SVS | Society for Vascular Surgery

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September 10, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1693–P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-1693-P – Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

The Society for Vascular Surgery (SVS), a professional medical society composed of 5,800 specialty-trained vascular surgeons and other medical professionals who are dedicated to the prevention and cure of vascular disease, offers the following comments on the Centers for Medicare and Medicaid Services' (CMS) Calendar Year (CY) 2019 Medicare Physician Fee Schedule (MPFS) Proposed Rule.

SVS will address the following issues in our letter:

1. Evaluation and Management Code (E/M) Modifications
2. Market-Based Supply and Equipment Pricing Update
3. Update on the Global Surgery Data Collection
4. Peripheral Artery Disease (PAD) Rehabilitation (CPT code 93668)
5. Removal of Intraperitoneal Catheter (CPT code 49422)
6. Scope Proposals for CY 2019
7. Proposed 2019 MIPS Program
8. Advanced Alternative Payment Models

I. CY 2019 Updates to the Medicare Physician Fee Schedule

Minimizing Documentation Requirements by Simplifying Payment Amounts

CMS is proposing changes to the documentation and reporting requirements for E/M office visit codes. The Agency is proposing these modifications to reduce documentation burden for physicians. CMS proposes a single set of RVUs and payment under the PFS for new patient office/outpatient E/M visit codes 99202 through 99205 with a work RVU of 1.90 and a single set of RVUs for established patient

E/M visit codes 99212 through 99215 with a work RVU of 1.22. CMS believes that the burden associated with documenting the selection of the level of E/M service arises from not only the documentation guidelines, but also from the coding structure itself.

CMS states that their intent with this policy change is to reduce documentation burden on clinicians. SVS fully supports CMS taking on this important initiative of putting 'patients over paperwork.' However, we cannot support the collapse of payment for this set of E/M office visit codes. We believe strongly that there are varying levels of E/M services that require different resources and a multiple level system should remain. We believe the documentation guidelines should be updated to reflect current medical practice. We recognize that CMS is eager to accomplish efforts to streamline the E/M documentation process effective January 1, 2019. However, we believe more time is needed for the medical community to thoughtfully consider changes to the E/M CPT Codes. SVS urges CMS to work with the new AMA CPT/RUC Evaluation and Management Workgroup to improve the E/M documentation and reporting process.

Accounting for E/M Resource Overlap Between Stand-Alone Visits and Global Procedures
CMS proposes to reduce payment by 50% for the least expensive procedure or office E/M visit that the same physician (or a physician in the same group practice) furnishes on the same day. CMS expressed concern about overlapping resource costs that are not accounted for when a standalone E/M office visit occurs on the same day as a global procedure. To correct the perceived overlap of resources, CMS proposes to add the office/outpatient E/M codes 99201-99215 to the MPPR list by changing the payment indicator to "2" although how this is to be implemented is not made clear in the rule. CMS is also not clear if this would apply only to office visit E/M codes with modifier 25 appended.

We note that vascular study codes do not have a global period. These codes are assigned "XXX" (*global concept does not apply*). In addition, the vascular study codes are currently assigned an MPPR indicator "6"*(Subject to 25% reduction of the second highest and subsequent procedures to the TC of diagnostic cardiovascular services, effective for services January 1, 2013, and thereafter).* We are concerned with the Agency's MPPR proposal for office visit E/M codes because some Medicare Contractors have started to require that providers append a modifier 25 to their E/M claims when performed on the same day as a vascular lab service for the same patient. Both services are currently paid in full. There is no overlap in resources between the E/M and the vascular lab study and urge CMS to be clear that XXX services are not subject to MPPR policy when performed on the same day as vascular study.

More importantly, we oppose this proposed policy to add office visit E/M codes to the MPPR policy. Both CMS and the AMA/RUC have identified procedure codes that are typically reported with and E/M code and have removed duplicative physician time and practice expense inputs. This includes all CPT codes (not just procedure codes) reviewed during the 2002-2004 practice expense review. If CMS is intent on implementing this policy, then it should not occur until the deleted duplicative inputs have been restored to all the codes where it has been removed.

<u>Changes to Practice Expense Per Hour (PE/HR)</u>
To achieve the new single rate for E/M office visit levels 2 through 5 services, CMS proposes to modify the practice expense (PE) methodology by blending the PE/HR across all specialties that bill E/M codes, which is then weighted by the volume of those specialties' allowed E/M services. The PE/HR specialty data is not based on specific code inputs, but instead on practice level inputs. There is no Medicare math

that would allow extracting data about PE/HR from practice level data, based on resources for all ages of patients. The Agency's proposed math is statistically not sound and distorts the relativity of the Resource-Based Relative Value Scale, which is the foundation of the current payment system. SVS has concerns that these PE modifications inappropriately impact on the relativity of the fee schedule.

In the 2007 proposed rule for CY 2008, when CMS changed the practice expense formula to its current "bottom up" methodology, there was a detailed step-by-step description regarding how the PE RVUs were calculated. CMS posted the data files needed to replicate this methodology on its website. In this current proposed rule, the PE calculation methodology description has not changed. However, the changes made to the inputs for the PE calculation are proposed to change in order to implement the E/M policy to collapse payment for E/M office visits. The change to the service volume count in the utilization file, which is the starting point for the calculation, has large and unexplained changes in volume for services compared to the actual paid claims counts available in the 2017 Physician Supplier Procedure Summary File. These changes are also greater than the changes that are documented in the analytic crosswalk file that was released with the rule. It is important to note that CMS added a specialty of "E/M" to the PE per hour file but that new category does not appear on the utilization file. Presumably the office visit codes should be mapped to the new "E/M" specialty, but exactly which codes and how this was done is not explained.

