SCAI
Society for Cardiovascular Angiography & Interventions

September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted via www.regulations.gov

Re: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements

Dear Administrator Brooks-LaSure,

The Society for Cardiovascular Angiography & Interventions (SCAI) is pleased to offer comments in response to the Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements. SCAI is a non-profit professional association with over 4,500 members representing interventional cardiologists and cardiac catheterization teams in the United States including 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; CY 2022 Payment Policies under the Physician Fee Schedule, offers the following comments:

CY 2022 Conversion Factor

SCAI urges CMS to maintain the 3.75% increase to the conversion factor through at least CY 2023. This payment reduction comes along at a time when other cuts will factor in for CY 2022, such as, the expiration of the moratorium on Medicare sequestration comes at the end of CY 2021, along with sequestration cuts required by pay-as-you-go legislation. These cuts come at a time when physician practices, hospitals that employ physicians and other stakeholders are facing uncertainty about the future of their pandemic recovery. At this time physicians' practices are also significantly challenged by other regulatory burdens (e.g., prior authorization, interoperability requirements and participating in Medicare quality programs such as MIPS). We urge CMS to continue to waive the budget neutrality adjustment considering the uncertainty of COVID-19 public health emergency (PHE).

CY 2022 Proposed Codes - Valuation of Specific Codes

Percutaneous Cerebral Embolic Protection: SCAI agrees with the rational provided by CMS for accepting the RUC-recommended work RVU's for the new Percutaneous Cerebral Embolic Protection add-on code. The RUC is a rigorous process, and our Society supports the AMA in this matter.

Endovascular Repair of Aortic Coarctation (CPT codes 338X1, 338X2, and 338X0): SCAI strongly recommends that CMS review their proposed low values and accept the RUC recommended values for the following new codes:

	Long Descriptor	CMS Proposed work RVU	Code
338X1	Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; across major side branches	18.27	21.70
338X2	Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; not crossing major side branches	14.54	17.97
338X0	Percutaneous transluminal angioplasty of native or recurrent coarctation of the aorta	10.81	14.00

In October 2020, the CPT Editorial Panel created two codes to report endovascular stent repair of coarctation of the thoracic or abdominal aorta and one code for percutaneous transluminal angioplasty. The RUC reviewed this new family of services at the January 2021 RUC meeting.

338X1

For CPT Code 338X1, CMS disagrees with the RUC recommended work RVU of 21.70 and proposes a work RVU of 18.27, which was the survey 25th percentile work value. The Agency stated that they found that the recommended work RVUs for these CPT codes were high when compared to other codes with similar time values. However, there are no 000-day global services with similar times. CMS does not provide any clinical foundation for their proposed alternate value and makes no acknowledgement that this service is for pediatric patients with congenital defects and the extra work that goes into working with these special patients.

The two reference codes that CMS lists are 37231 *Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed* and 93590 *Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve* (which was the code that the RUC had recommended to use as a direct work RVU crosswalk) have much less total time than the survey codes.

Relative to adult patients with normal cardiac anatomy, the pre-service evaluation time for pediatric patients with congenital defects includes additional time to discuss a patient's procedure with the parent. Similarly, the post-procedure work includes additional time to explain the pathology of the child to the parent. Furthermore, as a national standard, congenital heart programs are now also required to enter hemodynamic data and other procedural details into national registries such as Improving Pediatric and Adult Congenital Treatments (IMPACT), which can also add significant post procedure work time. In addition, the post-service period time typically includes time to diagram the congenital heart defect in the EHR and complete data submission to the registry. By solely comparing this service to adult patient population services with much lower total times, CMS' proposal does not provide adequate consideration for this additional work or that a pediatric population with congenital defects is a more intense and complex patient population.

SCAI strongly recommends that CMS accepts the RUC RVU of 21.70 for CPT code 338X1.

338X2

For CPT Code 338X2, CMS disagrees with the RUC recommended work RVU of 17.97 and proposes a work RVU of 14.54, derived by subtracting the increment between the RUC recommendations for 338X1 and 338X2 (3.73) from the CMS proposed value for 338X1. As CMS' rationale for rejecting the RUC recommendation for 338X1 is highly flawed as described above, it should not be used as the basis to derive a new value for 338X2. CMS indicated that the reason for their rejection of the RUC recommended value was based on a review of services with similar intra-service and total times, though did not list any specific reference codes.

