AMERICAN COLLEGE of CARDIOLOGY

Heart House
2400 N St. NW, Washington, DC 20037
1-202-375-6000 | 1-800-253-4636 | Fax: 1-202-375-6842
ACC.org

September 4, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: 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 Cardiology (ACC) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the CY 2025 Medicare Hospital Outpatient Prospective Payment System (OPPS) for hospital outpatient and ambulatory surgical center payment policy, and other policies addressed in this proposed rule. The Colleges comments will focus mainly on ambulatory payment classifications, hospital and ambulatory surgical center quality reporting programs and prior authorization.

The ACC is the global leader in transforming cardiovascular care and improving heart health for all. As the preeminent source for professional medical education for the entire cardiovascular care team since 1949, and now with more than 56,000 members from 140 countries, the ACC credentials cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards, and guidelines.

Proposed New Technology APCs

Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies

CPT code 78431 had over 26,000 single frequency claims in CY 2023 with a geometric mean of approximately $2,350. This falls within the codes currently assigned APC 1522 (New Technology-Level 22, $2,001-$2,500) with a payment rate of $2,250.50. CMS proposes to maintain 78431 in APC 1522.

CPT code 78432 had only 19 single frequency claims in CY 2023. As such, CMS applied the low volume New Technology APC policy to use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to four years of claims data. The arithmetic mean cost for 78432 was the highest at $1,923 which is above the code's current assignment of APC 1520 (New Technology-Level 20, $1801-$1900) with a payment rate of $1,850.50. CMS proposes assigning CPT code 78432 to APC 1521 (New Technology-Level 21, $1,901-$2,000) with a payment rate of $1,950.50.

CPT code 78433 had over 1,400 single frequency claims in CY 2023 with a geometric mean of approximately $2,010. This is above the cost band for CPT code 78433 current assignment of APC 1521 (New Technology-Level 21, $1,901-$2,000) with a payment rate of $1,950.50. CMS proposes to assign CPT code 78433 to APC 1522 (New Technology-Level 22, $2,001-$2,500) with a payment rate of $2,250.50.

The ACC supports the assignments of APC 1522 for CPT codes 78431 and 78433 based on cost data analysis by the agency. However, the College does not support the assignment of APC 1521 for CPT code 78432. We have commented during prior rulemaking that from a clinical workflow perspective, 78432 consumes more resources than 78431. 78431 requires two separate full procedures and uses two separate injections of a radiotracer for perfusion studies. 78432 requires those same steps, however, instead of two injections using the same perfusion radiotracer, two different tracers are injected for the image acquisition, one for perfusion and one for metabolic study. The second tracer used for metabolic studies—fluorodeoxyglucose (FDG)—requires more prep time than those used for perfusion studies. **With similar, but enhanced, clinical staff and radiotracer workflows to 78431, it is not appropriate for 78432 to be assigned to an APC with payments lower than 78431**. We believe the problem here is the dramatically lower volumes of 78432 in comparison to 78431, even given the fact that the low volume policy was used in determining the APC assignment. The low volume policy uses the higher of the geometric mean cost, arithmetic mean cost and median cost for up to four years. CPT code 78432 was implemented in 2020 and had no claims data for that year or 2021. Six claims were available from 2022 and 19 from 2023. Being that there were essentially only two years of claims data available with a total of only 25 claims, even the low volume policy may not be able to provide a fair cost estimate for this service. **The ACC urges CMS to assign CPT code 78432 to APC 1522 or higher to account for its resource usage.**

As discussed in previous rulemaking comments, the ACC reiterates its belief that CMS should make amendments to the APC cost bands and methodology to help smooth out often drastic changes in payment rates for services from year to year. This could be accomplished by consistently utilizing several years of cost data to determine APC assignment in all cases, rather than just the low volume services. Another option would be to narrow the pay bands of APCs. New technology APCs 1503-1521 proceed in $100 increments, while those from 1522-1537 proceed in $500 increments. It is not obvious that increments should grow to $500 starting at a $2001 threshold. Dropping payment from $2750.50 to $2250.50 is a more than an 18% payment reduction. In other areas, CMS has seen value in providing stability and avoiding large payment swings. Starting in the CY 2023 inpatient prospective payment system rule, CMS began a policy to provide stability by limiting weight reductions to no more than 10% in a given year. A similar policy—that could be achieved with narrower increments or a transition policy limiting reductions to 10%—in the OPPS setting would minimize disruption here.

