

September 2, 2022

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1770-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: Comments on CMS-1770-P: Medicare Program; Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Dear Administrator Brooks-LaSure:

The Society for Vascular Surgery (SVS) is a professional medical specialty society, composed primarily of vascular surgeons, that seek to advance excellence and innovation in vascular health through education, advocacy, research, and public awareness. SVS, on behalf of its approximately 6,000 members, offers comments on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making (Proposed Rule) on the revisions to Medicare payment policies under the Medicare Physician Payment Schedule (MFS) and provisions relating to the Medicare Shared Savings Program and the Quality Payment Program for calendar year (CY) 2023, published in the July 29, 2022, *Federal Register* (Vol. 87, No. 145 FR, pages 45860-46836).

**Comments relating to revisions to Medicare payment policies under the Medicare Physician Payment Schedule (MFS)**

**Ensuring Stability**

CMS' CY2023 physician fee schedule proposed rule once again undermines the long-term financial viability of physician practices and seniors' access to critical treatments and procedures by implementing significant cuts in physician reimbursement. CMS is proposing to cut the Medicare conversion factor (CF), the starting point for calculating Medicare payments, by approximately 4.5% for CY2023. These cuts, generated by the expiration of the Congressionally mandated 3 percent boost to the CF and other statutorily mandated budget neutrality adjustments, are simply not sustainable. For the third consecutive year, physicians must again rely on Congressional action to mitigate the scheduled reductions and these year-over-year cuts are a clear

indicator that the Medicare physician payment system is broken. Systemic issues such as the negative impact of the Medicare physician fee schedule's budget neutrality requirements and the lack of an annual inflationary update will continue to generate significant instability for health care clinicians moving forward, threatening beneficiary access to essential health care services. Our policy makers, both within the Administration and in Congress, have a duty to ensure a Medicare system that provides financial stability through a baseline positive annual update reflecting inflation in practice costs, and eliminate, replace, or revise budget neutrality requirements to allow for appropriate changes in spending growth. The ongoing inadequacies associated with physician payment shine the spotlight on our flawed payment system.

### **Practice Expense**

While the SVS commends CMS for attempting to remedy parts of the flawed payment system, the 'remedies' are exacerbating the underlying problems and making it nearly impossible to responsibly practice medicine.

In this proposed rule, CMS is signaling its intent to move to a standardized and routine approach to valuation of indirect PE. CMS states that interested parties have expressed concerns regarding their approach to indirect PE allocation. They go on to say that various interested parties have taken issue with the use of certain costs in the current CMS PE allocation methodology that they do not believe are associated with increased indirect PE. Some interested parties argue that the costs of disposable supplies, especially expensive supplies, and equipment are not relevant to allocating indirect PE; or that similarly, work in the facility setting (for example, work RVUs for surgical procedures) is not relevant to allocating indirect PE, though they agree that work in the office setting may be relevant to allocating indirect PE.

CMS does not believe that there is sufficient data or peer-reviewed evidence available to definitively show that shifting indirect PE allocations based on the setting of care, or based on specialty, would result in improved allocations of PE that reflect true costs. Further, varying indirect PE allocations based on setting of care or based on specialty might create unintended consequences such as reduced access to care for beneficiaries, or reduced competition and autonomy of small group practices or individual clinicians whose revenue is based in part on services furnished under contract in the facility setting.

CMS believes it is necessary to establish a roadmap toward more routine PE updates, especially because potentially improper or outdated allocation of PE across services may affect access to certain services, which could exacerbate disparities in care and outcomes. Establishing payments that better reflect current practice costs would mitigate possible unintended consequences, such as labor market distortions due to indirect cost allocations that do not reflect the current evolution of health care practice. As part of this effort, CMS has contracted with RAND to develop and assess potential improvements in the current methodology used to allocate indirect practice costs in determining PE RVUs for a service, model alternative methodologies for determining PE RVUs, and identify and assess alternative data sources that CMS could use to regularly update indirect practice cost estimates.

CMS is seeking comment on potential approaches for design, revision, and fielding of a PE survey that fosters transparency (for example, transparency in terms of the methods of survey design, the content of the survey

instrument, and access to raw results for informing PFS rate setting) and establishes mechanisms to ensure that data collection and response sampling adequately represent physicians and non-physician practitioners across various practice ownership types, specialties, geographies, and affiliations.

CMS is seeking comment on alternatives that would result in more predictable results, increased efficiencies, or reduced burdens. For example:

- Use of statistical clustering or other methods that would facilitate a shift away from specialty-specific inputs to inputs that relate to homogenous groups of specialties without a large change in valuation relative to the current PE allocations.
- Avenues by which indirect PE can be moved for facility to non-facility payments, based on data reflecting site of service cost differences.
- Methods to adjust PE to avoid the unintended effects of undervaluing cognitive services due to low indirect PE.
- A standardized mechanism and publicly available means to track and submit structured data and supporting documentation that informs pricing of supplies or equipment.
- Sound methodological approaches to offset circularity distortions, where variable costs are higher than necessary costs for practices with higher revenue.

In addition, CMS seeks comment on the cadence, frequency, and phase-in of adjustments for each major area of prices associated with direct PE inputs (Clinical Labor, Supplies/Equipment). CMS seeks recommendations on whether they should stagger updates year-to-year for each update or establish "milestone" years at regular intervals during which all direct PE inputs would be updated in the same year. CMS would like comments on the optimal method of phasing in the aggregate effect of adjustments, such that the impacts of updates gradually ramp up to a full 100 percent over the course of a few years (for example, 25 percent of the aggregate adjustment in Year 1, then 50 percent of the aggregate adjustment in Year 2, etc.). And finally, CMS would like to know how often they should repeat the cycle to ensure that direct PE inputs are based on the most up-to-date information, considering the burden of data collection on both respondents and researchers fielding instruments or maintaining datasets that generate data.

### **SVS Recommendation: Practice Expense Data Collection**

The SVS supports consistent and timely updates to practice cost data, paired with an open and transparent process to collect the requisite updated cost data. We urge CMS to collaborate with the AMA and specialty societies on data collection issues. Specialty societies can provide key insights into how their members practice medicine. The data collection process, including survey tools, should include specialty society input to ensure the most accurate data. Open discussions with specialties, whom might need to allocate significant resources to augment the data collection process, should start early in the process. Partial, incomplete, or inaccurate data will only exacerbate problems in the fee schedule methodology.

