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Society of Interventional Radiology
The vision to heal

September 1, 2022

The Honorable Chiquita Brooks-LaSureAdministrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05 7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted via: www.regulations.gov

Re: File Code CMS-1770-P; Medicare Program; CY 2023 Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (July 8, 2022)

Dear Administrator Brooks-LaSure:

The Society of Interventional Radiology (SIR) is a professional medical association representing approximately 8,000 members, including most US physicians practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advancesin minimally invasive, image-guided therapies. Therefore, SIR appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) CY 2023 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies proposed rule.

Payment Rates

Practice Expense RVUs - Payment Rates

Proposed: In the CY 2023 proposal, CMS could not override the 3 percent decrease which must be applied to the CY 2022 CF when determining the value for CY 2023 due to the Protecting Medicare and American Farmers from Sequester Cuts Act. Removing this and utilizing a CF of $33.5983, CMS applied a budget neutrality factor of minus 1.55 percent. This results in a proposed CY 2023 CF $33.0775. (Table 136: CY 2023 MPFS).

TABLE 136: Calculation of the CY 2023 PFS Conversion Factor

CY 2022 Conversion Factor		34.6062
Conversion Factor without CY 2022 Protecting Medicare and American Farmers from Sequester Cuts Act		33.5983
Statutory Update Factor	0.00 percent (1.0000)	
CY 2023 RVU Budget Neutrality Adjustment	-1.55 percent (0.9845)	
CY 2023 Conversion Factor		**33.0775**

Impact: The proposed combined impact to relative value units (RVUs) (Table 138: CY 2023 MPFS proposed rule) which for the specialties of interventional radiology and radiology along with the added reduction in CF for CY 2023, will again significantly reduce reimbursement. The proposed estimated reductions would result in minus 8.5 percent for interventional radiology and minus 7 percent for radiology. This is prior to any adjustment for the 2 percent sequestration and 4 percent PAYGO, which are outside the authority of CMS to adjust, but brings the impact to a minus 14.5 percent for interventional radiology and minus 13 percent for radiology.

TABLE 138: CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Interventional Radiology	$465	-1%	-3%	0%	-4%
Radiology	$4,712	-1%	-1%	-2%	-3%

* Column F may not equal the sum of columns C, D, and E due to rounding.

Reviewing the estimate by setting, as provided in Table 139: CY 2023 MPFS proposed rule, the decreases in payment will again predominantly impact non-facility settings. The largest reasons for deceases are related to year 2 of the 4-year phase-in of clinical labor rate changes and updates to malpractice (MP) RVUs. At the code level this results in cuts as high at 16.5 percent, before the external cuts are applied, in the non-facility setting and cuts as high as 13 percent, not including evaluation and management (E/M) visits. When analyzing specific procedural codes for CY 2023, IR will see decreases as high as 8.5 percent in reimbursement for procedures treating peripheral arterial disease (PAD), with other similar reductions for end-stage renal disease, and cancer. (SIR's Table A – PAD-Related Impact Analysis).

TABLE 139: CY 2023 PFS Estimated Impact on Total Allowed Charges by Setting

(A) Specialty	(B) Total Non-Facility/Facility	(C) Allowed Charges (mil)	(D) Combined Impact
Interventional Radiology	*TOTAL*	$465	-4%
	Non-facility	$365	-4%
	Facility	$100	0%
Radiology	*TOTAL*	$4,712	-3%
	Non-facility	$4,486	-3%
	Facility	$226	-1%

SIR's TABLE A: SIR's Impact Analysis on PAD-related IR Services

CY 2022 Final - CY 2023 Proposed MPFS Estimated Impact Comparative Analysis of Services Related to Interventional Radiology								National WORK 1.000				National PE 1.000		National MP 1.000		2022 CF 34.6062		2023 Proposed CF 33.0775			
Service Description			2022 Final RVUs				2022 Final RVU Totals		2023 Proposed RVUs				2023 Proposed RVU Totals		2022 Final Medicare Allowable Reimbursement		2023 Proposed Medicare Allowable Reimbursement		Payment Variances		% Variances	
															Non-Facility	Facility	Non-Facility	Facility				
HCPCS	MOD	DESCRIPTION	WORK RVU	NON-FAC PE RVU	FACILITY PE RVU	MP	NON-FACILITY TOTAL	FACILITY TOTAL	WORK RVU	NON-FAC PE RVU	FACILITY PE RVU	MP	NON-FACILITY TOTAL	FACILITY TOTAL	2022 National	2022 National	2023 National	2023 National	Non-Facility	Facility	Non-Facility	Facility
37220		Iliac revasc	7.90	68.59	2.02	1.78	78.27	11.70	7.90	65.84	2.02	1.83	75.57	11.75	$ 2,708.63	$ 404.89	$ 2,499.67	$ 388.66	$ (208.96)	$ (16.23)	-7.71%	-4.01%
37221		Iliac revasc w/	9.75	84.63	2.47	2.20	96.58	14.42	9.75	80.92	2.44	2.31	92.98	14.50	$ 3,342.27	$ 499.02	$ 3,075.55	$ 479.62	$ (266.72)	$ (19.40)	-7.98%	-3.89%
37222		Iliac revasc ad	3.73	14.34	0.85	0.85	18.92	5.43	3.73	13.85	0.85	0.88	18.46	5.46	$ 654.75	$ 187.91	$ 610.61	$ 180.60	$ (44.14)	$ (7.31)	-6.74%	-3.89%
37223		Iliac revasc w/	4.25	34.68	0.98	0.98	39.91	6.21	4.25	33.13	0.96	1.01	38.39	6.22	$ 1,381.13	$ 214.90	$ 1,269.85	$ 205.74	$ (111.29)	$ (9.16)	-8.06%	-4.26%
37224		Fem/popl revas	8.75	80.87	2.27	1.95	91.57	12.97	8.75	77.35	2.25	2.06	88.16	13.06	$ 3,168.89	$ 448.84	$ 2,916.11	$ 431.99	$ (252.78)	$ (16.85)	-7.98%	-3.75%
37225		Fem/popl revas	11.75	261.72	3.21	2.56	276.03	17.52	11.75	250.20	3.15	2.66	264.61	17.56	$ 9,552.35	$ 606.30	$ 8,752.64	$ 580.84	$ (799.71)	$ (25.46)	-8.37%	-4.20%
37226		Fem/popl revas	10.24	244.93	2.60	2.33	257.50	15.17	10.24	233.66	2.56	2.44	246.34	15.24	$ 8,911.10	$ 524.98	$ 8,148.31	$ 504.10	$ (762.79)	$ (20.87)	-8.56%	-3.98%
37227		Fem/popl revas	14.25	336.35	3.65	3.09	353.69	20.99	14.25	321.50	3.59	3.24	338.99	21.08	$ 12,239.87	$ 726.38	$ 11,212.94	$ 697.27	$ (1,026.93)	$ (29.11)	-8.39%	-4.01%
37228		Tib/per revasc	10.75	117.11	2.69	2.36	130.22	15.80	10.75	111.99	2.65	2.48	125.22	15.88	$ 4,506.42	$ 546.78	$ 4,141.96	$ 525.27	$ (364.45)	$ (21.51)	-8.09%	-3.93%
37229		Tib/per revasc	13.80	262.74	3.66	2.85	279.39	20.31	13.80	252.18	3.61	2.99	268.97	20.40	$ 9,668.63	$ 702.85	$ 8,896.86	$ 674.78	$ (771.77)	$ (28.07)	-7.98%	-3.99%
37230		Tib/per revasc	13.55	264.62	3.78	3.00	281.17	20.33	13.55	252.62	3.69	3.11	269.28	20.35	$ 9,730.23	$ 703.54	$ 8,907.11	$ 673.13	$ (823.12)	$ (30.42)	-8.46%	-4.32%
37231		Tib/per revasc	14.75	349.39	4.00	2.73	366.87	21.48	14.75	338.24	3.96	2.83	355.82	21.54	$ 12,695.98	$ 743.34	$ 11,769.64	$ 712.49	$ (926.34)	$ (30.85)	-7.30%	-4.15%
37232		Tib/per revasc	4.00	20.61	1.01	0.79	25.40	5.80	4.00	19.82	0.99	0.86	24.68	5.85	$ 879.00	$ 200.72	$ 816.35	$ 193.50	$ (62.64)	$ (7.21)	-7.13%	-3.59%
37233		Tibper revasc w	6.50	24.00	1.62	1.33	31.83	9.45	6.50	23.47	1.63	1.33	31.30	9.46	$ 1,101.52	$ 327.03	$ 1,035.33	$ 312.91	$ (66.19)	$ (14.12)	-6.01%	-4.32%
37234		Revsc opn/prq	5.50	106.58	1.56	1.20	113.28	8.26	5.50	102.88	1.53	1.23	109.61	8.26	$ 3,920.19	$ 285.85	$ 3,625.62	$ 273.22	$ (294.57)	$ (12.63)	-7.51%	-4.42%
37235		Tib/per revasc	7.80	112.18	2.12	1.26	121.24	11.18	7.80	110.62	1.94	1.13	119.55	10.87	$ 4,195.66	$ 386.90	$ 3,954.42	$ 359.55	$ (241.24)	$ (27.34)	-5.75%	-7.07%

