



September 16, 2021

Department of Health and Human Services
Attention: CMS-1753-P
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850
Submitted via: www.regulations.gov

Re: File Code CMS-1753-P; Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for information on Rural Emergency Hospitals (July 19, 2021)

Dear Administrator Brooks-LaSure:

The Society of Interventional Radiology (SIR) is a professional medical association representing approximately 8,800 members, including most US physicians practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapies. Therefore, SIR appreciates the opportunity to comment on the CY 2022 Centers for Medicare and Medicaid Services (CMS) Proposed HOPPS and ASC Rule.

Practice Expense RVUs - Payment Rates

Proposed: In the CY 2022 proposal, CMS reversed the 3.75 percent increase outlined as part of the Consolidated Appropriations Act of 2021, which reversed the 10.2 percent cut finalized to the conversion factor (CF) for CY 2022. Removing this and utilizing a CF of 33.6319, CMS applied a budget neutrality factor of minus 0.14 percent. Applying this to the conversion factor of \$33.6319, minus the 3.75 percent increase outlined as part of the Consolidated Appropriation Act of 2021, which had changed the CF to \$34.8931, the proposed CY 2022 CF is \$33.5848. (Table 121: CY2022 MPFS).

TABLE 121: Calculation of the CY 2022 PFS Conversion Factor

CY 2021 Conversion Factor		34.8931
Conversion Factor without CY 2021 Consolidated Appropriations Act Provision		33.6319
Statutory Update Factor	0.00 percent (1.0000)	
CY 2022 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
CY 2022 Conversion Factor		33.5848

Impact: The decrease in the CF will significantly reduce reimbursement as part of the CMS proposed total decrease in reimbursement of 9% for interventional radiology (IR) services and 2% for diagnostic radiology. (Table 123: CY2022 Proposed MPFS). Alarming, the AMA's independent impact analysis

estimates much higher reimbursement cuts: interventional radiology (12.9%), diagnostic radiology (5.7%). (SIR's Table A). In addition, CMS has also applied additional decreases to many of the practice expense (PE) values which reflect a deeper cut to certain specialties. Most of the resulting cuts for the impacted specialties are due to labor pricing transition values. When considering all proposed reimbursement cuts, IR will experience a 9% to 13% cut in overall reimbursement. Moreover, when analyzing specific procedural codes, IR will see a 20% and greater decrease in reimbursement for procedures treating peripheral arterial disease (PAD), end-stage renal disease, and cancer. (SIR's Table B - PAD impact analysis).

TABLE 123: CY 2022 Proposed MPFS - CY 2022 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	\$480	0%	-9%	0%	-9%
Radiology	\$4,397	0%	-2%	0%	-2%

SIR's Table A: AMA's Combined Impact of Proposed Rules and Conversion Factor Reduction for 2022

Medicare Specialty Description	Medicare Specialty Code	CY2021 Estimated Allowed Charges (using \$34.8931 CF and 2021 RVUs)	CY2022 NPRM Estimated Allowed Charges (using \$33.5848 CF and 2022 Proposed RVUs)	Estimated Impact (including expiration of 3.75% payment from CAA)
Diagnostic radiology	30	4,410,886,765	4,161,232,605	-5.7%
Interventional radiology	94	505,989,346	440,722,416	-12.9%

SIR's recommendation: The original 3.75% conversion factor was attributed to mitigating the financial loss caused by the COVID-19 pandemic. Interventional Radiologists (IRs) were, and continue to work as, frontline providers during this COVID-19 pandemic. In early 2020, when the pandemic emerged and hospitals were overwhelmed with increasing caseloads, IRs suspended their elective procedures and worked in emergency rooms around the country. They helped patients and their physician partners by using their diagnostic imaging skills to assist with reading radiology studies, while still providing image-guided procedures to treat respiratory complications or other life saving emergency services. In scenarios where hospitals were inundated with new COVID cases, IRs opened their outpatient centers and office-based labs as an alternative treatment site for patients. As of September 2021, the pandemic surge continues, with the multitude of COVID-variants changing the dynamic for even vaccinated patients. The daily infection and death rates continue to rise. Hence, SIR's disappointment at CMS's decision to reverse the 3.75% increase was introduced initially to address this pandemic's medical expenses. SIR strongly

recommends that CMS maintain the 3.75% increase in the conversion factor for CY 2022 and maintain its 2021 CF value of 34.8931.

