August 26, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1850-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CY 2027 Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; Including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities to Apply for Available Slots

Dear Administrator Oz,

On behalf of the American Society of Echocardiography (ASE), representing more than 17,000 physicians, sonographers, and allied health professionals dedicated to advancing cardiovascular ultrasound, we appreciate the opportunity to provide comments on proposed changes to the CY 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule, published in the Federal Register on July 7, 2026 (CMS-1850-P).

ASE supports CMS's continued efforts to promote a sustainable, equitable Medicare payment system. Echocardiography is a cornerstone of cardiovascular diagnosis, treatment planning, and longitudinal disease management, and ensuring appropriate payment and access to these services is fundamental to improving outcomes, advancing value-based care, and reducing avoidable morbidity and mortality among Medicare beneficiaries.

We have significant concerns, however, that several proposals in the CY 2027 OPPS/ASC proposed rule would create barriers to access, disrupt established care delivery models, and reduce the availability of essential echocardiography services. Our principal concern is the proposed extension of the volume-control methodology to imaging-without-contrast services furnished in excepted off-campus provider-based departments (PBDs) — an immediate payment reduction of approximately 60% for services that include comprehensive transthoracic echocardiography. We also urge CMS to ensure that emerging payment frameworks for software-enabled technologies, including artificial intelligence (AI)-enabled tools, provide the predictability required for responsible innovation. We respectfully urge CMS to evaluate carefully the impact of these proposals on echocardiography services, clinicians, and patients, and to adopt the modifications described below.

Our comments cover the following proposals:

- Interconnected Policy Proposals Across Inpatient, Outpatient, and Physician Payment Systems
- Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
    - Imaging Without Contrast Services
- CY 2027 Proposals for Software-as-a-Medical-Service (SaMS) Procedures

Interconnected Policy Proposals Across Inpatient, Outpatient, and Physician Payment Systems

ASE recognizes the complexity of administering Medicare payment policy across multiple settings of care and appreciates CMS's efforts to advance policies intended to promote efficiency, sustainability, and high-quality care for Medicare beneficiaries. However, as CMS considers significant changes across the Hospital Inpatient Prospective Payment System (IPPS), Hospital Outpatient Prospective Payment System (OPPS), Ambulatory Surgical Center (ASC) Payment System, and Physician Fee Schedule (PFS), it is essential that the agency evaluate and clearly communicate the interconnected impact of these policies across the healthcare continuum.

Many proposed payment policies - including site-neutral payment initiatives, changes to hospital outpatient reimbursement, new payment pathways for software-as-a-medical-service (SaMS) technologies, updates to resource-based valuation methodologies, and broader efficiency adjustments - have implications that extend well beyond the individual payment system in which they are introduced. For services such as echocardiography, which are delivered across hospital outpatient departments, physician offices, and other clinical settings, changes to one payment system can directly influence access, care delivery models, clinical workflows, and the adoption of innovative technologies throughout the healthcare system. For example, a comprehensive transthoracic echocardiogram furnished in an excepted off-campus PBD would be affected simultaneously by the PFS-equivalent payment reduction proposed in this rule and by efficiency-based adjustments to the professional interpretation proposed under the PFS — a combined, compounding effect on a single service that is not analyzed in either rule.

ASE encourages CMS to provide greater transparency and a comprehensive assessment of the anticipated impact of interconnected policy proposals before implementation. Stakeholders, including clinicians, hospitals, professional societies, and technology developers, need sufficient information regarding how proposed changes will interact across payment systems in order to meaningfully evaluate potential consequences and provide constructive feedback. Without clear information from CMS, there is a risk that well-intended policies may unintentionally create barriers to care, reduce patient access, or disrupt established models of high-quality cardiovascular care.

ASE urges CMS to include detailed explanations of proposed policies, anticipated downstream impacts, and supporting analyses within the formal rulemaking process rather than relying solely on supplemental data files or technical addenda. This transparency is particularly important for code-level changes, payment methodology updates, and service-specific adjustments that may significantly affect clinical practice. CMS should ensure that all proposed code-level changes and associated payment implications are clearly identified within the proposed rule materials to allow stakeholders adequate opportunity to review, analyze, and provide meaningful comments.