Note: The source of the Medicare payment information outlined in SIR's impact table utilizes the CMS NPRM addenda files Adedendum B Relative Value Units and Related Information CY 2022 CMS 1751-F2-CN updated on February 10, 2022, and Addendum B Relative Value Units and Related Information CY 2023 CMS-1770-P. Analysis estimates include using the proposed conversion factor value of $33.0775 for CY 2023 and finalized CF $34.6062 for CY 2022, and the floor base GPCIs of 1.000 for each year represented. Any additional reductions or values related to carrier-priced services, MPPR and Modifier-25 Payment Reductions, or the advanced imaging DRA cap were not applied.

Practice Expense RVUs – Clinical Labor

Proposed: CMS updated the values for clinical labor for the first time in 20 years in CY 2022 using CY 2019 survey data from the Bureau of Labor and Statistics (BLS) and other supplementary data when there is no BLS data available. Due to budget neutrality, specialties like family practice which have a higher-than-average share of the direct costs continue to see increases in values of codes while for other specialties like interventional radiology which have labor that is a lower-than-average share of the direct costs continue to see decreases in code value.

CMS has reiterated from the beginning if there is new clinical labor salary data available it can be presented to CMS at any time during the 4-year phase-in for consideration. Prior to the MPFS CY 2023 proposed rule release, data was presented by another entity to CMS regarding the accuracy of the value assigned to Lab Tech/Histotechnologist (L035A) clinical labor type. This is of importance to interventional radiology because the value used for clinical labor type Angio Technician is crosswalked to the value for Lab Tech/Histotechnologist (L035A) clinical labor type. The proposed value changes to Lab Tech/Histotechnologist (L035A) clinical labor type by CMS would increase the rate per minute from $0.55 to $0.60. SIR did request CMS use a different crosswalk in comment to the CY 2022 MPFS proposed ruling, which CMS did not accept.

Impact: Even though CMS finalized to 4-year phase-in the clinical labor updates, the ultimate impact is still a significant decrease to services for interventional radiology. As described earlier and outlined in SIR's TABLE A: SIR's Impact Analysis on PAD-related IR Services, services for treating peripheral arterial disease (PAD), end-stage renal disease, and cancer will still see a final impact as included in the CY 2022 MPFS proposed rule comment letter and reflected below in Table B: Health Inequity Impacts Due to Clinical Labor Cuts. These cuts may only delay the inevitable as practices will find they can no longer stay open, feel the push by CMS to be acquired by hospitals and disincentivize providers from opening office-based labs in disadvantaged communities. It will also limit patient access to critical services for many critical procedures such as:

- Hemorrhagic and ischemic strokes
- Maternal health (antepartum, intrapartum, and postpartum hemorrhaging)
- PAD (limb salvage)
- Dialysis access (creation and revision AVF, AVG, and central lines)
- Radiation oncology and other innovative cancer treatments
- Pain management such as non-opioid alternatives

Disease/Service	Health Inequity	2022 PFS Proposed Full Cuts	CY 2022 Final Impact from CY 2021	CY 2023 Proposed Impact from CY 2021
Venous Icer / Endovenous radiofrequency ablation	Black patients present with more advanced venousinsufficiency than White patients[1]	Key Code (36475) Cut by 23%	Key Code (36475) Cut by 12%	Key Code (36475) Cut by 7%
ERSD / Dialysis Vascular Access	Black and Latino's patients start dialysis with a fistula less frequently despite being younger[2]	Key Code (36902) Cut by18%	Key Code (36902) Cut by5%	Key Code (36902) Cut by 8%
Cancer / Radiation oncology	Black men are 111 percent more likely to die of prostate cancer; Black women are 39 percent more likely to die ofbreast cancer[3]	Key Code (G6015) Cut by 15%	Key Code (G6015) Cut by 3%	Key Code (G6015) Cut by 5%
Peripheral Artery Disease / Revascularization	Black Medicare beneficiaries are three times more likelyto receive an amputation[4]	Key Codes (37225-37221)	Key Codes (37225-37221)	Key Codes (37225-37221)

[1] Vascular and Endovascular Surgery, *Advanced Chronic Venous Insufficiency: Does Race Matter?*, 26 December 2016

[2] *Racial/Ethnic Disparities Associated With Initial Hemodialysis Access*. JAMA Surg.2015 Jun;150(6):529-36. doi: 10.1001/jamasurg.2015.0287

[3] Cure, *Cancer Sees Color: Investigating Racial Disparities in Cancer Care*, Katherine Malmo, 16 February 2021

[4] Dartmouth Atlas, *Variation in the Care of Surgical Conditions: Diabetes and Peripheral Arterial Disease*, 2014

	Latino are twice as likely[5]	Cut by 22%	Cut by 8-20%	Cut by 8%
Fibroid / Uterine Fibroid Embolization	Uterine fibroids are diagnosed roughly three times more frequently in Black women[6]	Key Code (37243) Cut by 21%	Key Code (37243) Cut by 6%	Key Code (37243) Cut by 7%

SIR's Comments: SIR seeks to have CMS update the clinical labor description of Angio Technician to Vascular Interventional Technologist to align with industry recognition of this advanced certification and increase the rate per minute to align with current industry salary data.

