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 12, 2025

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1834-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency

Submitted via www.regulations.gov

Dear Administrator Oz:

The American College of Cardiology (ACC) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) on the CY2026 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment System (OPPS) policies addressed in this proposed rule. The College's comments will focus primarily on ambulatory payment classifications (APCs), software as a service, the inpatient only list (IPO), the covered procedures list (CPL), and hospital and ambulatory surgical center quality reporting programs.

The ACC is a global leader dedicated to transforming cardiovascular care and improving heart health for all. For more than 75 years, the ACC has empowered a community of over 60,000 cardiovascular professionals across more than 140 countries with cutting-edge education and advocacy, rigorous professional credentials, and trusted clinical guidance. From its world-class JACC Journals and NCDR registries to its Accreditation Services, global network of Chapters and Sections, and CardioSmart patient initiatives, the College is committed to creating a world where science, knowledge and innovation optimize patient care and outcomes. Learn more at *www.ACC.org* or connect on social media at @ACCinTouch.

APC Payment Adjustments

Diagnostic Radiopharmaceutical Packaging Threshold Update

In CY2025 rulemaking CMS established a threshold of $630 per-day cost of diagnostic radiopharmaceuticals above which these materials would be reimbursed separately. This threshold

was to be adjusted in future rulemaking based on the producer price index (PPI) for pharmaceuticals for human use, prescription (BLS series code WPUSI07003). In following this plan, the threshold for diagnostic radiopharmaceuticals per-day use is proposed to be raised to $655.

The College supports this proposed increase and appreciates recognition of inflation on medical costs.

Comprehensive APCs (C-APCs) for CY 2026

Comment Solicitation on C-APC Complexity Adjustment

Since January 1, 2015, CMS has packaged payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. CMS uses complexity adjustments to provide increased payment for certain comprehensive services. For qualifying combinations of a service code and paired services and add-on services, a complexity adjustment is applied by promoting a qualifying C-APC (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs.

In response to various requests and prior public comments from stakeholders, CMS seeks feedback on potential refinements to the complexity adjustment criteria, such as expanding qualifying code combinations; identifying new, clinically appropriate pairings/clusters that are not currently evaluated for complexity adjustment; cost and frequency thresholds; and potential unintended consequences. The ACC has previously expressed concern that the existing complexity adjustment methodology is difficult to understand and replicate, sometimes leaving gaps in analysis as well as significant payment gaps for important services provided under the OPPS.

CMS could make significant strides in advancing engagement and understanding by simply providing additional information such that the methodology and calculations based on Appendix J of the rule could be comprehensively analyzed to inform well informed comments. Currently, stakeholders commonly lack the ability to replicate complexity adjustment assessments based on the information released in the proposed rule. Inclusion of additional information in the final rule and future proposed rules would enhance the process.

The current complexity adjustment eligibility threshold is set by doubling the comprehensive geometric mean cost of the lowest procedure in the primary procedure APC when modeled without complexity adjustment. A pair of services can only qualify for complexity adjustment if that threshold is crossed. However, in more costly APCs, this methodology creates thresholds that are higher than the cost of many/any procedures in the higher paying APC. Utilizing different or additional criteria to develop a threshold could more thoroughly address payment gaps under the C-APC system.

Finally, as ACC understands the system, CMS only evaluates paired code combinations of two codes from Appendix J. It does not evaluate combinations of more than two codes being performed together. The ACC recommends CMS begin such consideration in the future.

Proposed OPPS Treatment of New and Revised HCPCS Codes

New Percutaneous Coronary Intervention (PCI) Codes 92X01 and 92X02

In Addendum B of the OPPS, CMS proposes to assign CPT codes 92X01 (*Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); 2 or more distinct coronary lesions with 2 or more coronary stents deployed in 2 or more coronary segments, or a bifurcation lesion requiring angioplasty and/or stenting in both the main artery and the side branch*) and 92X02 (*Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; combined antegrade and retrograde approaches*) to APC 5193 (*Level 3 Endovascular Procedures*). **The ACC recommends CMS reconsider that assignment and instead place 92X01 and 92X02 in APC 5194 (*Level 4 Endovascular Procedures*).**

Existing and revised code 92928 (*Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed, single major coronary artery and/or its branch(es); one lesion involving one or more coronary segments*) is a straightforward version of 92X01 that is already assigned to APC 5193. As the code descriptor delineates, 92X01 describes PCI performed on 2 or more distinct coronary lesions with 2 or more coronary stents. 92X01 will consume more resources than 92928 and should be assigned to APC 5194. It would better align with the costs and clinical complexity of code 92933 (*Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed, single major coronary artery and/or its branch(es)*) that is already assigned to APC 5194. This assignment could be monitored in future years to assure alignment, but it would be counterproductive for the new service to be so undervalued from the outset.

Similarly, existing code 92943 (*Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft any combination of intracoronary stent, atherectomy and angioplasty; antegrade approach*) describes a version of treating coronary chronic total occlusions using an antegrade approach. It is currently assigned to APC 5193. In contrast, as the code descriptor notes, 92X02 involves both the antegrade approach *and* a retrograde approach in service of achieving revascularization. **92X02 will consume more resources than 92943 and should also be assigned to APC 5194 where it will better align with the costs and clinical complexity of 92933.**

Proposed New Technology APCs

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

CPT code 78431 had over 30,000 single frequency claims in CY2024 with a geometric mean of approximately $2,200. This falls within the cost range of codes currently assigned to APC 1522 (New Technology-Level 22, $2001-$2,500) with a payment rate of $2,250.50. CMS proposes to maintain 78431 in its current APC of 1522.

CPT code 78432 had only 31 single frequency claims in CY 2024. 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 $1,737 which is below the code's currently assigned APC 1520 (New Technology-Level 20, $1801-$1900) with payment rate of $1850.50. CMS proposes to move 78432 to APC 1519 (New Technology-Level 19, $1701-$1800) with a payment rate of $1750.50.

CPT code 78433 had over 1,400 single frequency claims in CY 2024 with a geometric mean of $2,037 which is above the code's current assignment of APC 1521 (New Technology-Level 21, $1901-$2,000) with a payment rate of $1950.50. CMS proposes reassigning 78433 to APC 1522 (New Technology-Level 22 $2001-$2,500) with a payment rate of $2,250.50.

The ACC supports the assignments of APC 1522 for codes 78431 and 78433 based on the cost data analysis by the agency. However, the College does not support the assignment of APC 1519 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, 19 from 2023, and 31 from 2024. Being that there were essentially only three years of claims data available with a total of only 56 claims, even the low volume policy may not be able to provide a fair cost estimate for this service. **The ACC urges CMS to use its equitable adjustment authority to assign CPT code 78432 to APC 1522 to account for its resource usage that is greater than the more voluminous related codes that have more reliable data.**

Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT)

Given the low volume of claims and recognition that any of the low-volume service cost methodologies would reimburse these services well below the required resources CMS proposes to maintain the current assignment of APC 1511 for CPT code 0625T and for its successor code of 75XX6, which will be effective January 1, 2026, with a payment rate of $950.50.

