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June 8, 2026

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Sent electronically via www.regulations.gov

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1849-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; and Other Policy Changes

Dear Dr. Oz:

The Society for Cardiovascular Angiography and Interventions (SCAI) has dedicated its work to advancing the profession and is the designated society for guidance, representation, professional recognition, education, and research opportunities for invasive and interventional cardiology professionals. For more than 40 years, SCAI has personified professional excellence and innovation globally, fostering a trusted community of more than 5000 members dedicated to medical advancement and lifesaving care for adults and children with cardiovascular disease. SCAI appreciates the opportunity to comment on this proposed rule.

NTAP Applications

CMS is proposing to approve the CARA System software for new technology add on payment for 2027 subject to market authorization. SCAI supports this decision, as it underscores the clinical importance of conduction-guided intervention for structural heart operators and the unmet need the CARA System addresses for managing conduction-disease risk in structural heart procedures by providing patient-specific anatomic visualization of the cardiac conduction system.

CMS is proposing to approve the GORE® VIABAHN® FORTEGRA Venous Stent for new technology add on payment for 2027. SCAI appreciates CMS' consideration and agrees that this technology meets NTAP payment requirements.

CMS is proposing to approve the InVision Precision Cardiac Amyloid for new technology add on payment in 2027. This technology is a SaMD machine-learning disease detection algorithm to identify high suspicion of cardiac amyloidosis from routinely obtained echocardiogram videos. SCAI agrees that this technology meets the requirements for NTAP payment.

CMS is proposing to approve the Micro Medical Solutions MicroStent and the MicroStent XL Peripheral Vascular Stent System for new technology payment in 2027 subject to market authorization. The permanent implantable stent is designed to improve luminal diameter in the treatment of ischemia in the lower leg. SCAI appreciates CMS' consideration, and agrees that this technology meets NTAP payment requirements.

CMS is proposing to approve the NEXUS® Aortic Arch Stent Graft System for new technology payment in 2027 subject to market authorization. The device is designed specifically for repair of aortic arch pathologies (including aneurysms, chronic dissections, penetrating ulcers, and intramural hematoma) involving Zone 0 ascending aorta and the arch. SCAI agrees that this technology meets the requirements for NTAP payment.

CMS is proposing to approve the PMcardio® STEMI AI ECG Model for new technology payment in 2027 subject to market authorization. The technology identifies ECG patterns of STEMI/STEMI-equivalents as an adjunctive decision support tool. SCAI agrees that this technology meets the requirements for NTAP payment.

CMS is proposing to approve the SAPIEN M3 Transcatheter Mitral Valve Replacement System for new technology payment in 2027 for replacement of the native mitral valve in patients with symptomatic mitral valve regurgitation or symptomatic mitral stenosis. SCAI appreciates CMS' consideration, and agrees that this technology meets NTAP payment requirements.

CMS proposes to approve the Spur Peripheral Retrievable Stent System for new technology add-on payments for 2027. SCAI agrees that the Spur Peripheral Retrievable Stent System meets the requirements for NTAP payment.

CMS proposes to approve the Trilogy™ Transcatheter Aortic Valve Regurgitation System for new technology add-on payments for 2027 for use to anchor in the diseased regurgitant aortic valve. SCAI agrees that this technology meets the requirements for NTAP payment.

CMS proposes to approve the ViaOne™ Epicardial Access System for new technology add-on payments for 2027 provided confirmation of the first date of U.S. sales for use in pericardial sac entry. SCAI agrees that this technology meets the requirements for NTAP payment.

CMS proposed to approve VUNO Med-DeepCARS® for new technology payment in 2027 subject to market authorization. The artificial intelligence based technology monitors and assesses the risk of impending cardiac arrest within a 24-hour period among inpatients. SCAI agrees that this technology meets the requirements for NTAP payment.

Proposed Alternative Pathway Repeal for New Technology Add-on Payment and Outpatient Prospective Payment System (OPPS) Device Pass-through

CMS is proposing to repeal the alternative pathway for new technology add-on payment and OPPS device pass-through applications and require all applicants for new technology add-on payments and OPPS device pass-through payments to demonstrate that they meet the same eligibility requirements to receive add-on payments and/or pass-through payments. SCAI understands that CMS is evaluating how best to ensure that breakthrough technologies have the smoothest path to adoption while still ensuring the best interests of Medicare beneficiaries. However, SCAI has concerns that completely repealing the alternative pathway will greatly limit innovation. The payments provided by this pathway has allowed hospitals to provide cutting-edge therapies, even during the time it takes for the costs of the new products to be incorporated into MS-DRG rates. Access to these new technologies may cease without a payment mechanism. SCAI would encourage CMS to ensure alternate methods for critical technologies that meet the newness and SCI criteria, but do not yet have the clinical data necessary for NTAP to receive payment are implemented before sunseting the existing program.

Conclusion

In conclusion, SCAI appreciates the opportunity to provide comment to CMS on issues of high interest to the interventional cardiology community. If SCAI can be of any assistance as CMS continues to consider and review this or related issues, please do not hesitate to contact Monica Wright, SCAI's director of regulatory affairs at mlwright@scai.org.

Sincerely,

A handwritten signature in blue ink that reads "Arnold Seto". The signature is written in a cursive style and is placed on a light gray rectangular background.

Arnold Seto, MD, MPA, FSCAI
Chair, Advocacy Committee