Other New Technology APC Assignments

The ACC concurs with the agency's APC assignments of the blinded procedure for heart failure, CardiAMP, Atherosclerosis Imaging-Quantitative Computer Tomography, Corvia Medical Interatrial Shunt Procedures, and Transcatheter Atrial Shunt System.

Cardiac Computed Tomography Services

CMS has requested information regarding cardiac CT services in this proposed rule. The agency notes that until December 2023 a billing edit was in place that precluded hospitals from billing cardiac CT services using the cardiology revenue code 048X. CMS states that this may have reduced the geometric mean cost (GMC) for cardiac CT services. Per claim simulations performed by the agency, it is stated in the proposed rule that if 50% or more of hospitals had reported these services using the cardiology revenue code the services would qualify to be moved from their current assignment of APC 5571 (Level 1 imaging with Contrast) to APC 5572 (Level 2 Imaging with Contrast).

CMS specifically poses three questions in this request for information:
1) Where are cardiac CT services performed in a hospital? Are cardiac CT services performed in a dedicated cardiology department, radiology department, or some other hospital outpatient department?
2) What factors determine the revenue code assignment for cardiac CT services (i.e., the department in which the service is performed, the type of service that is performed, or some other factor)?
3) What revenue codes are HOPDs reporting for these services in CY 2024? Are HOPDs using the cardiology revenue code on claims for cardiac CT services now that they are no longer restricted from using this revenue code?

The College has previously submitted comments expressing our concern regarding inadequate reimbursement of cardiac CT services and appreciates the agency's attention to this issue. The College has recognized that factors such as hospital cost reporting contributed to inadequate reimbursement of cardiac CT services. Use of generic CT and MR cost center reporting systems has chronically underrepresented costs for these services because they fail to account for enhanced clinical staff time, equipment, and additional medicines used to perform the service. That means that meaningful cost data could never have shown a geometric mean cost high enough to support APC reassignment based on costs. The College agrees that the restriction on revenue code usage has artificially lowered the GMC, and hence APC assignment, of cardiac CT services.

In the case of cardiac CT angiography, imaging acquisition time and resources are significantly different than other services in APC 5571. Cardiac CT work requires gating software, calcium scoring software, higher spatial resolution and faster gantry rotation times than non-cardiac CT scanners do, and this translates into a considerably higher cost structure. Image acquisition is performed by technologists with additional training. The CT scanner itself is more expensive than many other CT studies. Thus, the cost per case to perform the service is much higher. Before the scan begins, patients are evaluated by a highly trained cardiac CT technologist and a nurse who administers IV medications necessary to control heart rate. The patient is monitored for an extended period while these medications take effect, making the total time of acquisition longer. Electrocardiogram leads are attached for gating that allows images to be obtained at the exact moment in the cardiac cycle when the heart is not moving. When the scan is finally

complete, the CT technologist executes imaging processing, which takes longer than other single-organ studies. It is only because of the inadequate cost data that these services are placed in APC 5571 with less complex CT, MR, and X-ray services. Additionally, there are a growing number of structural heart procedures (transcatheter aortic valve replacement, transcatheter mitral edge-to-edge repair, transcatheter left atrial appendage closure, etc.) that depend on cardiac CT for procedural planning. CTA is more time and resource intensive to both perform and to read than general imaging services and should be reimbursed accordingly.

The college believes that the differential between cardiac CT and general imaging services described above warrant the movement of the cardiac CT codes from APC 5571 to the higher reimbursing APC 5572 as cardiac CT has similar homogeneity with respect to resource utilization and cost as procedures grouped under APC 5572.

The ACC attempts to answer the specific questions asked regarding cardiac CT to further this discussion and encourage a change here, but feels they are not entirely helpful. First, we have not ascertained empirical data on the location within hospitals that cardiac CT services are performed. However, the College does not believe this to be germane to the issue at hand, which is the cost inputs needed to perform cardiac CT acquisition. In general, CT scanners are located in imaging departments that image bones, organs, nerves, etc., as needed by treating physicians. Cardiac CT imaging requires the additional inputs noted above that exceed those of a traditional thoracic CT. The differential in time and resources noted above still stands, irrespective of where the scanner is physically located. Second, we are not aware of the specific or aggregate reasoning of a hospital or hospitals in how they assign their revenue codes to procedures performed in their facilities. Until recently, there was no decision to make because both claims software and processing rules required the use of 035X or 032X. We again note that regardless of this process, the difference in resource use between cardiac CT and general CT services is clear. Finally, for the question of what revenue codes are being reported for these services in 2024, the College agrees with the agency's note that many hospital outpatient departments may still be updating their billing practices. Beyond the hospital billing departments updating their systems with the newly available reporting options, many of the clearinghouses used by these departments will also have to update their systems. As such, it would be premature to examine any 2024 data with respect to which revenue codes are being utilized. We have heard anecdotally from members that these changes by hospitals and clearinghouses have been slow to occur, with resistance by hospitals to change reporting and little ability by clinicians to impact decisions by clearinghouses.