The clinical labor staff calculations address the payment for the technologists (e.g., Vascular Interventional Technologist) that work with the interventional radiologists in the performance of their procedures. The ARRT (American Registry of Radiologic Technologists) has a basic certification for a radiologic technologist (RT), and there are many advanced modality certifications for an RT, such as Computed Tomography (CT), Magnetic Resonance (MR), and Vascular Intervention (VI) (called angio technician by CMS). Many RTs will seek additional educational programs and training for these advanced modalities/disciplines when entering a career. For example, a vascular interventional technologist (currently referred to by CMS as an angio technician) assists physicians with minimally invasive, image-guided vascular procedures, including angioplasty, stent placement, thrombolysis, and also many non-vascular interventions. Using sophisticated fluoroscopic and other imaging equipment, they are responsible for capturing images of the blood vessels as well as assisting the physician during the procedure. To earn the certification in vascular interventional radiography, they must complete a post- primary eligibility pathway. This requires, among other things, that the individual already hold a primary credential (i.e., radiologic technologist).

Within the CY 2022 MPFS proposed rule, CMS proposed to update the clinical labor rates using CY survey data from the Bureau of Labor and Statistics (BLS) and other supplementary data when BLS data lists are not available applied in a single-year implementation. In response to this, SIR urged CMS to reconsider and use the BLS median wage data, instead of mean wage data, to capture typical wage rates and be more accurately consistent with the median statistic used for clinical staff time.

Additionally, SIR specifically commented on the proposed values related to "Angio Technician." CMS had proposed using BLS category 29-9000 Other Healthcare Practitioners and Technical Occupations as the proxy BLS wage rate for the Angio Technician. Historically, CMS had applied the crosswalk using primary radiologic technologists to the angio technician proxy BLS wage rate. SIR strongly disapproved of this crosswalk and the proposed updated crosswalk to "Other Healthcare Practitioners and Technical Occupations," due to the severe undervaluing of the median salary compared to the actual wage amounts being paid to "angio technicians" (technologists).

As a clinical staff member, an "angio technician" is most representative of an advanced level VI certified Radiologic Technologist. SIR requested in response to the CY 2022 MPFS proposed rule consideration be given to crosswalk the role of the "angio technician" to that of an "MR Technologist"; given an MR Technologist salary was more representative of the salary of a radiologic technologist with an advanced certification, such as VI, based on the data available at the time. According to the US Bureau of Labor Statistics, the median annual wage for magnetic resonance imaging technologists was $74,690 in May 2020, and the radiologic technologists and technicians were $61,900 in May 2020. Similar to the vascular technologist, and the magnetic resonance imaging (MRI) technologist also requires a post-primary pathway. Therefore, when the updated clinical labor rates went into effect, SIR recommended using 29-2035 Magnetic Resonance Imaging (MRI) Technologist as the proxy BLS wage rate for the "angio technician."

SIR also provided information on the complexity of the education and knowledge base of the angio technician, which we continue to believe is not the most appropriate clinical labor name to use. Since 2002 changes have been made to many of the job titles within radiology, and the most appropriate clinical labor type name for what was historically known as angio technician is vascular interventional technologist.

CMS did not move forward with their proposal of BLS category 29-9000 Other Healthcare Practitioners and

[5] J. A.Mustapha, *Explaining Racial Disparities in Amputation Rates for the Treatment of Peripheral Artery Disease(PAD) Using Decomposition Methods*, J. Racial and Ethnic Health Disparities (2017) 4:784–795

[6] University of Michigan, *Understanding Racial Disparities for Women with Uterine Fibroids*, Beata Mostafavi, 12 August 2020

Technical Occupations as the crosswalk for angio technician. Instead, CMS selected Lab/Histotechnologist, which according to CMS, is better aligned with data available from Salary Expert. This was an increase ($0.55 to $0.60) from the last data in 2002, but a decrease from the proposed value and does not even account for the baseline certification of radiologic technologist ($0.63), which has a higher rate per minute data than angio technician, which is an advanced certification above and beyond the radiologic technologist certification.

Since the release of the CY 2022 MPFS final rule, SIR met with CMS and discussed the possibility of submitting new salary data for consideration related to angio technician. CMS indicated they would consider new data if it was available. The American Society of Radiologic Technologists (ASRT) recently completed the Radiologic Technologist Wage and Salary Survey in 2022. A copy of the complete survey is provided with this comment letter.

The following table reflects CMS's finalized rate per minute compared to the ASRT 2022 survey data and calculated rate per minute with included fringe benefit factor.

Labor Description Used by CMS	CMS CY 2022 Finalized Rate per Minute	ASRT Labor Position	2022 ASRT Salary Survey Median Data	ASRT Data Rate per Minute
Radiologic Technologist	0.63	Radiologic Technologist	$61,005	0.63
Angio Technician	0.58	Vascular Interventional Technologist	$80,679	0.84
Mammography Technologist	0.63	Mammography Technologist	$76,248	0.79
CT Technologist	0.76	CT Technologist	$75,489	0.78
MRI Technologist	0.76	MRI Technologist	$79,305	0.82

In reviewing the data from ASRT, SIR requests CMS update the services, which list the clinical labor description under Direct Practice Expense from angio technician to the clinical labor description vascular interventional technologist. SIR also requests CMS recognize vascular interventional technologists with the same assigned clinical labor type as Genetic Counselor, BLS 29-9092, crosswalk which has a similar median salary and a CMS rate per minute of 0.85.

Malpractice RVUs

Proposed: CMS proposed updates to Malpractice (MP) RVUs which was last done in CY 2020 and is required every three years. Additionally, as finalized in 2020 CMS will align updates to the MP RVUs and MP GPCI at the same time to increase efficiency.

To update MP RVUs and GPCIs, premium data is obtained from State insurance rate filings and CMS was able to obtain data from all 50 states. Previously this had not been the case and resulted in crosswalks when values were not present. CMS proposed to improve and obtain a more comprehensive data set to identify specific insurer names when they do not match CMS database or include specialties not tracked by CMS and to create true risk index calculation.