The ACC supports maintaining 0625T/75XX6 in its current APC 1511. The College also recommends CMS proactively direct Medicare Administrative Contractors (MACs) not to issue restrictive revenue code edits on the Category I code for AI-CPA (75XX6 current placeholder code). CMS has acknowledged such restrictions led to previous codes being mandated

to be billed as radiology revenue codes when cardiology revenue codes were more appropriate. This led to skewed cost data that continues to require attention to correct. Prospective direction to the MACs would hopefully avoid a repeat of this scenario.

Other New Technology APC Assignments

The ACC concurs with the agency's APC assignments of CardiAMP, Corvia Medical Interatrial Shunt Procedures, LimFlow TADV, Surfacer Inside-Out Access Catheter System, and the Transcatheter Atrial Shunt System.

Diagnostic Testing and Related Services APC Codes and Concerns

The ACC notices that payment for the APCs for Diagnostic Testing and Related Services Levels 1-4 have all been dramatically reduced (see chart below). The text of the proposed rule does not discuss these changes, let alone provide detailed explanation or justification for the adjustments. The College presumes at least two factors may have contributed to these updates. First, numerous services have been moved to different APCs without, discussion or rationale in the text of the rule. The College notes with great concern that CMS has not provided sufficient transparency regarding the criteria employed in reassigning dozens of codes to different APC which has significantly reduced reimbursement for a wide variety of services. Second, CMS has acknowledged in this and previous rules the inclusion of errant cost reporting data pertaining to cardiovascular imaging services that were not allowed to be billed using cardiology revenue codes in the hospital setting and instead forced to use lower cost-to-charge ratio imaging revenue codes. These errant data inputs drive down the reimbursement rates for the affected APCs. **The ACC urges CMS to not finalize the broad reorganization of APCs 5721-5724 that results in changes to payment rates for all services within the Diagnostic Tests and Related Services APC Family for CY 2026.** Any such changes should be put forth in future rulemaking with clear explanations and rationales to allow public comment and should exclude any cost data that was negatively affected by the erroneous claim edit denying cardiology revenue code billing.

APC	Description	2025 Rate	Proposed 2026 Rate	% Change
5721	Level 1 Diagnostic Tests and Related Services	$156.46	$132.89	-15%
5722	Level 2 Diagnostic Tests and Related Services	$311.40	$221.14	-29%
5723	Level 3 Diagnostic Tests and Related Services	$530.60	$381.96	-28%
5724	Level 4 Diagnostic Tests and Related Services	$1,017.39	$879.34	-13.6%

93017 – Cardiovascular Stress Test, Technical Component

Among the many codes negatively impacted by the rate changes to the Diagnostic Tests and Related Services APC Family noted above, the College wishes to draw special attention to code 93017. This

code would see a 29% reduction in reimbursement rate due only to the unexplained shifts in APC assignments of other codes with no change or modification to the underlying cost data of the code itself. **The ACC urges CMS to maintain the current reimbursement rate of $311.40 for APC 5722 as well as the rest of the Diagnostic Tests and Related Services APC Family as noted above.**

Fractional Flow Reserve Derived From Computed Tomography (FFRct) CPT Code 75580

FFRCT code 75580 had over 17,000 single frequency claims in CY 2024 which produced a geometric mean of $278.51. However, CMS acknowledges that this geometric mean was likely negatively influenced by imposition of an outdated return-to-provider (RTP) HCPCS-to-revenue code edit that occurred when Category I CPT code 75580 became effective. This edit prevented providers from reporting the cardiology revenue code (0480), which has a higher cost-to-charge ratio than imaging revenue codes. This erroneously reduced the recorded costs as it was found to have done with cardiac CT codes 75572, 75573 and 75574. In light of this, CMS proposes to maintain code 75580 in its current assignment of APC 5724 (Level 4 Diagnostic Tests and Related Services).

The ACC supports the proposal to maintain CPT code 75580 in its current assignment of APC 5724. However, as noted above, we strongly urge CMS to not finalize the proposed adjustments to APCs 5721-5724, leaving them at their current reimbursement rates for 2026.

<u>Imaging with Contrast APCs</u>

Cardiac Computed Tomography Angiography (CCTA – CPT Codes 75572-75574)

The ACC supports CMS's proposal to continue assigning cardiac computed tomography angiography services to APC 5572, Level 2 Imaging with Contrast. This assignment appropriately reflects the clinical complexity and resource requirements of cardiac computed tomography angiography, the only noninvasive test for suspected coronary artery disease with Class I, Level A evidence in the AHA and ACC chest pain guidelines.

Cardiac computed tomography angiography remains underutilized in the Medicare population, in part due to historical underpayment and billing restrictions. In prior years, hospitals were not permitted to bill with cardiology revenue codes, which distorted cost data and resulted in assignment to a lower-level APC. CMS appropriately corrected this issue in CY 2025 using its equitable adjustment authority. The College urges CMS to maintain APC 5572 assignment for CY 2026, continue applying equitable adjustment authority for several years as claims data stabilize, and issue clear program instructions confirming that cardiology revenue codes are appropriate for these services.

Nuclear Medicine and Related Services APC Concerns

Cardiac Amyloidosis Diagnosis via CPT code 78803

Similar to the Diagnostic Tests and Related Services APCs, the ACC has concerns with movements of codes between Nuclear Medicine and Related Services APCs without clearly delineated rationale in the text of the proposed rule. Specifically, the College is concerned with the proposed reassignment of CPT code 78803 from APC 5593 with a 2025 payment rate of $1,305.48 to APC 5592 with a proposed 2026 payment rate of $558.70.

This proposed APC shift amounts to a 57% reduction in reimbursement of 78803. Physicians rely on stability in reimbursement rates to enable them to plan for practice expenses, supplies, and any required capital investment in the coming year. A cut of this magnitude seriously impairs the ability of nuclear cardiologists to provide this service and diagnose high mortality conditions.

In cardiology, this code is used in the diagnosis and treatment of Transthyretin Cardiac Amyloidosis as it detects amyloid using planar with Single Photon Emission Tomography (SPECT) using 99m TC- pyrophosphate. Cardiac Amyloidosis is a form of cardiomyopathy that comes from accumulation of misfolded protein deposits in the heart and, if left untreated, results in a median survival of less than 6 months.