Furthermore, it appears that as a result of these changes, to accommodate the proposed E/M policy, the Indirect Practice Cost Indices (IPCI) change significantly for some specialties. These IPCI values can vary from year-to-year, but normally the changes are relatively small (+/- 1%). However, in this rule the changes are dramatic for some specialties including vascular surgery (-10%). SVS is opposed to creation of a new specialty category—E/M—that is not a specialty to make the E/M payment changes policy work. The fact that the initial proposal cannot stand on its own without bandaid add-on codes and special math speaks to how this is not a sound policy. With respect to the IPCI and the PE/HR changes, SVS urges the Agency to release all the data and the steps needed to replicate the methodology so stakeholders can further analyze the math and implications of these changes and make informed comments about the process.

We agree that physicians should be given more flexibility regarding the documentation of patient services, so they may spend more time focusing on patient care and improving healthcare outcomes. SVS appreciates CMS' efforts to reduce the administrative burden associated with documentation requirements involving E/M codes, however this proposal will not achieve those goals. We urge the Agency to delay this E/M proposal and work with the medical community to develop consensus recommendations that will effectively allow physicians to spend more time focusing on patient care.

Market-Based Supply and Equipment Pricing Update

CMS contracted with the StrategyGen to perform a comprehensive review of current supply and equipment pricing. Based on the findings from StrategyGen, CMS is proposing updated pricing for 2,017 supply and equipment items currently used as direct practice expense (PE) inputs. StrategyGen's report states their review included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis.

SVS has concerns about the approach, data and methodology used to develop these updated proposed prices. The subscription-based benchmark databases, which are referenced in the proposed rule's StrategyGen DPEI Market Research Report are not publicly available and cannot be reviewed by specialties. Without access to the information used in determining the pricing update there is no systematic way to evaluate pricing accuracy which we suspect to be grossly inaccurate.

SVS is also concerned that CMS chose not to implement StrategyGen's recommendation on repricing (researched commercial price) related to the GSA schedule. Specifically, StrategyGen recommended against using GSA pricing in their approach, however CMS still used this pricing approach. The report echoed concerns raised by specialties for years that the GSA system by design provides the lowest available prices to government purchasers and is not representative of the typical prices available to a private practice.

CMS states in the proposed rule that there has not been a comprehensive review of supply and equipment prices since 2004-2005. That is a misleading statement. Countless supplies and equipment items have been re-priced annually through the AMA RUC process. Those ongoing re-pricing efforts are based on invoices submitted by specialty societies as part of their practice expense recommendation to the RUC. SVS is extremely concerned about repricing supply and equipment items based on opaque StrategyGen data in situations where actual invoices were submitted as part of the RUC process.

The limited time provided by the open comment period does not afford specialties the opportunity to conduct a thorough review of the CMS proposed recommended prices. SVS requests that CMS delay implementing the proposed price changes and release more information about the specifics used to price each item. We do, however, agree that when correct current prices are available that CMS use the proposed four-year phase-in as an opportunity for specialty societies to continue to evaluate the new pricing and submit invoices and other pricing data as needed.

SVS urges the Agency to delay implementation of **any** pricing changes for 2019. If, however, CMS disagrees, we believe we have provided sufficient information to request that the Agency (1) maintain current pricing for EL015 and EL016 for 2019; and (2) refer repricing of these two rooms to the AMA RUC Practice Expense Subcommittee.

Vascular Ultrasound Room

To underscore our concerns about the StrategyGen work, we would like to provide information about the impact this proposal has on the vascular ultrasound room. CMS is proposing to reduce EL016 (room, ultrasound, vascular) by 57% from $466,492 to $199,449.

The vascular ultrasound room currently has four components:

General Ultrasound Room, General	$369,945
Nicojet VasoGuard P84 (PPG & lower extremity)	$35,712
Nicolet Pioneer TC 8080 (transcranial)	$57,340
Atrium Medical Vaslab	$3,495

SVS is extremely concerned about the information given to StrategyGen that resulted in such a dramatic decrease in costs. Below are some of our questions:

1. Did the contractor have the existing components and details of EL016?
2. Did the contractor search for the terminology listed or did they include pricing for different items based on different technology?
3. How did the contractor handle vendor specifications?
4. How did the contractor handle weighting if different sources were available for the same item?

We question the validity of the StrategyGen pricing. In this very limited comment period, we focused our research efforts on the PPG/LE and transcranial components of the vascular ultrasound room (EL016). We reviewed society member invoices and an external membership database, which we can only assume is similar to what StrategyGen used in their process. Our findings support the current price for both the PPG/LE and transcranial components of the vascular ultrasound room. *[Please see documentation attached to this letter.]*

If CMS had notified stakeholders about their intent to update supply and equipment pricing, we would have commented that, in order to perform an accurate review of the cost for a current vascular ultrasound room, CMS must review all of the current room components and also determine what additional pieces are typical in current practice. There are required items in a vascular ultrasound (US) room that are excluded from current pricing and more significantly from proposed pricing. Below are some examples:

Service Contracts

Service contracts are mandatory to remain operational. Service contracts are primarily used to schedule preventive maintenance on ultrasound equipment, physiologic testing equipment, software maintenance and updates, proper functioning of specialized vascular ultrasound tables so that patients are not injured when placed in positions required for a vascular ultrasound exam. Without maintenance contracts, we cannot be assured of ongoing safety of equipment, thus putting patients at risk. Accreditation requires proof that equipment is in good working order, and to assure this, service contracts are required. The potential loss of income, and disruption of services provided to patients would be significant if equipment cannot be maintained for daily use. CMS's current methodology of 5% maintenance for equipment grossly undervalues the true service contract costs realized by physicians/practices.