CMS does not provide any clinical foundation for their proposed alternate value and again makes no acknowledgement that this service is for pediatric patients with congenital defects. As CMS provides no discussion at all regarding the clinical attributes of the surveyed procedure or any of the reference codes, CMS' review process in general for this code family and the reference code comparison have the appearance of selecting an arbitrary and capricious value from the vast array of possible mathematical calculations, rather than seeking a valid, clinically relevant relationship that would preserve relativity.
SCAI strongly recommends that CMS accepts the RUC RVU of 17.97 for CPT code 338X2.

338X0
For CPT Code 338X0, CMS disagrees with the RUC recommended work RVU of 14.00 and proposes a work RVU of 10.81, derived by subtracting the "…3.73 incremental difference between the codes in the family." The RUC recommendation of 14.00 does not have that increment with any other service so this does not make rational sense. As CMS' explanation for rejecting the RUC recommendation for 338X0 does not even have that increment with the other services in this family, is basis enough for additional review and we believe that it should not be used as the basis to derive a new value for 338X0. CMS indicated that the reason for their rejection of the RUC recommended value was based on a review of services with similar intra-service and total times, though did not list any specific reference codes.

CMS does not provide any clinical foundation for their proposed alternate value, and we will state again makes no acknowledgement that this service is for pediatric patients with congenital defects. As CMS provides no discussion at all regarding the clinical attributes of the surveyed procedure or any of the reference codes they reviewed, the review process in general and the identification of reference codes have the appearance of seeking an arbitrary and capricious value from the vast array of possible mathematical calculations, rather than seeking a valid, clinically relevant relationship that would preserve relativity.

Cardiac Catheterization for Congenital Defects (CPT codes 93X1X, 93X2X, 93X3X, 93X4X, 93X5X, and 93X6X)

Cardiac Catheterization for Congenital Defects (CPT codes 93X1X, 93X2X, 93X3X, 93X4X, 93X5X, and 93X6X)

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
93X1X	*Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections*	3.99	3.99
93X2X	*Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections*	6.10	6.10
93X3X	***Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections***	**5.50**	**6.00**
93X4X	***Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections***	**6.84**	**7.91**
93X5X	***Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections***	**8.88**	**9.99**
93X6X	***Cardiac output measurement(s), thermodilution or other indicator dilution method, performed during cardiac catheterization for the evaluation of congenital heart defects (List separately in addition to code for primary procedure)***	**1.44**	**1.75**

In May 2020, the CPT Editorial Panel replaced a family of four congenital cardiac catheterization codes with five new codes to describe cardiac catheterization for congenital cardiac defect(s). In addition, the Panel replaced two cardiac output measurement codes with one new add-on code to report cardiac output measurement(s), performed during cardiac catheterization for congenital cardiac defects.

CMS did not address the compelling evidence for this service. CMS appears to dismiss the fact that services and circumstances may change due to technological advances, changes in the patient population, shifts in the specialty of physicians providing services or changes in the physician work or intensity required to perform services. CMS appears to only propose blanket reductions instead of considering how a service and circumstances overtime may have changed or increased. **SCAI requests that CMS acknowledge and address the compelling evidence that**

was submitted with the RUC recommendations when the agency does not accept the RUC recommendation. Here is the compelling evidence argument for CMS' consideration:

> *The RUC reviewed and agreed that there is compelling evidence based on a change in the patient population and a change in technology. The specialty societies noted, and the RUC agreed that most diagnostic catheter studies were performed in children who were healthier with simpler cardiac defects when the previous code structure was last valued in 1997; children with more significant cardiac defects had no treatment options, so catheterization was not warranted. Over the past 23 years, as result of improvements in both technique and technology, the specialty has evolved and now performs a substantially larger number of more complex diagnostic evaluations to guide more complex interventional procedures, and the typical patient is now a more complex patient requiring more pathology. The specialties noted that one of the whitepapers that they provided by Nicholson et al. confirms that these procedures were unable to be previously accomplished on the current typical patient with earlier technology/techniques. The specialties provided additional literature to further demonstrate the changes in congenital catheterization over the past two decades.*
>
> *The specialties noted that, relative to adult patients with normal cardiac anatomy, the pre-service evaluation time for pediatric patients with congenital defects includes additional time to discuss a patient's procedure with the parent. Similarly, the post-procedure work includes additional time to explain the pathology of the child to the parent. Furthermore, as a national standard, congenital heart programs are now also required to enter hemodynamic data and other procedural details into national registries such as Improving Pediatric and Adult Congenital Treatments (IMPACT), which can also add significant post procedure work time. In addition, the post-service period time typically includes time to diagram the congenital heart defect in the EHR and complete data submission to the registry.*

93X3X

For CPT code 93X3X, CMS disagrees with the unanimously approved RUC recommended work RVU of 6.00 and proposes a work RVU of 5.50, based on a direct work RVU crosswalk to CPT code 32607 *Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral* (work RVU= 5.50, intra-service time= 45 minutes, total time of 178 minutes). Beyond performing a basic search for other services with similar intra-service time, it is unclear what criteria CMS used to reject the RUC recommendation or to select this specific reference code as a direct work value crosswalk. CMS does not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale and makes no acknowledgement that this service is typically for pediatric patients with congenital defects. Without a clear and compelling rationale, the decision-making process used in this instance appears unnecessarily arbitrary and capricious.