The geometric mean data associated with 78803 decreased sharply from the 2024 to 2025 final rule. In 2024, the geometric mean cost of 78803 was $1,136.62 and it fell to $588.32 in the 2025 final rule. A number of services in nuclear medicine APC 5593 had cost data using high-cost low volume radiopharmaceuticals. That cost data was pulled out of APC 5593 when CMS made the decision to separately pay for radiopharmaceuticals over the $630 payment threshold. Physicians and hospitals need time to properly account for resources and inputs associated with 78803 for services that do not use high-cost radiopharmaceuticals. **Thus, the ACC urges CMS to collect several years of geometric mean data before reassigning 78803 from its current APC 5593.** During this time, physicians and hospitals can ensure costs are being accurately captured after the significant changes brought about by the separate payment policy for high-cost radiopharmaceuticals. It is uncertain whether the reduction in cost data is only from the change to separately pay for some tracers or if it has to do with other factors. One development that we suspect is not captured well in current data is the use of more different tracers in recent years when shortages of technetium-99m pyrophosphate (PYP) have occurred with regularity. It is also unknown whether all sites are charging for the tracer or if they are charging accurate, updated costs for that tracer. Finally, the costs of PYP have also increased as there a fewer companies making the product and there have been production issues. Providers need time to understand and to educate for accuracy.

The College also asks that in future rulemaking, any such movement between APCs be accompanied by detailed rationale and justification in the text of the proposed rule to allow stakeholders the opportunity to review and offer public comments on such changes.

Comment Solicitation on Payment Policy for Software as a Service (SaaS)

CMS describes the advance and increasing use of SaaS algorithm-driven services that assist clinicians in making clinical assessments. Providers pay for SaaS on a per-use or subscription basis. This is in contrast to other software which has traditionally been purchased with hardware acquisitions or as add-ons to enhance features/services. New CPT codes have been developed for a variety of SaaS procedures. In some instances, the costs associated with the SaaS procedures exceed the costs of the underlying service that underpins the SaaS.

Citing the heterogenous, novel, and evolving nature of SaaS technologies, CMS states it is challenging to compare SaaS procedures to existing medical services for the purposes of ratesetting. Therefore, the Agency seeks public comment on several aspects of payment policy that would broadly apply to SaaS procedures. The ACC appreciates the Agency's efforts to devise a cogent strategy in this space and offers preliminary thoughts on the questions posed in the rule. However, more work and policy need to be done in this space, and the ACC looks forward to additional engagement on this topic.

● *What factors could Medicare consider when setting payment rates for SaaS?*
One factor CMS should consider is the direct and indirect costs incurred by a hospital to utilize SaaS. Some SaaS is provided on a per-click fee basis. Others may be offered as a subscription. Some SaaS capabilities are even built into purchased software. Mechanisms should be available to practices that allow those direct costs to be covered in whichever format the product is sold. Members' experience has been that SaaS fees are the main cost of these services.

Physician work is a second important factor that must be incorporated. The ever-present buzz that software and artificial intelligence (AI) is going to make medicine better and more efficient remains exciting and promising. For example, dictation and documentation assistants have already demonstrated utility, yet even these solutions require a meaningful degree of physician review and oversight to correct errors, ensuring relevant information is included, and preventing inaccurate information from being inserted. In the cardiology space so far, most SaaS are additional calculations and services of existing imaging and diagnostic data. Generally, these services *add* to clinician work in an effort to improve patient care, becoming a new report that must be interpreted and incorporated into care planning. This additional work must be recognized in some manner. That could be as a discrete service, a complicating element of an E/M, or some other approach. This trend also demonstrates an important point that ACC has made in other comments on AI in health care—clinicians and patients must retain decision making abilities when it comes to patient care. As AI capabilities continue to evolve, it is essential that policies reaffirm that clinicians and patients—not algorithms—remain at the center of care.

● *How should we assess the costs of SaaS, and how can we account for hospital acquisition costs?*
The ACC has grown increasingly concerned that the potential growth and cost of SaaS will rapidly increase and consume scarce health care resources. SaaS pricing models include subscription, usage-based, tiered, freemium, per-user, and flat-rate. It remains uncertain what constitutes an appropriate

mechanism to set pricing for these services. Is it the cost to research, develop, and implement a machine-learning algorithm amortized across some number of expected units of service to derive a return of some percentage on the required investment? If SaaS can avoid downstream costs, would the rate be the downstream costs saved? If so, how would downstream cost savings be assessed, as services are usually assessed by costs to deliver? Perhaps the price is simply whatever the market will bear?

In every instance with which ACC is familiar, it is unknown what determines the price a facility or practice is billed for an individual SaaS. Beyond the traditional components of supplies, equipment, and labor, the price of a unit of SaaS analysis appears to be a black box for which derivation of the invoiced price is unknown. The most common example to date in cardiology SaaS is re-analysis of cardiac CT angiography studies, fractional flow reserve CT (FFRCT) and CT artificial intelligence coronary plaque assessment (AI-CPA)—which are addressed in this rule. The OPPS payment for the underlying CT study is currently $358 nationally. That is a service that includes clinical staff time, various supplies, and an expensive CT machine, software, and other equipment. The invoiced costs for the SaaS technical component of FFRCT and AI-CPA that provides new and enhanced information from those studies as a new service is roughly 3 to 5 times more expensive than the $358 hospital technical fee to obtain the data. In the same manner that technical fee costs must be itemized for services in the physician fee schedule, some new level of scrutiny seems to be in order to better understand the price of SaaS items to ensure Medicare is getting value for beneficiaries.

Decisions will have to be made about whether the "costs" are represented by a subscription or per-click fee as opposed to inherent in purchased software or equipment. If a result obtained through SaaS can also be obtained through other manipulation of already-owned software tools, are the additional costs of that effort added to the traditional version of the service, or are they considered in the same pool as the SaaS? I.e., if CT software that accompanies a scanner has or develops the ability to do the same thing as SaaS that has obtained a dedicated billing code, does the software-based version qualify to bill the service even though the costs for that version are dramatically lower with the software functioning as a piece of equipment? Depending on the rate charged for SaaS, the inherent/derived versions may be much more affordable and there would be reasons and incentives to want to identify low-cost options.

● *What cost or claims data should be used to establish the payment rates for the services?*
Invoices and payment rates for services are one piece of information that could be used to inform ratesetting. The ACC suggests CMS even consider separate data collections and payment mechanisms for SaaS. Vendors could more extensively detail approved costs in dedicated reporting streams; CMS could use a mechanism similar to average sales price or average wholesale price systems it deploys for drug payment based on that information. CMS should also consider that in some instances, it may be possible to perform SaaS services with software inherent to an imaging machine, making the costs more like a durable piece of equipment than a per-click fee.

● *Why are the geometric mean costs, as provided in our claims data, for SaaS currently assigned to APCs (both clinical and New Technology APCs) consistently lower than the manufacturers' purported costs of the technologies?*

Having engaged in the work to obtain invoices for SaaS services, the ACC can only speculate that something in the hospital cost reporting system/formula fails to adequately capture/estimate geometric mean costs. Every invoice—whether from a physician practice or a large academic institution—that has been shared with the College for valuation activities shows SaaS costs to the physician practice or hospital that exceeds current payment rates and geometric mean costs.