Ergonomic Equipment

Over 85% of Sonographers and Vascular Technologists work in pain and have experienced some type of injury because of poor ergonomics, inappropriate equipment, difficult working conditions and sick and obese patients who require extreme positioning of the sonographer to acquire the ultrasound images. Ergonomic equipment is designed to decrease injuries to the sonographer, provide support to easily injured shoulder, back and neck muscles and support the sonographer while scanning or reviewing studies. The ergonomic exam tables are unique because they are adjusted with a foot pedal, are easily raised and lowered to provide the best access to patient anatomy and have straps, rails and footboards to support patients and assure safety.

Additional Transducers

The current general and vascular ultrasound rooms (EL015 and EL016) include several transducers. However, the vascular ultrasound room has additional transducers. Below are examples of typical vascular ultrasound transducers that would be included in the vascular

ultrasound room:

- 2-7 MHz wide bandwidth, multifrequency linear array probe
  This transducer complements the 5-12 MHz linear array transducer. As stated above, the lower frequency is required to achieve the necessary penetration in larger patients and to perform adequate Doppler studies even in moderate and smaller patients. The tradeoff with the lower frequency of this transducer is reduced resolution. As a result, this transducer cannot provide the high resolution required for the more superficial 2D imaging that allows for detection of thrombi, masses, and imaging of small part structures.

- Small linear "hockeystick" linear array 6-18 MHz
  These transducers are designed for extremely superficial imaging with high resolution in the absolute near field. They are used to assess superficial vessels and are especially advantageous for intraoperative and percutaneous interventional procedures (small footprint and high resolution near field allows for direct physical application onto exposed vessels.)

- 2-5 MHz sector transducer
  With the epidemic obesity levels in the country, there are many times in which the broadband curved linear transducer has inadequate penetration, and a diagnostic visceral vascular study cannot be achieved without the use of a transducer designed specifically for low frequency imaging. Sector transducers with center frequencies near 2.0 and 2.5 MHz, although originally designed for cardiac imaging (small footprint allows for image acquisition through small intercostal spacing of the ribs), are often the only transducer capable of adequate penetration in large patients. These transducers are designed with a higher Q-factor at the expense of some bandwidth. In other words, the design trades off bandwidth for increased sensitivity at the operating frequency.

  These transducers are also used for transcranial imaging for assessment of the intracranial vessels. The attenuation through the zygomatic arch of the skull is approximately 17 dB one way (34 dB roundtrip). This enormous amount of attenuation of the sound beam penetration through the skull bone is exacerbated by the fact that the bones are of non-uniform thickness as well as curved in structure, resulted in significant refraction and beam aberration. Compounded by the fact that Doppler assessment requires reflection from Rayleigh scattering red blood cells, producing extremely weak signals, and the fact that the intracranial vessels are tiny, the transducer requirements to perform these studies are the most stringent of all transducer designs. The low frequency sector transducer is the only imaging transducer capable of adequate intracranial penetration.

Standing Stairs

In multiple published articles, the SVS and the American Venous Forum (AVF) have outlined clinical practice guidelines for the care of patients with varicose veins in the lower limbs and pelvis. Duplex scanning is recommended as the first diagnostic test for patients with suspected venous disease. Using a 4-7 MHz linear array transducer to assess the deep veins, patients must be examined in the standing position. In order to fully evaluate venous physiology and response to evocative maneuvers, the vascular technologist must stabilize the image of the vein and place

a Doppler sample volume at discrete levels within the vein to assess flow. This technique often requires the vascular technologist to kneel on the floor next to the patient, sit on the floor or squat in a very awkward position while stabilizing the patient, the transducer and the ultrasound machine. To address patient safety and stability, prevent injuries to the vascular technologist and optimize data acquisition, standing stairs have been developed for this examination. These stairs must be standard equipment for every vascular room where venous insufficiency studies are performed. Because venous insufficiency studies are lengthy and tedious, the patient often becomes restless and uncooperative. The standing stairs help stabilize the patient by providing a handrail and comfortable step for this lengthy exam. The vascular technologist can sit on an ergonomically stable chair, access the patient's veins and operate the ultrasound machine carefully and safely. It is important to note that the venous insufficiency study is a widely utilized examination. The injury rate to vascular technologists who perform this exam is the highest rate reported among all work-related injuries in ultrasound. The standing stair is critical to optimizing the exam and minimizing injuries.

Treadmill

Patients with claudication may have normal ankle systolic pressures at rest. Therefore, the treadmill evaluation may unmask arterial lesions. Collateral circulation that sustains flow at rest will be challenged with exercise, accentuating pressure gradients as flow rates are increased with exercise. Therefore, the treadmill
exam is important in detecting less severe degrees of peripheral arterial disease, providing management options that can favorably impact patient outcomes. According to Bernstein(4th Edition, Vascular Diagnosis), the treadmill exam provides the following information:

1. walking time at a constant work load
2. location, time of onset and severity of pain
3. walking pattern as symptoms appear
4. the critically important relationship between the ankle pressure response and walking time
5. the degree of improvement following arterial surgery
6. the changes in the capacity of the collateral circulation

In summary, Bernstein notes that the treadmill study simulates the activity that produces the patient's symptoms and determines the degree of disability under strictly controlled conditions. Walking on the treadmill is continued, when possible, for at least five minutes or until symptoms occur, forcing the patient to stop. The vascular technologist immediately assesses the magnitude of the drop in the ankle pressure and the time required for the patient's ankle pressures to return to resting pressure values.