The College applauds the removal of restrictions on what revenue codes can be billed for the cardiac CT services. We also fear that the slow adoption of and technical ability to utilize this change will potentially lead to years of cardiology revenue code usage that is below the actual intent of the hospitals. This would hence fail to achieve the more accurate reporting of resources used and needed for these services. **As such, the College urges CMS to reassign the cardiac CT codes (75572-75574) to APC 5572 for CY 2025 while continuing to gather data and monitor the revenue code reporting over the several years it will likely take for the changes in regulation to be fully adopted**.

Finally, the agency describes running simulations that assumed 25 percent, 50 percent, and 75 percent of the total number of hospital outpatient provider departments assigning these services to cardiology revenue code 048X and cardiology cost center 03140. Only the result of the 50 percent simulation was

explained further in detail. The ACC believes it would be useful to know how costs present in the 25 percent and 75 percent simulations, and that a simulation of 100 percent assignment to 048X would be in order. It is not possible to obtain cardiac CT images without the more expensive inputs described above, so 100 percent of studies have enhanced costs. While future years' data would be instructive, a simulation of 100 percent may prove the most accurate analysis of all.

Cardiac Magnetic Resonance Imaging (MRI)

As with cardiac CT, the College remains concerned about payment stability for cardiac magnetic resonance (MR) imaging (Code 75557/APC 5523, Code 75559/APC 5524, Code 75561/APC 5572, and Code 75563/APC 5573). Cardiac MRI has generally faced declining or unsteady payment levels in recent years. While the 2025 proposed rule maintains the same APC assignments for these services, payments for 75561 and 75563 approaches either the median or geometric mean cost.

Cost data presented by CMS in addenda materials suggest these two services cost more than the payment rate, though not approaching the two-times rule. The ACC believes that, like cardiac CT, collected cost data for both of these services significantly underrepresent the true costs because of limitations of reporting within general MR revenue codes. Allowing cardiac MR services to be billed using cardiology or stress testing revenue codes will assign a more appropriate cost-to-charge ratio to current services and result in a cost estimation that more accurately reflects the true cost of cardiac MR. It could be illustrative for modeling similar to that completed for cardiac CT with cardiology revenue code 048X to be executed for cardiac MR. **The ACC urges CMS to consider that analysis for this final rule or for future rulemaking.**

75563 was previously included in a nuclear medicine APC, 5593, which was appropriate given the clinical and resource homogeneity of cardiovascular magnetic resonance and cardiac nuclear imaging services. MRI exams of static body parts such as the brain or spine with which 75563 is now grouped typically require only a single MRI technologist to perform and can be completed in less time. CMR exams typically take at least twice as long to perform, and stress CMR exams require additional personnel to administer stress agents and monitor the patient. Thousands of images are generated in a typical CMR exam, covering multiple slices, orientations, and temporal phases of dynamic physiological processes such as perfusion, cardiac function, and blood flow, while brain and spine MRI provide static images of structures only. Additionally, CMR requires intensive post-processing to extract quantitative information and generate the CMR report. Until 2017, CPT 75563 was placed in an APC with comparable nuclear medicine services. **The ACC recommends that CPT 75563 be moved back to APC 5593**.

Before 2017, 75561 was placed in an APC with other MR imaging and angiography services with contrast that better aligned with clinical effort and costs. That APC was dismantled when a number of imaging APCs were restructured for 2017. Under the proposed APC structure for 2024, this code remains in APC 5572, grouped with services that are not clinically similar or similar in resource use. For example, CPT 75561 has little in common with CT of the abdomen or pelvis or MRI of the neck and spine. CPT 75561 is more comparable to services in APC 5573 (Level 3 Imaging with Contrast). **ACC recommends that CMS move CPT 75561 to APC 5573**.