● *In the context of setting Medicare payment rates, how can CMS best reflect the quality and efficacy of SaaS technologies?*
The CPT Editorial Panel process could generally be relied upon to describe effective services which are distinct from the underlying, base test or professional service fee or needing physician judgment and quality oversight for clinical adjudication. Part of the CPT application requires literature of a certain caliber that supports the efficacy of a service. Such parameters could be used by CMS. In instances where CPT is not utilized for some reason, it seems likely that stakeholders have every incentive to be in contact with CMS to identify appropriate solutions to recognize which analyses are effective. The ACC is concerned that many new SaaS technologies could quickly be seeking distinct coding options for services that fit the criteria to be a distinct service but may also have similarities to software that is purchased by an imaging lab or already included in equipment and subscriptions used to make similar assessments.

Add-on Payment for Technetium-99m Derived from Domestically Produced Molybdenum-99 (Mo-99)

One hundred percent of cardiac imaging radioisotope Technetium-99m (Tc-99m), which is produced from radioactive decay of molybdenum-99 (Mo-99), is produced outside the United States. Production by aging reactors abroad and the quick decay of the isotope over long shipping distances motivated Congressional passage of the American Medical Isotopes Production Act of 2012 (AMIPA) to support the development of a reliable supply of Mo-99 produced in the United States. Implementing AMIPA, CMS initiated a policy in CY 2013 rulemaking providing an additional payment of $10 for the marginal cost of radioisotopes produced by non-Highly Enriched Uranium (HEU) sources. In 2023 rulemaking, CMS believed that by CY 2025 Medicare claims data utilized to set payment rates (likely CY 2023 claims data) would only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, meaning the data would reflect the full cost of the Tc-99m diagnostic radiopharmaceuticals that would be used by providers in CY 2025. As a result, there would no longer be a need for the additional $10 add-on payment for CY 2025 or future years. As such, a policy was adopted in CY 2024 rulemaking to end the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2025 to continue to ensure adequate payment for non-HEU-sourced Tc-99m.

In 2025 rulemaking, CMS explained that the Department of Energy and other interested parties raised another issue affecting the domestic supply chain for Mo-99 and Tc-99m that, left unaddressed, could cause payment inequity among outpatient hospital providers. Foreign Mo-99 production has historically been subsidized by foreign governments, resulting in prices below the true cost of production. These artificially low, foreign government-subsidized prices have created a disincentive for domestic investments in Mo-99 production infrastructure and a barrier to entry for

new producers, including U.S. companies, which in turn has resulted in unreliable production and periodic shortages. Unlike many foreign producers, U.S. companies must price their products high enough to cover the full cost of operating their production facilities. Based in part on these differences in pricing models, U.S. companies have experienced challenges in competing with foreign producers for customers in the past.

Multiple companies have since developed technologies to produce Mo-99 that are predicted to enter the market within the coming years. Additionally, U.S. companies have made significant progress towards establishing the infrastructure needed for large-scale Mo-99 production. Currently, there is no domestic production of Mo-99. However, once U.S. companies initiate Mo-99 production, the difference in pricing models will likely create a payment inequity, as hospitals purchasing Tc-99m derived from domestically produced Mo-99 would likely pay higher prices than those purchasing Tc-99m derived from imported Mo-99. Additionally, as domestic companies enter the market, we expect this transition to introduce new costs into the payment system that are not accounted for in the historical claims data.

Thus, in 2025 rulemaking, CMS set a plan to address the payment inequity resulting from the higher cost of Tc-99m derived from domestically produced Mo-99 by establishing a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1, 2026, using the equitable adjustment authority. The Department of Energy, National Nuclear Security Administration (DOE/NNSA) would establish the criteria to certify whether the Tc-99m radiopharmaceutical dose is derived from domestically produced Mo-99 and eligible for the add-on payment, which would be included in this CY 2026 OPPS/ASC proposed rule. Once those requirements were established to define a domestically produced Tc-99m radiopharmaceutical, CMS would consider any requirements for providers to document that the Tc-99m radiopharmaceutical used in a procedure was domestically produced and can qualify to receive the add-on payment in future rulemaking. Recognizing that there may not be domestic production of Mo-99 and Tc-99m in CY 2026, CMS felt it was better to have a regulatory framework for this policy in place for when domestic production of Tc-99m radiopharmaceuticals begins. Specifically, by having a regulatory framework already in place, providers will be knowledgeable about the availability of additional payments for domestically sourced Tc-99m radiopharmaceuticals. Likewise, producers of domestic Mo-99 will be certain that the Medicare OPPS payment policy considers the additional costs of domestic production of Mo-99.

AT DOE/NNSA recommendation, CMS proposes: to define a domestically produced dose of Tc-99m as a dose of Tc-99m generated from domestically produced Mo-99; similarly, to define domestically produced Mo-99 to mean Mo-99 that was both irradiated and processed in the United States; to define "irradiated" as the process of bombarding a uranium or molybdenum target with radiation in order to produce Mo-99; to specify that irradiation is typically performed with a nuclear reactor or particle accelerator; lastly, to define "processed" in this context to refer to the purification of Mo-99 from irradiated material. A dose of Tc-99m generated from Mo-99 that was irradiated or processed outside the United States would not qualify for this add-on payment, even if the Mo-99 was loaded into a Tc-99m generator in the United States or if the Tc-99m was eluted at a radiopharmacy in the United States. For example, Mo-99 imported and shipped separately to a US-

based generator manufacturer or radiopharmacy, and then loaded in a generator stateside, would not be considered domestically produced Mo-99 for the purposes of this add-on payment. More specifically, although the Mo-99 was loaded into a generator or eluted in the United States, the Mo-99 was irradiated and processed abroad, imported, and then loaded into the domestic generator, and would therefore be excluded from this add-on payment.

CMS proposes to establish new HCPCS C-code C917X (*Tc-99m from domestically produced non-HEU Mo-99, [minimum 50 percent], full cost recovery add-on, per study dose*), effective January 1, 2026. Similar to the implementation plan for the non-HEU add-on payment policy and the reporting of the corresponding HCPCS code Q9969, hospitals will be able to report new HCPCS C-code C917X once per dose, along with any diagnostic scan or scans furnished using Tc-99m derived from domestically produced Mo-99. Hospitals can bill this add-on code if the hospital can certify that at least 50 percent of the Mo-99 in the Tc-99m generator to produce the Tc-99m was domestically produced Mo-99.

The ACC appreciates CMS preparing a framework to allow facilities to report C917X to identify domestically produced Mo-99 and qualify for the $10 add-on payment and supports it as a helpful starting point for the day Mo-99 is actually domestically produced. As CMS discusses, it will be necessary to monitor costs such as production, transportation, and storage that outpatient hospital departments may incur that would not be accounted for in historical claims data to inform future adjustments to the add-on payment rate.

Services That Will Be Paid Only as Inpatient Services

Background

The Inpatient Only (IPO) list was established in rulemaking as part of the initial implementation of the Outpatient Prospective Payment System (OPPS) in 2000. The IPO list was created to identify services for which Medicare will make payment only when furnished in the inpatient hospital setting because of the invasive nature of the procedures, the underlying physical condition of the Medicare patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. The creation of the IPO list was based on the premise (rooted in the practice of medicine at that time) that Medicare should not pay for procedures furnished as outpatient services which are performed on an inpatient basis virtually all of the time for the Medicare population because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules.

Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting. Conversely, the absence of a procedure from the list should not be interpreted as identifying that procedure as appropriately performed only in the hospital outpatient setting. CMS emphasized the expectation that, in every case, the physician or surgeon and hospital will exercise their professional judgment and assess the risk of the procedure or service to the individual patient, taking into account the site of service and

act in that patient's best interest. For procedures that are not included on the inpatient list, the practitioner's judgment was relied upon to determine on a patient-by-patient basis whether or not a particular procedure would be most appropriately performed in the inpatient setting.

The IPO list policy has elicited both opposition and support in public comments since its establishment in CY 2000, with some commenters indicating through the years that such a regulation was unnecessary—expert physicians and their patients should have the discretion to make decisions about the site of service for a particular medical procedure without such a limitation by CMS. Some felt the existence of the IPO list suggested that services that are not on the list or have been removed from the list should be/must be provided in the outpatient setting, regardless of the clinical judgment of the physician or the needs of the patient. Other commenters have defended the need for the list, stating that the IPO list serves as an important programmatic safeguard and maintains a common standard in the Medicare program.

In CY 2021 rulemaking, a policy was finalized to eliminate the IPO list over the course of 3 years. In CY 2022 rulemaking, elimination of the IPO list was reversed and most removed services were returned to the IPO list in CY 2022 rulemaking. Five longstanding criteria for determining whether a service or procedure should be removed from the IPO list were codified. For CY 2023 through CY 2025, the IPO list was maintained and continued to evaluate services brought forth by interested parties for removal using the five longstanding criteria. The IPO list was reviewed annually to identify any services that should be removed from, or added to, the list, based on the most recent data and medical evidence available. While only one criterion was required to be met for removal consideration, satisfying only one criterion does not guarantee that the service will be removed; instead, the case for removal is strengthened with the more criteria the service meets. Interested parties, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and determine whether services should be added to or removed from the list. The criteria for assessing procedures for removal from the IPO list are:

- Most outpatient departments are equipped to provide the service or procedure to the Medicare population.
- The simplest service or procedure described by the code may be performed in most outpatient departments.
- The service or procedure is related to codes that CMS has already removed from the Inpatient Only list.
- CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.
- CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center, and is specified as a covered ambulatory surgical procedure, or CMS has proposed to specify it as a covered ambulatory surgical procedure.

Proposed CY 2026 Changes to IPO List

Citing anew the desire of some interested stakeholders to eliminate the IPO list and the evolution of technologies and techniques in surgery and infection control, CMS proposes to eliminate the five criteria for removing procedures from the IPO list and to eliminate the IPO list through a 3-year transition starting in CY 2026, completing the elimination by January 1, 2029. CMS believes this will allow greater exercise of clinical judgment and increase the ability of hospitals to provide Medicare-reimbursed services on an outpatient basis when clinically appropriate, while preserving inpatient beds for individual patients who truly need to be admitted. A number of safety mechanisms would continue to ensure the safety of our beneficiaries and the quality of care, including physician judgment, State and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives.

Under a related proposal, procedures removed from the IPO would continue to be exempt from certain medical review activities that assess for compliance with the 2-midnight rule until the Secretary determines that the service or procedure is more commonly performed in the Medicare population in the outpatient setting. **The ACC supports the proposal to exempt from certain medical review activities procedures removed from the IPO and urges a transparent process of advance notification for providers should services be deemed more commonly performed in the outpatient setting in the future.**

285 mostly musculoskeletal procedures are proposed for removal in 2026. Most of these procedures would be assigned to a newly established seven-level Musculoskeletal Procedures Ambulatory Payment Classification (APC) series, to allow for the assignment of musculoskeletal procedures removed from the IPO list to an APC with an applicable range of estimated costs.

Restating previously expressed concerns that migration of services to the OPPS could increase beneficiary financial burden under different cost sharing mechanisms in OPPS, CMS clarifies that OPPS cost sharing for a service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. This explanation is helpful for stakeholders to understand.

The ACC agrees that technological and clinical advances increasingly continue to allow procedures to move to lower acuity sites of service. Physicians' clinical knowledge and judgment can be relied upon to appropriately determine whether a procedure can be performed in a hospital outpatient setting or whether inpatient care is required for the beneficiary based on the beneficiary's specific needs and preferences. When executed under general coverage rules requiring that any procedure be reasonable and necessary, payment should be made pursuant to applicable payment policies. However, it is unknown exactly how smoothly such a transition can be made in such a short period of time. While the ACC appreciates the intent to allow clinicians greater autonomy in making these decisions, the **ACC urges CMS to slow proposed removal of the IPO list until a greater measure of certainty can be offered to stakeholders in terms of OPPS payment rates, mitigation of new documentation burdens to justify the selected site of service, care quality, and beneficiary impact.**

The ACC is not expert in the services proposed for initial migration, so cannot comment specifically on the appropriateness of those APC assignments. However, little information was included in the rule to explain how APCs were selected. The ACC finds this concerning since cost reporting mechanisms and payment structures for IPPS and OPPS are entirely different. This is one aspect of the proposal that would benefit from greater transparency and a longer lead time.

Physicians already devote significant time and attention to selecting the appropriate site of service for procedures not on the IPO. These considerations include balancing patient input and preference with clinical factors and anticipated resource needs. Part of this process entails ensuring appropriate documentation and rationale is in place to validate the decision and protect against possible compliance or audit issues. A benefit of the IPO has been reduced administrative burdens for these compliance concerns because these were thought to be services that so obviously need the acuity of the inpatient setting that it would be unnecessarily risky to provide them in the outpatient setting. A fear of physicians is that this change will increase the burden and risk they and hospitals face to justify selecting a higher acuity setting. A related concern is that administrators or other payers may view the removal of the IPO as a requirement to provide services in the outpatient setting that would not otherwise be considered appropriate for that level of care. Specific proposals or guidance from the agency for navigating these aspects of site selection could make providers more comfortable with this change.

Little discussion was provided in the proposed rule regarding the impact on quality measurement programs already in place. For instance, acute myocardial infarction and heart failure mortality and readmission measures have been analyzed and publicly reported for inpatients for more than a decade. It is not clear that consideration was given to any methodological changes that may be warranted. **The College recommends that CMS consider how to measure and maintain the quality and safety of services newly provided in the outpatient setting as procedures migrate.** At a minimum, CMS should continue to ensure that services for high-risk patients are performed in the most appropriate setting as defined by clinical guidelines. Specific discussion and proposals regarding how the quality of care will be assured after potential movement to the outpatient setting would prepare providers for these changes.

Finally, CMS elsewhere in the proposed rule indicates an interest in site neutrality between different settings. The ACC sees the potential for parallel arguments to be made here when it comes to moving services from inpatient to outpatient settings. The ACC recognizes the opportunities to reduce costs through site-neutral payment policies but warns against rushing to the lowest possible payment. The same deference CMS proposes to give to beneficiaries' preferences and physicians' clinical knowledge and experience when it loosens policies that could shift services from the hospital inpatient setting to the hospital outpatient setting should also be given to patients' physicians when they choose NOT to move to a lower acuity care setting.

