to the patient and personnel. Onsite personnel should continue to be a part of radiologist led teams. To ensure patient safety is prioritized, CMS should ensure APRNs and PAs continue to work alongside physicians as part of physician-led teams.

Maintaining Access

By making the definition of direct supervision to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications permanent, CMS will help ensure afterhours access to radiology services. Additionally, virtual supervision services will allow for better access to services across rural areas where access issues persist. The ACR maintains the importance of patient safety while allowing for access in underserved areas.

Coverage Changes for Colorectal Cancer (CRC) Screening Services

Proposal

CMS proposes to remove coverage for double contrast barium enema for colorectal cancer screening and add coverage for computed tomography colonography (CTC). CMS also proposes to expand the existing definition of a "complete colorectal cancer screening" to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker colorectal cancer screening test. CMS proposes to place CPT 74263 for CT colonography screening in APC 5522 (Level 2 Imaging without Contrast) and payment rate of \$106.30 for CY 2025.

ACR Perspective and Comments

The ACR would like to applaud and strongly support the proposal to expand coverage of colorectal cancer screening to include computed tomography colonography (CTC) as referenced in the Medicare Physician Fee Schedule (MPFS) for CY 2025. This minimally invasive colorectal cancer screening option will save Medicare beneficiary lives by detecting pre-cancerous polyps and/or identifying cancer at an early stage. CTC has been an untapped resource that will be beneficial to broaden screening options and mitigate access issues for Medicare beneficiaries. In addition, with the lowering of the screening age from 50 to 45 years old due to the trends of early age onset of colorectal cancer, there is an even greater demand for screening tests to cover the expanded pool of eligible patients. CTC provides a proven,

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150 ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY 1100 Wayne Ave., Suite 1020



safe and minimally invasive exam to both screen for precursor polyps and colorectal cancer and save lives.

The ACR would like to thank CMS for the opportunity to provide feedback on the proposal to reimburse CT colonography screening services. While Medicare does not pay for screening CT colonography in 2024, the PFS shows a 2024 payment for the technical component of CPT code 74263 of \$566.22 using the resource-based practice expense methodology. However, CMS is proposing to cap the technical component payment for 2025 at the same rate that is paid under the outpatient prospective payment system (OPPS) or \$106.30. This reduction of \$459.92 (or 81.2 percent) will make it untenable for radiologists to provide screening CT colonography. Therefore, while ACR is appreciative that CMS is changing its longstanding policy by proposing to pay for screening CT colonography under the colon cancer screening benefit, the proposed change will have limited benefit unless CMS can provide payment for screening colonography under the PFS at a rate that makes it viable to perform.

CMS proposes to cap the payment for screening CT colonography under section 5102(b)(1) of the Deficit Reduction Act (DRA) of 2005. Under the DRA, the technical component of certain imaging services paid under the PFS is capped at the amount paid under the OPPS. The DRA defines imaging services as "imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography."

The logic behind the DRA provision is that the hospital costs should always be greater than physician costs when performing imaging services. However, the cap assumes that, if a PFS payment is above the hospital payment, the problem must be that the PFS payment is too high rather than the OPPS payment is too low. As explained in more detail below, the ACR does not believe this is the case with CT, MRI and other advanced diagnostic imaging services, including CTC, where the OPPS payment is well below the resources required to perform the test.

Under the OPPS, CMS uses a highly complex methodology to develop the OPPS relative weights. At its basic level, CMS uses hospital charges on claims reduced to costs using cost-to-charge ratios (CCRs) from hospital cost reports. However, the CCR for advanced diagnostic imaging cost centers, specifically CT and MRI, are the lowest being reported by hospitals. In the FY 2025 IPPS proposed rule, the CCRs for CT and MRI respectively are 0.033 and 0.067.⁴

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150

⁴, Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes, public display copy released on August 1, 2024, page 332