CMS should consider a thorough and informed approach to fee schedule methodology changes, particularly related to practice expense. We have seen the wildly inappropriate shifts in payment rates directly resulting from policies implemented to ‘improve’ the system. The Medicare program was designed to provide the elderly with financial protection from the cost of medical care and, in the process, to increase access to services of high quality. The guiding principles used to protect and improve the Medicare program are<sup>1</sup>:

- Access to care
- Quality of care
- Financial protection for beneficiaries
- Equity among physicians
- Reductions in the growth of supplemental medical insurance (SMI) outlays
- Understandability
- Orderly change
- Pluralism

We must provide Medicare beneficiaries access to care and financial protections. And we must provide equity among physicians. To that end, we urge CMS to pause partial practice expense methodological changes to the fee schedule and to meaningfully engage stakeholders (i.e. town halls, AMA RUC network, etc.) in discussions regarding MFS improvements until at least 1/1/2025.

### **Rebasing and Revising the Medicare Economic Index (MEI)**

The MEI measures changes in the prices of resources used in medical practices including, for example, labor (both physician and non-physician), office space and medical supplies. These resources are grouped into cost categories and each cost category is assigned a weight (indicating the relative importance of that category) and a price proxy (or proxies) that CMS uses to measure changes in the price of the resources over time. The MEI also includes an adjustment to account for improvements in the productivity of practices over time.

In this proposed rule CMS discusses a policy they considered to rebase and revise the Medicare Economic Index. The Agency is not making proposed changes for CY2023 related to this policy; however, they are seeking comments because such a proposal would result in significant redistribution.

### **SVS Recommendation: MEI Rebasing**

The SVS appreciates CMS’ willingness to explore policies to improve the physician fee schedule. However, the MEI proposal included in this proposed rule raises more questions than it answers. The changes in the MEI that CMS is proposing are almost entirely related to the category weights. Adjusting the MEI with such a heavy reliance on these weights will result in significant specialty and geographic redistributions. The proposal includes significant decreases in physician liability payments, which seem unrealistic given the trends in the PLI premium data. CMS’s impact analysis should be expanded to consider how significant decreases in PLI payment may negatively impact geographical areas with relatively high PLI premiums.

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<sup>1</sup> <https://babel.hathitrust.org/cgi/pt?id=mdp.39015030280716&view=1up&seq=12&skin=2021>

### **Clinical Labor Pricing Update**

CY2023 marks the second year of a four-year transition to the new clinical labor cost data that will be completed in CY2025. This new CMS policy increases the source clinical labor pricing and then disproportionately cuts physician services with high-cost supplies and equipment to account for the budget neutrality requirements in place to offset the clinical labor rate increases. This update puts a huge and unfair burden on specialties that require expensive supplies and/or equipment to care for their patients. While the increase in clinical labor is appropriate, it is not appropriate that physicians, notably from a few small specialties, are negatively impacted by the change. These dramatic cuts will also further exacerbate disparities in access to care and health outcomes among rural and minority populations by constraining and in some cases preventing physicians in community-based office settings from providing critical patient care to underserved populations.

### **Angio Tech**

SVS appreciates the modest increase in the angiography technician (L041A) rate for CY2022 however, SVS continues to believe CMS should crosswalk the angiography technician to an MRI technician for rate setting purposes. 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. 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). The magnetic resonance imaging (MRI) technologist also requires a post primary pathway. Both the angiography technician and MRI technologist require a post-primary pathway to certification (after primary credentialing such as radiologic technologist), therefore, SVS recommends using 29-2035 Magnetic Resonance Imaging (MRI) Technologist as the proxy BLS wage rate for an angiography technician.

*Error in Table 5: The CY 2023 Clinical Labor Pricing for the Angio Technician be 0.60 rather than 0.58. It is also missing an \* to denote one of the three clinical labor types with a pricing increase this year. According to the preamble text, "We are also proposing the same increase to \$0.60 for the Angio Technician (L041A) clinical labor type, as we previously established a policy in the CY 2022 MFS Final Rule that the pricing for the L041A clinical labor type would match the rate for the L035A clinical labor type."*

### **Request for Information: Medicare Potentially Underutilized Services**

In this proposed rule, CMS expressed concerns regarding the potential underutilization of high value health services, particularly among potentially underserved communities. In concert with the CMS strategy to advance health equity in addressing health disparities that underlie our health system, CMS seeks to engage with interested parties and solicit comment regarding ways to identify and improve access to high value, potentially underutilized services by Medicare beneficiaries.

CMS is seeking comment on how to best define and identify high value, potentially underutilized health services. The Agency also seeks to better understand what existing services within current Medicare benefits may represent high value, potentially underutilized services.

CMS is seeking comments on ways to recognize possible barriers to improved access to high value services and how they might best mitigate some of the obstacles to care. CMS is inviting the public to submit information about specific obstacles to accessing these services and how specific potential policy, payment or procedural changes could reduce potential obstacles and facilitate better access to high value health services. Specifically, they are soliciting new and innovative ideas that may help broaden perspectives about potential solutions. Ideas may include, but are not limited to:

- Educational or marketing strategies (informed by beneficiary input) to promote awareness of available programs and resources that advance the utilization of “high value” services;
- Aligning of Medicare and other payer coding, payment and documentation requirements, and processes related to “high value” services;
- Recommendations from States and other interested parties regarding how to best raise awareness of underutilized services, with special consideration for the dual-eligible population;
- Enabling of operational flexibility, feedback mechanisms, and data sharing that would enhance the utilization of “high value” services; and
- New recommendations regarding when and how CMS issues regulations and policies related to “high value” services and how CMS can advance rules and policies for beneficiaries, clinicians, and providers.

The SVS believes the underlying issues with the fee schedule methodology and the staggered practice expense changes impact these “high value” services. We recommend CMS work with stakeholders to identify a list of “high value” services and implement corresponding incentivized payment policy for those services. The Agency can consider attaching a guaranteed percentage increase to the relative value units for each of the services, for a period of time (i.e. 5 years).

### **Valuation of Specific Codes**

CMS continues to use flawed methodologies to arrive at valuations such as time ratios, reverse building block adjustments and incremental adjustments in the valuation of specific codes. While CMS sometimes provides crosswalk codes and other reference codes with similar times in support of their proposed values, CMS’ selection process has the appearance of seeking an arbitrary value from the vast array of possible mathematical calculations, rather than seeking a valid, clinically relevant relationship that would preserve relativity. CMS’ comparison codes often seem to have been selected solely for their work RVUs to the Agency’s desired reduction and to justify similarly chosen time ratio comparisons. Significant clinical expertise of all medical specialties (including primary care) goes into developing RUC recommendations. SVS urges the Agency to thoughtfully consider all aspects that go into developing RUC recommendations (i.e. time, intensity, magnitude estimation, etc.) instead of relying solely on simple mathematical computations.

**Refinement Process/Appeals Process**

In 2016, CMS permanently eliminated its Refinement Panel process by making the nomination requirements so specific that no services could be eligible going forward. For two decades, the CMS Refinement Panel Process was considered by specialties like SVS to be an appeals process. The complete elimination of the Refinement Panel discontinued CMS' reliance on outside stakeholders to provide accountability through a transparent appeals process. SVS recommends that CMS create an objective, transparent and consistently applied formal appeals process that can act as a peer-review to the work / time changes the Agency proposes.