To prepare for IPO sunset activities in future rulemaking, CMS seeks comments from the public on whether 3 years is an appropriate time frame for the transition, whether there are other services that would be ideal candidates for removal from the IPO list in the near term, given known technological and other advances in care, and the order of removal of additional clinical families of services,

and/or specific services, for each of the CY 2027 and CY 2028 rulemakings, until the IPO list is completely eliminated. Additionally, feedback is requested on whether any APCs should be restructured or any new APCs or C-APCs created to allow for efficient OPPS payment for services that are removed from the IPO list.

Three years is not long to complete this transition, and the ACC suggests a longer timeframe would be preferable. Only 285 of 1,731 services are proposed to be removed from the IPO in this first year. It would be prudent to evaluate the effectiveness of this change before making the same changes for the remaining 1,446 services in just two more rulemaking cycles to ensure these considerations are appropriately addressed when services are performed in the OPPS setting. This transition should be spread over more years to allow identification of obstacles. Because of the high costs of inpatient cardiovascular services and the acuity of the patients undergoing those procedures, the **ACC recommends cardiovascular services be among the last codes removed from the sunsetting IPO list if CMS proceeds with its proposed timeline.**

The ACC expects many new APCs or C-APCs will need to be created to accommodate complex cardiovascular services that are currently on the IPO. For example, many outpatient cardiovascular services are assigned to APCs for Endovascular Procedures. There are four levels of endovascular procedures. Level 4 Endovascular Procedures APC 5194 is for the most complex and pays the most--$18,791.32 in this proposed rule. Transcatheter structural heart therapies, complex percutaneous coronary interventions, and coronary artery bypass grafts are all services with costs that exceed that payment amount. These services performed by ACC members will not fit into existing APCs in future years, requiring new APCs or C-APCs. **The ACC urges CMS to transparently elaborate on its methodology for developing new APCs for transitioned services.** Certainly, cost and clinical similarity are part of that, but *which* costs from IPPS are applied to OPPS ratesetting will be determinative in creating new APCs.

Request for Information: Adjusting Payment under the OPPS for Services Predominately Performed in the Ambulatory Surgical Center or Physician Office Settings

Through this RFI, CMS seeks input on the possibility of further pursuing site-neutral payment policies for ambulatory services at high risk of shifting to the hospital setting based on financial incentives rather than medical necessity. CMS asks whether OPPS payment should be limited to the ASC or PFS rate if the service is predominantly performed in one of those sites of service.

The ACC recognizes the opportunities to reduce costs through site-neutral payment policies but warns against rushing to the lowest possible payment. CMS proposes in this rule to give significant deference to beneficiaries' preferences and physicians' clinical knowledge and experience when it loosens policies that could shift services from the hospital outpatient setting to the ASC setting and from the inpatient setting to the outpatient setting. Comparable deference must also be given to patients and physicians when they choose NOT to move to a lower acuity care setting. The ACC has previously devoted significant consideration to meaningful principles that should guide site-neutral payment policies and shares them here for consideration.

• Changes to Medicare payment should prioritize patient access, quality and value of care.

• Approaches to remove unnecessary and/or unexpected cost to patients and the health care system, including equity across outpatient ambulatory settings, should be discussed.

• Significant changes to address payment disparities between sites of service must be phased in over time to safeguard the stability of the health care system.

• Proposals must consider the financial impact of changes on the stability of the health care system, particularly those providing care to underserved populations.

• Site of service payment policies must be aligned with programmatic and systemic changes to avoid unnecessary complexity and promote the successful transition to a value-based payment system.

• Any payment differences across sites should be related to documented differences in the resources needed to ensure patient access and high-quality care.

• Medicare payments for all sites of care should account for costs related to emergency capacity, compliance with regulatory requirements, geographic differences, quality improvement activities, higher need populations, or other factors relevant to a site of service.

As CMS moves more surgical services to the ASC setting, CMS should consider whether updates to the ASC payment methodology are needed in order to provide sufficient and sustainable payment.

Virtual Direct Supervision of Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services and Diagnostic Services Furnished to Hospital Outpatients

In the CY 2026 Physician Fee Schedule (PFS) proposed rule CMS proposes to revise the definition of direct supervision to make permanent the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS, except for services that have a global surgery indicator of 010 or 090. As explained in the rule, this proposal is made in response to overwhelming support and requests to extend this policy permanently for a wider set of services than the ones that were finalized in the CY 2025 PFS Final Rule and would build on the incremental approach of making the virtual supervision of certain services permanent which began in the CY 2025 PFS rule. As noted in the CY 2026 PFS proposed rule, this approach would recognize that virtual supervision has been available and widely utilized since the beginning of the PHE while excluding certain services to ensure quality of care and patient safety, and in particular, the ability of the supervising practitioner to intervene if complications arise, particularly in complex, high-risk instances where unexpected or adverse events may occur or for procedures that may be riskier or more intense since a patient's clinical status can quickly change.

To align payment systems, CMS proposes to revise regulations and supervision definitions in regulations that govern hospital outpatient payment to make the availability of the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications

technology (excluding audio-only) permanent, except for diagnostic services that have a global surgery indicator of 010 or 090. CMS notes that permanently adopting a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for CR, ICR, PR and diagnostic services, except for diagnostic services that have a global surgery indicator of 010 or 090 does not mean that it is appropriate to allow virtual presence for every service for every Medicare beneficiary in every clinical scenario. As always, the physician or nonphysician practitioner should use his or her complex professional judgment to determine the appropriate supervision modality on a case-by-case basis. **The ACC entirely agrees with that sentiment and supports the proposal to align OPPS supervision regulations with the related PFS proposal, which the ACC also supports.**

Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

Proposed Additions to ASC Covered Procedure List (CPL)

Under regulations promulgated for CY 2022 rulemaking, CMS covers services in the ambulatory surgery center (ASC) that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Beyond these general standards, general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15.

In this proposed rule for CY 2026, CMS proposes to again revise regulatory criteria to evaluate potential additions to the ASC CPL by removing certain general standards and also the five general exclusion criteria. These would be recast in a new regulatory section as nonbinding physician considerations for patient safety. Using this new rubric, CMS proposes to add 276 procedures to the ASC CPL based on these criteria changes and add an additional 271 codes to the ASC CPL that are proposed for removal from the IPO list for CY 2026. CMS seeks to expand beneficiary access to services, while maintaining the safety for Medicare beneficiaries through the nonbinding physician considerations for patient safety. Covered surgical procedures would be those specified by the Secretary that are separately paid under the OPPS and that are not (1) currently designated as requiring inpatient care under § 419.22(n) of this subchapter; (2) only able to be reported using a CPT unlisted surgical procedure code; or (3) otherwise excluded under § 411.15 of this chapter. CMS believes that these proposed policies will increase the flexibility for physicians to exercise their complex medical judgment, factoring in patient safety considerations, and for patients to choose from more settings of care in which to receive surgical procedures.