The increasing complexity and cross-functional nature of Medicare payment policy requires robust collaboration between CMS and the clinical communities responsible for delivering care. ASE welcomes continued engagement with the agency and offers the expertise of the echocardiography community to help ensure that payment policies support innovation, maintain patient access, and appropriately recognize the clinical value of cardiovascular imaging services.

CY 2027 Proposals for Utilization of Imaging Without Contrast Services

ASE strongly opposes the proposal to extend the OPPS volume-control method to imaging without contrast services furnished in excepted off-campus provider-based departments (PBDs). CMS proposes to pay services assigned to APCs 5521 through 5524, as well as the applicable multiple-imaging composite APCs 8004, 8005, and 8007, at the Physician Fee Schedule (PFS)-equivalent rate when furnished by excepted off-campus PBDs that bill with modifier PO. For many affected services, this would reduce payment to approximately 40% of the otherwise applicable OPPS rate. CMS's own analysis, however, demonstrates that the PFS-equivalent amount varies considerably by APC, ranging from approximately 31% to 54% of the OPPS payment rate. For affected services, including comprehensive transthoracic echocardiography (CPT 93306), this would represent a substantial and immediate payment reduction.

ASE is concerned that the proposal would broadly encompass important cardiovascular imaging services, including transthoracic echocardiography, without adequately demonstrating that observed utilization patterns reflect unnecessary volume rather than changes in clinical need, patient complexity, care-delivery models, or access to integrated cardiovascular services. Before implementing a non-budget-neutral payment reduction of this magnitude, CMS should undertake a more targeted, service-specific, and evidence-based assessment of the affected services and the patients who receive them. ASE therefore urges CMS to withdraw the proposal as currently structured.

Hospitals and health systems increasingly reduce barriers to care by providing convenient local access to highly specialized cardiovascular programs that historically were available primarily on the main hospital campus. Off-campus PBDs may support complex disease-specific programs in structural heart disease, electrophysiology, hypertrophic cardiomyopathy, cardiac amyloidosis, pericardial disease, and cardiovascular disease in pregnancy, among others. Bringing this expertise closer to patients can reduce travel burdens and improve access to coordinated specialty care. As a result, patients treated in off-campus PBDs may have clinical complexity comparable to those seen in on-campus hospital settings, and the services furnished in these departments should not be presumed to be equivalent to those provided in a typical freestanding physician office.

CMS expressly cites CPT code 93306 in support of the proposal, characterizing it as a high-volume imaging-without-contrast service. CMS reports that Medicare paid 294% more for the service in a hospital outpatient department than in a freestanding physician office in 2023 and that excepted PBDs accounted for approximately 79% of 93306 volume in 2025. ASE recognizes that these payment and site-of-service trends warrant careful examination. However, these data alone do not establish that comprehensive transthoracic echocardiography furnished in excepted PBDs is clinically unnecessary, nor do they demonstrate that payment at the PFS-equivalent rate would adequately support safe, timely, and coordinated cardiovascular diagnostic care.

Comprehensive transthoracic echocardiography is a foundational, noninvasive cardiovascular diagnostic service used in the evaluation and management of heart failure, valvular heart disease, cardiomyopathy, pulmonary hypertension, ischemic heart disease, arrhythmias, congenital heart

disease, and numerous other cardiovascular conditions. Although CMS categorizes CPT code 93306 as imaging "without contrast," the absence of a contrast agent is not a proxy for the clinical complexity of the examination, the expertise required to acquire and interpret diagnostic images, or the resources necessary to care for the patients receiving the service. The value of echocardiography also extends beyond image acquisition. When performed within an integrated cardiovascular care setting, findings may immediately inform clinical assessment, treatment decisions, additional testing, and follow-up.

Accordingly, a payment policy that treats comprehensive echocardiography as operationally interchangeable across sites of service based principally on the absence of contrast does not fully account for these clinical and operational realities. Reliance on broad APC-level categories and composite APCs is therefore an overly blunt approach for establishing a payment differential of this magnitude.

ASE also encourages CMS to consider how the proposal could affect patterns of ultrasound enhancing agent (UEA) use. Because the proposed payment adjustment applies specifically to imaging performed without contrast, imaging performed with a UEA would remain outside the affected APCs and continue to receive full OPPS payment. This distinction could create a meaningful payment differential based on contrast use, even though the decision to administer a UEA should remain grounded in clinical considerations.