Budget Neutrality and clinical labor pricing update

Proposed: Based on budget neutrality adjustments of Medicare payments, CMS proposed coordination with the final year of the 4-year supply and equipment updates due to stakeholder feedback and requests. Clinical labor rates were last updated in CY 2002, and CMS is proposing to update the values for CY 2022 using CY 2019 survey data from the Bureau of Labor and Statistics (BLS) and other supplementary data when BLS data lists are not available.

Impact: As Table 5 illustrates, these proposed direct costs associated with clinical labor will cause IR to experience significant decreases in payment for their services and increase expense for all practitioners in the non-facility setting. (Table 5: CY 2022 Proposed MPFS). CMS believes that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing. This data will appropriately reflect changes in clinical labor resource inputs to set PE RVUs under the PFS. Therefore, CMS utilizes the mean wage data to establish updated clinical labor rates in the clinical labor pricing update proposal. At the same time, the majority of the MPFS data inputs are based on the median.

TABLE 5: CY 2022 Proposed MPFS - Proposed Clinical Labor Pricing Update

Labor Code	Labor Description	Source	Current Rate Per Minute	Updated Rate Per Minute	% Change
L041A	Angio Technician*	BLS 29-9000	0.41	0.62	51%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.69	68%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.69	68%
L043A	Mammography Technologist*	BLS 29-1126	0.43	0.70	63%
L046A	CT Technologist*	BLS 29-2035	0.46	0.81	76%
L047A	MRI Technologist	BLS 29-2035	0.47	0.81	72%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.83	66%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.84	65%
L054A	Vascular Technologist*	BLS 19-1040	0.54	1.07	98%
L152A	Medical Physicist	BLS 19-2012 (75th percentile)	1.52	1.80	18%

SIR recommendation: We urge CMS to consider using the BLS median wage data, instead of mean wage data, to more accurately capture typical wage rates and be consistent with the median statistic used for clinical staff time. Additionally, the Angio Technician does not have a direct BLS labor category. As such,

CMS proposes using BLS category 29-9000 Other Healthcare Practitioners and Technical Occupations as the proxy BLS wage rate for the Angio Technician. Historically, CMS has applied the crosswalk using primary radiologic technologists to the angiography technician proxy BLS wage rate, and SIR strongly disapproves of this crosswalk as well as the proposed updated crosswalk to "Other Healthcare Practitioners and Technical Occupations."

The ARRT (American Registry of Radiologic Technologists) has a basic certification for a radiologic technologist (RT). With several advanced modalities/disciplines within radiology, there are also many advanced modality certifications for an RT, such as CT, MR, and VI (Vascular Interventional). Many RTs will seek additional educational programs and training for these advanced modalities/disciplines when entering a career. For example, an angiography technician, often referred to as a vascular interventional radiographer, assists physicians with minimally invasive, image-guided vascular procedures, including angioplasty, stenting, thrombolysis, and more. Using sophisticated fluoroscopic 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, you must complete a post-primary eligibility pathway. This requires, among other things, that the individual already holds a primary credential (i.e., radiologic technologist).

Angiography technician does not have a direct BLS labor category. We believe that the staff type of "angio technician" is the most representative of an advanced level VI certified Radiologic Technologist. SIR is requesting consideration be given to crosswalk the role of the "angio technician" to that of an "MR technologist,"; given that an MR tech salary is representative of the salary of a radiologic technologist with an advanced certification, such as VI. 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. (references below). The magnetic resonance imaging (MRI) technologist also requires a post-primary pathway. When the updated clinical labor rates go into effect, SIR recommends using 29-2035 Magnetic Resonance Imaging (MRI) Technologist as the proxy BLS wage rate for the "angio technician."

Proposed: In the proposed rule, CMS displayed the isolated anticipated effects of the clinical labor pricing update on specialty payment impacts in Table 6. CMS estimates a 5% reimbursement cut for IR services and 1% for DR, considering only the labor pricing update.