Complexity Adjustment for Coronary Intravascular Lithotripsy (IVL)

In prior rulemaking comments and other communications with the agency, the ACC had urged CMS to address the expiration of transitional pass-through (TPT) payment for IVL as of June 30, 2024. It has been presented to the College and the agency by the manufacturer that data analysis shows the standard complexity adjustment policy for percutaneous coronary interventions (PCI) would apply to the APC when utilizing IVL. The College had suggested that the agency apply the standard complexity adjustment early via the quarterly program update. While this recommendation was not acted upon by the agency, it was presumed that the complexity adjustment analysis for coronary IVL would be performed and included as part of the CY 2025 OPPS proposed rule. This analysis was not included in the proposed rule.

The College noticed that in Addendum B of the proposed rule the HCPCS code for IVL, C1761, has a status indicator of "H" which denotes separate pass-through payment is active. As the TPT payment for this code was scheduled to expire on June 30, 2024, it was anticipated that the status indicator for C1761 would be "N" denoting no separate payment APC payment. **We ask the agency to clarify if this was a typographical oversight or if TPT payment has been extended for some period of time for this code.** If this is an error, we encourage the agency to examine whether payments are still being made on these codes as this could lead to disruptive recoupment of funds in the future.

Presuming the status indicator of "H" for C1761 was an error and TPT has not been extended, we are concerned with the absence of the complexity adjustment analysis for IVL in this proposed rule. **The College urges CMS to perform the complexity adjustment analysis for IVL performed with PCI codes and include the outcome in the CY 2025 final rule.**

Radiopharmaceutical Payment Policy Update

CMS had requested information in prior rulemaking on how to address the high cost of certain diagnostic radiopharmaceuticals that far exceed the payment bundled into the related diagnostic procedures reimbursements. After collecting input from a wide array of stakeholders and considering several options, the agency proposes to pay separately for radiopharmaceuticals with a per-day cost greater than $630. CMS arrived at this amount by calculating the volume-weighted average offset of the policy packaged radiopharmaceuticals on average for each of the four nuclear medicine APCs then averaged that total dollar amount against the total number of single claims of all four nuclear medicine APCs combined. This resulted in a dollar amount of $314.28 which was multiplied by two and rounded to the nearest $5 amount resulting in $630. The agency states that this was done to somewhat resemble the OPPS outlier policy used to address certain high-cost procedures which is triggered when the procedure cost is 1.75 times greater than the APC payment.

The ACC appreciates CMS's aim of addressing beneficiary access to high-cost low-volume diagnostic radiopharmaceuticals. With the proposed policy to address this issue it is clear the agency seeks to focus on separate payments for "only those diagnostic radiopharmaceuticals whose costs significantly exceed the

approximate amount of payment already attributed to the product in the nuclear medicine APC." The College believes this approach will both increase access to those high-cost low-volume services while also mitigating the negative impact on the remaining nuclear medicine procedures to the greatest reasonable degree. We do urge the agency to carefully monitor the affected nuclear medicine APCs and address any larger than expected alterations to their reimbursement or other unintended consequences of this policy should it be enacted**. With cautious observation going forward, the ACC supports the proposed policy to issue separate payment for diagnostic radiopharmaceuticals with per-day costs above $630.**

CMS proposes to determine a per-day cost of non-pass-through diagnostic radiopharmaceuticals that exceed the $630 payment and assign them to an APC, making the product a specified covered outpatient drug. Ordinarily, CMS would use the Average Sales Price (ASP) methodology to pay for these products. However, radiopharmaceuticals are not required to submit data on ASP, and CMS notes the data it does have is limited, does not reflect what it would expect based on the cost and mean unit cost data reported by hospitals, and is not usable for payment purposes. Therefore, CMS believes manufacturers should have the opportunity to submit, certify, or restate the ASPs of their products and is proposing to use mean unit cost as an alternative for 2025.

The ACC supports the use of mean unit cost as a reasonable alternative methodology for payment of radiopharmaceuticals that exceed the $630 threshold for CY2025. The College also agrees that ASP should be considered in future years and is strongly supportive of CMS' continued dialogue with manufacturers to understand some of the unique challenges associated with meeting the reporting requirements for ASP.

Proposed OPPS Treatment of New and Revised HCPCS Codes

Replacement Code for Heart Failure System, HCPCS Code GMEM1

In the CY 2025 Medicare Physician Fee Schedule proposed rule, CMS proposes creation of a PE-only replacement code for the external reader that patients use to acquire and transmit data from an implantable wireless pulmonary artery pressure monitor.[1] Regular data acquisition and transmittal is necessary to optimize care of these heart failure patients. With time, a reader meets the end of its useful life or may be lost or damaged. A replacement must be obtained to avoid rendering the implanted device useless. As described in the fee schedule proposed rule, it appears new code GMEM1 is intended to reflect the cost of the reader. It is not clear why such a piece of equipment would not be treated as durable medical equipment. **The ACC believes payment for a replacement reader as durable medical equipment (DME) would be the most appropriate way to address this need.** Though the College is not familiar with exact pricing, payment to date has been sought and occasionally obtained using DME code L9900, with payment anecdotally ranging from $3,000 to $5,000.