General Ultrasound Room

SVS is extremely concerned with CMS' recommended pricing for EL015 (room, ultrasound, general). CMS is recommending a significant reduction of 65% from $369,945 to $130,252 for the general U/S room. CMS' careless approach to repricing the ultrasound room does not accurately account for all typical room components. Because of the closed-door nature of this proposal, stakeholders have no way of reviewing the information used to establish the proposed pricing of the room. Similar to the arguments we stated regarding the vascular U/S room, we ask whether CMS provided a list of components currently included in EL015? What instruction was giving for inclusion of probes, transducers, software, etc? What did the contractor do when they had questions about specific probe

inclusion? Revised technology/terminology?

The short comment period afforded through the proposed rule regulatory process is by no means enough time for stakeholders to thoroughly weigh in on this issue. CMS did not propose their intent to undertake such a study about pricing and did not release any data or guidelines. This is not transparent and does not allow stakeholder to provide informed comments.

Again, SVS urges the Agency to delay implementation of **any** pricing changes for 2019. If, however, CMS disagrees, we believe we have provided sufficient information to request that the Agency (1) maintain current pricing for EL015 and EL016 for 2019; and (2) refer repricing of these two rooms to the AMA RUC Practice Expense Subcommittee.

Update on the Global Surgery Data Collection

SVS encourages CMS to reconsider their regulation requiring practitioners in groups with 10 or more practitioners in nine states (Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon, and Rhode Island) to continue to report the no-pay CPT code 99024 *(Postoperative follow-up visit, normally included in the surgical package, to indicate that an E/M service was performed during a postoperative period for a reason(s) related to the original procedure)*for postoperative visits for approximately 300 services. SVS also strongly opposes the implementation of an enforcement mechanism. Requiring physicians to report this no-pay code adds additional administrative burden to an already overburdened payment system. SVS encourages the Agency to work with the RUC if they are concerned about the number of office visits associated with a particular service.

10-Day Global Period

SVS strongly opposes the elimination of 10-day global codes. We believe CMS' analysis of "robust reports of 99024", their justification to eliminate the 10-day global codes, is flawed. CMS admits that 99024 is underreported, so to base policy on those data is inappropriate. Again, if CMS has concerns with the post-operative follow-up care for a particular service, they should forward that service for review to the RUC.

RAND

SVS strongly encourages CMS to abandon the RAND survey that was piloted to collect post-operative visit data. RAND reports a very low response rate and the specialties have identified countless flaws with the survey document and process. No meaningful data will come out of these surveys and no CMS policy should be based on the flawed data.

Peripheral Artery Disease (PAD) Rehabilitation (CPT code 93668)

During 2017, CMS issued a national coverage determination (NCD) for Medicare coverage of supervised exercise therapy (SET) for the treatment of peripheral artery disease (PAD). Previously, the service had been assigned noncovered status under the PFS. CPT code 93668 (Peripheral arterial disease (PAD) rehabilitation, per session) was payable before the end of CY 2017, retroactive to the effective date of the NCD (May 25, 2017), and for CY 2018, CMS made payment for Medicare-covered SET for the treatment of PAD, consistent with the NCD, reported with CPT code 93668.

SVS was among the stakeholders that recently developed RUC practice expense recommendations for

PAD. SVS supports the CMS proposal to use the recently submitted direct practice expenses to value CPT Code 93668.

Removal of Intraperitoneal Catheter (CPT code 49422)

In October 2016, CPT code 49422 (Removal of tunneled intraperitoneal catheter) was identified as a site of service anomaly and a RUC survey was requested. The code was resurveyed using a 0-day global period for the April 2017 RUC meeting. SVS appreciates the Agency's acceptance of the RUC recommended value for CPT Code 49422.

Scope Proposals for CY 2019

SVS appreciates CMS recognition of the RUC's Scope Equipment Reorganization Workgroup. We support the CMS decision to delay proposals for any further changes to scope equipment until CY 2020 so that they can incorporate the feedback from the aforementioned workgroup. We believe working together to analyze the data and make consensus recommendations is a prudent approach to payment reform.

II. CY 2019 Updates to the Quality Payment Program

MIPS Program Details

MIPS Determination Period

CMS is proposing that beginning with the 2021 MIPS payment year, the MIPS determination period would be a 24-month assessment period including a two-segment analysis of claims data consisting of: (1) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period; and (2) a second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs.

The SVS does not support a 24-month MIPS determination period. Assessing MIPS eligibility twice is a waste of CMS resources and will cause confusion for physicians regarding when to verify their eligibility for a given reporting year. CMS is already struggling with getting updated eligibility information on to the Quality Payment Program (QPP) website for a given year. 2018 eligibility data was not available for the 2018 reporting period until March of 2018. With a 12-month reporting period for quality measures, many physicians were already behind as they were waiting to check their 2018 eligibility, in part because of the confusion surrounding whether a physician has been listed by an Alternative Payment Model as part of their network.

SVS understands that the Medicare Access and CHIP Reauthorization Act (MACRA) Law of 2015 requires that CMS use an eligibility and reporting period as close to the actual performance year as possible to make the program meaningful to physicians. However, CMS also needs to use a MIPS Determination Period that will allow for physicians to be able to check their eligibility in the preceding

December of the reporting period to determine their MIPS eligibility to be able to manage their quality reporting for the 12-month reporting period.

SVS recommends to CMS that the MIPS Determination period be a single, 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs. And, we urge CMS to use its resources to then have these results available on the QPP website for eligibility determination by December of the preceding applicable performance period. In the current economic climate for medicine, verifying a performance 2 years prior is a waste given the changing of practices and where physicians are working.