TABLE 6: CY 2022 Proposed MPFS - Anticipated Clinical Labor Pricing Effect on Specialty Impacts

Specialty	Allowed Charges (mil)	New CL Pricing Change
Radiology	\$5,275	-1%
Interventional Radiology	\$499	-5%
Diagnostic Testing Facility	\$748	-6%

Impact: By increasing the clinical labor pricing in a budget-neutral manner, specialized care that provides services with high-cost supplies and equipment, but the lower-than-average share of direct costs, are heavily impacted. More specifically, groups of services to treat PAD, dialysis access evaluation and

Proposed: SIR supports CMS' proposal to introduce MVPs and a subgroup reporting option in 2023. SIR appreciates that CMS identifies innovative approaches to measuring value and flexible pathways to submit formal comments for patient-facing and non-patient-facing specialties. The MIPS quality measures are mapped to 46 specialties and sub-specialties that provide guidance for stakeholders developing MVP candidates based on specialties. Please view the current MIPS quality measures list and their associated specialty sets in the 2021 MIPS Quality Measures List on the Quality Payment Program Resource Library for more information. Currently, 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 many other quality measures can be meaningful to our specialty. For example, it is imperative to alert SIR when CMS considers working on a condition-focused MVP (e.g., stroke) because many physicians may want to be part of the conversations.

SIR recommendations: SIR recently launched its clinical registry, called VIRTEX. SIR would like to work with CMS to establish a far more flexible MVP framework that allows co-development of a pathway like an APM. It centers on quality improvement, efficient resource use, patient-reported outcomes and satisfaction, and enhanced technology to care for patients with specific medical conditions. Providers are using Clinical Information from EHRs and Registries in Addition to Claims Data. In many cases, the critical information that distinguishes differences in patient needs is not captured in claims data, so clinical data will also be needed. Our new registry can help track appropriate clinical data that CMS can utilize in the future for a formal QCDR program for interventional radiology. The potential structure can also house quality and cost measures based on clinical pathways and patient-reported outcome measures (PROM) for diagnosing and treating specific medical conditions. CMS should allow SIR the opportunity to be able to inform CMS how these measures would replace the traditional MIPS requirements in the new, more innovative MVP framework.

AMA's recommendations: Based on specialty societies' and stakeholders' experience with the initial round of MVP co-development with CMS, the AMA makes several recommendations to refine the process, including (1) adding an MVP development criterion that MVP development is clinician-led, (2) establishing an informal process to ensure transparency and coordination among the relevant specialty societies in the development of an MVP, (3) publishing CMS' intentions for future MVP development priority areas to encourage early specialty society collaboration, and (4) clear and timely feedback about why a candidate MVP submission has not been proposed for implementation. The AMA greatly appreciates the active engagement between CMS and specialty societies in developing some of the initial seven MVPs proposed for the 2023 performance period. We have heard from several specialty societies that the initial outreach and subsequent communication from CMS were positive as CMS reached out to the specialty individually to schedule a call about a potential MVP, discussed the thinking behind the goal of the MVP and selected measures, and provided an opportunity to give input. However, we have also heard from specialty societies that they were not informed or engaged in any conversations. As a result,

we could not provide any information before a clinically relevant MVP was published in the proposed rule. Therefore, CMS should establish an informal process to ensure transparency and coordination among the relevant specialty societies in the early development.

Potentially Misvalued Services Under the PFS and Valuation of Specific Codes

Proposed: CMS is proposing several valuations to IR service codes and code sets for CY 2022, which include trabecular bone score (CPT® codes 77X01-77X04), needle biopsy of lymph nodes (38505), arthrodesis compression (CPT® codes 630XX and 630X1), destruction by Neurolytic Agent (CPT® codes 64633, 64634, 64635, and 64636), destruction of Intraosseous Basivertebral Nerve (CPT® codes 646X0 and 646X1), cholangiography and pancreatography X-Rays at surgery add-on (CPT® code 74301).

Impact:

- Trabecular bone score (77X01-77X04) - The trabecular bone score codes are new for CY 2022. Since these codes meet the definition of "imaging services," CMS proposes including them on the list of codes where the Outpatient Prospective Payment System (OPPS) cap applies. CPT® codes 77X01 and 77X03 include new TBS iNight Software supply input. A licensing fee is associated with the software; typically, this is valued as part of the indirect PE.