[1] https://www.federalregister.gov/d/2024-14828/p-553

In this OPPS proposed rule, CMS assigned GMEM1 to APC 5741 for Level 1 Electronic Analysis of Devices. The national payment rate for 5741 is $36.90. That is nowhere near a sustainable payment for a piece of equipment that costs many times more than that. However, that amount would be plausible to reflect the technical work by clinical staff to gather and analyze data from a transmission. That work is reported using code 93264, *Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional.* However, 93264 is assigned status indicator M in Addendum B, "Items and services not billable to the FI or MAC." **If the agency is seeking to pay a hospital for the technical component of 93264, the simplest approach would be to assign status indicator Q1 to 93264—similar to other device interrogation-type codes—and assign it to APC 5741.**

As DME coding and payment are separate from OPPS, **the ACC urges officials at the Agency to coordinate across payment systems to ensure a mechanism to pay for a reader is instituted so patients in need of replacements can optimize their heart failure management.** If CMS determines that one path for this is or must be payment of a replacement recorder through OPPS, APC 5741 is inadequate for that purpose. One approach inside OPPS could be assignment to a New Technology APC. Based on the one invoice obtained and shared below, that would be APC 1528 for services with costs between $5001-$5500. Other invoices obtained by or provided to CMS may indicate a higher or lower amount.

Acelis Connected Health

Acelis Connected Health Supplies
30 SOUTH KELLER ROAD,
SUITE 100 B
ORLANDO, FL 328106297

Phone: 888-683-7351
Fax: 888-583-9635
Acelis.com

INVOICE

[redacted]

Date: 09/03/2024
Bill Number: 000003901811
Grand Total: 6025.00

Service Dates	Procedure Description	Unit Amount	Supply Units	Extended Amount
10/18/2023	CardioMEMS Patient Electronics System	5,000.00	1	5,000.00
10/18/2023	WiFi Adaptor	25.00	1	25.00
			Grand Total	6,025.00

9/3/2024 8:35:44 AM Page 1 XIFIN Proprietary and Confidential

Proposed OPPS Payment for Devices

Proposed Pass-Through Payment for Devices
CMS discusses transitional pass-through payment (TPT) proposals for several devices utilized in cardiovascular care. The AGENT Paclitaxel-Coated Balloon Catheter, Aveir DR Dual Chamber Leadless Pacemaker System, Paradise Ultrasound Renal Denervation (RDN) System, Symplicity Spyral Renal Denervation (RDN) System, and PulseSelect Pulsed Field Ablation (PFA) System each seek TPT through the alternative pathway available given their designation as Breakthrough Devices by the Food and Drug Administration. By nature of that status, these technologies are deemed to meet the substantial clinical improvement criterion for TPT.

The ACC typically focuses comments to the substantial clinical improvement criterion, and thus considered saying little on these applications. However, for many of these technologies, the agency raised questions regarding whether an existing device category could possibly apply. In each of these instances, the ACC feels the potentially conflicting device category is far removed from the application at hand and would not be appropriately described by any existing category. The ACC notes the devices' status as Breakthrough indicates a certain level of novelty, and that all but one of these technologies was just awarded a New Technology Add-on Payment in the FY 2025 inpatient hospital prospective payment system final rule, or already had been awarded that payment in a prior year.

Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (PR) Services and Diagnostic Services Furnished to Hospital Outpatients via Two-way Audio/Video Communications Technology

Noting concerns about an abrupt transition to the pre-PHE policy that defines direct supervision to require the physical presence of the supervision practitioner after December 31, 2024 after practitioners established new practice patterns during the PHE, CMS proposes 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. **Since the beginning of the PHE, the ACC has supported this flexibility and appreciates this extension**.

Payment Policy for Devices in Category B Investigational Device Exemption (IDE) Clinical Trials Policy and Drugs with a Medicare Coverage with Evidence Development (CED) Designation

CMS finalized a policy in CY 2023 rulemaking to make a single, blended payment for devices and services in Category B IDE studies in order to preserve the scientific validity of these studies by avoiding differences in Medicare payment methods that would otherwise unblind the treatment or control group to which a patient had been assigned. In the CY 2025 proposed rule CMS outlines a similar policy for drugs and devices being studied in clinical trials under a national coverage determination (NCD) that utilizes the Coverage with Evidence Development (CED) pathway. Technical proposals specifying payment for placebo control arms and coding and payment of device and drugs are also proposed. The ACC supported CMS's 2023 proposal for payment of Category B IDE studies.