Proposed Addition of Low-Volume Threshold Criterion Based on Number of Covered Professional Services

For the 2021 MIPS payment year and future years, CMS is proposing to add one additional criterion to the low volume threshold determination—the minimum number of greater than 200 covered professional services furnished to Part B-enrolled individuals by the clinician.

SVS is concerned that CMS is adding an additional criterion for eligible Healthcare professionals to be exempted from the QPP program. If QPP is going to have the desired effect to increase the value of care for Medicare beneficiaries, then CMS needs to support that with providing support for physicians to participate versus just exempt more of them.

While most SVS members are not impacted by any of these low-volume criteria, CMS continuing to expand them does impact the availability of bonus money given the budget neutral nature of the QPP program. We are concerned that CMS is creating an environment in which the bonuses available do not cover the costs of participating in MIPS nor are there Advanced APMs in which vascular surgeons might participate. CMS needs to create a better balance here for future MIPS reporting and performance years.

Low-Volume Threshold Opt-In

Beginning with the 2021 MIPS payment year, CMS is proposing to allow an eligible clinician or group that meets or exceeds at least one, but not all, of the low-volume threshold determinations, to opt-in to MIPS.

SVS supports CMS encouraging low-volume physicians to participate in the MIPS program, and we would ask that CMS provide a report each year of the number of low-volume eligible healthcare providers that participate. SVS would request that CMS use this experience to modify their proposed Low-Volume Threshold Criteria in future years to move more physicians into value-based programs.

Group Reporting for Subgroups

CMS is considering facilitating the use of a subgroup identifier in the Quality Payment Program Year 4 through future rulemaking to allow for group reporting by Subgroups, as necessary. In addition, it has come to CMS' attention that providing a sub-group option may provide potential gaming opportunities. Therefore, CMS is requesting comment on implementing sub-group level reporting through a separate

sub-group sub identifier in the Quality Payment Program Year 4 and possibly future years of the program.

The SVS urges CMS to move forward in the Quality Payment Program Year 4 Proposed Rule and provide an option for specialty-specific subgroups within a larger TIN. SVS has long believed that CMS should create an identification option where physicians can "split TIN or group" to identify themselves as a specialty-specific group for reporting under MIPs. If physicians are only allowed to be in the TIN-identified group that they bill with, then a large proportion of physicians who are employed by large multi-specialty groups will have no meaningful experience under MIPS. Large groups will select measures that are non-specialty specific – they will not select improvement activities that are related to specialty-specific Qualified Clinical Data Registries (QCDRs) – and they will be attributed a score for the purpose of a bonus or penalty that has no relevance to the care they have provided to Medicare beneficiaries. For, example, it is very important to follow vascular surgery patients after vascular procedures yet measures covering aspects of this care are unlikely to be followed in large groups where more general measures are easily captured. Specialty-specific group reporting will allow the granularity of quality care to reach a more widely encompassing patient population.

SVS understands CMS' concern that a sub-group option could provide potential gaming opportunities for high performing physicians to come together to create a sub-group. This is a reason that SVS has always proposed that subgroups would have to be specialty specific and would have to include all the physicians for that specialty or subspecialty that are identified as practicing within the larger TIN recognized group. Another mechanism that CMS could employ to help against potential gaming opportunities is that CMS could require that all members of the specialty specific subgroup would have to report through the specialty specific Qualified Clinical Data Registry and would have to report on all the measures in the said registry to be considered a subgroup.

Subgroups could be required to apply to CMS to be a subgroup in a similar fashion as CMS has prescribed for the Virtual Group Program and CMS could review their submissions to ensure that all the high performers for a given TIN are not separating out into a subgroup and that the subgroup is specialty specific and includes all physicians within that group for that given specialty.

Data Submission Types

CMS is proposing for purposes of the 2021 MIPS payment year and future years, beginning with the performance period occurring in 2019, to allow individual MIPS eligible clinicians and groups to submit data on measures and activities, as applicable, via multiple data submission mechanisms for a single performance category (specifically, the quality measures, improvement activities, or advancing care information performance category).

Under this proposal, individual MIPS eligible clinicians and groups that have fewer than the required number of measures and activities applicable and available under one submission mechanism could be required to submit data on additional measures and activities via one or more additional submission mechanisms, as necessary, provided that such measures and activities are applicable and available to them to receive the maximum number of points under a performance category.

SVS supports CMS' proposal to allow data for each of the MIPS categories to be submitted via multiple data submission mechanisms. This will allow eligible clinicians to select the mechanism that best fits

their practice's capabilities and resources. However, we are concerned that CMS is also considering making it part of the validation process for the review of whether six measures are available for reporting by a given specialty in all mechanisms.

To mandate that an eligible clinician take on the added expense of submitting measures via two different mechanisms is not appropriate nor does it help eligible clinician practices, particularly those in private practice, to be able to cover the costs of MIPS participation. The SVS wants to ensure that this flexibility CMS is proposing is truly that, flexibility, to help those that are struggling to participate in the QPP and not a barrier created as an unintended mandate.

Quality Performance Category

Contribution to Final Score

CMS is proposing that the quality performance category comprises 45 percent of a MIPS eligible clinician's final score for the 2021 MIPS payment year.

Given the amount of resources required by SVS members and their practices to achieve the reporting of six quality measures on 60% of their patients for an entire 12-month period, SVS recommends that CMS maintain the Quality Performance Category's contribution to the final 2021 MIPS Payment Year score at 50%.