This means that CMS is assuming a mark-up for CT of 30 times its cost and for MRI nearly 15 times its cost. ACR believes these extremely low CCRs are more likely the result of faulty cost reporting than the actual level of mark-up of hospitals charges over cost. The magnitude of these mark-ups appears implausible and date back to the FY 2009 IPPS where CMS discussed a contract awarded to Research Triangle International (RTI) to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the CCRs across services within cost centers."⁵ Charge compression describes higher percentage mark-ups on low-cost items than high-cost items. Using a single CCR that groups low and high-cost item. While RTI's study was largely undertaken because of concerns about high-cost medical devices being reported in the same cost center as low-cost supplies, RTI's analysis went beyond that narrow issue.⁶

For MR and CT, the charge-compression hypothesis would set out to determine if higher cost diagnostic tests like MR and CT have lower percentage mark-ups than lower cost X-ray tests. While MRI and CT scans are more expensive than traditional X-rays, the results of creating separate cost centers for them has produced the opposite result than would be expected—higher mark-ups for the more expensive services than the less expensive services.

The CCRs for selected CT and MR procedures also show a significant number of CCRs that are close to zero. These near zero CCRs indicate that even when hospitals create standard cost centers, they are likely not able to accurately re-allocate many costs that are already allocated across hospital departments to new CT and MR departmental cost centers. For these hospitals, the CCRs probably reflect allocations of staffing and dedicated departmental expenses, while the costs of equipment, some costs associated with space (e.g., lead in walls), other administrative costs have been spread across all hospital departments and have not been moved. The presence of these near zero CCRs will contribute to underestimated costs used in rate setting, pulling rates for CT and MR procedures down below their actual cost and further eroding payment accuracy. No other high-cost technologies are treated in this manner. Hospitals have standard accounting practices for high-cost moveable equipment, and it is inconsistent and burdensome to expect them to account for these two types of equipment in a different manner than they deal with other types of equipment.

Rather than demonstrating the charge compression hypothesis for CT and MRI, the cost reporting showed the opposite, a lower mark-up on a higher cost services likely due to flawed cost reporting. CMS should have considered the hypothesis to be unproven not that the

HEADQUARTERS 1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 **CENTER FOR RESEARCH AND INNOVATION** 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150

⁵ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, Final Rule, August 19, 2008, page 48451.

⁶ Dalton, Kathleen, A Study of Charge Compression in Calculating DRG Relative Weights, RTI International, January 2007.



opposite is true—that MR and CT have lower percentage mark-ups than other diagnostic X-ray tests. As the results are counter-intuitive, it makes more sense to conclude that how costs are reported to these costs centers is problematic rather than that CT and MR are overvalued with a single radiology CCR.

Indeed, public comments acknowledged by CMS on this issue suggest the data is problematic.

The commenters believed that the CCRs for advanced imaging may reflect a misallocation of capital costs on the cost report. They further stated that this could indicate that many hospitals are reporting CT and MRI machines as fixed equipment and allocate the related capital costs as part of the facility's Building and Fixtures overhead cost center instead of reporting the capital costs directly in the Radiology cost center.⁷

In responding to commenters' statements that hospitals would have problems with accurate creation of these new standard cost centers, CMS acknowledged that the allocation of very high cost "moveable equipment" to the department using that equipme may not be a standard practice in hospitals. CMS recognized that such practice would not produce accurate CCRs resulting in several years of delays by CMS in using some hospital CCRs to set OPPS rates.⁸

ACR has repeatedly requested that CMS not use the CT and MRI-specific cost centers and instead estimate cost using the single diagnostic radiology cost center, believing this will solve the inaccurate reporting of costs for CT and MR services. The benefits of using a single diagnostic radiology cost center include consistent reporting across hospitals, properly accounting for high-cost medical equipment, simplifying and standardizing cost reporting within the diagnostic radiology cost center, eliminating partial allocation of costs to CT and MR cost centers, and reducing burden. CMS has not adopted this comment. Beginning in 2021, CMS has been setting the imaging APC payment rates at 100 percent of the payment rate using the standard payment methodology.⁹

ACR contrasts the OPPS payment methodology where CMS is using obviously flawed cost reporting data to the PFS payment methodology for practice expenses that uses micro-costing to determine the direct practice expense share of the total payment with an algorithm for allowing indirect costs. Even this methodology applies a scaling adjustment to direct costs (proposed to be 0.4386 in the 2025 PFS proposed rule) before adding indirect costs yet

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150 ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY 1100 Wayne Ave., Suite 1020 Silver Spring, MD 20910

703-648-8900

⁷ FY 2009 IPPS Final Rule, page 48456.