While the ACC is not directly involved with any CED studies utilizing intervention and control arms, the

same rationale applies broadly here**. The College supports application of this approach to such CED NCDs starting in 2025.** The maintenance of the blind in randomized clinical trials is crucial to the validity of the study. The differential reimbursement is a potential source of breaking the blind, and the foresight by CMS to adjust coding and payment to maintain blind is admirable. The attention to scientific validity outweighs the small chance for differential reimbursement based on randomization, should a research site happen to perform more placebo/sham services than intervention services.

Proposed Additions to Ambulatory Surgery Center (ASC) Covered Surgical Procedures and Covered Ancillary Services Lists

Cardiac Catheter Ablation Procedures

CMS evaluates the ambulatory surgery center (ASC) covered procedures list (CPL) each year to determine whether procedures should be added to or removed from the list. Changes are often made in response to specific feedback shared by stakeholders. Surgical procedures that meet general standards and are not excluded under general exclusion criteria may be placed on the CPL.

Cardiac catheter ablation procedures that treat cardiac rhythm disorders have been nominated for addition to the CPL each of the past several years without action by CMS. **The ACC believes these services can be safely performed in the ASC setting in appropriately selected patients as adjudicated by physician judgment (with case selection determined by physician discretion, facility considerations, and patient social-support factors/co-existing clinical conditions) and urges CMS to add them to the CPL in the final rule.**

Cardiac catheter ablation procedures are already being covered in the ASC setting by many private payors. Experience-based data from those procedures and from pandemic-era practices demonstrate sites' ability to provide these services safely in the ASC setting. Outcomes data acquired during the COVID-19 public health emergency with CMS's Hospitals Without Walls Program[2] and other favorable clinical data[3] have been identified. In response, prior CMS statements focused on concerns surrounding cardiac catheter ablation codes not being "surgical" or not being included in the surgical section of CPT codes. Though it is difficult to know the exact reason; responses from the agency in the CY 2024[4,5] and CY 2023[6,7] final rules addressed groups of services rather than responding to comments individually. Based on those responses, it is not clear whether CMS felt that cardiac ablation services had an unfavorable risk profile or were medicine codes in the 90000 series. Some of the ablation codes in question do begin with a code descriptor that states "Comprehensive electrophysiologic evaluation…" Those codes are bundled services that include ablation later in the descriptor. A more specific response to the nomination of codes ranging from 93613 to 93657 would help stakeholders understand the agency's decision—to this point—not to add these services to the CPL. The ACC believes cardiac ablations are transcatheter percutaneous

[2] https://www.heartrhythmjournal.com/article/S1547-5271(24)03106-0/abstract
[3] https://www.heartrhythmopen.com/article/S2666-5018(23)00139-3/fulltext
[4] https://www.federalregister.gov/d/2023-24293/p-2966
[5] https://www.federalregister.gov/d/2023-24293/p-2971
[6] https://www.federalregister.gov/d/2022-23918/p-2582
[7] https://www.federalregister.gov/d/2022-23918/p-2587

procedures that should be treated in a similar fashion as other cardiovascular procedures that are already on the ASC CPL (e.g., percutaneous coronary intervention, cardiac implantable electronic device implant procedures, or lower extremity revascularization).

In 2023, the ACC with the Heart Rhythm Society established a joint workgroup to develop: A) A survey to assess the current clinical landscape of ablation in the ASC setting, B) A strategy that aligns with patient and physician needs, C) A document to inform cardiologists in this space. The survey revealed the following: 1) Cardiac catheter ablation procedures have increasingly moved toward same-day discharge, 2) Cardiac catheter ablations are increasingly being performed in the ASC setting to address patient access issues. The results of this survey have been published in the medical journal *Heart Rhythm*.[8] Since the COVID-19 PHE, there has been a significant shift in the performance of cardiac catheter ablation procedures in a same-day discharge context.