CMS has also proposed for those specialties where the updated MP premium data results in 30 percent or greater reduction in risk index compared to 2022, CMS will phase-in these impacted MP RVUs at 1/3 of the change each year over next three years, until the next update, rather than over two years. The following table outlines the projected risk index for radiology and interventional radiology over the next three years. Neither society is impacted by the more than 30 percent change and not proposed to have values as part of the phase-in.

CY 2023 Malpractice Risk Index and Premium Amounts by Specialty

Specialty Code	Specialty Name	2022 Service Risk Group	2022 Risk Index*	2022 Normalized Premium Rate	2023 Service Risk Group	2023 Risk Index**	2024 Risk Index**	2025 Risk Index**	2025 Normalized Premium Rate
30	Diagnostic Radiology	All	0.937	$20,105	All	1.009	1.009	1.009	$21,889
94	Interventional Radiology	All	1.144	$24,532	All	1.404	1.404	1.404	$30,457

*Note: CMS is moving from a "Risk Factor" construct to a "MP Risk Index" beginning in 2023. 2022 Risk Index is shown above for illustrative purposes only. See "CY 2023 Medicare PFS Update to the GPCIs and MP RVUs, Interim Report" for more information.
**Note: This reflects the policy of allowing up to 3 years for risk index values to fully reflect the updated premium data as discussed in "CY 2023 Medicare PFS Update to the GPCIs and MP RVUs, Interim Report."
Specifically, each specialty's risk index value may not decrease by more than 33% of the specialty's CY2022 risk index value in a given year.

SIR's Comments: SIR appreciates CMS' update and appropriate collection of practice insurance premiums from all 50 states. We believe the alignment of the MP RVUs and MP GPCI at the same time increases efficiency and will assist in valuing services to the appropriate primary specialties with realtime application of the premiums as necessary.

Geographic Practice Cost Index (GPCI)

Proposed: CMS completed their review of GPCIs and as required for CY 2023 the work floor GPCI is set at 1.000 and reflected in the proposed values. Alaska continues the permanent 1.500 work GPCI and the Frontier States continue the permanent 1.000 floor for work RVUs as well. Additionally, CMS proposed new GPCIs beginning for CY 2023 and seeking comments on refining several of the California locales as they are not transition areas. This would decrease the 32 California payment locales to 29, but there would be no payment implications under MPFS if the change was enacted.

CMS is proposing to change the California following identities:

- Los Angeles-Long Beach-Anaheim MSA, containing Orange County and Los Angeles County, by one unique locality number, 18, as opposed to two, retiring locality number 26, as it is no longer needed.
- San Francisco-Oakland-Berkeley MSA containing San Francisco, San Mateo, Alameda, and Contra Costa counties by one unique locality number, 05, as opposed to four, retiring locality numbers 06 and 07, as they are no longer needed.
- Modify the MSA names as follows:
    - San Francisco Oakland-Berkeley (San Francisco Cnty) locality (locality 05) would become San Francisco-Oakland-Berkeley (San Francisco/San Mateo/Alameda/Contra Costa Cnty)
    - Los Angeles-Long Beach-Anaheim (Los Angeles Cnty) locality (locality 18) would become Los Angeles-Long Beach-Anaheim (Los Angeles/Orange Cnty).
    - Because Marin County is in a transition area and subject to the hold harmless provision CMS must retain a unique locality number for San Francisco-Oakland-Berkeley (Marin Cnty), locality 52.

SIR's Comments: SIR agrees with the proposal by CMS to reduce the number of California payment locales for those locations which are not transition areas and more appropriately align with current data.

Specific Codes and Code Set Valuations

Percutaneous Arteriovenous Fistula Creation (CPT® codes 368X1 and 368X2)

Proposed: In October 2021 the CPT® Editorial Panel created the SIR lead CPT® codes 368X1 *(Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation)* and 368X2 *(Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation)* to describe the creation of an arteriovenous fistula in an upper extremity via a percutaneous approach.

CPT® codes 368X1 and 368X2 are intended to replace the HCPCS G codes G2170 and G2171, which have been requested to be deleted by the RUC. CMS proposed to delete HCPCS codes G2170 and G2171 and replace them with CPT® codes 368X1 and 368X2.

The RUC recommended a work RVU of 7.50 for CPT® code 368X1, and a work RVU of 9.60 for CPT® code 368X2. CMS indicated they disagree with the RUC-recommended RVUs for CPT® codes 368X1 and 368X2 and felt they were too high when compared to other codes with similar time values. Per CMS, The RUC-recommended RVU of 7.50 for 368X1 is the second highest RVU for codes with 55 to 65 minutes of intraservice time and 94 to 114 minutes of total time, with RVUs ranging from 2.45 to 8.84. Similarly, the RUC-recommended RVU of 9.60 for 368X2 is the third highest RVU for codes with 65 to 85 minutes of intraservice time and 109 to 129 minutes of total time, with RVUs ranging from 4.69 to 10.95. Therefore, CMS proposed a work RVU of 7.20 for CPT® code 368X1 using the second reference code of 36905 due to the intraservice and total time were closer in value.

CMS stated they also disagreed with the RUC-recommended work RVU of 9.60 for CPT® code 368X2. They agreed the relative difference in work between CPT® codes 368X1 and 368X2 is equivalent to the RUC-recommended interval of 2.10 RVUs and believed the use of an incremental difference between these CPT® codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, CMS proposed a work RVU of 9.30 for CPT® code 368X2, based on the RUC-recommended interval of 2.10 RVUs and using the CMS proposed work RVU of 7.20 for CPT® code 368X1.

Regarding direct practice expense (PE), CMS is requesting additional information on two equipment and four supply items presented for CPT® code 368X1 and 368X2.

SIR's Comments: In July 2020, CMS replaced HCPCS codes C9754 and C9755 with G codes (G2170 and G2171) which described the surgical work of percutaneous arteriovenous fistula creation for two distinct technologies and enabled physicians to bill for their work in the physician office setting.

- G2170 *Percutaneous arteriovenous fistula creation (avf), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed.*
- G2171 *Percutaneous arteriovenous fistula creation (avf), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed.*

When the G codes were valued for payment by CMS for CY 2021 under Hospital Outpatient Prospective Payment System (HOPPS), CMS proposed HCPCS code G2170 (Ellipsys System) a payment rate of $10,222.32, based on claims data which showed a geometric mean cost of approximately $10,068. For G2171 (WavelinQ System) the claims data based on predecessor HCPCS code C9755, showed a geometric mean cost of about $13,519. However, at the August 31, 2020, HOP Panel Meeting a presenter requested the payment rate and ambulatory payment classification (APC) assignments for the technologies not be adjusted due to low volume claims data.