93X3X is typically somewhat more intense to perform than 93X2X, justifying a somewhat higher assigned physician work intensity. CMS proposed value would produce a rank order anomaly

between 93X3X and 93X2X as the difference in intensities between these two services would not be appropriately reflected. For a normal connection patient, it will be straightforward. Risk of arterial catheterization is always high due to risks of stroke, bleeding into the brain for infants on heparin, femoral artery injury for infants. For an abnormal connection patient, things get more complicated because doctors are now also talking about crossing arterial shunts or the PDA to evaluate the pulmonary arteries, or evaluating other vascular structures like MAPCAs, which can be multiple. Although the overall structures evaluated are still fewer than from a right heart catheterization (93X2X), when assessing the pulmonary arteries across shunts or a PDA, this is not typically well tolerated. These shunts are 3 or 3.5mm in diameter with a catheter being ~1.5mm, the procedure involves blocking roughly 50 percent or more of the entire blood flow to the lungs. Due to this added complexity, the physician work intensity is very high.

The RUC recommendation was based on the median work RVU from robust survey results and favorable comparison to CPT code 93453 *Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed* (work RVU=5.99, intra-service time of 45 minutes, total time of 113 minutes) and CPT code 37248 *Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein* (work RVU= 6.00, intra-service time of 50 minutes, total time of 109 minutes). **SCAI urges CMS to accept a work RVU of 6.00 for CPT code 93X3X.**

93X4X

For CPT code 93X4X, CMS disagrees with the unanimously approved RUC recommended work RVU of 7.91 and proposes a work RVU of 6.84, based on a direct work RVU crosswalk to CPT code 32608 *Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral* (work RVU= 6.84, intra-service time= 60, total time= 195). CMS does not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale and makes no acknowledgement that this service is typically for pediatric patients with congenital defects. Furthermore, CMS' proposed value would assign 93X4X an intensity that is substantially lower than the top two key reference codes, even though 3/4ths of the survey respondents that selected those top reference codes indicated that the survey code was a more intense service than either reference code.

The RUC recommendation was based on the median work RVU from robust survey results and favorable comparison to CPT code 93461 *Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization…* (work RVU=7.85, intra-service time of 60 minutes, total time of 143 minutes) and CPT code 52356

Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (eg, Gibbons or double-J type) (work RVU= 8.00, intra-service time of 60 minutes, total time of 133 minutes). **SCAI urges CMS to accept a work RVU of 7.91 for CPT code 93X4X.**

93X5X

For CPT code 93X5X, CMS disagrees with the unanimously approved RUC recommended work RVU of 9.99 and proposes a work RVU of 8.88, based on the survey median work value. However, following detailed review of the physician work typically involved in this service, CMS felt that the survey respondents had underestimated the typical work involved. CMS' proposed value would assign this service a similar intensity to CPT code 93X4X, even though 93X5X is for a more complex patient with an abnormal native connection. CMS does not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale and makes no acknowledgement that this service is typically for pediatric patients with congenital defects.

The RUC recommendation was based on the current work RVU for the code currently used to report this service (deleted code 93532) and favorable comparison to CPT code 92920 *Percutaneous transluminal coronary angioplasty; single major coronary artery or branch* (work RVU= 9.85, intra-service time of 68 minutes, total time of 127 minutes). **SCAI urges CMS to accept a work RVU of 9.99 for CPT code 93X5X.**

93X6X

For CPT add-on code 93X4X, CMS disagrees with the unanimously approved RUC recommended work RVU of 1.75 and proposes a work RVU of 1.44, based on a direct work RVU crosswalk to CPT code 37253 *Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (List separately in addition to code for primary procedure)* (work RVU= 1.44, intra-service time= 20 minutes, total time= 21 minutes). However, 37253 is a relatively less intense and less risky service typically performed in the lower extremity of an adult patient, making it an inappropriate crosswalk. The survey code is a more intense service typically performed on a more complex pediatric patient, where a Swan Ganz catheter is introduced from the venous sheath, advanced through the right heart, and placed into the pulmonary artery for purpose of assessing cardiac output by thermodilution. CMS does not provide any clinical foundation for their proposed alternate value, did not seem to consider the compelling evidence provided in the RUC rationale and makes no acknowledgement that this service is typically for pediatric patients with congenital defects.