SIR recommendation: CMS should eliminate the limitations and restrictions on this code and make it easier to bill the service wherein both the technical service and the geographical adjustments are applied under OPPS. Moreover, CMS should not incorporate the licensure fee into the indirect PE. If physicians utilize technologies that rely on software and licensing fees, the overall cost can become extremely high. Our proposals to use crosswalks to set values for codes describing trabecular bone score would allow us to account for overall resource costs involved in furnishing the services. The possible crosswalks for Fractional Flow Reserve Computed Tomography (FFRCT) may also account for the overall resource costs involved in delivering the service. We also believe it is essential to accurately account for resource costs for innovative and emerging technologies, such as ongoing service-specific software costs. As explained above, such costs are not well accounted for in the PE methodology. We continue to be interested in potentially refining the PE methodology and updating the underlying data, including the PPIS data that is the data source that underpins the indirect PE allocation. How might CMS consider updating such data to reflect ongoing advances in technology so that we could establish appropriate relative values without resorting to crosswalks?

Impact:

- Needle Biopsy of Lymph Nodes (38505) - CPT® code 38505 (*Biopsy or excision of lymph node(s); by needle, superficial (e.g., cervical, inguinal, axillary)*) was identified through the screening process with claims submissions over 30,000. Based on changes with the service, including larger tissue samples, CMS is proposing the RUC (Relative Value Update Committee) recommendations for Work and PE RVS.

SIR recommendation: CMS should give the primary specialties that use this code time to investigate and identify the root cause of the claim submission, provide appropriate education to their providers regarding appropriate use criteria, and present that data to the RUC subcommittee or workgroup for

evaluation.

Impact:

- Arthrodesis Compression (630XX and 630X1) - The arthrodesis compression codes are new for CY 2022. The codes 630XX (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)*) and 630X1 (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)*) were recommended by the RUC.

SIR recommendation: CMS's current valuation of these codes is extremely low, cutting the recommended wRVU by almost 40%. CMS should accept the RUC recommendations recommended values (5.55 for CPT® code 630XX and 4.44 CPT® code 630X1). The RUC's methodology is transparent and precise, with clear crosswalks to existing procedures with similar valuation. CMS should also provide a detailed methodology on their proposed recommendations and their different results from the RUC.

Impact:

- Destruction by Neurolytic Agent (64633, 64634, 64635, and 64636) - Issues with the valuation of the deconstruction by neurolytic agent date back to September 2014 when the Relativity Assessment Workgroup (RAW) identified a work neutrality issue related to how they were originally valued. In the May 2015 CPT® Editorial meeting, the panel updated parenthetical notes for the five codes. Those codes describe paravertebral facet joint nerve destruction. In addition, the panel clarified that these codes are billed per joint, not per nerve. However, they were recommended for review because of the original issues with valuation and the significant growth of the use of these codes.

SIR recommendation: SIR strongly disagrees with CMS' recommendation for direct PE inputs. CMS' current valuation of these codes is inappropriate and should implement the RUC recommendations. RUC's methodology is transparent and precise, with clear crosswalks to existing procedures with similar valuation. CMS should also provide a detailed methodology on their proposed recommendations and their different results from the RUC.

Impact:

- Destruction of Intraosseous Basivertebral Nerve (646X0 and 646X1)- the destruction of intraosseous basivertebral nerve codes is new for CY 2022. CMS is not proposing the RUC recommended Work values because they are higher than other similar codes with 10-day global periods, intra-service, and total time. Instead, CMS is proposing a Work RVUs of 7.15 and 3.77, respectively. In addition, CMS is proposing the RUC recommended direct PE inputs without refinement for 646X0; since 646X1 is an add-on code, it does not have any direct PE inputs.

SIR recommendation: CMS' current valuation of these codes is inappropriate and should implement the RUC recommendations.

Telehealth and Other Services Involving Communications Technology

Proposed: CMS indicated when the American Medical Association (AMA) adopted the new guidelines for outpatient and office setting E/M visits, CMS also adopted the changes. In the months since implementation, CMS indicated a need for clarification or adjustment to previous guidelines to align all guidance more fully with the updates. The CMS specifically addressed a few areas, such as Split (or Shared) Visits, New and Established Patients, and Initial and Subsequent Visits, Payment for the Teaching Physician Services.