Stakeholders commented within the CY 2021 HOPPS CMS-1736-FC suggesting the payment rates for G2170 and G2171 be maintained as they were set in CY 2020, a national payment of $15,939.97. In response CMS indicated these procedures are furnished to dialysis patients with chronic kidney disease affecting thousands of Medicare beneficiaries and to ensure access to the dialysis-related procedures in the facility setting, CMS agreed to maintain the payment rates for CY 2021. CMS also stated after review of the median costs for both technologies and noted there were very similar, it would be inappropriate to assign the codes to different payment rates (different APCs). CMS using their equitable adjustment authority finalized the codes at a higher payment rate than proposed and has continued to pay for these services within the same APC, increasing payment each year since.

Subsequently, physicians in the office-based setting utilizing G2170 and G2171 were not provided the same considerations for payment attributable to cost. As contractor priced codes, there has been little to no consistency in the manner in which payment is assigned and some Medicare Administrative Contractors (MACs) do not assign any

payment rates for these codes.

In September 2021, in response to what several specialties identified as a gap in care to appropriately capture the percutaneous approach to creating an arteriovenous anastomosis in End Stage Renal Disease patients requiring hemodialysis, and the inconsistent payments or acceptance of HCPCS codes G2170 and G2171 by payers, applications were formally submitted to the American Medical Association (AMA) for the creation of new Category I CPT® codes.

CPT® codes available at the time of the Category I applications for arteriovenous anastomosis described an open surgical approach only. The technologies developed by, and available with, the Ellipsys and WavelinQ systems allow for less invasive approach utilizing percutaneous image-guided methods.

Utilizing the Ellipsys system (368X1), the physician will percutaneously access a single vessel under continuous ultrasound guidance for CPT code 368X1 and then, using ultrasound, find and select the nearby artery and directly puncture this artery using the same needle. This requires diligent interpretation of real time imaging. The needle is then removed over a wire and a device passed through each vessel. Once position is carefully confirmed using ultrasound guidance, the device is used to deliver energy to the two adjacent vessels to create a permanent connection, or fistula, to arterialize the vein. The potential for complication is very high and as mentioned and the management becomes an emergent situation for the patient if a complication does occur. Thermal energy is applied to fuse the artery and vein together and to cut an elliptical anastomosis, permanently connecting the artery and vein. These techniques may also use balloons or coils to direct blood flow as well as different imaging methods (e.g., ultrasound and/or fluoroscopy) to guide the percutaneous procedure.

Utilizing the WavelinQ system (368X2), the physician will place two catheters from two different percutaneous access sites, one in the vein and one in the artery, under continuous ultrasound guidance. This requires the physician to handle and maneuver two points of access into the patient with just one set of hands. Most percutaneous endovascular procedures are performed through a single access; the use of two accesses now increases the number and types of complications which can arise. As with the single access, the physician will find and select a vein and adjacent artery, requiring fluoroscopic guidance to select the correct vein, sometimes in a retrograde fashion against the flow blood. Catheters are then inserted into each vessel using fluoroscopic guidance and energy is activated to pull the vessels together and create a permanent connection, or fistula, to arterialize the vein. A second access into the artery increases the risk and physician intensity of this procedure relative to 368X1.

The applications for the two new codes were accepted by the AMA, one to represent the Ellipsys system and one to represent the WavelinQ system.

- Ellipsys – 368X1 - *Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation*
- WavelinQ – 368X2 - *Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation*

A multi-disciplinary survey conducted by four specialty societies was distributed randomly to the members of the representative societies. For code 368X1, 37 surveys were completed and for code 368X2, 39 surveys were completed. The surveys were reviewed by the multi-specialty group and determined to be valid and reflective of the work and intensity involved.

The survey data collected by the RUC was presented at the January 2022 meeting. When comparing the survey results for each code to the key reference service, the same code supported survey data of CPT® code 36906, which is also an MPC code, the RUC recommended the 25th percentile survey work RVU for each code, 368X1 = 7.50 and 368X2 = 9.60. As this is the first and only FDA approved Category I code for a percutaneous approach to create an arteriovenous anastomosis, when there is a complication, it will require emergent embolization or surgical exploration, which reflects the increased intensity of physician work for the codes. The recommended values appropriately ranked each code relative to other services in a well bracketed manner and account for the complexity

and intensity of the procedures.

Survey for 368X1 (Ellipsys System)													
Source	IWPUT	Work Per Unit Time	WORK RVU			Total Time	PRE-TIME			INTRA-TIME			IMMD POST
			25th	MED	75th		EVAL	POSIT	SDW	25th	MED	75th	
1st Ref Code 36906	0.104	0.074		10.42		141	22	4	5		90		20
Combined Survey Data	0.147	0.085	7.50	10.00	12.00	118	18	10	10	45	60	70	20
RUC Recommended Values	**0.109**	**0.070**	**7.50**			**104**	**15**	**5**	**6**	**60**			**18**

Survey for 368X2 (WavelinQ System)													
Source	IWPUT	Work Per Unit Time	WORK RVU			Total Time	PRE-TIME			INTRA-TIME			IMMD POST
			25th	MED	75th		EVAL	POSIT	SDW	25th	MED	75th	
1st Ref Code 36906	0.104	0.074		10.42		141	22	4	5		90		20
Combined Survey Data	0.132	0.085	9.60	11.00	13.75	130	15	10	10	60	75	90	20
RUC Recommended Values	**0.116**	**0.081**	**9.60**			**119**	**15**	**5**	**6**	**75**			**18**

SIR does not agree with CMS's statements within MPFS CMS-1770-P the RUC-recommended RVUs were too high when compared to other codes with similar time values for CPT® codes 368X1 and 368X2. CMS did not provide any rationale or transparency how they arrived at the arbitrary reductions applied to CPT® codes 368X1 (proposed work RVU 7.20) and 368X2 (proposed work RVU 9.30) for the RUC to appropriately understand the process followed.

The values submitted by the RUC, and reviewed above, are supported through a well-established process with full transparency. Each code was surveyed by physicians performing the service in the clinical setting on what they indicated were typical patients. The patients benefiting from these services are still Medicare beneficiaries. Providing appropriate access to care for thousands of beneficiaries and establishing reasonably valued payments, assists in ensuring physicians are not penalized for providing these necessary services in a non-facility setting. SIR requests CMS accept the RUC survey supported work RVU values of 7.50 for CPT® code 368X1 and work RVU of 9.60 for CPT® code 368X2.

CMS requested comments on the differences in cost of the generators utilized for the percutaneous arteriovenous fistula creation with the Ellipsys EndoAVF generator (EQ404) and WavelinQ EndoAVF generator (EQ403) systems. The equipment inputs submitted as part of the practice expense (PE) valuation correspond to the industry specific/procedure specific radiofrequency (RF) generators for these catheters. The Ellipsys Generator and the WavelinQ Generator can only be used for their respective service and respective catheter.