ASE has long supported the appropriate use of UEAs, which can improve diagnostic accuracy in patients with suboptimal acoustic windows and remain underutilized relative to guideline recommendations. At the same time, payment policy should preserve clinical neutrality and avoid inadvertently influencing decisions regarding contrast administration. A substantial payment differential between otherwise comparable studies with and without a UEA could affect utilization patterns and introduce additional costs associated with the agent itself, intravenous access, nursing, and related resources. These downstream effects could also offset a portion of the savings CMS anticipates from the proposal.

For these reasons, ASE does not believe that the presence or absence of contrast provides a sufficiently precise or clinically meaningful basis for a payment reduction of this magnitude. A broad payment policy built on this distinction risks overlooking substantial differences in patient complexity, site-of-service resources, and the role of imaging within integrated cardiovascular care. ASE therefore strongly urges CMS to withdraw the proposal and undertake a service-specific, evidence-based assessment before implementing any comparable payment reduction. Any future policy should be grounded in demonstrated differences in resource use and clinical need, avoid creating unintended incentives, and preserve beneficiary access to timely, high-quality cardiovascular diagnostic services.

Illustrative Clinical Scenarios

The following examples illustrate why clinical complexity, and the resources needed to support it, cannot be inferred from the imaging code or the absence of a contrast agent alone:

- **Heart failure with preserved ejection fraction (HFpEF):** An elderly beneficiary with hypertension, atrial fibrillation, and stage 3b–4 chronic kidney disease presents with progressive dyspnea. A comprehensive TTE with diastolic assessment (CPT 93306) is required to establish the diagnosis and guide therapy, with serial studies needed to titrate guideline-directed medical therapy. Because her advanced renal disease limits the use of contrast-enhanced cardiac MR and CT protocols, echocardiography is the principal imaging pathway — and the hospital-affiliated

PBD's shared electronic health record and same-visit coordination with her heart failure team allow findings to change management the same day, with rapid escalation if she decompensates.

- **Cardio-oncology surveillance:** A patient receiving potentially cardiotoxic cancer therapy requires serial echocardiography with speckle-tracking strain imaging (CPT 93306 with myocardial strain) to detect subclinical left ventricular dysfunction. Interpretation requires the specialized expertise concentrated in accredited, hospital-affiliated echocardiography laboratories, and same-day availability of results within the shared oncology record determines whether the next cycle of therapy proceeds, is modified, or is held.
- **Suspected infective endocarditis / bacteremia:** A patient with S. aureus bacteremia, a prosthetic valve, intracardiac device, or persistent fever may require an urgent non contrast TTE to evaluate for vegetations, valve destruction, new regurgitation, abscess-related findings, or hemodynamic compromise. Abnormal or indeterminate findings may prompt expedited TEE, infectious disease consultation, cardiac surgery evaluation, or hospital admission.
- **Acute change following a cardiovascular procedure:** A patient recently undergoing TAVR, ablation, PCI, pacemaker implantation, or another cardiovascular intervention may develop dyspnea, hypotension, chest pain, or other concerning symptoms requiring urgent TTE to evaluate for pericardial effusion, new ventricular dysfunction, valve complications, or other procedural adverse events. Although billed under the same code as an elective outpatient study, the examination may require immediate physician interpretation and rapid escalation of care.
- **Kawasaki disease:** A 6-year-old with a history of extreme prematurity, chronic lung disease, and pulmonary hypertension develops Kawasaki disease. Comprehensive TTE without contrast is essential to assess the coronary arteries, ventricular function, valvulitis, and pulmonary pressures, and to monitor for coronary aneurysms, thrombosis, stenosis, and ventricular dysfunction during follow-up. The absence of contrast does not reflect lower clinical complexity; these studies directly inform management decisions aimed at preventing myocardial ischemia, chronic heart failure, and sudden cardiac death.

In each case, the clinical decision to perform the study in an excepted off-campus PBD reflects the patient's complexity and the need for coordinated, same-setting cardiovascular care, not a discretionary or cost-driven choice between otherwise interchangeable sites of service. The cost structure of these departments derives from hospital conditions of participation and related regulatory obligations that apply to off-campus PBDs no less than to on-campus departments.