⁸ Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; CY 2022 Final Rule, November 12, 2019, page 61151. ⁹ CY 2022 final rule, page 61152.

produces a payment for 2024 that is more than \$353 and 300 percent higher for 2024 than CMS is proposing for 2025 for screening CT colonography. Despite its flaws, the PFS payment for screening CT colonography, absent the OPPS cap, produces a payment that is at least tenable for it to be performed by radiologists in 2025.

The best long-term solution to this problem would be to eliminate the DRA cap for imaging services. This approach would at least allow for resource-based payment for screening CT colonography and other imaging services when paid under the PFS. As a complementary solution, ACR again requests that CMS default all costs and charges under the OPPS to a single diagnostic radiology cost center and not use the CT and MRI-specific cost centers for valuing services under the OPPS and the IPPS. ACR recognizes that CMS cannot adopt the first of these two solutions as it would require a statutory change that could only be enacted by Congress. However, ACR requests CMS pursue the second of these solutions in the 2025 OPPS final rule.

A short-term solution that CMS could potentially adopt would be to not apply the DRA cap to screening services like CT colonography. The DRA excludes screening and diagnostic mammography from eligibility for the cap. It is unclear why Congress selected only these procedures for exclusion from the cap, but it seems likely they had a concern specifically about the impact of the cap on screening and diagnostic services to identify breast cancer. Given the prevalence of colon cancer and the relatively new availability of colon cancer screening using CT colonography, it seems plausible, if not likely, that if the DRA cap were to be enacted today, Congress would have excluded additional screening services from the cap.

Another option that is clearly within CMS' authority would be to assign screening CT colonography to a higher paying APC. Screening CT colonography is assigned to APC 5522 for Level 2 Imaging without Contrast. An alternative APC assignment would be APC 5524 Level 4 Imaging without Contrast that has a proposed 2025 OPPS payment amount of \$544.85—which is far more comparable to the resource-based 2024 PFS payment of \$566.22.

Again, ACR requests CMS consider the public policy implications of assigning screening CT colonography to a higher paying APC. Given the impact of screening services on public health, public policy encourages their provision on a recommended schedule supported by public health research. The proposed payment of \$106.30 would make the provision of screening CT colonography financially unviable for many imaging practices which will likely disproportionately affect underserved communities and exacerbate colorectal cancer disparities in diagnosis and early treatment. A payment of \$566.22 will encourage the provision of screening CT colonography and contribute to early identification and treatment of colon cancer to the better of patients and our health care system.

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215–574–3150



Hospital Outpatient Quality Reporting (OQR) Program Updates

Proposed Measure Removals from the Hospital Outpatient Quality (OQR) Reporting Program Measure Set

CMS proposes to remove the MRI Lumbar Spine for Low Back Pain measure (OP-8) from the Hospital OQR program beginning in CY 2025. Per the proposed rule, CMS cited concerns with MRI overuse and evidence demonstrating that MRI results associated with low back pain have not equated to changes in treatment. Further, CMS analysis shows that national performance on the measure has remained stable, and low average volumes indicate limited reliability and the inability to improve the quality of care for patients with reported lower back pain. Studies have shown that documentation of conditions that fall into the exclusion criteria of the measure increased after implementation, resulting in a smaller patient population, indicating that the measure may not translate to improvement in imaging appropriateness. Additionally, the measure has not correlated with improved outcomes, and from public comment periods, CMS received feedback stating that the use of this measure may delay diagnoses.