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

In July 2020, CMS created two HCPCS codes that describe two approaches to percutaneous arteriovenous access creation: 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*) and 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*). In October 2021, the CPT Editorial Panel created CPT codes 368X1 and 368X2 to describe the creation of an arteriovenous fistula in an upper extremity via a percutaneous approach. HCPCS codes G2170 and G2171 were proposed to be deleted and replaced with CPT codes 368X1 and 368X2, which specifically represent two percutaneous approaches to create arteriovenous access for End-Stage Renal Disease (ERSD) patients during hemodialysis.

**CPT Code 368X1**

CMS disagrees with the RUC recommended work RVU of 7.50 for CPT code 368X1 and proposes a work RVU of 7.20. In their rationale, CMS notes that the RUC proposed work RVU of 7.50 is the second highest RVU within the range of reference codes they reviewed between 55 to 65 minutes of intra-service time and 94 to 114 minutes of total time, with RVUs ranging from 2.45 to 8.84. Instead of using a direct crosswalk valuation, CMS proposes a work RVU of 7.20 based on an intra-service time ratio calculation that uses the second key reference service and MPC code from the RUC survey, CPT code 36905 (*Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty*) (work RVU = 9.00, 75 minutes intra-service time, and 126 minutes total time). Using the RUC recommended 60 minutes intra-service time for CPT code 368X1, CMS divided by 75 minutes of intra-service time for CPT code 36905, then multiplying by the RVU of 9.00 for CPT code 36905 ( $(60/75) \times 9.00 = 7.20$ ). In their rationale for this methodology, CMS states that the proposed work RVU of 7.20 is supported by the reference CPT codes they compared to CPT code 368X1 with the same 60 minutes of intra-service time and similar total time, including CPT code 47541 (*Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (e.g., rendezvous procedure), percutaneous,*

*including diagnostic cholangiography when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation, new access*) (work RVU = 6.75, 60 minutes intra-service time, and 111 minutes total time) and CPT code 33991 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transeptal puncture*) (work RVU = 8.84, 60 minutes intra-service time, and 113 minutes total time). CMS believes that a work RVU of 7.20 is a more appropriate value for this procedure than the RUC-recommended work RVU of 7.50 when compared to the range of codes with the same intra-service time and similar total time.

SVS strongly disagrees with CMS' proposed work RVU of 7.20 for CPT code 368X1. The CMS proposed value of 7.20 does not reflect the intensity of the physician work associated with the service. 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 is passed through each vessel. Once a 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. When physicians who perform this procedure were surveyed by the RUC, 75% of the survey respondents selected top key reference code 36906 indicating it was a more intense and complex service to perform. Additionally, when compared to MPC code 36905 (the second reference code for this survey), 80% of the survey respondents that selected this reference code indicated the survey code was more intense and complex to perform. Therefore, CMS' usage of 36905 in their proposal was inappropriate. The values recommended by the RUC for CPT code 368X1 account for the complexity and intensity of the procedure and are supported through the survey data collected. SVS urges CMS to accept a work RVU of 7.50 for CPT code 368X1.

#### CPT Code 368X2

CMS disagrees with the RUC recommended work RVU of 9.60 for CPT code 368X2 and proposes a work RVU of 9.30, which is below the survey 25<sup>th</sup> percentile. In their rationale, CMS notes that the RUC proposed work RVU of 9.50 is the third highest RVU within the range of reference codes they reviewed between 65 to 85 minutes of intra-service time and 109 to 129 minutes of total time, with RVUs ranging from 4.69 to 10.95. Instead of using a direct crosswalk valuation, CMS proposed a work RVU of 9.30 for CPT code 368X2, which is based on an increment between the RUC for CPT codes 368X1 and 368X2. CMS' rationale for rejecting the RUC recommendation for 368X1 is flawed, as described above, and should not be used as the basis to derive a new value for 368X2. In their rationale for this methodology, CMS incorrectly asserts the use of an incremental difference between these CPT codes is a valid approach for setting values. It is inappropriate to ignore the clinical intricacies of relative services, especially within a family of codes where it is essential to maintain relativity.

The values recommended by the RUC for CPT code 368X2 account for the complexity and intensity of the procedure and are supported through the survey data collected. As with CPT code 368X1, CPT code 368X2 also

uses the percutaneous approach to create an arteriovenous anastomosis but includes additional complexity and intensity while still presenting the potential for complications, which also may require emergent embolization and/or further surgical exploration.

For CPT code 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 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 of 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. Second access into the artery increases the risk and physician intensity of this procedure relative to 368X1.

When physicians who perform this procedure were surveyed by the RUC, 90% of the physicians that selected top key reference code 36906 indicated the survey code was a more intense service to perform. Additionally, when compared to MPC code 36905 (the second reference code for this survey), 67% of the survey respondents that selected this reference code indicated the survey code was more intense and complex to perform.

SVS strongly disagrees with CMS' proposed work RVU of 9.30 for CPT code 368X2. Most importantly, CMS does not provide a rationale that would warrant the RVU to fall below the multispecialty RUC survey 25<sup>th</sup> percentile. The methodology does not adequately reflect the level of complexity involved with the service.

For additional support, the RUC reviewed 000-day global codes with 75 minutes of intra-service time, similar total times, and relative intensity with the surveyed code and found that the RUC recommended RVU maintains relativity within the payment schedule. The RUC found the CMS comparators toward the low end of the list and not comparable via intensity. The RUC offers an additional comparative MPC code 36905 (*Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transluminal balloon angioplasty, peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty*) (work RVU = 9.00, 75 minutes intra-service time, and 126 minutes total time), which has identical intra-service time, similar total time, and similar intensity to the surveyed code. The RUC maintains that CPT code 368X2 is appropriately valued at a work RVU of 9.60. SVS urges CMS to accept a work RVU of 9.60 for CPT code 368X2.

### **Practice Expense**

CMS questions several supply items for the two codes in this family. The multispecialty group included details about supply inputs SD149 *catheter, balloon inflation device*, SD152 *catheter, balloon, PTA*, SF056 *detachable*

*coil*, and SF057 *non-detachable embolization coil*. These supply inputs are typical and should be included in the direct PE inputs. CMS is also seeking clarification on why the EQ403 *Wavelinq EndoAVF generator* used for CPT code 368X2 is considerably more expensive than the EQ404 *ellipses EndoAVF generator* used for CPT code 368X1. The specialty societies submit invoice pricing for supplies and equipment. They do not have any influence on the prices that vendors set for their products. SVS urges CMS to accept the RUC recommended direct practice expense inputs for CPT codes 368X1 and 368X2.