The costs represented by the invoices for the equipment (Ellipsys = $3,000 and WavelinQ = $18,850) submitted as part of the RUC valuation and subsequently to CMS were provided directly by the vendors of these generators. Any disparity in the costs is not something the RUC manages; these are set by the respective vendors and the way they arrive at their own set cost is to their own making.

CMS also requested comments on the RUC included supply items SD149 (catheter, balloon inflation device) and SD152 (catheter, balloon, PTA), whether these supplies were typical and how often they are used. CMS indicated they were trying to establish whether these supplies are appropriate to consider as direct PE. Each system (Ellipsys and WavelinQ) utilizes specific catheters which are necessary for creating the fistula and both procedures require gentle angioplasty of new anastomosis which is typical with each procedure and support to be counted as direct

PE supplies.

CMS also requested comments on the supply items SF056 (detachable coil) and SF057 (non-detachable embolization coil) as direct PE inputs for CPT® code 368X2 (one each for SF056 and two each for SF057). The detachable coil (SF056) embolization is typical as dialysis embolization typically is high flow, requiring a detachable coil first to secure location. The two non-detachable embolization coils (SF057) are utilized once a secure coil is placed and typically are necessary to effectively perform the percutaneous arteriovenous fistula creation for hemodialysis patients. Coil embolization is a typical part of a fistula creation procedure when performed with the WavelinQ device (368X2) and is performed at least 75% of the time, if not more. The supply inputs are typical for the manner in which coil embolization is performed in high flow vascular structures and is reflected in codes which represent similar clinical scenarios (36909 and 37241).

SIR believes through the established RUC process the data collected through the multi-disciplinary survey supports the values presented to CMS for CPT® codes 368X1 and 368X2. The selection of the 25th percentile for each code reflects the RUC's appreciation for the physician work and time necessary to perform these new technologies. Additionally, the details of the calculated practice expense including the vendor specific generators, catheters, and coils for the Ellipsys and WavelinQ systems also speak to the process and transparency of how the values were derived and supported. SIR requests CMS reconsider their proposed work RVU adjustments and finalize the RUC recommended work RVUs for CPT® codes 368X1 (work RVU 7.50) and 368X2 (work RVU 9.60). SIR believes through the data submitted originally by the RUC and within these comments SIR has supported the values established through a well-defined process. Additionally, SIR requests CMS accept the SD149 (catheter, balloon inflation device), SD152 (catheter, balloon, PTA, SF056 (detachable coil), SF056 (detachable coil), and SF057 (non-detachable embolization coil) as direct PE supply inputs.

Lastly, SIR agrees with CMS's proposal to delete HCPCS codes G2170 and G2171 and replace them with CPT® codes 368X1 and 368X2.

Proposed: In total, CMS proposed to not accept the RUC recommended values for 18 codes and/or code families. As reiterated above this is very concerning to SIR. The valuation of codes and code families presented to CMS is accomplished through a detailed well-established process. When presented at the table during the RUC meeting by the various specialty societies there is transparency to how the values were established, supported, and any disagreement has an opportunity to be addressed. When codes are presented at the table there is opportunity by CMS to question or discuss the presented values. In the case of the codes for percutaneous arteriovenous fistula creation, no comments or arguments were heard by CMS. While it is appreciated CMS may not be able to voice all concerns at the table of the RUC meetings, it is concerning the increased non-acceptance by CMS within each proposed ruling of the values calculated by the RUC, and the lack of transparency for how CMS calculated alternative values.

SIR requests CMS provide feedback or questions at the table of RUC meetings when code values are discussed so there is a more appropriate opportunity to work through any issues. The ability to discuss concerns in realtime can lead to better outcomes, than to wait for CMS' response in the proposed ruling and discussions taking place now through "letter writing" which creates a lag time in responses. SIR believes there are better solutions to this process and gives the appearance of targeting highly specialized technology services by not accepting the RUC recommended values.

Addressing Changes to "Other" Evaluation and Management (E/M) Services

Proposed: CMS proposed the intention to accept and move forward with the AMA CPT® Editorial Panel changes to what they are calling "Other E/M" visits (inpatient and observation visits, emergency department (ED) visits, nursing facility visits, domiciliary or rest home visits, home visits, and cognitive impairment assessment) except critical care services to match the framework (medical decision making or time-based) of the outpatient and office E/M visits which changed in 2021.

The primary area where CMS indicated they were not in agreement with the AMA centered around the application of prolonged services codes. This matches the disagreement between the two entities for the outpatient and office E/M visits as well. CMS proposed three new HCPCS codes to be used in place of the AMA created CPT® code 993X0

for prolonged services. One code for hospital inpatient or observation care, one for nursing facilities, and one for home or residence. The prolonged services codes are not billable in conjunction with emergency department (ED) visit codes because ED visits are not reported based on time spent with the patient.

As with the outpatient prolonged services, CMS did not agree with the AMA how time was counted to meet the threshold for billing the new codes. CMS proposed the prolonged service period described by GXXX1 begins 15 minutes after the total time (as established in the Physician Time File) for CPT® codes 99223, 99233, and 99236 have been met. Additionally, CMS proposed GXXX1 prolonged code would be for a 15-minute increment, and the entire 15-minute increment must be completed in order to bill GXXX1.

CMS also proposed GXXX1 would apply to both face-to-face and non-face-to-face time spent on the patient's care within the survey timeframe. For CPT® codes 99223 and 99233, this would be time spent on the date of encounter. For CPT® code 99236, this would be time spent within 3 calendar days of the encounter.

CMS clarified their proposal to slightly amend the definitions for "initial" and "subsequent" in relation to E/M visits for inpatient services. CMS does not recognize subspecialties, as is outlined in the CPT® manual, so CMS is proposing the following language.

- *An initial service would be defined as one that occurs when the patient has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay.*
- *A subsequent service would be defined as one that occurs when the patient has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice during the stay.*

CMS addressed Split (or Shared) Visits for new and established patients will be fully integrated in policy year beginning 2024, a one-year delay, to allow full acquaintance and implementation of the other E/M visit changes for providers.

SIR's Comments: SIR appreciates and supports CMS' proposal to align the new E/M coding guidelines for CY 2023 with those provided by the AMA. SIR is concerned, however, with CMS' proposal to again not align all coding guidelines and billing applications with what the AMA has designed for prolonged services. It is apparent from the observed conversations regarding the new prolonged services by both agencies there is a disconnect in the understanding and intent on both sides. The varying guidelines resulting in different codes for the same services creates burden on providers and their coders and billers to ensure appropriate documentation and selection of the code based on payer. SIR recommends both agencies find a system for reviewing and implementing better solutions to these situations, including discussions which are not spent simply restating definitions at each other and instead are spent talking practically and clinically about the services.