Topped Out Measures

CMS is proposing that once a measure has reached an extremely topped out status (for example, a measure with an average mean performance within the 98th to 100th percentile range), it will propose the measure for removal in the next rulemaking cycle, regardless of whether it is during the topped-out measure lifecycle.

SVS is concerned about CMS' proposal given the small numbers of cases and providers that may be reporting on any given measure and how a small sample could influence an individual year's performance.

SVS did not support a removal cycle of only 4 years, for this same reason – low volume and potential for high fluctuations in an individual measure's performance in a single year. SVS would recommend that CMS instead look at the trends in a measure's reporting history over time and then decide on a measure's removal, especially given that most new measures are not being created by medical societies and CMS is not approving many new measures each year.

Most medical societies have all but abandoned the measure development and endorsement process through the National Quality Forum. Therefore, CMS should not remove measures each year, unless they have worked with the medical society whose members are reporting that measure to create a replacement.

Removal of Quality Measures

Beginning with the 2019 performance period, CMS proposes to implement an approach to incrementally remove process measures where prior to removal, considerations will be given to several factors.

SVS opposes CMS targeting for removal measures specifically because they are process measures. Many healthcare delivery processes contribute to better outcomes for patients. SVS also opposes CMS' proposal because it does not discuss any process by which CMS would work with the specialty society that is the measure developer in their efforts to evaluate the measure for its continuance. CMS has the PQMM run process where each year measure developers work with CMS to update and maintain the MIPS quality measures. CMS needs to use this process to have a systematic process and conversation with the measure developers prior to any removal of any measures.

Cost Performance Category

Weight in the Final Score

CMS is proposing the cost performance category would make up 15 percent of a MIPS eligible clinician's final score for the 2021 MIPS payment year and then to provide for a smooth transition, CMS anticipates it would increase the weight of the cost performance category by 5 percentage points each year until it reaches the required 30 percent weight for the 2024 MIPS payment year.

SVS objects to this proposal to raise the weighting of the Cost performance category to 15% of the MIPS final score calculation for the 2019 performance year. CMS' contractor, Acumen, Inc., is still working with a multi-specialty technical expert panel to refine the Medicare Spending per Beneficiary Measure (MSPB) specifically issues regarding attribution of this cost measure to individual physicians. We believe increasing the weight of this category is problematic for many physicians as the validity of the metrics for this category are still not fully tested regarding the changes that are being developed by the Acumen technical expert panel and are not generally understood by many physicians.

This is also the case with the eight episode-based cost measures, as well. SVS was surprised to see that this proposed rule does not address several of the issues raised during field testing of the eight-episode codes measures, specifically problems with a patient being attributed multiple times to the same episode, just at different time periods. Also, issues with risk adjustment still need to be resolved. SVS urges CMS to continue to have the cost performance category make up 10% of a MIPS eligible healthcare providers final score for the 2021 MIPS payment year given the errors in episode-based cost measures and the limited number of diseases/procedures covered by the measures.

SVS also objectives to CMS finalizing specific percentage increases in the cost category for future payment years in this CY 2019 rule. In part because the cost category is still new and the measures have very limited field testing.

Episode-Based Measures Proposed for the 2019 and Future Performance Periods

Reliability

CMS is proposing a case minimum of 10 episodes for the procedural episode-based measures. CMS is also seeking comment on whether we should consider expanding the performance period for the cost performance category measures from a single year to 2 or more years in future rulemaking.

SVS is concerned that a case minimum of 10 episodes is too small of a denominator to accurately calculate a cost measure for those that only meet or barely exceed the minimum. With a threshold of only 10 cases, one outlier case, could lead to a very mis-leading episode-based cost measure result.

Given that there are only 8-episode cost measures for reporting year 2019, SVS asks that CMS use a higher case minimum of at least 20 episodes for determining if the episode measure will be used to calculate an individual physician's cost measure. SVS urges CMS to only use episode-based cost measures calculating the cost score for 2021 payment, if the use of the episode-based cost measure would be to the physician's benefit. Given the lack of real field testing and the inability of individual SVS' members to gain access to their field-testing reports, CMS does not have real scientific rigor behind the ischemic limb episode cost measure. In fact, its use in the 2019 reporting year can really serve as another year of field testing, which is needed and was recommended to Acumen by SVS last fall.

Two items regarding reliability that were not address in the proposed rule that SVS brought to Acumen's attention last fall are risk adjustment and the actual dates of the specific episodes being measured. During the initial field testing, SVS members had an extremely difficult time determining how CMS would calculate the risk scores from the information contained in the cost measure field testing reports. This is problematic because this number has a huge impact on cost. CMS does not speak to this in the proposed rule. Therefore, we believe that 2019 should be used as another year of field testing and that SVS members be held-harmless from the episode-cost measure results.

SVS understand that it is very difficult to get the details of all the chronic illnesses—yet, these are certainly captured in the hospital coding as it constitutes the case-mix index for the hospital—a vital metric for the hospital's payment. Therefore, SVS recommends that all claims data – hospital and physician – be used to gather all the patient's risk factors to allow for a complete understanding of said patient's risk-adjusted costs with these 8-episode cost measures.

Attribution Rules for the Proposed Episode-Based Measures

For procedural episode groups specified beginning in the 2019 MIPS performance period, CMS proposes to attribute episodes to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes. The reliability of Episode-based measures has not been established and there are multiple issues with identifying appropriate costs to the episode. For example, in the Hemodialysis Access Creation measure being developed, planned two stage procedures using the -58 modifier can only be captured for a limited time frame. In addition, there is no reliable way to assess the number of hemodialysis access attempts that have been made on a patient, more access attempts usually translates into fewer options for a successful hemodialysis access placement which is an important aspect of risk adjustment that cannot be captured with administrative data.