### **Evaluation and Management (E/M) Visits**

SVS commends the Agency for accepting the work RVU recommendations for the hospital inpatient and observation codes. SVS urges CMS to finalize the published recommendations for all the inpatient, observation, and consultation E/M visits.

### **Office Visits Included in Codes with a Surgical Global Period**

SVS strongly rejects CMS' establishment of a two-tiered system for evaluation and management services. The increased 2021 valuation of the office E/M visits should be incorporated in the surgical global packages and SVS disagrees with the CMS decision to not apply the office E/M visit increases to the visits bundled into global surgery payment. The increases in the hospital visits and discharge day management services should be applied to the surgical global period. SVS continues to strongly recommend that CMS apply the office E/M visit increases to the office visits included in surgical global payment, as it has done historically.

### **Global Surgical Package Valuation**

In this proposed rule, CMS is seeking public comment on strategies to improve the accuracy of payment for the global surgical packages. SVS is insulted by CMS' ongoing argument that they do not believe physicians are performing follow-up care with their patients. Stakeholders have articulated in great detail the fatal flaws with the RAND study, which CMS uses to defend their position that physicians are not seeing patients for follow-up care. We urge the agency to follow the established process of identify individual codes as potentially misvalued if there is concern with the post operative visits assigned to a particular service. A blanket approach to address all 010-day and 090-day inappropriately impacts physicians performing surgeries.

### **Split (or Shared) Services**

CMS is proposing to delay the split (or shared) visits policy finalized in CY 2022 that requires only the physician who spends more than half of the total **time** with the patient during a split or shared visit can bill for the visit. SVS appreciates the delay until January 1, 2024, as the policy (to report only on time) would disrupt team-based care. SVS urges CMS to allow physicians to bill split or shared visits based on time or medical decision-making.

### **G2211 E/M Inherent Complexity Add-on Code**

For CY 2021 CMS established HCPCS Code G2211 *Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add on code, list separately in addition to office/outpatient evaluation and*

*management visit, new or established*) (which replaced temporary code GPC1X) as an add-on code that may be billed for visits that are part of ongoing healthcare services and/or visits that are part of ongoing care related to a patient's single, serious condition, or a complex condition. The omnibus appropriations billed signed by President Trump on December 27, 2020, delayed implementation of this code for three years until 2024.

The SVS continues to believe that code G2211 is not a separately identifiable service given the extensive changes to the office/outpatient E/M codes. Specifically, CMS stated in the CY 2019 final rule that the code was created "to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits." That rationale no longer holds true under the finalized policy of retaining the multiple levels, because physicians may bill a higher-level E/M code for such visits, based on the level of MDM or time. We note that the AMA and almost all the medical and surgical specialties agreed that G2211 was not necessary given the ability to upcode based on MDM or time.

SVS urges the Agency to delete HCPCS Code G2211 prior to the scheduled 1/1/2024 implementation. Allowing implementation of G2211 will cause further erosion to the Medicare Fee Schedule.

### **Separate Payment for High-Cost Medical Supplies**

The SVS urges CMS to separately identify and pay for high-cost disposable supplies using distinct HCPCS Level II codes, rather than bundle into the service described by CPT, so that these expenses may be monitored closely and paid appropriately. There are approximately 30 disposable supply items with prices in excess of \$1,000 and bundled into the practice expense RVU for various CPT codes. SVS urges CMS to establish HCPCS codes for high-cost supplies. The pricing of these supplies should be based on a transparent process, where items are annually reviewed and updated similar to drug pricing.

### **Payment for Skin Substitutes**

CMS is proposing several changes to their policies for skin substitute products. Specifically, CMS is proposing to change the terminology of skin substitutes to 'wound care management products' and to pay for these products as incident to supplies under the PFS beginning on January 1, 2024. SVS does not support the CMS proposed terminology change and encourages the Agency to work with specialty societies and the AMA CPT Editorial Panel to address terminology confusion.

### **New Clinical Staff Pre-Time Package for Major Surgical Procedures**

Major vascular/surgical procedures are no longer defined just by 090 day global periods. Many of the newly created (or revised) vascular procedures have been assigned 000 or 010 day global periods by CMS. To that end, there are some instances in which those 000 or 010 day procedures that require greater pre time than provided by the standard staff times package. As such, the SVS supports the creation of a new pre time package establishing an option for those 000 and 010-day global period procedures in the facility-setting that require pre-service clinical staff time corresponding with a 090-day procedure.

### **Determination of Professional Liability Insurance (PLI) Relative Value Units (RVUs)**

CMS is seeking comment on the proposed methodological improvements to the development of the professional liability insurance (PLI) premium data. CMS is proposing to change from using risk factor score, which benchmarked each specialty to the physician specialty with the lowest premiums, to a risk index score which benchmarks each specialty's premiums to the volume-weighted average of all specialties. CMS noted their understanding that this change to a risk index had no change on the actual PLI RVUs, however, it appears that this change may have in fact contributed to a technical error impacting all CPT/HCPCS codes with the Professional Component (PC)/ Technical Component (TC) split. When services have separately billable PC and TC components, the payment for the global service PLI RVU equals the sum of the payment for the TC component (reported separately using the -TC modifier) and PC (reported separately using -26 modifier).

SVS urges CMS to rectify the technical error before finalizing MP RVUs for 1/1/2023. If CMS is unable to resolve the error, we recommend that CMS delay implementation and apply the previous methodology for PC/TC codes until the technical error is corrected.

### **PE RVU Methodology and Professional Liability Insurance (PLI) RVUs – Expected Specialty Overrides for Low Volume Service Codes**

The SVS appreciates CMS' policy of using expected specialty overrides for certain low volume services. The specialty assignments for these codes are intended to appropriately represent the professional liability risk that is inherent in the code itself and reflected in the professional liability risk of a singularly qualified specialty. The purpose of assigning a specialty to these codes is to avoid the major adverse impact on PLI RVUs that result from errors in specialty utilization data magnified in representation (percentage) by a small sample size. We recommend working with the AMA RUC to ensure specialty society input on appropriate low volume service override recommendations.

### **CY 2023 Updates to the Medicare Shared Savings Program and the Quality Payment Program**

#### **1. Medicare Shared Savings Program**

**Proposed Rule:** CMS proposes changes to the Medicare Shared Savings Program (MSSP) to encourage accountable care organizations (ACOs) in rural and underserved areas and to advance health equity, including advanced shared savings payments to low revenue ACOs, inexperienced with performance-based risk Medicare ACO initiatives. Specifically, CMS is proposing the following changes to MSSP:

1. Providing advance shared savings payments to low revenue ACOs that are inexperienced with performance-based risk Medicare ACO initiatives, which are new to the Shared Savings Program (that is, not a renewing ACO or a re-entering ACO), and that serve underserved populations. Advance investment payments would include a one-time fixed payment of \$250,000 and quarterly payments for the first 2 years of an ACO's 5-year agreement period.
2. Allowing ACOs applying to the program that are inexperienced with performance-based risk to participate in one 5-year agreement under a one-sided shared savings model, in order to provide these ACOs more

time to invest in infrastructure and redesigned care processes for high quality and efficient health care service delivery before transitioning to performance-based risk.