After the Public Health Emergency (PHE)

Proposed: After the release of the CY 2023 MPFS proposed rule, the Health and Human Services Secretary extended the public health emergency (PHE) which is now set to expire October 13, 2022. This would mean many of the provisions and waivers as part of the initial response to the COVID-19 pandemic will continue through the end of the PHE and as finalized in separate legislation for 151 days post the end of the PHE.

Codes not part of the telehealth list of services identified as continuing permanently or temporarily as a Category 3 telehealth service will end on day 152 post the end of the PHE (e.g., initial inpatient CPT® codes 99221, 99222, and 99223). Telehealth visits will no longer be allowed for patients in their homes or anywhere outside of an originating site other than the statutory exceptions for diagnosis, evaluation and treatment of mental health disorders, home dialysis end stage renal disease related visits, and diagnosis, evaluation, and treatment of acute stroke symptoms.

CMS has proposed the telephone or audio-only codes (99441-99443) will not be available on the list of telehealth services after the end of the PHE. Since they are audio-only and will not meet the criteria which will require all telehealth services to be performed by realtime audio-video capabilities after the end of the PHE and 151-day extension.

CMS proposed for codes included on the list of telehealth services performed on or before the 151st day after the PHE ends will continue to be paid at the same rate as if performed in person with modifier 95 applied to the telehealth services. For telehealth services on day 152 and beyond they will no longer require modifier 95, but the appropriate place of service (POS) code (02 or 10) must be applied to process for payment.

Under Medicare Part B, certain types of services, including diagnostic tests, services incident to physicians' or practitioners' professional services, and other services, CMS requires to be furnished under specific minimum levels of supervision by a physician or practitioner. For professional services furnished incident to the services of the billing physician or practitioner and many diagnostic tests, direct supervision is required.

CMS again reiterated that *"…outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service."* CMS has clarified "immediate availability" requirement means in-person, physical, not virtual, availability in two different recent rulemakings (April 6, 2020 IFC (85 FR 19245) and the CY 2022 PFS final rule (86 FR 65062)).

CMS also reminded stakeholders that after December 31st of the year in which the PHE ends, the pre-PHE rules for direct supervision would apply. CMS is not proposing to make the temporary exception to allow immediate availability for direct supervision through virtual presence permanent, instead they are continuing to seek comments whether to allow flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology.

CMS is also seeking comment on the possibility of permanently allowing immediate availability for direct supervision through virtual presence using real-time, audio/video technology for only a subset of services. CMS recognizes for some services there are potential concerns over patient safety if physician supervision was provided without physical presence by the physician. As discussed in last year's final rule, and based on gaps in the currently available evidence, CMS needs more information as they review whether to make permanent a temporary exception to their direct supervision policy.

SIR's Comments: SIR appreciates CMS' proposal to return telehealth services to the pre-pandemic status and guidelines given the data supports most telehealth services have dropped off from the beginning of the PHE. There is concern however as the impacts related to COVID-19 are still pertinent. Whether this is from increased infections, lack of regulatory support for mitigating spread, or burnout for many healthcare staff. SIR is extremely concerned the payment decreases proposed by CMS for CY 2023 along with the ongoing fallout from the PHE, a return to normal is not possible. Add into this CMS' proposal to continue to adjust requirements for physician direct supervision of services and what it means to be immediately available in the office-based setting.

In CY 2020, pre-pandemic, CMS relaxed physician supervision for therapeutic services in the facility (hospital) setting to general supervision. This allows for the physician to be elsewhere, across or out of state, performing another procedure, or available peripherally. Clinical staff in the hospital have been told there is a physician somewhere available who will assist if needed. This puts the burden on these clinical staff members to make decisions to determine the qualifications of a physician to assist compared to their own training and experience to provide a response, which should not have to be a consideration or decision they are forced to make.

The comments CMS is seeking would be to consider allowing flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology. While it was understood the intent of allowing provisions for direct supervision with realtime audio/video technology during the PHE was to provide coverage and emergent care as needed with limited staffing. There are concerns with the burden on clinical staff to make up much of the decision making in the physical absence of the physician, lack of appreciation the expertise the physician brings with their presence to staff and patients, and ultimately the shift to interjecting mid-level practitioners in place of physicians.

SIR recommends this is limited to nonspecialized care only and clearly defined at the code level for any services which will allow direct physician supervision to be immediately available through use of realtime, audio/video technology if finalized. It is also recommended; CMS consider the larger picture of allowing mid-level practitioners more and more latitude and ability to perform physician services and the message this sends to physicians and

their value.

Additional Request for Comments by CMS

Medicare Economic Index (MEI)

The Medicare Economic Index (MEI) is a fixed-weight input price index comprised of two broad categories: (1) Physicians' own time (compensation); and (2) physicians' practice expense (PE). The current 2006-based MEI is based on data collected by the AMA for self-employed physicians from the Physician Practice Information Survey (PPIS). The AMA has not conducted another survey since the 2006 data collection effort. Due to this the MEI continues to be based on 2006-based costs.

Previous updates to the conversion factor were calculated based on a statutory formula that used a combination of the sustainable growth rate (SGR) and the MEI, which ended with MACRA in April 2015. It is also used to calculate the GPCI cost share weights to weigh the four components of practice expense GPCI (employee compensation, office rent, purchased services, and medical equipment, supplies, and other miscellaneous expenses). The MEI was last updated in 2014 and CMS indicated they need to update it to reflect more current market conditions impacting physicians for physician services.

CMS proposed to rebase and revise the MEI based on a methodology using publicly available data sources for input costs representing all types of physician practice ownership, not just self-employed physicians.

SIR's Comments: When CMS finalized changes to the MEI for CY 2014 the decision was based on what was *"less disruptive to the public review of values that determines the PFS rates."* This decision unfairly burdened physicians in the office-based setting who had higher direct practice expenses. This is and was predominantly specialized care, like interventional radiology, which continues to take the brunt of payment reform by paying for and supporting nonspecialized care over and over.

SIR is concerned the proposal to update the MEI, even to include all types of physician practice ownership, not just self-employed physicians, is another adjustment and potential payment rate factor which specialized care will shoulder the burden. The budget neutrality adjustments to the clinical labor updates, as previously outlined, and the updates to E/M services will require specialties like interventional radiology to work harder for less. This continued payment policy approach is driving care for beneficiaries away from specialized care to unspecialized care. It may appear as a win in the short term, but it means beneficiaries are given temporary care which only precipitates sicker patients needing more, ongoing, expensive care in the long run. If the proposed changes to the MEI move forward, specialties with higher practice expense will finally see a reprieve from payment adjustments, only to have it shift to specialties with higher work RVUs. Many of these specialties are one in the same. Instead of the office-based practices offsetting the payment adjustments, it will now be the specialized care by hospital-based practices taking their turn.