ACC Feedback on CPL Changes

The ACC agrees that technological and clinical advances continue to allow procedures to move to lower acuity sites of service, and previously offered qualified support to add a number of diagnostic cardiac catheterization and percutaneous coronary intervention procedures to the CPL. The ACC also agrees access to care is paramount and quickly shifting in uncertain times. Allowing more services in ASCs may ease burdens on patients seeking care. Though the ACC cautions that ASCs are not necessarily located in areas that face care shortages (rural or underserved urban areas) and urges CMS and providers to consider implications of these policy changes on care equity.

The ACC does support placing other codes proposed in Table 80 on the CPL for 2026. Performance of cardiac ablation services in the ASC setting has been the focus of interest and study by ACC members in recent years. The ACC has worked closely with the Heart Rhythm Society to consider the safety profile of these services. A recent publication of data underscored the benefits of cardiac ablation SDD strategies on patient safety and access, as well as advances in technology that are helping to improve procedural efficiencies and reduce the length of hospitalization and mitigate costs.[1] A pending publication outlines the ways technological and procedure advancements and same-day discharge protocols create the possibility of shifting traditionally hospital-based intracardiac procedures to ASCs. **As such, the ACC supports placing codes 93650-93657 on the CPL for 2026.**

Other proposals on Table 80 are likely acceptable but also confusing. The percutaneous coronary interventions (PCI) on the list are fragmented. Table 80 includes several HCPCS C codes without their CPT counterparts. Complex procedures are included while more straightforward ones are not. Such inconsistencies are confounding and ACC suggests CMS review more completely the inclusion of PCI services on the CPL. Providing physicians the discretion to rely on their judgment and choose a site of service with these patients is appropriate. **The ACC supports the addition of the remainder of the PCI code set 92920-92979 to the ASC-CPL list to allow physician discretion on a case-by-case basis.**

Some services not proposed by CMS for inclusion on the CPL should be considered for inclusion in the final rule or in future rulemaking. Comprehensive electrophysiologic study codes 93619 and 93620 are the evaluative portion of an ablation. The outcome of a cardiac ablation procedure does not always culminate in the successful induction and ablation of a cardiac arrhythmia. In some cases, the procedure may not yield an "inducible" cardiac arrhythmia; alternatively, it may yield the induction of an arrhythmia that is not amenable to catheter ablation. Without the inclusion of 93619 and 93620 procedure codes, no payment would be made in instances when the procedure is stopped after the diagnostic portion. **The ACC recommends codes 93619 and 93620 be added to the CPL for 2026.** If not, they should be considered in future rulemaking.

[1] HRS/ACC Scientific Statement: Guiding Principles on Same-Day Discharge for Intracardiac Catheter Ablation Procedures https://www.jacc.org/doi/10.1016/j.jacep.2025.03.019

Finally, cardioversion is a widely used procedure for restoring sinus rhythm in patients with cardiac dysrhythmias, requiring deep sedation comparable to other ASC-approved pain management procedures. This procedure is integral for arrhythmia management to ensure planning and success of ablations and other EP interventions. **The ACC recommends code 92960 be added to the CPL for 2026.** If not, it should be considered in future rulemaking.

The College recommends that CMS consider how to measure and maintain the quality and safety of patient care provided in the ASC setting as more procedures are covered in this setting. At a minimum, CMS should continue to ensure that services for high-risk patients are performed in the most appropriate setting as defined by clinical guidelines. Additionally, participation in a national data registry allows benchmarking, risk adjustment and facilitates outcomes analysis of local data and should be required.

As CMS moves more surgical services to this setting, CMS should consider whether updates to the ASC payment methodology are needed in order to provide sufficient and sustainable payment. Recognizing the costs of device-intensive procedures in the ASC setting, the ACC encourages CMS to continue to evaluate policies and the appropriateness of payment amounts for services provided in the ASC as additional cardiovascular services are added to the ASC CPL. A specific consideration for these services should be the appropriate incorporation of related services recommended by literature and guidelines as commonly important for successful PCI. Coronary intravascular ultrasound (IVUS) (92978-92979) and fractional flow reserve (FFR) (93571-93752) are both assigned status indicator "N" and are packaged into other services. IVUS decreases mortality when used as an adjunct for stenting and is a Class 1 recommendation in the 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes.[2] The same guideline summarizes evidence that FFR-guided PCI reduces the number of stents used during PCI and lowers the incidence of major adverse cardiovascular events. With payment for ASC services made at a fraction of the OPPS payment rate, the ACC is concerned that packaging these services at the ASC payment rate could create an incentive for operators to forgo these enhancing technologies in some instances. **One way to address this regarding PCI would be for CMS to unpackage these services, a solution the ACC recommends.**

Proposed Changes to the Hospital OQR, REHQR, and ASCQR Program Measure Sets

Proposed Removal of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure from the Hospital OQR and ASCQR Programs Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

Although not specialty-specific, this measure's removal may affect hospitals and ASCs where cardiovascular services are delivered. We defer to hospital systems and infection control experts on whether continued tracking remains clinically and operationally necessary. Cardiovascular patients

[2] 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines | JACC https://www.jacc.org/doi/10.1016/j.jacc.2024.11.009

remain vulnerable to COVID-19, and healthcare worker vaccination rates remain an important component of infection prevention and trust. A revised, lower-burden approach may preserve public health benefits without overburdening providers.

Proposed Removal of the Hospital Commitment to Health Equity (HCHE) Measure

While we understand CMS's intent to reduce reporting burden, this measure plays a unique and foundational role in signaling the importance of commitment to equity from health systems and hospitals. Health equity should be viewed as essential to improving clinical outcomes and achieving sustainable population health, particularly in cardiovascular care. This measure incentivizes institutions to establish the infrastructure necessary to identify, monitor, and act upon disparities in care delivery. Instead of removing the measure entirely, we encourage CMS to explore refinements such as adjusting the scoring methodology or adopting a tiered attestation framework to better balance burden with accountability. Addressing disparities upstream reduces costly complications downstream. Rather than eliminating this measure, a refined approach would still address accountability while aligning with its stated goal of improving value and lowering overall costs.

Proposed Removal of Two Social Drivers of Health Measures from the Hospital OQR, REHQR, and ASCQR Programs

We encourage CMS to retain the Screening for Social Drivers of Health (SDOH-1) and Screen Positive Rate for Social Drivers of Health (SDOH-2) measures in these programs. Social drivers of health, including food insecurity, housing instability, and transportation access, are well-documented determinants of cardiovascular outcomes and broader health disparities. Although we acknowledge concerns around the resource burden of implementing these measures, we believe their continued inclusion is vital for encouraging health systems to integrate non-clinical determinants into care delivery strategies. These measures are among the few nationally reported metrics that reflect hospitals' recognition of upstream health needs, particularly for patients at an increased risk of adverse outcomes due to social vulnerability.