Aggregate Claims Trends Do Not Establish That Services Are Unnecessary

CMS cites growth in utilization and spending for selected imaging-without-contrast services furnished in excepted PBDs, including service-specific comparisons with physician-office volume. Those aggregate claims trends may be useful for identifying questions for further study, but they do not, standing alone, establish that the services were clinically unnecessary. Claims data cannot fully account for patient complexity, referring patterns, the availability of appropriate local alternatives, changes in the prevalence or management of cardiovascular disease, practice consolidation, hospital affiliation, or the role of an off-campus PBD in providing coordinated specialty care.

CMS's utilization comparison treats the volume of CPT 93306 furnished in excepted off-campus PBDs as evidence of unnecessary growth, but it does not examine the referral patterns that determine where a beneficiary's echocardiogram is actually performed. Physicians refer patients for echocardiography to a hospital-affiliated off-campus PBD for reasons unrelated to payment, including

an existing relationship with a hospital-employed or hospital-affiliated cardiology practice, the need to coordinate the study with a same-system cardiologist who will interpret the images and manage the patient's care, and the ability to obtain same-day or urgent access when a hospital-based practice is the point of entry for a patient's cardiovascular care. As physician practices have continued to consolidate, a growing share of echocardiography referrals now flow through hospital-affiliated networks as a structural matter, independent of any change in the clinical necessity of the underlying test. CMS's claims-based comparison of site-of-service volume cannot distinguish this kind of referral-driven and consolidation-driven migration from a genuine, unnecessary increase in the use of echocardiography, yet the proposal relies on that comparison as though the distinction were immaterial. Before attributing 93306 volume growth in excepted PBDs to a payment differential, CMS should analyze referral sources, the affiliation status of referring practices over time, and whether the same patients would have received comparable testing volume regardless of site of service.

CMS Has Not Conducted the Necessary Service-Specific Analysis

CMS acknowledges that hospital outpatient departments serve unique and medically complex patient populations yet concludes that higher payment is not justified for affected imaging services. **This conclusion is not supported by a sufficiently granular, service-specific analysis.** In cardiovascular care, a patient's clinical complexity may not be reliably represented by the imaging code alone. A transthoracic echocardiogram may be ordered as part of a time-sensitive diagnostic evaluation for a patient with new or worsening symptoms, a complex cardiac history, multiple comorbidities, or a need for rapid coordination with a cardiovascular specialist. The ability to furnish the test in an integrated off-campus outpatient setting may be clinically appropriate even if a similar image-acquisition service can also be furnished elsewhere.

Before characterizing increased use of cardiovascular imaging services as unnecessary, CMS should analyze service-level clinical indications, patient characteristics, referral sources, geographic access, care coordination needs, and outcomes. Without that analysis, the proposal does not establish the necessary connection between the payment differential and unnecessary utilization for the full range of services captured by the policy.

The PFS-Equivalent Rate Does Not Capture the Resources Required in Excepted Off-Campus PBDs

CMS proposes to apply the site-specific PFS-equivalent rate used for non-excepted off-campus PBDs. CMS describes this as an approximately 40% OPPS payment level and estimates that the PFS-equivalent amount ranges from about 31% to 54% of the OPPS amount across the affected APCs. This is a substantial and immediate reduction in payment for services furnished in facilities that remain hospital outpatient departments and continue to bear the operational, clinical, regulatory, and infrastructure obligations of that setting.

Excepted off-campus PBDs may support functions and costs that are not captured by a simple comparison to a freestanding physician-office payment rate. These can include:

- Accreditation and quality oversight specific to echocardiography, such as Intersocietal Accreditation Commission (IAC) laboratory accreditation and adherence to ASE guideline-based imaging and reporting protocols, which impose standards, staffing ratios, and equipment requirements beyond what a freestanding office may maintain.
- Credentialed sonographer staffing, including ARDMS/CCI-certified sonographers and ongoing competency assessment, continuing education, and peer-review/quality-assurance programs correlating echocardiographic findings with surgical, catheterization, or pathology outcomes.