Indirect Practice Expense

Proposed: CMS is looking to standardize and make routine the valuation for indirect practice expense (PE) and seeking comments from stakeholders on how best to do this. Indirect PE RVUs is made up of costs such as office rent, IT costs, and other non-clinical expenses. It has been over a decade since this information was last updated and the primary source of the information is the Physician Practice Information Survey (PPIS), by the AMA.

The last survey was conducted in 2007 and 2008 and reflects 2006 data. The participants were self-employed physicians and selected nonphysician practitioners. CMS has received concerns regarding how indirect PE is allocated and the data was surveyed. Concerns expressed included lack of ways to update date based on experience, payment differentials for same procedure depending on setting, and may not accurately reflect variation in practice expense across different types of services, different practice processes, or changing business models.

Another concern raised is the high cost of supplies and equipment, including disposable supplies, are not relevant to allocating indirect PE. Indirect PE allocated based on setting or specialty could create unintended scenarios where access to care could be limited, or a reduction in competition and lack of small group practices or individual clinicians who provide some services in facility settings.

SIR's Comments: The last PPIS survey was conducted in 2007/2008, reflecting 2006 data, as mentioned previously. The impact of the physician self-employed data had a significant redistribution on MPFS at that time. Even though there has been a shift in physician employment and ownership of many physician practices and office-based settings, the direct practice expense within the MPFS highlights those factors which are most consistent. Additionally, processes, like the one used by the RUC, provides transparency at the clinical level for establishing values.

SIR urges CMS to engage with physicians in all specialties, especially those where practice expense is a higher cost. Their first-hand experience and knowledge of how direct and indirect practice expense impacts their practices would be invaluable. Additionally, the quality of data used to value services must be reviewed. Data, which is outdated, from a limited subset, and questionable in authenticity, does not serve the whole. To continue to maintain the status quo because it benefits a certain population, while another continues to shoulder the responsibility and financial impact cannot be sustained.

Specialties which have the highest costing practice expense have been required to subsidize nonspecialized care. It is important the physicians who understand practice expense, direct and indirect, assist CMS in leading the conversation and any potential changes.

MIPS Value Pathways (MVPs), Quality Measures, and Qualified Clinical Data Registry Participation Plan

Proposed: SIR supports CMS' proposal to move forward with MVP implementation in 2023. CMS also introduced a subgroup reporting option for MVP participants beginning in 2023 that will require multispecialty groups that choose to report through an MVP to participate as subgroups beginning in 2026. SIR appreciates that CMS identifies innovative approaches to measuring value and flexible pathways for both patient-facing and non-patient-facing specialties. The MIPS quality measures currently represent 47 specialties and sub-specialties. Currently, SIR's stewarded quality measures for interventional radiology include Clinical Outcome Post Endovascular Stroke Treatment, Door to Puncture Time for Endovascular Stroke Treatment, Varicose Vein Treatment with Saphenous Ablation: Outcome Survey, Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal, Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure, and Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries.

Impact: SIR believes additional quality measures relevant to interventional radiology can further demonstrate the specialty's high-quality care and lower costs. It is imperative for SIR to be involved in CMS measure development on clinical topics where interventional radiologists are part of the care team.

SIR recommendations: SIR supports the five new proposed MVPs and seven modified MVPs for the 2023 performance year. Interventional radiologists are directly involved in many of these areas, including oncology, dialysis and renal care, stroke treatment, pain management and joint treatments, and chronic disease management (peripheral arterial disease and critical limb ischemia). SIR has submitted comments on measures that CMS is currently developing and/or re-evaluating on these topics and should continue to be included in the measure development and evaluation process.

SIR recently launched VIRTEX, its clinical data registry. SIR supports working with CMS to establish a more flexible MVP framework that allows co-development of a pathway, like an APM. VIRTEX centers on quality improvement, efficient resource use, patient-reported outcomes and satisfaction, and enhanced technology to care for patients with specific medical conditions. VIRTEX will leverage clinical information from EHRs and other registries, in addition to claims data, to form a complete vision of patient care events. The VIRTEX registry will help track appropriate clinical data that CMS can utilize in the future for a formal QCDR program for interventional radiology. The potential structure will also house quality and cost measures based on clinical pathways and patient-reported outcome measures (PROM) for diagnosing and treating specific medical conditions. SIR intends to continue to work with CMS and provide feedback on the impact of replacing the traditional MIPS requirements with the new, more innovative MVP framework. SIR would also be interested in discussing the measure development process with CMS and supporting a more cost-effective approach to creating quality measures.

AMA's recommendations: CMS' proposed finalized MVP scoring methodology responds to some of the recommendations made to CMS by the AMA after significant consultation with specialty and state medical

societies, such as fewer check-the-box reporting requirements. Specifically, CMS requires MVP participants to select four, rather than six, quality measures, and be scored on only the cost measures included in the MVP. However, CMS maintains many of the same traditional MIPS reporting and scoring requirements that the AMA had previously noted as overly burdensome and not clinically relevant, including requiring reporting on Promoting Interoperability measures.

Health Inequities

Proposed: In recognition of persistent health disparities and the importance of closing the health equity gap, CMS has issued two Requests for Information (RFI) for the future of QPP that impact interventional radiology. The stated goals of these two RFIs are to address racial disparities and improve patient care through development of measures with health equity factors.

- MIPS Quality Performance Category Health Equity
- Developing Quality Measures that Address Amputation Avoidance in Diabetic Patients

SIR supports CMS' initiatives to address health inequities and improve patient outcomes through the development of measures in these focus areas.

Impact: SIR believes that the development of quality measures relevant to interventional radiology will improve awareness of treatment options that directly impact health inequities. It is imperative for SIR to be involved in CMS measure development on disease-focused MVPs in topic areas where health disparities exist.

SIR's recommendation: SIR is committed to advocating not only for our physician membership, but also the patients our members serve. Interventional radiologists are valuable members of care teams directly involved in treating conditions where known health disparities exist. In particular, venous insufficiency, dialysis vascular access, radiation oncology, peripheral arterial disease, and uterine fibroid embolization all demonstrate racial health inequities and access issues (see Table B: Health Inequity Impacts Due to Clinical Labor Cuts). Interventional radiology's involvement in the treatment of peripheral arterial disease and critical limb ischemia directly impacts amputation avoidance in patients. SIR strongly supports increasing the number of measures with a focus on these health inequities. SIR and interventional radiologists should be involved in the CMS development process of all measures in these areas.

SIR appreciates the opportunity to provide meaningful feedback to the CY 2023 MPFS proposed rules. If you have any questions, please feel free to reach out to SIR's Manager of Coding and Reimbursement, Ashley Maleki, at amaleki@sirweb.org or (703) 844-0378.

Sincerely,

Parag J. Patel, MD, FSIR
President, Society of Interventional Radiology

Cc: Keith M Hume
Executive Director, Society of Interventional Radiology