Rather than eliminate these measures, we encourage CMS to consider several strategies to support their continued implementation and impact. This includes providing technical assistance to help integrate screening into electronic workflows, exploring options to stratify reporting by patient demographics to better assess equity impact, and offering a confidential reporting option to facilitate iterative improvement before public reporting. We also recommend that CMS seek opportunities to collaborate with states, providers, patients, community organizations, and other stakeholders to develop and implement effective strategies to advance these goals. In addition, CMS should explore the development and use of AI-enabled technologies to streamline data capture, reduce reporting burden, and generate actionable insights, thereby improving both the feasibility and utility of SDOH screening. Overall, most CV outcomes are influenced by SDOH. Acknowledging that at the hospital level and collecting the data as well designing measures that potentially impact SDOH is critical to improving CV outcomes. We would recommend redesign as suggested, but not removal.

Proposed Adoption of the Emergency Care Access & Timeliness eCQM to the Hospital OQR Program Measure Set, REHQR

This proposed digital measure aims to replace two existing chart-abstracted measures: Median Time from ED Arrival to Departure for Discharged Patients and Left Without Being Seen. This eCQM captures four critical ED performance metrics: whether a patient waited more than one hour to be placed in a treatment room, left the ED without being evaluated, boarded in the ED for more than four hours after a decision to admit, or remained in the ED for longer than eight hours. The measure is designed to be automatically extracted from EHRs, reducing manual data abstraction burden while addressing growing concerns over ED crowding and boarding. CMS is proposing voluntary reporting beginning in CY 2027, with mandatory reporting starting in CY 2028 for the CY 2030 payment determination.

ED boarding and care delays can have an impact on outcomes for patients with acute cardiovascular conditions such as heart failure exacerbations, arrhythmias, or STEMI. Since timely treatment is essential in many cardiac cases and cardiologists may be involved in triaging or admitting patients from the ED, there may be indirect effects on cardiology workflows. These include increased pressure to expedite consults, triage decisions, or admissions to meet ED timeliness thresholds. These pressures could affect the quality or pacing of care for complex cardiovascular patients, particularly in high-volume or tertiary centers.

While the goals of this eCQM are aligned with improving access and safety, there may be unintended consequences of such a measure. For example, patients with complex cardiac needs may experience delays due to required specialty evaluations or limited telemetry beds, which could affect the measure, even when clinical care is appropriate. In addition, given the expansion of eCQMs in multiple programs and the technical investment needed to update EHR systems, CMS should ensure realistic timelines and avoid penalizing hospitals for factors beyond their control, particularly for tertiary centers managing complex cardiovascular patients. CMS may want to consider exclusions or stratification approaches for specialized care pathways and ensure that the measure is implemented in a way that supports timely access to care.

Modification of Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults

The ACC supports the intent of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults eCQM, particularly its aim to promote patient safety by minimizing unnecessary radiation exposure without compromising image quality. We applaud CMS' recognition of the potential burdens for hospital and health systems in terms of IT integration, system compatibility, and information security. We would like to note that there is limited national consensus around what constitutes "excessive" radiation dose, however, and no endorsed benchmark currently exists. A one-size-fits-all approach could result in unintended consequences such as test substitution or avoidance of clinically appropriate imaging simply to meet metric thresholds. In certain scenarios, a higher radiation dose may be necessary to achieve diagnostic accuracy, which aligns with patient-centered care. The ACC supports CMS's proposal to continue

voluntary reporting of this measure, allowing time for broader validation and stakeholder input while minimizing disruption to clinical decision-making and avoiding premature penalization of appropriate imaging practices.

Proposed Changes to the ASCQR Program Measure Set: Addition of the Information Transfer PRO-PM

We believe the Information Transfer PRO-PM is relevant to patient and cardiovascular care, where procedures such as diagnostic catheterizations, PCI, or device implantations may be performed in the outpatient setting. These episodes often rely on the clarity of post-discharge instructions, medication adherence, and timely follow-up, all of which depend on effective communication. Therefore, we cautiously support CMS's proposal to include this measure beginning in Performance Year 3, allowing hospitals time to build familiarity and refine workflows before scores impact payment. However, CMS should provide materials such as technical guidance and standardized tools to assist with reporting.

One caution is that patient understanding may be influenced by factors beyond provider control, such as health literacy, language barriers, or other influences. Many cardiovascular patients are older, medically complex, and face barriers like low health literacy or language access, factors not accounted for in the current unadjusted design. To ensure fair and actionable use, we recommend: 1) further stratification by race/ethnicity, language, dual-eligibility, and education, 2) set basic data-quality rules: a minimum response-rate threshold, disclose which languages were used, and report (and adjust for) nonresponse. and 3) conduct an annual review of the measure to determine if any bias or meaningful differences emerge.

Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care Measure Group

The ACC supports CMS's ongoing efforts to strengthen patient safety across the care continuum and recognizes that the Safety of Care measure group plays a critical role in evaluating hospital performance. However, CMS should proceed cautiously in finalizing the proposed methodology changes to the Overall Hospital Quality Star Rating, particularly the 4-star cap for hospitals in the lowest quartile of Safety of Care beginning in 2026 and the 1-star blanket reduction beginning in 2027. These penalties introduce sharp consequences that may disproportionately affect large hospitals, tertiary centers, and facilities that provide complex cardiovascular services, where higher patient risk and intensive procedures can drive up rates of complications despite best practices and adherence to clinical guidelines. Importantly, they may also adversely affect resource-limited and rural hospitals that already face financial and infrastructure challenges, as well as those serving underinsured populations. Such facilities could experience additional penalties that undermine their ability to invest in safety improvement initiatives, potentially widening disparities in care.

Hospitals that perform high volumes of invasive cardiology procedures, advanced imaging, and critical care may be more likely to encounter events flagged by Safety of Care measures (e.g., hospital-acquired conditions, healthcare-associated infections, or postoperative complications).

Without relevant risk adjustment or clinical context, these safety metrics may not fully account for the complexity of cardiovascular patients or the higher baseline complexities these hospitals manage. We are also concerned that imposing a mandatory 1-star downgrade, regardless of a hospital's overall performance, could mask quality distinctions and unintentionally discourage hospitals from accepting high-risk cases or participating in innovation efforts such as structural heart programs or advanced heart failure management. CMS should consider incorporating additional safeguards, including more detailed stratification, risk adjustment for procedure-specific cohorts, and opportunities for clinical peer review or appeals before enforcing automatic star reductions for hospitals in the lowest safety tier. Clarity in definition of postoperative complications, specifically avoidable complications, is required before this automatic downgrade in star ratings is implemented. Very broad definitions are not helpful in identifying true safety events.

Conclusion

Thank you for your consideration of these comments and the Agency's work on behalf of Medicare beneficiaries. Please contact Matthew Minnella, Associate Director of Medicare Payment Policy, at mminnella@acc.org should any additional information be needed.

Sincerely,

Christopher Kramer, MD, FACC
President, American College of Cardiology