- Hospital electronic health record (EHR) integration, enabling real-time delivery of echocardiographic findings into the patient's full hospital-based cardiovascular record, immediate availability to the ordering physician and care team, and interoperability with inpatient, emergency department, and specialty systems.
- Immediate physician over-read and same-day reporting integrated with on-site or on-call cardiology coverage, supporting same-day clinical decision-making rather than delayed, asynchronous interpretation.
- 24/7 or extended on-call capability for urgent and STAT echocardiography, including studies requested from the emergency department or inpatient units to evaluate for tamponade, endocarditis, acute heart failure, or suspected aortic pathology.
- Capacity to escalate care in real time, including the ability to proceed same-day to TEE, stress echocardiography, or urgent cardiology, electrophysiology, or surgical consultation when an echocardiographic finding requires immediate action.
- Compliance with hospital conditions of participation and EMTALA-related obligations, which apply to hospital-based outpatient departments and are not imposed on freestanding physician offices.
- Integration with multidisciplinary heart-team and specialty programs (heart failure, structural heart, arrhythmia/electrophysiology), where echocardiographic findings directly inform same-day, coordinated treatment planning.

The importance of these functions varies by service and by patient population; that variation is precisely why a categorical payment reduction is inappropriate without a service-specific evaluation of resource use.

CMS should not assume that a facility's off-campus location means that its services are operationally equivalent to services furnished in a freestanding physician office. The appropriate question is whether the proposed PFS-equivalent rate adequately supports the resources required to furnish each affected service safely and reliably to the patients served in the excepted PBD setting. CMS has not provided that analysis.

<u>The Policy May Impair Beneficiary Access to Timely, Coordinated Cardiovascular Diagnostic Services</u>
The proposal could reduce the availability of non-contrast imaging services, including echocardiography, at excepted off-campus PBDs. These departments often provide a convenient access point for patients receiving specialty care outside the main hospital campus. For patients with cardiovascular disease, the ability to obtain an echocardiogram in a coordinated setting can facilitate timely diagnosis and management and may avoid delays associated with referral to a separate site.

CMS proposes an exemption for Rural Sole Community Hospitals, recognizing that such hospitals may be the only source of care in their communities and that beneficiaries and providers in rural areas may not have a meaningful choice between a hospital outpatient department and a lower-cost physician office. ASE appreciates CMS's recognition that access circumstances matter. However, this narrow exemption does not address access concerns in other medically underserved areas, including urban and suburban communities with limited specialty capacity, transportation barriers, a high prevalence of cardiovascular disease, or few accessible imaging providers.

CMS should evaluate access consequences at the service, provider, and community levels before finalizing a policy that could materially change the economics of providing diagnostic imaging. A

claims-based comparison of aggregate utilization cannot substitute for a prospective assessment of whether patients will retain meaningful access to timely, integrated cardiovascular diagnostic services.

CMS Should Not Extend Its Existing Volume-Control Policy Without a More Targeted Evidentiary Foundation

CMS cites its prior use of Section 1833(t)(2)(F) for off-campus clinic visits and drug-administration services as precedent for the proposed expansion of its volume-control policy. Those prior applications, however, do not establish that the same methodology is appropriate for all imaging-without-contrast services. Any expansion of this authority should be supported by evidence specific to the services affected and demonstrate that the policy is appropriately targeted to address unnecessary utilization without compromising beneficiary access or disrupting clinically appropriate care.

The proposed policy does not make these distinctions. Instead, it would apply broadly to all services assigned to four APCs and three composite APCs, would be implemented on a non-budget-neutral basis, and is estimated to reduce CY 2027 payments by $260 million, including $190 million in Medicare payments and $70 million in beneficiary coinsurance. While these figures quantify the anticipated savings, they do not demonstrate that the underlying utilization is inappropriate, that the PFS-equivalent rate adequately reflects the resources required to furnish these services in excepted PBDs, or that access to necessary imaging would be preserved.

Importantly, CMS already has multiple mechanisms available to promote appropriate imaging utilization. Imaging services furnished in hospital outpatient departments are subject to medical-necessity requirements, accreditation standards, utilization management, claims review, and other program-integrity safeguards. In addition, specialty societies have invested substantially in clinician-developed appropriate use criteria (AUC) and clinical practice guidelines designed to support evidence-based imaging decisions. These tools recognize that appropriate utilization must be evaluated in the context of the individual patient, clinical indication, disease trajectory, and need for serial assessment—not simply aggregate volume.

