September 6, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
PO Box 8013
Baltimore, MD 21244-8013

**Submitted electronically via
and by email to Andy.Slavitt@cms.hhs.gov**

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model [CMS-1654-P]

Dear Mr. Slavitt:

The Society for Cardiovascular Angiography and Interventions (SCAI) is a non-profit professional association with over 4,500 members representing the majority of practicing interventional cardiologists and cardiac cath teams in the United States including the majority of structural heart disease specialists. SCAI promotes excellence in interventional cardiovascular medicine through education, representation and the advancement of quality standards to enhance patient care.

SCAI, having reviewed the “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model [CMS-1654-P]”, offers the following comments:
CY 2017 Identification and Review of Potentially Misvalued Services- 0-day Global Services that are Typically Billed with an Evaluation and Management (E/M) Service with Modifier 25/ TABLE 7: 0-day Global Services that are Typically Billed with an Evaluation and Management (E/M) Service with Modifier 25

In the proposed rule, CMS has recommended review of 0-day Global Services that are typically being billed with an Evaluation and Management (E/M) service with modifier -25. CMS presents a listing of codes in “TABLE 7” that supposedly are being commonly reported with same day E/M codes. Code 92941 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel) is erroneously included in this listing of codes. Per claims data provided by the American Medical Association, code 92941 does NOT meet the criteria for inclusion in Table 7. Claims data finds that code 92941 was only reported with same day E/M, 5% of the time. It has also been surveyed within the past 5 years. Even the code previously used to report these services, deleted code 92980 was not typically reported with an E/M.

SCAI respectfully requests the removal of code 92941 from the Table 7 listing of potentially misvalued codes for which same day E/M with modifier -25 is typically occurring, as claim data clearly supports code 92941 is rarely reported with a same day E&M code. Additionally, this code has been surveyed in the past 5 years. Code 92941 does not meet CMS’s inclusion criteria for Table 7.

Valuing Services that Include Moderate Sedation as an Inherent Part of Furnishing the Procedure

The 2017 proposed rules speaks to the CY 2016 PFS rulemaking cycle in which CMS sought input regarding “establishing a uniform approach to the appropriate valuation of all Appendix G services for which moderate sedation is no longer inherent”.

We are aware that CMS initially identified codes contained in Appendix G of the CPT Manual for which there is claim data supporting a change in clinical practice with moderate sedation no longer being inherent. However, there remained a significant number of codes in Appendix G for which there is claims data clearly indicating that moderate sedation is inherent. SCAI has consistently and vehemently opposed a “one size fits all” approach to addressing the Appendix G codes. We do not believe providers of services for which there is existing claims data supporting the inherent nature of moderate sedation should be unduly burdened with the added administrative costs resulting from the separate, additional reporting of this inherent aspect of physician work.
SCAI strongly opposed this action by the CPT Editorial Panel. In response to our opposition, the AMA CPT Editorial Panel indicated that their recommendation to address all the codes in Appendix G with a “one size fix all” approach, even those codes for which claims data clearly supports that moderate sedation is still inherent, was based on a request from CMS. On March 25, 2015, SCAI submitted a written request to CMS asking that CMS reiterate to the AMA CPT Editorial Panel that the request in the 2016 PFS final rule was to address Appendix G services for which moderate sedation is no longer inherent. CMS never provided any response to this written request.

For those codes for which claims data clearly supports moderate sedation as being inherent, we see no benefit to unbundling the value of this inherent work; resulting in the separate, additional billing of moderate sedation. This proposed unbundling of inherent moderate sedation leaves providers uncertain as to what correct coding will even be for these services, which are commonly in excess of 60 minutes. As the RUC was unable to tease out the clearly, inherent physician work associated with providing moderate sedation beyond the initiation of moderate sedation and the first 15 minutes of the procedure, there is no physician work value for the new “each additional, 15 minute” moderate sedation add-on code. Will facility-based provider still be expected to report the add-on code with no associated physician work value? Or, will they just be burdened with reporting the “initiation and first 15 minute” moderate sedation code?

Either way, there will be at minimum a doubling of the data entry burden to bill for same session, same day services that were previously reported using just one code. MACs will now be unnecessarily paid to process two/three transactions (line-items per claim), for which there was previously one transaction associated with one line-item.