Impact: Broadband and audio-visual telehealth services are not accessible by all Medicare patients. We urge CMS to continue covering audio-only evaluation and management services through 2023 like the currently proposed Category 3 services. The AMA has adopted a significant policy to address equity in telehealth. We recognize access to broadband internet as a social determinant of health and encourage initiatives to measure and strengthen digital literacy, emphasizing programs designed with and for historically marginalized and minoritized populations. We also support efforts to develop telehealth technology, including voice-activated technology, with and for those with difficulty accessing technology, such as older adults, individuals with vision impairment, and individuals with disabilities

SIR recommendation: Per AMA recommendations, SIR strongly opposes the proposal to implement the previous Administration's plan to cease paying for the CPT® codes for telephone visits at the end of the PHE. Instead, these codes, 99441-99443, should be included in Category 3, and payment should be maintained for them through 2023 like the other Category 3 services. Furthermore, eliminating coverage for telephone services as soon as the PHE ends would counter this Administration's goals for improving equity for minoritized and marginalized patient populations, as stated in President Biden's Executive Order on Advancing Racial Equity and Support for Underserved Communities.

SIR appreciates and supports the following CMS proposed changes:

- Appropriate Use Criteria (AUC) - Delay the penalty payment phase of the Appropriate Use Criteria (AUC) program until January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID-19.
- Permanently adopt coding and payment for HCPCS code G2252, one of the communication-based services.
- Removal of National Coverage Determination (NCD) 220.6, Positron Emission Tomography (PET) Scans to allow the Medicare Administrative Contractor (MAC) to make the decisions of coverage per their beneficiaries. This NCD is outdated. It was created in 2000 to provide broad nation non-coverage for non-oncologic indications of PET. This created the need for every non-oncologic indication to have an individual NCD receive coverage. CMS believes by leaving this to the MACs to decide; they can provide the necessary immediate means to provide coverage for non-oncologic indications or not.

Health Inequities

Proposed: In recognition of persistent health disparities and the importance of closing the health equity gap, CMS requests information on several CMS programs to make reporting of health disparities based on social risk factors, race, and ethnicity more comprehensive and actionable for hospitals, providers, and patients.

Impact: As CMS begins to consider addressing health inequities, CMS must consider the potential unintended consequences of its proposed cuts disproportionately targeting interventional radiology services. SIR is committed to advocating for not only our physician membership but the patients that it serves. In addition, SIR is devoted to providing the necessary education to ensure that these proposed cuts do not exacerbate inequities. However, suppose CMS implements the proposed cuts. In that case, interventional radiology (IR) specialty will experience roughly 9% to 13% cut in overall reimbursement and 20% and more cuts in reimbursement for procedures treating peripheral vascular disease, end-stage renal disease, and cancer. As a result, IR practices will negatively impact 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
Venous Ulcer / Endovenous radiofrequency ablation	Black patients present with more advanced venous insufficiency than White patients ¹	Key Code (36475) Cut by 23%
ERSD / Dialysis Vascular Access	Black and Latino's patients start dialysis with a fistula less frequently despite being younger ²	Key Code (36902) Cut by 18%
Cancer / Radiation oncology	Black men are 111 percent more likely to die of prostate cancer; Black women are 39 percent more likely to die of breast cancer ³	Key Code (G6015) Cut by 15%
Peripheral Artery Disease / Revascularization	Black Medicare beneficiaries are three times more likely to receive an amputation ⁴ Latino are twice as likely ⁵	Key Codes (37225-37221) Cut by 22%
Fibroid / Uterine Fibroid Embolization	Uterine fibroids are diagnosed roughly three times more frequently in Black women ⁶	Key Code (37243) Cut by 21%

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

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

SIR's recommendation: CMS must retain the 3.75% conversion factor increase for CY 2022 Final MPFS. CMS should not implement the clinical labor pricing updates. Interventional radiology will continue providing high-quality, innovative, and cost-effective services. IR will continue fighting in the frontlines of the COVID-19 pandemic. IR will continue servicing critical life-saving procedures for those in the underserved and at-risk communities. If CMS is genuinely dedicated to closing the health equity gap, the agency should not implement the proposed cuts.

SIR appreciates the opportunity to provide meaningful feedback to the CY 2022 Proposed HOPPS. If you have any questions, please feel free to reach out to SIR's Senior Director, Clinical and Practice Affairs, Miata Koroma Ekanem, at mkoroma@sirweb.org or (703) 460-5599.

Sincerely,



Matthew S Johnson, MD, FSIR
SIR President

Cc: Keith M Hume
SIR Executive Director