The RUC recommendation was based on a direct work value crosswalk to CPT code 36483 *Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a*

chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (work RVU= 1.75, intra-service time= 20 min) and favorable comparison to CPT code 20931 *Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)* (work RVU= 1.81, intra-service time of 20 minutes). **SCAI urges CMS to accept a work RVU of 1.75 for CPT code 93X6X.**

Clinical Labor Pricing Update

CY 2022 marks the final year of the 4-year market-based transition for supply and equipment pricing. The clinical labor pricing has not been updated since 2002.

By increasing the clinical labor pricing, physician services with high-cost supplies and equipment are disproportionately impacted by the budget neutrality component within the practice expense relative values. The scaling of direct expenses, to 44 cents on every dollar (instead of the current 59 cents), puts a huge and unfair burden on specialties that require expensive supplies and other direct costs to care for their patients. While the increase in clinical labor is appropriate, it is not appropriate that physicians and other qualified health care professionals, and notably some small specialties, are negatively impacted by the change, especially during a declared Public Health Emergency.

By increasing the clinical labor pricing, physician services with high-cost supplies and equipment are disproportionately impacted by the budget neutrality component within the practice expense relative values. In the proposed rule, CMS displayed the isolated anticipated effects of the clinical labor pricing update on specialty payment impacts in one Table. CMS highlights in the text that specialties with a substantially lower or higher than average share of direct costs attributable to labor would experience significant declines or increases, respectively, if this proposal is finalized. It goes on to say that that the Table impacts do not include complete impacts of all the policies that CMS is proposing for CY 2022, only the anticipated effect of the isolated clinical labor pricing update. The impacts published in Tables are misleading. For example, the highest negative impact in one Table is -9% and in another Table is -10%. In reality, the negative impact is much greater. As described above, this proposal disproportionately hits those services that are incurring the most direct practice expense. More specifically, groups of similar services in the non-facility setting are projected to incur **reductions greater than -20%** for many of their services. While SCAI understands the impact tables are for illustrative purposes for aggregate impacts on specialties, and not meant to be code specific, it would be more transparent to share actual impacts when they are so devastating to providers of office-based procedures with high supply and equipment costs.

In addition, CMS has requested comment on whether to implement a four-year transition to the new clinical labor cost data. There is precedent for a phased transition for significant MPFS changes, across several calendar years. CMS utilized a 4-year transition for the market-based supply and equipment pricing update concluding in CY 2022. CMS also utilized a 4-year transition, starting in 2010, for the practice expense proposal. **SCAI requests that CMS update pricing data on a more frequent basis for all inputs, so adjustments will not be so dramatic and sudden. We understand the underlying unfairness that the real increase in clinical labor costs is not recognized through an update to the conversion factor and calls on CMS to urge Congress to provide a positive update to the Medicare conversion factor in 2022 and all future years.**

Telehealth and Other Services Involving Communications Technology, and Interim Final Rule with Comment Period for Coding and Payment of Virtual Check-in Services--Payment for Medicare Telehealth Services Under Section 1834(m) of the Act.

SCAI commends CMS on your proposal to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. We would urge CMS to allow continued access to these telehealth services after the public healthcare emergency.

Appropriate Use Criteria (AUC)

CMS indicates that the earliest claims processing system can begin screening claims using the AUC program claims processing edits for the payment penalty phase is October 2022. This is because it would not be possible to finalize implementation and claims processing plans in this final rule (typically published on or before November 1) and make those decisions effective any earlier than the 3rd calendar quarter of 2022. Therefore, CMS believes the earliest practicable effective date for the AUC program claims processing edits and payment penalty phase is January 1, 2023. Therefore, CMS proposes to begin the AUC claims processing systems edits and payment penalty phase of the program on the later of January 1, 2023, or the January 1 of the year after the year in which the PHE for COVID-19 ends. **SCAI agrees with CMS regarding this decision as proposed.**

Conclusion

SCAI appreciates the opportunity to provide comments on this Proposed Rule for fiscal year 2022 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 Curtis Rooney @ 202-216-2987 or at crooney@scai.org if there are any questions or further requests.

Sincerely,

Timothy D. Henry, MD, MSCAI
President
The Society for Cardiovascular Angiography and Interventions