SCAI members are reporting that they do NOT currently transmit the data elements that will now be required to accurately separately, additionally bill moderate sedation to their billing offices. SCAI members do NOT have billing systems that support the automated calculation of time-based procedures, relegating the calculation that may be required to accurately report moderate sedation separately to a manual task, fraught with potential human error. There is no assurance that the new proposed moderate sedation codes will be recognized by non-Medicare insurance carriers. The result for providers will be significant increases in administrative and billing costs, and the likely loss of reimbursement for the inherent moderate sedation services that are performed and at present are fairly compensated under the current system.

Another reason not to unbundle the moderate sedation payments, particularly from code 92941 (used to report acute MI PCI procedures) is that CMS is actually proposing to bundle payments for AMI services as a part of its’ proposed rule titled: “Medicare Program; Advancing Care Coordination through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR) (RIN 0938-AS90).” That proposal is scheduled to start July 1, 2017 and we suspect that having one part of CMS unbundling an aspect of AMI payments while another part of CMS bundles AMI payments may complicate CMS’s analysis of the effectiveness of either change. We
recommend that CMS not unbundle moderate sedation payments from physician payments to avoid confusion and inaccurate data.

SCAI opposes the unbundling of the value, and separate, additional reporting of moderate sedation for those codes for which CMS has claims data clearly supporting that this work is inherent. SCAI opposes the unnecessary administrative burden being placed on providers and the additional claims processing transaction costs MACs will charge associated with the separate and additional billing of inherent moderate sedation.

Collecting Data on Resources Used in Furnishing Global Services

SCAI supports CMS’s collection of data regarding the resources used in furnishing global services to ensure the fair and accurate valuation for codes with 10- and 90-day global periods. Valuation accuracy within the Resource-Based Relative Value Scale (RBRVS) is critical for maintaining fair and accurate compensation for medical services. Even as CMS moves forward with alternative payment models, the RBRVS will remain the scaffolding on which many of these alternative payment models are built.

However, CMS is proposing an overly complex and administratively burdensome process to gather this data. CMS is proposing the creation and use of a series of data-only, G-codes, largely based on time (with every 10 minute increment of time being reported) to report post-procedure follow-up care. SCAI strongly cautions CMS against relying so heavily on time as a determinate of resource use. Reliance on time as a primary determinate, is a direct disincentive to efficiency. Rather than rewarding the practitioner that is quick and efficient in their engagements with patients, CMS is creating a system that will potentially reward the inefficient, dawdler.

SCAI believes the wide array of existing E/M codes are adequate to capture data regarding the follow-up care provided within 10- and 90-day global periods. While NCCI edits exist to prevent the inadvertent payment of E/M codes reported within a global period, if CMS has concern that claims could inadvertently be paid, CMS could easily direct the creation of a unique modifier to communicate to the MACs that the E/M claim being submitted is for data collection purposes only. Use of such a unique modifier, could clearly identify these claims as being for data collection purposes only, as well as support the appropriate messaging to patients via the patients’ Explanation of Benefits that the claim was submitted by the practitioner for data collection purposes only.

SCAI urges CMS to use the existing E/M CPT codes available to gather data regarding follow-up care provided within 10- and 90-day global periods. If CMS has concerns in regards to communications to patients about these claims, a unique, data collection-only modifier could be created to clearly identify these claims as being for data collection purposes only.
CY 2017 Proposed Codes

Closure of Left Atrial Appendage with Endocardial Implant (CPT code 333X3)

CMS is proposing a reduction to the RUC recommended work value for the new code created to report left atrial appendage occlusion with endocardial implant (LAAO) procedures.

333X3 Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

RUC Recommended work RVU 14.00; CMS proposed work RVU 13.00

CMS is incorrectly asserting that the RUC recommended value was based on the 25th percentile RUC survey result. The 25th percentile RUC survey result was actually 19.88 work RVUs. Based on this incorrect information, CMS is now proposing that the value should be based on the minimum survey result, claiming based on their “clinical judgment and that the key reference codes discussed in the RUC recommendations have higher intraservice and total service times than the median survey results for new LAAO, CPT code 333X3, [CMS] believe[s] a work RVU of 13.00 more accurately represents the work value for this service”.

While the RUC certainly took into consideration the comparison of the new LAAO code to the key reference codes from the RUC survey, it was found that the key reference codes were describing services more commonly performed on a pediatric population. The new LAAO procedures will be performed on an elderly patient population that is sicker and has more co-morbidities than that of the RUC survey reference service codes CMS considered. Additionally, these key reference codes were valued back in 2002 and there has been significant, continual improvement and refinement to the RUC process since that time including the adoption of pre- and post-service packages.