ASE therefore does not believe that high or increasing utilization, standing alone, provides a sufficient basis for concluding that imaging is unnecessary or excessive. In cardiovascular care, increased utilization may reflect an aging and increasingly complex Medicare population, expanded access to specialty care, advances in guideline-directed management, and the need for repeat imaging to monitor disease progression or treatment response. A volume-control methodology that does not distinguish among these factors risks reducing payment for clinically appropriate services along with any utilization CMS may be seeking to address.

For similar reasons, ASE does not support layering an additional HOPD-specific AUC requirement onto this payment reduction. Hospital outpatient departments frequently care for patients with complex cardiovascular conditions for whom standardized decision-support tools may not fully capture the need for imaging, particularly when repeat studies are required to assess changes in ventricular function, valvular disease, pulmonary pressures, treatment response, or other evolving clinical findings. Applying an additional utilization-control mechanism at the same time CMS substantially reduces payment could compound barriers to timely access without demonstrating a corresponding improvement in quality or appropriateness.

CMS should not rely on anticipated aggregate savings as a substitute for the detailed clinical and operational analysis necessary to support a policy of this magnitude. Nor should projected beneficiary coinsurance reductions be viewed in isolation from their potential impact on access. A nominal reduction in cost sharing provides little benefit if beneficiaries experience delays in obtaining timely, local, clinically necessary cardiovascular imaging.

ASE therefore urges CMS to withdraw the proposal and instead develop a transparent, service-specific evidentiary foundation that examines utilization patterns, clinical indications, patient complexity, and utilization-management safeguards, resource requirements, and access implications. If CMS continues to consider additional volume-control or AUC policies, they should be supported by demonstrated evidence of inappropriate utilization, developed with meaningful specialty-society input, and sufficiently targeted and flexible to preserve physician judgment and beneficiary access to medically necessary imaging.

ASE's Recommendations

ASE respectfully urges CMS to withdraw the proposal to apply the PFS-equivalent payment rate to imaging-without-contrast services furnished in excepted off-campus PBDs.

If CMS nevertheless elects to proceed, ASE urges CMS to do the following before finalizing or implementing any payment change:

1. **Limit any policy to individual services** supported by clear, service-specific evidence that an unnecessary volume increase is attributable to a payment differential, rather than applying a categorical reduction to entire APCs and composite APCs.
2. **Exclude echocardiography and other cardiovascular imaging services** until CMS has conducted a transparent analysis of clinical indications, patient complexity, resource use, beneficiary access, and the role of coordinated specialty care in excepted off-campus PBDs.
3. **Conduct a robust access assessment** that considers medically underserved urban, suburban, and rural communities, not solely rural Sole Community Hospitals.
4. **Publish the underlying data and analytic methods** necessary for stakeholders to assess CMS's conclusions regarding utilization, patient acuity, site-of-service migration, and payment adequacy.
5. **Provide a phased-in approach and ongoing monitoring** if CMS ultimately finalizes a more narrowly tailored policy, with explicit safeguards and corrective action if access or service availability deteriorates.
6. **Accreditation:** ASE supports accreditation as an appropriate mechanism to promote quality and appropriate imaging utilization in HOPDs. Accreditation provides established standards for equipment, personnel qualifications, imaging protocols, quality assurance, and clinical performance without imposing an additional, burdensome AUC requirements.

CY 2027 Proposals for Software-as-a-Medical-Service (SaMS) Procedures

ASE supports CMS's efforts to establish a dedicated payment pathway for software-based medical technologies and appreciates the agency's recognition that emerging digital health solutions, including advanced clinical decision support tools and artificial intelligence (AI)-enabled technologies, may not align with traditional payment methodologies designed around procedures, equipment, and physical resource inputs. A thoughtful and predictable payment framework is essential to support the responsible integration of these technologies and ensure Medicare beneficiaries have access to innovations that enhance diagnostic accuracy, clinical decision-making, and patient care.