ACR Perspective and Comments

ACR acknowledges that this measure is not ideal for improving patient outcomes, partly because of variations in practice patterns often influenced by sociodemographic factors. Although OP-8 should improve outcomes, it is known that inappropriate advanced imaging studies drive most unnecessary surgeries.¹⁰ Hence, surgeons may treat the images rather than proceed primarily on clinical grounds. Unfortunately, marginalized communities often receive unnecessary imaging and the ensuing spinal surgeries, which contribute to poor surgical outcomes and poor patient well-being so prevalent in these communities.¹¹ Ideally, measures based on well-crafted clinical practice guidelines (CPGs), such as the ACR Appropriateness Criteria and other Appropriate Use Criteria, that may be implemented, despite sociodemographic differences are needed. Moreover, provider and patient education should be coupled with disseminating CPGs to improve their adoption and adherence. **ACR welcomes discussion from CMS on alternative measure concepts that could improve care for patients with low back pain.**

Previously Finalized Hospital OQR Program Measure Set Beginning With The CY 2027 Payment Determination

In this rule, the quality measure, #3663e: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults was noted as beginning with voluntary reporting for the CY 2025 reporting period, followed by mandatory reporting

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 **CENTER FOR RESEARCH AND INNOVATION** 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150

¹⁰ Lurie JD, Birkmeyer NJ, Weinstein JN. Rates of advanced spinal imaging and spine surgery. Spine (Phila Pa 1976). 2003 Mar 15;28(6):616-20.

¹¹ Reyes SG, Bajaj PM, Alvandi BA, Kurapaty SS, Patel AA, Divi SN. Impact of Social Determinants of Health in Spine Surgery. Curr Rev Musculoskelet Med. 2023 Jan;16(1):24-32.



beginning with the CY 2027 reporting period/CY 2029 payment determination, as discussed in the CY 2024 OPPS/ASC final rule (88 FR 81988 through 81992).

ACR Perspective and Comments

Although this measure was previously finalized for inclusion in HOQR reporting, the ACR would like to provide ongoing comments related to measure challenges that we have gathered as practices, hospitals, radiation dose monitoring system and other technology vendors and supporting entities have gained experience with measure implementation as they work towards making it available for reporting to CMS by their clients, radiologists or constituents.

Our primary concerns are regarding the lack of specificity in the published eCQM specifications and logic as provided on the eCQI Resource Center. There is limited or lack of details on the exact steps, algorithms or computations required to convert the primary data elements (CT exam administrative coding data: CPT/ICD10 code combinations, patient age; CT exam DICOM data: image pixel values, patient size/diameter, and radiation dose (dose length product-DLP)) to the measure intermediate data elements' (CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise) LOINC codes for measure computations. The specifications even state that the "eCQM requires the use of additional software (translation software) to access the primary data elements that are required for measure computation and translate them into data elements that can be ingested by this eCQM".

The capability for technology vendors and other entities to develop products and tools that will support measure calculation, scoring and reporting should be expected and acceptable, and numerous vendors and entities have or are developing such products. Without clear, detailed insight or availability of primary data conversion algorithms or logic used in the sole, proprietary provider's translation software, variability in other vendor or provider's products may exist.

For example, the CT Exam Category exam assignments require use of tables for binning by radiation dose levels (low, routine, high) and the associated category assignment logic. This was initially available from the National Quality Forum (NQF), the consensus-based entity (CBE) at this time, during the required CBE review and evaluation for the measure endorsement, as provided by the measure steward. It is no longer available on the NQF website and is not known to be documented or published in its entirety elsewhere, although a recent publication provides a framework of the methods (Smith-Bindman R, et. al, Radiology 2022; 302:380–389, https://doi.org/10.1148/radiol.2021210591). Additionally, the methods and logic used to determine CT Global Noise (image quality) are unclear. NQF measure steward endorsement documentation cited several publications related to derivation of image quality or global noise, but the measure materials did not describe or detail calculations. Similarly, detailed methods of algorithms, computation methods or validation for determining

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 **CENTER FOR RESEARCH AND INNOVATION** 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150



Calculated CT Size-Adjusted Radiation Dose are not known to be published except for limited information in the NQF endorsement materials. Additionally, for the measure exclusions, how to determine what primary data is missing when any of these three intermediate variables cannot be calculated is unclear.