Rather, than merely relying on a cursory comparison of the new LAAO code to the survey reference services codes, the RUC elected to subject the new code to the more intensive RUC facilitation process that involves a significantly deeper review of the new code’s value. The RUC Facilitation Committee compared the new LAAO code, 333X3 to codes that have more recently gone through the valuation process including CPT code 93583 [Percutaneous transcatheter septal reduction therapy (e.g., alcohol septal ablation) including temporary pacemaker insertion when performed], which has a work RVU of 14.00 and intra-service time of 90 minutes. The RUC Facilitation Committee found that this value, with identical intra-service time, accurately accounted for the physician work involved in the new LAAO code, 333X3. For additional support, the Facilitation Committee also reviewed another code believed to be more clinically similar that has also more recently gone through the valuation process, code 37244 [Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation,
intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation], which also has a work RVU of 14.00 and intra-service time of 90 minutes. Based on this in depth, thorough review and analysis, the RUC has recommended a work RVU of 14.00 for CPT code 333X3.

SCAI strongly opposes CMS’s proposed reduction in physician work values for the new Left Atrial Appendage Occlusion code, 333X3. SCAI finds that CMS did not conduct as in depth of an analysis and consideration of the proposed value for this new code, as that performed by the RUC. The RUC recommended work value of 14.00 RVUs for the new LAAO code was based on a thoughtful, deeper analysis with comparison to more recently valued codes which are performed on a fairly comparable patient population, unlike CMS’s analysis. SCAI urges CMS to reconsider and accept the expert, multispecialty and fairly-balanced guidance provided to them by the RUC in regards to valuing this new code.

Closure of Paravalvular Leak (CPT codes 935X1, 935X2, and 935X3)

CMS is proposing a reduction to the RUC recommended values for the three new codes created to report aortic and mitral Paravalvular Leak Closure (PVL) procedures.

935X1 - Percutaneous transcatheater closure of paravalvular leak; initial occlusion device, mitral valve

RUC Recommended Value 21.70; CMS proposed value 18.23

935X2 - Percutaneous transcatheater closure of paravalvular leak; initial occlusion device, aortic valve

RUC Recommended Value 17.97; CMS proposed value 14.50

935X3 - Percutaneous transcatheater closure of paravalvular leak; each additional occlusion device (list separately in addition to code for primary service)

RUC recommended value 8.0; CMS proposed value 6.81

CMS is proposing to reduce the RUC recommended value for the aortic PVL code (935X2) from 17.97 work RVUs to 14.50 work RVUs, based on the false assumption that aortic PVL is fairly comparable in time and intensity to CPT code 37227 [Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed].

SCAI vehemently opposes CMS’s assertion that a cardiovascular intervention performed in an immobile leg is comparable in intensity and patient risk to an intervention performed in a beating, moving heart. Further speaking to the difference in intensity and risk, Lower Extremity
Revascularization (LER) procedures (such as that represented by 37227) are safely performed in the non-hospital, non-facility, office setting. As a matter of fact, more than half of the procedures reported using code 37227 are performed in the office setting. Whereas, structural heart disease (SHD) procedures, such as PVL cannot be performed in the office setting. Due to the intensity and risks associated with these procedures, they MUST be performed in a facility setting and most typically are performed in special hybrid suites, in collaboration with imaging (e.g. TEE) and cardiac anesthesia expertise, needed to accommodate the special imaging needs above and beyond traditional angiography.

SHD procedures are more intense than cardiovascular LER procedures. Unlike LER procedures, which are most commonly performed under moderate sedation, SHD procedures, like PVL, are most typically performed under general anesthesia, involving greater intensity and supporting the need for greater coordination amongst the Heart Care Team (interventional cardiologist, cardiac anesthesiologist, imaging specialist, heart failure specialist). Frequently, the approach to paramitral defects includes a complex antegrade transseptal procedural expertise.

In addition to the unique cardiac anesthesia needs and coordination, SHD procedures also have unique imaging needs as compared to LER, requiring intraoperative transesophageal echocardiography (TEE) or real-time 3-dimensional TEE guidance be provided, in addition to standard angiography techniques, with TEE being performed by yet another physician member of the Heart Care Team, leading to even more coordination amongst providers with greater intensity and patient risk. Some procedures (e.g. for paramitral defects) require collaboration of a cardiothoracic surgeon, with alternative approaches including retrograde transaortic cannulation or transapical access and retrograde cannulation.