The societies are completing an analysis and preparing a manuscript on same-day discharge for cardiac catheter ablation procedures. Analysis of both claims and clinical data have suggested that cardiac catheter ablation procedures (often performed with same-day discharge) have lower complication rates versus other cardiac procedures already included in the ASC CPL (i.e. percutaneous coronary intervention, cardiac implantable electronic device procedures). Moreover, by reducing required hospital resources with reduced length of stay with same-day discharge, patient access is improved, with a net financial benefit to patients and overall healthcare spend. In the coming months, further guidance document development for performance of cardiac catheter ablations in the ASC setting is planned.

While advocating for patient access, patient safety is prioritized first and foremost. Performance of cardiac catheter ablations in the ASC setting absolutely requires safeguards and well validated protocols for timely management of complications. In this context we strongly support the use of registries and quality measures to track outcomes in real time and help guide future decision making.

Interventional Transesophageal Echocardiography (TEE)

In the ASC addenda for the proposed rule, CMS includes CPT code 93355, *Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D* on the ASC Ancillary Services CPL. These services are intended to be integral to covered surgical procedures, even if payment for them is packaged into the underlying procedure and APC payment.

The ACC appreciates CMS's interest in ensuring important cardiac imaging services are available to patients in the ASC setting, However, 93355 is not a good fit for the covered ancillary services CPL at this time. Per CPT language, interventional TEE is intended to accompany transcatheter intracardiac therapies such as transcatheter aortic valve replacement, transcatheter left atrial appendage closure, and transcatheter mitral valve repair. It includes the work of passing the endoscopic ultrasound transducer through the

[8] https://www.heartrhythmjournal.com/article/S1547-5271(24)02307-5/fulltext

mouth into the esophagus, when performed by the individual performing the TEE, diagnostic transesophageal echocardiography and ongoing manipulation of the transducer to guide sizing and/or placement of implants, determination of adequacy of the intervention, and assessment for potential complications. Real-time image acquisition, measurements, and interpretation of image(s), documentation of completion of the intervention, and final written report are included in this code.

Since none of the referenced transcatheter intracardiac structural heart with which 93355 would be utilized are on the CPL, the ACC is confused by the proposed addition to the ancillary services CPL. In fact, each of these services are on the hospital inpatient-only list, so they are not even currently performed in the hospital outpatient setting. Any movement of those services to the ASC setting is many years away, were it ever to occur. To avoid confusion in this space, removal of 93355 from the ancillary services CPL in the final rule is likely appropriate. If CMS has some other rationale for including it at this time that it could present in the final rule, that would be instructive for the ACC and other stakeholders who were surprised to see the code included.

Proposed Quality Program and Measure Updates

Proposal to Adopt the Information Transfer PRO–PM Measure

The Information Transfer Patient Reported Outcome-Based Performance Measure (PRO–PM) may be a useful tool for improving patient care and appears to align with the ongoing shift towards value-based care and patient-centered outcomes. Since the measure emphasizes the importance of clear and effective communication about recovery instructions, this can lead to better patient understanding and adherence to post-procedure care plans, ultimately enhancing patient communication. With an emphasis on providing clear recovery information, this can significantly reduce complications and hospital readmissions, leading to improved patient outcomes. Additionally, focusing on this measure can increase patient satisfaction and trust in their healthcare providers, as patients feel more informed and supported during their recovery.

However, there are challenges associated with implementing this measure. Integrating it into practice may require changes in workflow, additional staff training, and time to ensure compliance. Ensuring consistency in communication, so all patients receive the same quality and clarity of recovery information, can also be challenging, especially in busy hospital outpatient departments. Clinicians may need to place greater emphasis on patient education and ensure that they or their staff are available to answer questions and clarify instructions. From a professional standpoint, this measure aligns with the broader goals of value-based care, focusing on quality and patient-centered outcomes, which are increasingly important in healthcare reimbursement models. This PRO–PM can provide valuable feedback to clinicians about their communication practices, highlighting areas for improvement.

Proposal to Remove the Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery Measure from the OQR Program

This measure calculates the percentage of stress echocardiography, single photon emission computed tomography myocardial perfusion imaging (SPECT MPI), stress magnetic resonance imaging (MRI), or computed coronary tomography angiography (CCTA) performed at each facility in the 30 days prior to an ambulatory non-cardiac, low-risk surgery performed at any location. CMS is proposing to remove this

measure since there are a range of cases, which creates limitations when assessing and interpreting comparative performance trends over time. Additionally, performance data make it difficult for consumers to distinguish performance in care. Finally, there is little room for improvement on the measure based on performance rate data. CMS' measure removal criteria, performance or improvement on a measure does not result in better patient outcomes, would apply in this situation.