Those few SVS members who were able to gain access to their field-testing reports noted having the same patient attributed multiple times to the same provider for different episodes. This does not seem to fit with the concept of patient attribution to a single episode attributed to a single provider, and it makes the episode's cost score unreliable. The data provided is helpful from a global perspective to understand how one individual surgeon compares to the universe of everyone that is providing that episode of care. However, since the goal is to improve care, it is very difficult (if not impossible) to learn from the data

as provided in the field testing reports to improve the delivery of care. Furthermore, attribution of other provider's care to a specific patient influences the metric in an undiscernible manner. SVS believes this is an area of the episode-based cost measure reports that needs attention prior to their official use.

Promoting Interoperability (PI) (Previously Known as the Advancing Care Information Performance Category)

Certification Requirements Beginning in 2019

Beginning with the performance period in 2019, MIPS eligible clinicians must use EHR technology certified to the 2015 Edition.

SVS is opposed to this blanket requirement that all physicians regardless of specialty must use EHR technology certified to the 2015 edition. SVS believes that CMS should base the 2015 certification requirement on specific EHR modules being available and at a reasonable cost. Forcing physicians to purchase EHR systems that are substandard for their specific patient documentation needs is not in keeping with the CMS' philosophy of paperwork burden reduction. We would ask that CMS modify this requirement to reflect 2019 EHR market conditions and availability.

Proposed Scoring Methodology Beginning with the MIPS Performance Period in 2019

CMS is proposing a new scoring methodology, beginning with the performance period in 2019, to include a combination of new measures, as well as the existing Promoting Interoperability performance category measures, broken into a smaller set of four objectives and scored based on performance. The smaller set of objectives would include e-Prescribing, Health Information Exchange, Provider to Patient Exchange, and Public Health and Clinical Data Exchange.

SVS is concerned about CMS' proposal that if a physician was unable to complete one out of the four objectives they would receive a score of zero on the PI elements of the MIPS program. SVS does not support an all or nothing scoring methodology for PI. Instead, we join with our medical society colleagues in suggesting that CMS consider the approach in the IPPS final rule which states that an eligible hospital or CAH must earn 50 points or more to satisfy the program's requirements. CMS justifies this approach in the IPPS rule, and states that the "50-point minimum Promoting Interoperability score provides the necessary benchmark to encourage progress in interoperability."

As such**,** CMS should apply the same 50-point scoring standard finalized in the PIP to MIPS PI**.** In other words, physicians who earn 50 points or higher in MIPS PI should be deemed to have satisfied the category's requirements and be eligible to receive points for the PI category based on their performance, regardless of the objectives for which they receive their points.

MIPS Final Score Methodology

Small Practice Bonus

CMS is proposing a small practice bonus for the 2021 MIPS payment year specific to the quality performance category versus a practice's overall final MIPS Score.

While SVS agrees with CMS that small practices may be disadvantaged regarding resources to apply to successfully completing activities within the MIPS program, we do not agree that moving the small practice bonus to the quality performance category is the right action. It is true that the quality performance category does probably require the most resources to complete; however, by adding the bonus to only approximately half of the practices' MIPS score versus to its overall final score, dilutes the impact of the small practice bonus. Therefore, SVS would recommend CMS continue to add the small practice bonus to the final overall MIPS score for a given payment year.

Establishing the Performance Threshold

CMS is proposing a performance threshold of 30 points for the 2021 MIPS payment year. CMS believes it would provide a gradual and incremental transition to the performance threshold it would establish for the 2024 MIPS payment year, which it has estimated would be between 63.50 and 68.98 points. CMS also seek comment on its approach to estimating the performance threshold for the 2024 MIPS payment year.

The SVS has concerns with CMS raising the performance threshold at the same time it is changing the measures and requirements for Promoting Interoperability which is worth 25% of a physician's final MIPS score. Also, for vascular surgeons CMS is proposing to remove two quality measures that are specialty specific. Therefore, SVS would ask that CMS allow for some points for all of the Promoting Interoperability measures be counted even if a practice can't do one of the four objectives. This will help more practices to receive partial credit for that element.

Regarding the performance threshold for the 2024 MIPS payment year, SVS would recommend CMS use an analysis that is specialty specific and practice size specific to set the 2024 performance threshold. The MACRA law does speak to being compared to ones peers and comparison to ones peer would be a specialty specific and practice size comparison.

APM Incentive

Advanced APMs

Nominal Amount of Risk

CMS is proposing for QPP Performance Periods from 2021 through 2024 that eight percent of the average estimated total Medicare Parts A and B revenue of participating APM Entities as the revenue-based standard; or for all QP Performance Periods, three percent of the expected expenditures for which an APM Entity is responsible under the APM (the benchmark-based standard) for the nominal risk standards.

SVS greatly appreciates CMS not proposing an increase in the nominal risk factor for future performance periods. SVS continues to be concerned with CMS' statement that "8 percent... represents a reasonable standard to determine what constitutes a more than nominal amount of financial risk." We believe that it is a high nominal risk standard and does make it harder in developing Advanced APMs. Therefore, we would ask that CMS view these proposed nominal risk factors as a ceiling, not a floor for all payment years.

MACRA already provides for steep increases in financial risk requirements for Advanced APMs over time by increasing the percentage of participants' revenues that must come through the APM for participants to attain QP status. APM entities that are accountable for repaying losses under models that involve 75 percent of their 2021 revenues will be at higher financial risk than in the years when the QP thresholds are set at 25 and 50 percent of revenues coming through the APM. We remain concerned that if CMS does not provide a phase-in and some flexibility in the financial risk standard, it will discourage physicians from working to design and participate in Advanced APMs.