Along with the eCQI Resource Center specifications, the reference materials are available to the extent mentioned above and can be used by technology vendors and entities for developing products and tools that translate the primary data, compute the intermediate variables and calculate measure scores. It can only be assumed that at some points in the process conclusions and inferences need to be made, absent clarity in the specifications.

It should be expected that a measure specification should be easily or reasonably translatable by measure users to produce comparable calculations and scores. If that can only be accomplished by a single resource, there are concerns about reliability and replicability of the measure. The ACR strongly recommends that CMS obtain and publish on the eCQI Resource Center detailed methods and specifications to translate primary data elements and further clarify computations. In doing so, broader implementation of the measure may be accomplished.

In closing, we reiterate our position as a strong advocate and proponent for patient radiation safety as demonstrated by the multiple and various ongoing efforts and activities in which our organization and the radiology community are involved. The ACR fully supports entities and individuals that put forward valid, feasible and reliable tools to optimize patient exposure to radiation through dose monitoring and imaging appropriateness.

Provisions Related to Medicaid & CHIP

Proposal

CMS proposes to update the Medicaid and CHIP regulations to conform to the Consolidated Appropriations Act (CAA, 2023) to make the previously optional 12-month continuous eligibility policy a requirement under the state plan or a waiver of the state plan for children enrolled in Medicaid and CHIP. Specifically, CMS proposes to require 12 months of continuous eligibility for children under the age of 19 enrolled in Medicaid and CHIP regardless of changes in circumstances (such as family income) that otherwise would impact their eligibility for these programs. Additionally, CMS proposes to remove the previous options of applying continuous eligibility to a subgroup of enrollees or limiting continuing eligibility to a period of less than 12 months. CMS also proposes to remove failure to pay premiums as one of the optional exceptions to continuous eligibility for CHIP beneficiaries.

HEADQUARTERS

1892 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150



ACR Perspective and Comments

The ACR supports CMS's provisions in this rule for children enrolled in Medicaid and CHIP. The College believes that providing 12 months of uninterrupted health coverage for children promotes access to appropriate preventive care, necessary treatment for any acute needs that may arise, and continuity of care. The ACR also believes that CMS's statutory interpretation is correct that these statutory changes in CAA, 2023 prohibit states from disenrolling children from separate CHIP coverage for failure to pay required premiums or enrollment fees during the continuous eligibility period; thus, we support CMS's proposed regulatory policy. These provisions also support CMS's goal of promoting health equity, a goal in which the College shares.

The ACR appreciates the opportunity to comment on the CY 2025 HOPPS proposed rule. We hope you find these comments provide valuable input for your consideration. For any questions, please contact Kimberly Greck (kgreck@acr.org) or Christina Berry (cberry@acr.org).

Respectfully submitted,

D Smitherman

Dana Smetherman, MD MPH MBA FACR FSBI Chief Executive Officer, American College of Radiology

Cc: Cory Duke, CMS Kimberly Go, CMS Janis Grady, CMS Cassie Lagorio, CMS Josh McFeeters, CMS Gil Ngan, CMS Au'Sha Washington, CMS Emily Yoder, CMS Gregory Nicola, MD FACR ACR Andrew Moriarity MD ACR Michael Booker, MD MBA ACR Angela Kim, ACR Kathryn Keysor, ACR Christina Berry, ACR Kimberly Greck, ACR Samantha Shugarman, ACR Judy Burleson, ACR

HEADQUARTERS

GOVERNMENT RELATIONS

1892 Preston White Drive Reston, VA 20191

505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670

CENTER FOR RESEARCH AND INNOVATION

50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150

ACR INSTITUTE FOR RADIOLOGIC PATHOLOGY