3. Establishing a health equity adjustment of up to 10 bonus points that would upwardly adjust an ACO's quality performance score, to reward ACOs that report all-payer electronic clinical quality measures (eCQMs)/Merit-Based Incentive Payment System clinical quality measures (MIPS CQMs), that are high performing on quality, and serve a high proportion of underserved beneficiaries.
4. Extending the incentive for reporting eCQMs/MIPS CQMs through performance year 2024 to align with the sunset of the CMS Web Interface reporting option.
5. Revising benchmarking policies to incorporate a prospectively projected administrative growth factor; adjust benchmarks to account for prior savings; and reduce the impact of negative regional adjustments on ACO benchmarks by reducing the cap on negative regional adjustments and gradually decreasing the negative regional adjustment amount as an ACO's weighted-average prospective hierarchical condition category (HCC) risk score increases, or the proportion of dually eligible Medicare and Medicaid beneficiaries increases, or both.

**SVS Response:** The SVS supports the proposed changes in the MSSP to assist and incentivize physician participation in ACOs that will strengthen health care delivery systems in rural and underserved areas and make important strides in achieving health equity.

While we appreciate CMS delaying the transition away from the GPRO Web-Interface through performance year 2024 and allowing for a longer glide path, we remain concerned with the feasibility of having to begin reporting on one eCQM and all-payer data starting in 2023. While the proposed revisions may reduce administrative burden, they narrow the lens through which quality is assessed. We question whether these proposed changes will appropriately protect patients when ACOs are being financially penalized for their failure to reduce spending through a program that does not change the underlying payment system. It is also unclear how CMS decided on the proposed measure set. One of the strengths of the current set of quality measures is the inclusion of several measures related to preventive care, which incentivize providers to deliver preventive care services to their patients. Reducing preventive care may achieve short-term savings yet cause higher spending in the long-term. The shared savings methodology already gives ACOs a direct financial incentive to reduce avoidable admissions and readmissions, therefore it is inappropriate to have one-third of the quality measures focused on these narrowly defined utilization measures.

We also do not believe that CMS has struck an appropriate balance between ensuring quality of care and minimizing administrative burden in a program that has a primary goal of reducing spending. We urge CMS to consult with the ACO community and patient representatives to determine the best-balanced measure set.

We are also disappointed that CMS plans to continue to move forward with its proposals to align MSSP quality scoring methodology with the MIPS methodology. It is inappropriate to compare ACO quality performance to MIPS quality performance scores. Instead, we urge CMS to revert to the previous methods for evaluating the MSSP quality performance standard, those currently used in calculations to determine shared savings/losses

for ACOs. We also stress the importance of providing ACOs with their performance benchmarks prior to the beginning of the performance year.

## **2. Quality Payment Program**

### **Merit-Based Incentive Payment System (MIPS) Value Pathways (MVPs)**

**Proposed Rule:** CMS is proposing five new MIPS Value Pathways (MVPs) in 2023, including Advancing Cancer Care, Optimal Care for Kidney Health, Optimal Care for Neurological Conditions, Supportive Care for Cognitive-Based Neurological Conditions, and Promoting Wellness, resulting in a total of 12 optional MVPs for physicians to choose from in 2023. CMS is also proposing to add more opportunities for public comment during the MVP development process. First, prior to proposing an MVP in rulemaking, CMS will post near-final MVPs on the QPP website and solicit feedback from interested parties for a 30-day period. If CMS determines changes are appropriate, it will not notify the specialty society or other stakeholder that initially submitted the candidate MVP prior to rulemaking. Second, CMS proposes to solicit recommendations for potential updates to established MVPs on an annual basis. CMS would host an annual webinar to go over the feedback on potential revisions to the MVPs. CMS seeks comment about aligning MVPs and APM reporting requirements, how to ensure that MVP reporting serves as a bridge to APM participation, and how to reduce burden for APM participants in multispecialty groups who choose to participate in MVPs, including whether the agency should develop a process for a composite score that incorporates both APP measures and other MVP specialty measures.

**SVS Response:** The SVS appreciated CMS' outreach regarding its creation of an MVP for Stroke Care, one of the initial seven MVPs that are proposed for the 2023 performance period. We also appreciate the proposal for a public comment process on MVPs that have yet to be finalized. We believe, however, that the developers and/or specialty societies involved in the development of an MVP should be able to view and respond to public comments, are part of this process since it is the developers and medical societies who will have a more nuanced view as to how the changes suggested in the comments might be applied or related to the MVPs under consideration before they are finalized. This process will help ensure transparency and coordination among the relevant specialty societies in the development of an MVP.

Additionally, SVS would recommend that CMS alert specialties at least one year prior regarding which clinical areas CMS is considering working on for condition-focused MVPs (e.g., stroke), versus areas that will be based on "specialty," specific MVPs or areas that will be "procedure," based MVPs. We suggest that CMS consider assigning MVPs based on volume and resources (e.g., stroke centers for stroke MVP). This would help physicians and medical societies who may want to be part of efforts regarding MVP development to know how and when to formulate their ideas regarding potential MVPs which might be of interest to their members.

We understand that CMS may not be aware of all the physicians who are engaged in potential MVP development; therefore, SVS would offer several suggestions to ensure all clinically appropriate stakeholders receive notices about MVPs that are under development:

- First, CMS should publish and update on a quarterly basis a list of MVPs under consideration on the QPP website along with the MVP developer to contact for coordination.
- Second, CMS should also publish a list of its MVP priority areas, also on a quarterly basis, to alert specialty societies that they should begin to collaborate and engage with CMS to build out those MVPs and provide specific timeframes whereby CMS would open a formal notice and comment period on a specific priority area. This could mirror the process that CMS uses when it opens a concept for potential consideration for a national coverage determination.
- Third, CMS should require that all MVPs submitted around a condition or other broad clinical topic be subjected to a 60-day comment period to allow MVP developers a guaranteed opportunity for public feedback and input outside of the annual proposed rule notice and comment period. MVP developers would then be given the opportunity to revise their MVP submission during a subsequent 60-day period and then provide any needed updates to CMS.
- Finally, when CMS decides not to propose a candidate MVP for implementation that was developed by a medical specialty society, SVS urges the Agency to provide clear and timely feedback about why CMS is not moving forward with the MVP, and what, if anything, should be added, removed, or altered within the MVP that might render it acceptable and allow it to be submitted for reconsideration. Ideally, MVP development should be an iterative process. MVP creation is a resource intensive process and developers would surely appreciate the feedback. This process for clear and timely feedback should be articulated and published so that medical societies that are spending the time and resources to develop MVPs are aware of this process and also understand the criteria for MVP selection and what their options will be for re-submission if they choose to incorporate CMS' feedback. We also urge CMS to provide more clear criteria for MVP selection.