We concur that removal aligns with evidence-based practices that discourage unnecessary preoperative cardiac imaging for low-risk surgeries. Studies have shown that such imaging often does not change patient management or outcomes and can lead to unnecessary costs and patient anxiety. While it is a well-intended measure, it is challenging to implement. It is difficult to have a measure of "low risk" (where no testing is needed) vs. "non-low risk", as ultimately clinician judgment may be a factor, and is not easy to capture. Additionally, the removal of this measure can help cardiovascular specialists focus on more meaningful and high-value care practices, aligning with initiatives like Choosing Wisely, which advocates for avoiding unnecessary medical tests and procedures.

Some specialists may be concerned that the removal of the measure might lead to underuse of necessary imaging in certain borderline cases. Additionally, there is the potential for missing subtle but significant cardiac issues that might impact surgical outcomes. Hospitals and cardiovascular specialist departments may need to adjust their quality reporting practices, and there might be initial confusion or concern about how the removal will affect overall quality scores and reimbursement tied to similar metrics.

Professionally, the ACC and the American Heart Association provide guidelines on the appropriate use of cardiac imaging. Cardiovascular specialists may need to reinforce adherence to these guidelines in the absence of the measure. Overall, we view the proposal primarily as a positive step towards reducing unnecessary procedures and focusing on patient-centered, high-value care. However, it is essential to balance this with continued vigilance in preoperative assessments to ensure patient safety and optimal outcomes.

Proposed Update to the Form, Time, and Manner Requirements for the Hybrid Hospital-Wide All-Cause Readmission (HWR) and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measures for the FY 2026

CMS has indicated that, based on hospital performance during the most recent voluntary reporting period, hospitals are currently unprepared for the mandatory reporting of the Hybrid Hospital-Wide Readmission (HWR) and Hybrid Hospital-Wide Mortality (HWM) measures. Data shows that three-fourths of participating hospitals would not have met the reporting thresholds for Core Clinical Data Elements (CCDEs) and linking variables if these requirements had been mandatory. Consequently, these hospitals would have faced a one-quarter reduction in their annual payment update under the Hospital Inpatient Quality Reporting (IQR) Program for the specified fiscal year.

These hybrid measures, which combine clinical data from EHRs with claims data, enhance risk adjustment and provide a more comprehensive assessment of hospital performance. However, the transition from voluntary to mandatory reporting has highlighted significant challenges, particularly for hospitals with fewer resources. The reported difficulties in meeting CCDE and linking variable thresholds indicate that additional time and support are necessary to ensure compliance and data accuracy.

Extending voluntary reporting for the Hybrid HWR and Hybrid HWM measures for the FY 2026 payment determination is a prudent step. This extension will allow hospitals more time to address reporting challenges and improve data collection processes. CMS is encouraged to provide additional guidance and resources to assist hospitals in meeting the CCDE and linking variable thresholds, which could include technical assistance, best practice sharing, and targeted support for small and rural hospitals.

The ACC supports the proposed extension of voluntary reporting for the Hybrid HWR and Hybrid HWM measures, recognizing the need for additional time to address reporting challenges. Specific recommendations include targeted support for smaller and rural hospitals, collaboration with health IT vendors to streamline CCDE collection, and the establishment of clear guidelines for unit standardization. Continuous monitoring and a formal feedback mechanism will be essential for ongoing improvement and the successful implementation of these hybrid measures.

Changes to the Review Timeframes for Hospital Outpatient Department (OPD) Prior Authorization Process

The ACC reiterates our deep concern over the ever-growing demands of prior authorization by payers. Prior authorization puts burden on clinicians and can delay or prevent necessary patient care. The College does support CMS in its proposal to decrease mandatory response times for standard prior authorization request from ten business days to seven calendar days. The standardization of these timeframes to match those required by Medicare Advantage and Medicaid plans could help to streamline the process for clinicians and their staffs and potentially decrease the time patients wait for services. The ACC also supports CMS' proposal to not change the current two business day decision timeframe for expedited decisions to match the 72-hour time frame required of other payers. The benefits of a standardization of timeframes certainly do not outweigh the importance of decreasing patient wait times for care, especially in cases clinicians have determined are urgent and in need of expedited review.

Conclusion

Thank you for your consideration of these comments from the ACC. The College appreciates the thought and effort that go into rulemaking and looks forward to future engagement on topics included in this and other rules and policy discussions. Please contact Matthew Minnella, Associate Director, Medicare Payment Policy at mminnella@acc.org if additional information would be helpful.

Sincerely,

Cathie Biga, MSN, FACC
President, American College of Cardiology