As CMS continues to refine its long-term payment methodology for Software as a Medical Service (SaMS), ASE emphasizes the importance of maintaining payment stability while sufficient claims, utilization, and cost data are collected to support informed policy development. ASE believes the establishment of the **01 modifier represents an important step toward improving the identification of AI-enabled services and capturing the data necessary to better understand their use and associated costs in the hospital outpatient setting.** Continued use and evaluation of this modifier can help CMS build a more reliable evidence base for future payment decisions.

At the same time, ASE notes that existing hospital cost-reporting structures may not fully or consistently capture the resources associated with software-based services, particularly when these technologies are embedded within broader imaging and clinical workflows. ASE therefore encourages CMS to continue evaluating complementary data-collection approaches that can more accurately identify the costs and resources attributable to SaMS and support the development of a sustainable, evidence-based payment methodology.

Over the longer term, ASE urges CMS to consider a distinct payment approach for SaMS furnished in the hospital outpatient setting. As AI-enabled technologies become increasingly integrated into diagnostic imaging and clinical decision-making, existing payment structures may not adequately recognize these technologies as a distinct clinical resource or account for the costs associated with their deployment and use.

Any future framework should also preserve appropriate reimbursement for the physician services that accompany and are augmented by these technologies. ASE encourages CMS to avoid methodologies that could inadvertently place SaMS technologies in competition with physician services or create downward pressure on physician reimbursement. A clearly defined payment framework that separately recognizes the resources associated with SaMS, while maintaining appropriate payment for physician interpretation and clinical integration, would support responsible adoption of innovative technologies and provide greater payment stability for both hospitals and physicians.

ASE encourages CMS to provide greater detail regarding the evaluation of SaMS technologies, including clinical decision support tools, algorithm-based analysis platforms, and other software-enabled solutions used in cardiovascular care. CMS should also outline a long-term framework addressing how new technologies will enter the SaMS pathway, how payment methodologies will evolve as evidence and utilization mature, and how SaMS policies will align with existing CPT, HCPCS, and APC processes.

Specifically, ASE recommends that CMS:

1. Publish transparent eligibility criteria for SaMS designation, with cardiovascular imaging examples such as AI-enabled automated chamber quantification and strain analysis.
2. Commit to a defined period of payment stability - for example, no less than three years - while claims and cost data mature.
3. Clarify that SaMS payment will be additive to, and not offset against, payment for the underlying imaging service
4. Describe how technologies will enter and progress through the SaMS pathway as evidence and utilization evolve, in alignment with existing CPT, HCPCS, and APC processes.
5. Establish SaMS payment mechanisms that are independent of the MPFS and its budget-neutrality mandate, so that payment for AI-enabled technologies does not reduce payment for directly furnished physician services.

ASE supports CMS's continued leadership in developing payment pathways that recognize the growing role of software-enabled technologies in healthcare delivery. A transparent, evidence-based, and sustainable SaMS framework will be increasingly important as artificial intelligence and advanced analytics become integrated into cardiovascular imaging and clinical practice. ASE looks forward to continued collaboration with CMS to ensure these policies promote innovation while preserving access to high-quality, patient-centered care.

Conclusion

ASE appreciates the opportunity to comment on the CY 2027 OPPS/ASC proposed rule and CMS's continued efforts to modernize Medicare payment policy in a manner that supports quality, access, and innovation in cardiovascular care. As outlined above, ASE urges CMS to provide greater transparency regarding the interconnected effects of payment proposals across care settings, to withdraw or substantially narrow the proposed extension of the volume-control methodology to imaging-without-contrast services, and to continue developing a predictable, evidence-based SaMS payment pathway that accounts for the true resource requirements of software-enabled cardiovascular technologies. Echocardiography remains an essential, often time-sensitive diagnostic service, and payment policy should reflect the clinical complexity of the patients who depend on it and the infrastructure required to deliver it safely and reliably.

ASE stands ready to serve as a resource to CMS as the agency refines these policies, and we welcome the opportunity to share the clinical and operational expertise of our members, including physicians, sonographers, and laboratory administrators who deliver these services every day. We would welcome further dialogue with CMS staff on any of the issues raised in this letter and are glad to provide additional data or clinical context as needed.

Thank you for your consideration of these comments. If you have any questions, please contact Katherine Stark, ASE Director of Advocacy at kstark@asecho.org.

Sincerely,

Cynthia Taub, MD, MBA, FASE
President
American Society of Echocardiography