In addition, proceeding with the planned rise in the APM QP threshold score to 50% in FY19 and 75% in FY21 may affect advanced APM adoption by specialty physician groups. Vascular surgeons, like other specialists, treat a wide range of disorders that will be difficult to encompass under one Advanced APM, and therefore may never qualify as participants despite the potential cost and quality impact of their participation. The proposed threshold incresase will prevent physicians with broad practices from meaningful participation in value improvement under an accurate APM. Therefore, SVS discourages CMS from proceeding with this planned threshold increase.

The SVS again urges CMS to move forward with providing an APM participation option for specialty subgroups within a larger TIN by creating an identification option where physicians can "split TIN or group" to identifying themselves as a specialty-specific group.

Use of CEHRT in APMs

In 2019 for Medicare APMs and 2020 for Other Payer APMs, CMS proposes to increase from 50 to 75 the percentage of an APM's participating physicians that will be required to use CEHRT for the APM to qualify as an Advanced APM.

SVS recommends that CMS take a different approach to assessing an APMs' use of health information technology (health IT) to coordinate and improve patient care. For physicians to be successful in APMs, the SVS believes physicians need health IT that responds to and supports physician, patient, and care team interactions, not merely billing and documentation.

Instead of requiring that 75 percent of APM participants use CEHRT, CMS should retain the current 50 percent requirement and allow APM entities to attest that APM participants are using health IT in some fashion to support the clinical care improvement interventions proposed in the Advanced APM. For instance, in addition to using certified EHRs, APMs would be able to attest to using customized messaging or care coordination technology developed for the unique needs of the patients in that APM or to support the integration of other clinical care tools such as evidence-based clinical practice guidelines. This approach balances the importance of using CEHRT while rewarding APMs for using innovative technology that meets physician and patient needs.

Need Better Process for Approval of More Advanced APMs for Physician Specialists

SVS has significant concerns that as we enter the third QPP performance year, participation in APMs is still not a viable option for the majority of physicians. To date, none of the stakeholder models recommended to the Secretary by the Physician-Focused Payment Model Technical Advisory

Committee (PTAC) is being tested. Better APMs are needed that would address problems in the fee-for-service (FFS) payment system and correct important weaknesses in the current CMS models. Many specialty societies have been working to develop such APMs, and they need support from CMS to put them into operation. SVS is one of these specialty societies.

We encourage CMS and CMMI to consider how the physician community and the agency can better collaborate to improve the availability of APMs, the number of physicians participating in them, and the number of Medicare patients receiving care through APMs. The SVS stands ready to assist CMS/CMMI in working together to establish Advanced APMs for vascular surgeons.

Proposed MIPS Quality Measures

New Quality Measures for 2019

Ischemic Vascular Disease – Use of Aspirin or Anti-platelet Medication:

The percentage of patients 18-75 years of age who had a diagnosis of ischemic vascular disease (IVD) and were on daily aspirin or anti-platelet medication, unless allowed contraindications or exceptions are present.

SVS has several concerns with this measure that were voiced to the National Quality Forum during the Measure Application Partnership process. First, does this measure relate to acute or chronic conditions and what specific conditions are included in the dominator for this measure? SVS believes this measure is too broad and could be better defined prior to use.
But, the main problem here with this measure is attribution. IVD encompasses many conditions that are cardiac related. Patients that vascular surgeons treat are usually for a one-time consultation and they have the specific condition of coronary artery diseae. While vascular surgeons can advise regarding medications, our recommendation is only that –effectively a recommendation to the referring physician. So, this measure does not replace MIPS measure #257.

Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years

Vascular Surgery: Measures Proposed for Removal

Quality ID #257 (NQF 1519): Statin Therapy at Discharge after Lower Extremity Bypass (LEB) – National Quality Strategy Domain: Effective Clinical Care:

Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge

Statins are a completely different class of medications from antiplatelet medications and have a different mechanism of action. Statins have been shown to improve outcomes after lower extremity bypass, even in patients who do not have hyperlipidemia. For this reason, statins are recommended for all patients after lower extremity bypass to improve patency and mortality. Therefore, this measure is not duplicative of the new measure for Ischemic Vascular Disease – Use of Aspirin or Anti-platelet Medication proposed for 2019.

Quality ID #423 (NQF 0465): Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy - National Quality Strategy Domain: Effective Clinical Care:

Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent) within 48 hours prior to surgery and are prescribed this medication at hospital discharge following surgery

An important part of this measure is its timeframe. In many institutions, anti-platelet agents are stopped 7 days prior to any procedure/operation. This often is done by providers other than the operating surgeon, such as anesthesia pre-op clinic or primary care providers. Ensuring that the patient STAYS on the antiplatelet agent in the pre-operative period often requires extra effort and coordination. This measure emphasizes the importance of that extra step and SVS would urge it be maintained for 2019.

In general, these measures are being proposed for removal due to being covered by broader measures that will be presumably under the control of primary care physicians. There are limited quality measures for surgical specialists. These are patients in whom vascular surgeons are charged with managing their care—at the very least the aspect of their care related to the surgical procedure we performed. The benefit of statins has been well-documented and to not prescribe it is almost malpractice. SVS would urge CMS to not remove these measures for 2019.

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The SVS appreciates the opportunity to provide comments on this Proposed Rule. If you have any questions or need additional information, please contact Mindi Walker, Director of the SVS Washington Office at mwalker@vascularsociety.org or 202-787-1220.

Sincerely,

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