The basis for CMS’s proposed reduction in work value for the mitral PVL code 935X2, from the RUC recommended work RVU of 21.70 to the CMS proposed value of only 18.23 RVUs, is based on the same flawed rationale CMS presented for reduction of value for the aortic PVL code, 935X1. As the CMS proposed reduction in value for the 935X1 code is believed to be inappropriate, as explained above, so is the proposed reduction in value for code 935X2.

CMS also is proposing a reduction to the work value for the new PVL add-on code (935X3) that will be used to report the placement of additional PVL occlusion devices. CMS is again rejecting the RUC recommended value of 8.00 work RVUs, proposing a reduced work value of 6.81 RVUs. CMS is again proposing to use the value of a procedure, performed on an immobilized leg, 35572 [Harvest of femoropopliteal vein, 1 segment, for vascular reconstruction procedure (eg, aortic, vena caval, coronary, peripheral artery) (List separately in addition to code for primary procedure)] as the proxy for the intensity of an intervention performed in a continually moving, beating heart. This comparison is just clearly inappropriate and does not recognize the intensity and skill level needed to place a PVL device in a moving, beating heart, frequently in the setting of heart failure. In contrast, harvesting a vein from the leg, alone, may be performed by a non-physician (ie, PAs) assistant-at-surgery provider; does not require intensive general
anesthesia nor does it require coordination with the Heart Care Team to provide intraoperative transesophageal echocardiography (TEE) guidance and optimal multidisciplinary care.

SCAI strongly opposes the proposed reduction in physician work values for the new PVL Codes (codes 935X1, 935X2, and 935X3). SCAI finds CMS’s proposed use of cardiovascular codes for procedures performed in or on a leg as proxies for the intensity of SHD, PVL procedures performed on a heart requiring a Heart Care Team approach, typically involving general anesthesia and intraoperative transesophageal echocardiography (TEE) guidance, and with greater risk to the patient to be INAPPROPRIATE. SCAI urges CMS to accept the expert, multispecialty and balanced guidance provided to them by the RUC in regards to valuing these new codes.

Determination of Malpractice Relative Value Units (MRVUs) “CMS-1654-p_MP RVUs Invasive Cardiology Outside of Surgical Range”

SCAI appreciates the inclusion of the spreadsheet, “CMS-1654-p_MP RVUs Invasive Cardiology Outside of Surgical Range” in the supporting document files posted on the CMS Web site for the 2017 PFS proposed rule. This spreadsheet details the invasive cardiology codes that appear in the 90000 series of CPT, outside of the traditional surgical range, for which a surgical malpractice factor is applicable. The new codes created to report Closure of a Paravalvular Leak (CPT codes 935X1, 935X2, and 935X3) should be added to the list of invasive cardiology codes for which the application of the surgical factor is appropriate in calculating PLI RVUs.

Additionally, upon review of the spreadsheet, “CMS-1654-p_MP RVUs Invasive Cardiology Outside of Surgical Range”, code 93355 (Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcathether pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intraprocedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D) is not included in the listing of 90000 series invasive cardiology procedures subject to the surgical malpractice factor in the calculation of PLI RVUs. While 93355 is a TEE imaging code, this code is used to report inprocedural guidance for invasive cardiac SHD interventions including procedures that may even involve an open surgical approach, such as Transcatheter Aortic Valve Replacement performed from a transapical approach. TEE imaging during structural heart procedures directly guides further procedural aspects such as insertion of a second valve or dealing with emergencies with the risk of decision-making and potential for misdiagnosis much higher than with standard TEE diagnostic studies.
SCAI requests the addition of the new Paravalvular Leak (PVL) Closure codes (935X1, 935X2 and 935X3) and, existing TEE intraoperative guidance code (93355) to the listing of invasive cardiology codes for which the surgical malpractice factor is applied, as detailed in the “CMS-1654-p_MP RVUs Invasive Cardiology Outside of Surgical Range” spreadsheet.

In conclusion, SCAI appreciates the opportunity to provide comment to CMS on issues of high interest to the interventional cardiology community contained in the “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model [CMS-1654-P]”. If SCAI can be of any assistance as CMS continues to consider and review these issues, please do not hesitate to contact Mrs. Dawn R. Gray (Hopkins), Director of Reimbursement & Regulatory Affairs at (800) 253-4636, ext. 510 or dgray@scai.org.

Sincerely,

Kenneth Rosenfield, MD, MHCDS, MSCAI
SCAI President-Elect, 2015-2016

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