### ***MVP Subgroup Reporting***

**Proposed Rule:** Subgroup reporting will be an option for MVP participants beginning in 2023. CMS would require multispecialty groups that choose to report through an MVP to participate as subgroups beginning in 2026. CMS proposes to limit an individual physician to one subgroup. CMS would score subgroups on population health administrative claims measures and cost measures based on their affiliated group score and, if there is no group score, the administrative claims measures and cost measures would be excluded from the final score. CMS would not assign a score for subgroups that register but do not submit data for an applicable performance period.

**SVS Response:** We appreciate CMS' recognition of the importance of subgroup reporting. Consistent with our previous comments, we continue to believe subgroup reporting will be crucial to MVPs as it would facilitate participation by specialists who may be practicing within multispecialty groups. CMS needs to provide more complete proposed instructions on how the deadlines for signing up as a subgroup will work, what happens if a subgroup is not allowed to sign up by their employer and whether there

would be an option to sign up later in the year if they were able to convince their employer to allow a subgroup to form for the purposes of reporting a specific MVP.

In order to incentivize MVP reporting and make MVPs a viable path to APM participation, we again urge CMS to hold physicians harmless from a penalty for the first two years of their participation in a new MVP, similar to the phased-in implementation approach to MIPS that CMS took in 2017 and 2018. Such a transition period should be rolling and begin when a new MVP is introduced into the program.

A transition period is critical for incentivizing specialists who have been participating at a group level but would have the opportunity to move to sub-group participation in an MVP, which is potentially more administratively burdensome than reporting as a group. CMS should also consider the expenses to adopt and administer an MVP for physicians in small practices who have been reporting via electronic health records. We urge CMS to consider incentives to participating in MVPs, such as aligning scoring of MVPs with MIPS alternative payment models (APMs) and across payment systems similar to the facility-based scoring methodology.

### **Merit-Based Incentive Payment System (MIPS)**

#### ***Quality Performance Category***

**Proposed Rule:** CMS proposes that this category will continue to be weighted at 30% of the final MIPS score for 2023. No changes to Quality measure data completeness requirements were proposed for 2023, so quality measure submission must continue to account for at least 70% of total exam volume. This number defines the minimum subset of patients within a measure denominator that must be reported. However, CMS proposed to increase this threshold to 75% beginning with the 2024 and 2025 performance years.

**SVS Response:** The SVS believes that the cost to a practice of reporting any quality measures should be recognized by maintaining at least a 3-point floor regardless of practice size for each quality measure that a physician reports. SVS continues to oppose the removal of bonus points on additional outcome measures. Physicians should continue to be recognized and compensated for this increased effort through bonus points. Also, to promote the infrastructure needed to eventually allow a subgroup to report an MVP, CMS needs to continue to award bonus points for end-to-end reporting.

As we have stated in previous comments, the increased reporting requirement is counter to CMS' goals of reducing administrative burden within the MIPS program. Annual program changes such as this proposal increase the administrative burden and complexity of the MIPS program. Physicians do not stop complying with quality protocol once they hit minimum threshold requirements. However, they may just stop submitting data to CMS due to the administrative burden of data collection and reporting, especially if reporting on patient reported outcome measures and all-payer data. Physicians should be offered a bonus potential for having increased reporting requirements as an incentive to do that work instead of being penalized.

The SVS appreciates CMS' proposal to continue the data completeness criteria at 70% for the upcoming 2023 performance period and urges CMS to reconsider increasing it to 75% beginning in the 2024 and 2025 MIPS performance period. Until physicians and other eligible clinicians can work within an environment where data and care are integrated seamlessly across settings, and providers, the SVS believes it is premature to increase the data completeness requirement to 75% for 2024. It would be both reasonable and appropriate for CMS to scale data completeness with reporting burden. Until a greater number of valid claims based on other electronic health measures are available in the MIPS program, it seems unfair to increase the data completeness requirement.

### ***Cost Category***

**Proposed Rule:** Under statute, the weight of the Cost Performance Category will continue to be 30% of the final MIPS score. CMS proposes to change the designation of the Medicare Spending Per Beneficiary (MSPB) Clinician cost measure to a care episode group. Finally, CMS proposes to establish a maximum cost improvement score of 1 point out of 100 percentage points available for the cost performance category starting in the 2022 performance period, which corresponds to the 2024 payment year.

**SVS Response:** The COVID-19 pandemic has interrupted MIPS participation across three performance years so far and will continue to impact the healthcare delivery system. The MIPS program has been curtailed by the COVID-19 pandemic with cases, hospitalizations, and deaths across the United States and continued uncertainty about the impact of future waves and new variants that may arise, essentially an ongoing crisis with an unclear future/end at this time. The SVS greatly appreciates the flexibilities that CMS has put in place to hold physicians harmless from undue MIPS penalties during this time as physicians care for patients diagnosed with COVID-19. We ask that CMS continue to allow for hardship exemptions at least through 2023. We also ask that CMS consider a maximum cost improvement score of at least 5 bonus points, similar to the bonuses provided for rural and small practices in the past.

As we noted in comments to the CY 2022 fee schedule proposed rule, CMS was granted increased flexibility in the Bipartisan Budget Act of 2018 (BBA) to set the performance threshold and category weights. The SVS was disappointed that CMS chose to weight both the quality and cost performance categories at 30% in 2022 during the COVID-19 public health emergency (PHE) and we still question the validity of the cost category as the PHE continues to result in the under-representation of many procedures causing volatility in the claims. The episodes-based measures under the cost category have questionable reliability, and it is still unknown how the PHE will impact the physicians' claims data used to calculate these cost measures.

SVS continues to disagree with CMS that a 0.4 threshold for mean reliability is appropriate. Prior to the implementation of the Wave 1 episode cost measures, SVS urged CMS to include more cases in the minimum calculation of a cost measure, given our experience in review data as part of working on the Acumen TEPs and Clinical Subcommittees to develop the Wave 1 and 2 cost measures.

The minimum case thresholds should be set at the level needed for reliability and CMS and Acumen; LLC should accept the fact that this will lead to fewer clinicians being attributed the measure. We strongly urge CMS to increase the case minimums for these measures to improve reliability. At a minimum, CMS should increase reliability in the first few years that a measure is introduced into the program to ensure that it is reliably and consistently measuring resource use during an episode of care.

