SCAI
Society for Cardiovascular Angiography & Interventions

September 8, 2024

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

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Attention: CMS–1809-P
7500 Security Boulevard
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Dear Administrator Brooks-LaSure:

The 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.

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

CMS is proposing to change the current timeframe for outpatient prior authorization requests from 10 business days to seven calendar days to better align with the CMS Interoperability and Prior Authorization final rule. SCAI thanks CMS for acknowledging the need for this change. CMS does not propose to align the expedited time frame with the final rule because the 72 hours may take longer than the current expedited time frame of 2 business days. SCAI appreciates that CMS is

aiming to keep the turnaround time as short as possible and supports retaining the current timeframe.

Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (PR) Services Furnished to Hospital Outpatients
CMS is proposing to revise the definition of direct supervision to extend the availability of virtual direct supervision of therapeutic and diagnostic services through December 31, 2025. SCAI agrees with the assessment that abruptly prohibiting virtual supervision may cause a barrier to access to necessary services. Extending this flexibility for another year will allow more time for both planning for the change in requirements and for CMS to assess the feasibility of extending the policy permanently.

Proposed OPPS New Technology APC and Status Indicator Assignments

LimFlow
CMS has requested comment on whether LimFlow meets all criterion for pass through payment. LimFlow is an important new technology in the fight against lower limb amputation. SCAI believes that all criteria are met by this technology and encourages CMS to grant pass through payment status to this technology.

OPN NC Percutaneous Transluminal Coronary Angioplasty (PTCA) dilatation catheter
We believe that the OPN balloon meets the newness criterion of 419.66(b)(1) because unlike prior balloons including noncompliant balloons, it is specially designed to achieve 35-55 atmospheres (atm) of pressure which is far beyond the 20 atm of conventional balloons.This can be particularly and uniquely useful for under-expanded stents from fibrotic or calcified vessels, which even new technologies such as lithotripsy and older technologies such as laser are unable to expand.

We believe that the OPN balloon meets the 419.66(b)(3) criterion as it is integral to the service provided and used for one patient only, that is, it is disposable. It does not appear to meet the 419.66(b)(4) exclusion criterion as it is not equipment.

With regards to 419.66(c)(1), the device is similar in purpose and function other devices under C1725, however, the double-layer construction is unique in the coronary space, and enables the high-pressure inflation needed for angioplasty of resistant lesions. While this is similar in mechanism of conventional angioplasty balloons (dilatation through pressure, rather than through lithotripsy), it creates a unique functionality of using pressure to dilate lesions and stents that would otherwise be resistant to dilatation.

While the OPN device has not been tested in randomized trials, its demonstrated utility in cases of prior device failure , i.e. where conventional balloons have failed to dilate a lesion, effectively demonstrates its use case in selected cirsumstances. As a result, we believe that the OPN NC balloon is substantially different from the predicate NC Euphora Rapid Exchange Balloon Dilatation Catheter.

AGENT Paclitaxel-Coated Balloon Catheter
CMS has requested comment on whether AGENT should be included in C-code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) with peripheral drug coated balloons that are reported

with femoral or popliteal artery revascularization procedures. While C2623 has been expanded and can be used with procedures on other arteries, we believe that interventions in the coronary arteries are more complex based on the anatomy and the proximity to a beating heart. AGENT was designed specifically for these complexities and existing peripheral drug coated balloons are not suitable for use. Therefore, we believe that AGENT is different enough in size and function to warrant its own C-code. SCAI also supports assigning CPT® code 0913T to APC 5193.

Paradise® Ultrasound Renal Denervation (RDN) System
CMS has requested comment on whether the Paradise Ultrasound Renal Denervation System meets all criterion for pass through payment. SCAI believes that all criteria are met by this technology and encourages CMS to grant pass through payment status to the single use portion of this technology.

Symplicity Spyral™ Renal Denervation System
CMS has requested comment on whether the Symplicity Spyral™ Renal Denervation System meets all criterion for pass through payment. SCAI believes that all criteria are met by this technology and encourages CMS to grant pass through payment status to this technology.

Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System Device Category Code Establishment
CMS has requested comment on whether both the Paradise® Ultrasound RDN System and the Symplicity Spyral™ RDN System should be placed in the same category or be broken out by technology. SCAI strongly believes from a physician work perspective that the two systems are similar in time and technique. Both devices have the same intended use, for the same patient population, with nearly identical FDA approved indications, and are deployed similarly, on the same anatomy. **As such, SCAI believes that the two technologies can appropriately be described by the same category.**

ASC Covered Service List
In the addenda of the proposed rule, SCAI noted that CPT code 93355, echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) was added to the covered services list for ancillary services. SCAI firmly believes that imaging services should be included on the covered services list and separately reimbursed to ensure proper usage as necessary with appropriate primary procedures. However, SCAI believes that the use of 93355 in the ASC setting would be miscoding, as none of the primary procedures that are performed with 93355 are on the covered services list. In fact, most of the structural heart services billed with 93355 are on the inpatient only list, and not even billed in the outpatient hospital setting, Without the addition of the primary procedures that use 93355, SCAI believes that the timing is wrong to add 93355 to the covered services list. SCAI would certainly entertain having 93355 on the covered services list in the future, when its primary procedure codes are also under consideration.

Further, there is no discussion of this addition in the proposed rule text, it is only listed in the addenda. This lack of transparency has made it difficult for SCAI to ascertain the reasoning behind the addition to make an informed comment. In future rulemaking, SCAI would request that CMS provide more transparency into the covered services list nomination process for purposes of clinical review.

Request for Information on Cardiac CT Services
CMS removed an inaccurate coding edit that restricted Cardiac CT services from being billed as cardiology services and as noted by CMS modeling, possibly adversely affecting payment by not covering service costs. SCAI applauds CMS for researching this coding issue and its willingness to correct the edit. To determine payment appropriateness, CMS has requested information on how hospitals report cardiac CT services so that proper reimbursement rates can be determined. While CMS' questions are important, it is too soon to determine how hospitals are billing for cardiac CT services. We request that enough time be allowed to pass for hospital billing systems to reflect the collection of these new revenue codes. Cardiac CT, regardless of the department where the services are performed, requires increased clinical staff, equipment, supplies, and medication as compared to any other CT service. These higher costs need time to be reflected in the data.

SCAI urges CMS to reassign the cardiac CT codes (75572- 5574) to APC 5572 for CY 2025 while monitoring revenue code reporting to allow adequate time for changes in regulation to be fully adopted. Providing this update now, based on the findings of CMS modeling will have an immediate impact on patients' access to this important diagnostic service.

Coronary IVL Complexity Adjustment
As the Transitional Pass-Through (TPT) Payment Status for coronary intravascular lithotripsy (IVL) expired on June 30, 2024, SCAI was surprised that there was no calculation for a complexity adjustment for the technology in 2025. One issue that may have lead to this oversight is the fact that the technology transitioned from a Category III to a Category I CPT code in 2024. SCAI assumes that this code confusion and mid-year pass through end date lead to a technical error, and asks CMS to provide the calculations for 2025 in the final rule.

Conclusion
SCAI appreciates the opportunity to provide comments on this Proposed Rule for CY 2025 and we look forward to continuing 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,

James Hermiller, MD, MSCAI
President