

January 24, 2025

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Submitted electronically via: <http://www.regulations.gov>

Jeff Wu

Acting Administrator

Centers for Medicare and Medicaid Services

Attention: CMS-4208-P

7500 Security Boulevard

P.O. Box 8013

Baltimore, MD 21244-8013

RE: Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Dear Mr. Wu:

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 important proposed rule.

Prior Authorization

SCAI agrees with CMS' assessment that the disaggregation of the reported health equity analysis metrics for all items and services could assist in increasing transparency and ensure the most accurate data regarding prior authorization is available. Prior authorization data must be disclosed on an individual service

basis to have real meaning. Without service level data, it is not possible to reduce the potential disproportionate impact of prior authorization on disabled and dual eligible enrollees or to target the particular service lines requiring priority attention.

Transparency is imperative for understanding the full burden including delays, care repercussions and costs of prior authorization. Access to data in the areas of timelines, authorization processing, appeal personnel, and the role of AI would allow for a clearer understanding of where further reforms are needed. Additionally, more clarification on denials including evidence used in the determinations would help physicians navigate the prior authorization process.

Artificial Intelligence

The use of AI in decision making processes is becoming more common, and depending on its use is problematic. SCAI appreciates CMS' requirement that AI must be used in a manner that preserves equitable access to MA services and that the rule spells out some ways that plans can remain in compliance. However, we believe that more guardrails are needed to ensure proper use of AI beyond limiting bias. Improved visibility is needed into algorithm development and decision-making processes to ensure that medical decisions are being made by a clinician, not a computer to ensure appropriate access to services for all beneficiaries.

Network Adequacy

CMS should use data collection efforts in a manner that helps to strengthen network adequacy and access so that beneficiaries have access to services in accordance with National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) and are aware of their access to clinical trials. SCAI has concerns that interventional cardiology is not included as one of the 27 specialty provider types in CMS' requirements. This oversight could limit patient access to care performed by the specialist most qualified to perform the procedure, or as required such as within the NCD for TAVR. SCAI recommends that access to specialty types detailed in NCDs be a requirement for determining network adequacy.

Internal Coverage Criteria

CMS is proposing to define "internal coverage criteria," which would establish guardrails to ensure access to benefits, and add more specific rules about publicly posting internal coverage criteria content on Medicare Advantage plan websites. SCAI applauds CMS' efforts to clarify coverage for both beneficiaries and providers and make the coverage criteria more easily accessible. These changes will help ensure that Medicare Advantage enrollees are receiving the same level of coverage as fee for service beneficiaries.

SCAI appreciates the opportunity to provide comments on this proposed rule and we look forward to continue working with CMS to address these important issues. If SCAI can be of any assistance as CMS continues to consider and review these issues, please do not hesitate to contact SCAI's director, regulatory affairs, Monica Wright at 202-327-5451 or at mlwright@scai.org if there are any questions or further requests.

Sincerely,

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

Arnold Seto, MD, MPA, FSCAI
Advocacy Committee Chair