### ***Improvement Activities***

**Proposed Rule:** CMS will maintain the 15% weight for the Improvement Activities (IAs) category. CMS proposes to add 4 new activities and removes 5 previously adopted activities. The IAs proposed for addition are: 1) Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data; 2) Create and Implement a Plan to Improve Care for LGBTQ Patients; 3) Create and Implement a Language Access Plan; and 4) COVID-19 Vaccine Achievement for Practice Staff. The IAs proposed for removal are: 1) IA\_BE\_7: Participation in a QCDR that promotes use of patient engagement tools; 2) IA\_BE\_8: Participation in a QCDR that promotes collaborate learning network opportunities that are interactive; 3) IA\_PM\_7: Use of QCDR for feedback reports that incorporate population health; 4) IA\_PSPA\_6: Consultation of the Prescription Drug Monitoring Program; and 5) IA\_PSPA\_20: Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes.

**SVS Response:** SVS continues to encourage CMS to develop ways to automatically award IA credit to eligible clinicians performing activities that overlap with similar Quality, Cost, and PI measures.

SVS would also encourage CMS to outline the process for suspending and/or retiring IAs due to safety concerns or activities becoming obsolete to allow for IA activities to be developed that are MVP specific.

### ***Promoting Interoperability Category***

**Proposed Rule:** CMS is proposing that the Promoting Interoperability category will continue to be weighted at 25% of the overall MIPS score, with reweighting options for non-patient facing clinicians and small and rural practices. CMS has proposed modifications to Promoting Interoperability objectives and measures for participants reporting this performance category. CMS is proposing to modify the levels of active engagement for the required *Public Health and Clinical Data Exchange Objective* measures. CMS is proposing to reduce the number of active engagement options from three down to two. In addition to requiring a yes/no response for the *Public Health and Clinical Data Exchange* measures, CMS is also proposing to require physicians to submit their level of active engagement.

CMS is proposing to make the *Query of Prescription Drug Monitoring Program (PDMP) measure* a required measure beginning with the 2023 performance period. CMS is proposing to add exclusions for the measure and make it worth 10 points. CMS is also proposing to expand the scope of the measure to include not only Schedule II opioids but also Schedules III and IV drugs. CMS is proposing a third option for satisfying the *Health Information Exchange (HIE) objective* for the 2023 performance period, in addition to the two existing options.

Proposed Option 3: Participation in the Trusted Exchange Framework and Common Agreement (TEFCA). CMS also proposes to publicly report a telehealth indicator on the Physician Compare site for those clinicians furnishing covered telehealth services and utilization data.

**SVS Response:** The SVS opposes CMS' proposal to make the PDMP Query measure a required measure in 2023, as many physicians and health systems remain incapable of interconnecting their health information technology with PDMP systems.

SVS strongly urges CMS to reconsider its proposal to tie physicians' PI category success to the "all or nothing" approach proposed for the Public Health and Clinical Data Exchange objective requirements. Public health agencies' (PHA) reporting is new for many physicians. It is likely that physicians will misunderstand active engagement or exclusion requirements. Missing even a small part of the objective's requirements would mean that a physician would receive a zero for the entire PI category—significantly impacting a physician's overall MIPS performance. Moreover, PHA data infrastructure is inconsistent, and thousands of physicians rely on their EHR vendor for IT support. EHR vendors may also lack the expertise to assist physicians in electronic PHA reporting. There should be burden on EHR vendors to develop software updates to make this reporting more accurate rather than placing the burden on physicians to figure it out in order to be compliant with this all or nothing measure. There are too many unknowns, missteps, potholes, and variables in electronic PHA reporting for CMS to directly tie PI success to such a complex and unproven set of requirements. For those physicians who fail or are excluded from the objective, we recommend that CMS instead not provide points in the Public Health and Clinical Data Exchange objective but continue to score the other PI objectives as they would normally do.

### ***MIPS Performance Threshold Scores***

**Proposed Rule:** CMS proposes to maintain the MIPS performance threshold, which is the minimum score necessary to avoid a penalty, at 75 points. Under MACRA, the \$500 million exception performance bonus expires in payment year 2024, so 2023 will be the first performance period without a corresponding exceptional performance bonus and exceptional performance threshold.

**SVS Response:** The SVS strongly urges CMS to automatically apply the Extreme and Uncontrollable Circumstances Hardship Exception for the 2023 MIPS Performance Period, so that physicians are held harmless from the 9 percent MIPS penalty due to the significant, ongoing disruptions that the COVID-19 PHE is having on physician practices.

Although the rate of COVID-19 cases, hospitalizations, and deaths has decreased, the Administration has recently announced an extension of the PHE, and further extensions may be warranted. Clinicians on the front lines are still confronting challenges from the pandemic and do not have time to focus on MIPS, their patient case mix is different, and their utilization has and will continue to vary geographically as physicians in hot spots once again delay or cancel non-essential procedures. Furthermore, this may disadvantage smaller groups, who may be under resourced and unable to score as highly as larger groups.

We think all eligible clinicians and groups should be held harmless from a MIPS penalty during the 2023 performance year due to the ongoing circumstances of the COVID-19 pandemic. SVS urges CMS to continue these flexibilities until COVID cases are markedly reduced and more Americans have been vaccinated and urge CMS to make this determination sooner rather than later so physicians can focus on caring for patients during this extraordinary time.

### **Alternative Payment Models (Advance APMs)**

**Proposed Rule:** CMS is proposing to introduce a voluntary option for APM Entities to report the Promoting Interoperability performance category at the APM Entity level. The agency is clarifying that the criterion for Advanced APMs that payment must be based on quality measures can be met using a single quality measure. CMS would permanently establish the generally applicable revenue-based nominal amount standard at 8% of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for the applicable Qualifying APM Participant (QP) performance period, beginning in 2023. In addition, the agency proposes to apply the Medical Home Model 50 eligible clinician limit to the APM Entity, not the parent organization for the APM Entity. CMS is also requesting comments on (1) QP determination calculations at the individual eligible clinician level and (2) the gap in statutory financial incentives for QPs in the 2025 payment year after the APM bonus expires but before the 0.75 update to the conversion factor begins in 2026, and the difference in financial incentives between QPs and MIPS eligible clinicians beginning in 2026.

**SVS Response:** The SVS urges CMS to reconsider permanently establishing the generally applicable revenue-based nominal amount standard at 8% of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for the applicable QP performance period beginning in 2023. We believe that 8% is too high and a more appropriate and reasonable revenue-based nominal amount standard would be 3-5%.

SVS supports the proposal to take additional actions to identify changes that may occur in APM participants' organization affiliations so that their incentive payments may be correctly paid. CMS should consider developing a process that would allow physicians to notify CMS of changes in these affiliations earlier and to allow for verification of APM participation. The SVS also recommends that CMS work collaboratively with the physician community to improve payment model design and implementation so that more physicians have opportunities to voluntarily participate in APMs that support the delivery of high-quality care to their patients.

CMS recognizes that under the Quality Payment Program, Qualifying APM Participants (QPs) eligible to receive an APM Incentive Payment from performance 2 years prior are sometimes disassociated from the practice where the payment was earned. The APM Incentive Payment is sent to the organization based on the Tax Identification Number (TIN) in CMS' system. The lag time between earning and paying the APM Incentive Payment should not cause a QP who has changed practices to be denied what they have rightfully earned.

Many SVS members whose QPP participation is through an APM are unsure if they have received any of the 5% incentive money that was paid to the APM.

SVS supports the clarifications CMS is making for the APM Incentive Payments to QPs. CMS should carry out its proposal to expand the search at each step to identify potential payee TINs that are so associated with the QP so that their incentive payments can be sent to them, directly.

SVS also urges CMS to continue incentivizing participation in Advanced APMs by using every administrative level to lower the thresholds for CY 2023 as well as to work with Congress to address the statutory QP cliff in the 2025 payment year when the 5% bonus payment expires.

### **Requests for Information**

#### ***RFI: Developing Quality Measures that Address Amputation Avoidance in Diabetic Patients***

CMS believes lower extremity amputation (LEA) avoidance in diabetic patients is a priority clinical topic for development of both a process quality measure and a composite measure for MIPS. CMS is prioritizing the potential future development of a measure (Ulcer Risk Assessment and Follow-up) which would assess the percent of patients with diabetes who receive neurologic and vascular assessment of their lower extremities to determine ulcer risk, have a documented risk level, and who receive a follow-up plan of care if identified as having a high risk for ulcer. CMS is considering either adoption and modification of an existing measure or development of a new measure. CMS seeks feedback on the following questions to help development of the process measure.

1. Are neurological and vascular assessments, and the determination of risk the most important care processes in the prevention of foot ulceration among individuals with diabetes?
2. Once a process quality measure concept would be developed and implemented, would high performance on the measure contribute to a reduction in diabetes-related LEA? Why or why not?
3. Once a process quality measure concept was developed and implemented, should performance be measured at the clinician level or group level? Is the measure appropriate for all clinicians? If not, to whom should the measure apply?
4. What would be the benefits and/or unintended consequences of the process quality measure concept?

### **SVS Response:**

1. Are neurological and vascular assessments, and the determination of risk the most important care processes in the prevention of foot ulceration among individuals with diabetes?

While these are both vital for assessing risk and tracking progression, they are just that, assessment tools. Prevention of foot ulcers depends on a number of other factors including access to ongoing care, appropriate medication and footwear as indicated, control of diabetes (blood sugar), and control of additional factors contributing to the development of peripheral vascular disease including smoking, diet, obesity, and exercise.

Early identification and treatment of minor ulcers or injuries is also essential. The neurological and vascular assessments proposed will inform the intensity and cost of preventative effort required.

Peripheral neuropathy testing is part of the annual foot exam guidelines as published by the ADA. What could add a major improvement in diabetes care is a vascular study (ABI) and an assessment of diabetic neuropathy in any patients with diabetes presenting with a foot wound as part of a Diabetes MVP. Although an MVP addressing diabetes care is not directly related to vascular surgery, it directly affects patients that we treat. Some primary care physicians may do in-office “ABIs,” but these are not always accurate. SVS would recommend some standard of ABI/TBI measurement, e.g., from an ICAVL approved lab.

2. Once a process quality measure concept would be developed and implemented, would high performance on the measure contribute to a reduction in diabetes-related LEA? Why or why not?

A measure related to diabetes control and optimization would help in a multidisciplinary setting. If a particular population has better diabetes control, the incidence of major amputation will decrease. A measure centered around diabetes control that includes a neurologic and vascular assessment and maybe referral to a specialist as well would enhance its effectiveness in reducing diabetes-related LEA. However, the denominator for the measure would need to be carefully defined to ensure the measure does not lead to unnecessary interventions like angiography for just “low” ABI/TBI.

3. Once a process quality measure concept was developed and implemented, should performance be measured at the clinician level or group level? Is the measure appropriate for all clinicians? If not, to whom should the measure apply?

Performance should be measured differently between primary care and specialists as they are managing patients in a different stage of their disease. When we discuss limb loss associated with diabetes it is difficult for vascular surgeons to be held to the same set of measures as primary care. Although vascular surgeons may measure HbA1c, they usually are not seeing diabetic patients until their disease has progressed to the point when peripheral disease occurs, or they have already developed the gangrene or wounds on their feet. For these reasons, we believe this measure would not be appropriate for specialists, who are seeing patients after an ulcer has been identified, but rather the measure will be appropriate for primary care providers at the group level within the same specialty, and those treating the patients’ underlying conditions who have frequent contact with the patients. We believe it would be appropriate for HbA1C levels to be a part of the MVP process correlated to the outcomes.

Some vascular assessments will necessitate non-invasive vascular lab studies, with associated costs, for which clinicians should not be responsible. The early identification of vascular disease may also prompt an increased referral to specialists, again, with an attendant increase in costs, which ideally would be offset by the reduction in costs achieved by reducing the amputation rate.

4. What would be the benefits and/or unintended consequences of the process quality measure concept?

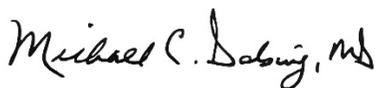
Ideally, the benefits are earlier referral and decreased amputation rates, resulting in improved patient outcomes and improved quality of life and well-being for patients. Fewer amputations would also reduce program costs. A potential unintended consequence could be overtreatment and/or over-screening in patients without an active wound, resulting in unnecessary program costs.

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The SVS appreciates the opportunity to provide comments and feedback regarding the policies included in the CY2023 Medicare Physician Fee Schedule Proposed Rule. However, and as is outlined in our comments, we remain deeply concerned with the inherent instability within the Fee Schedule and the residual impact that year-over-year payment reductions have on physician practices and the patients they serve. Absent systemic reform(s), the discrepancy between what it costs to run a physician practice and actual payment, combined with the administrative and financial burden of participating in Medicare, is limiting the viability of many private and/or community-based practices and incentivizing market consolidation, as well as driving physicians out of rural and underserved areas. None of these things are good for patient care. However, the SVS reiterates its commitment to work with all relevant stakeholders to identify and advance reforms that will ensure the Medicare physician payment system remains on a more sustainable and efficient path. We are continuing with collaborative efforts across the House of Medicine to educate and build interest among Members of Congress regarding necessary reforms and we look forward to additional engagement with the Agency to strengthen the Medicare physician payment system now, and for the future.

If you have questions regarding the SVS' comments, please contact the SVS' Director of Advocacy, Megan Marcinko, at [mmarcinko@vascularsociety.org](mailto:mmarcinko@vascularsociety.org).

Sincerely,



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