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June 27, 2016

The Honorable Andrew Slavitt Acting Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-5517-P P.O. Box 8013 Baltimore, MD 21244

## RE: CMS-5517-P: Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule and Criteria for **Physician-Focused Payment Models**

Dear Acting Administrator Slavitt:

The Society for Vascular Surgery (SVS), a professional medical society composed of 5,400 specialtytrained 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 & Medicaid Services (CMS) Proposed Rule on MIPS and APMs and criteria for Physician-Focused Payment Models in the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015:

#### **Concerns Regarding the Quality Payment Program**

The SVS was very supportive of repealing the Sustainable Growth Rate formula, streamlining the three quality reporting programs – Physician Quality Reporting System (PQRS), Value-Based Payment Modifier and Electronic Health Records Incentive Program into the new MIPS and providing incentive payments for participation in APMs. However, we have the following concerns with the proposed **Quality Payment Program:** 

#### **MIPS Program Details**

#### **MIPS Eligible Clinician Identifier**

CMS is proposing to use multiple identifiers that allow MIPS eligible clinicians to be measured as an individual or collectively through a group's performance. CMS is also proposing that the same identifier be used for all four performance categories; for example, if a group is submitting information collectively, then it must be measured collectively for all four MIPS performance categories: Quality, Resource Use, Clinical Practice Improvement Activities (CPIA) and Advancing Care Information.

As stated in our comments on the Request for Information (RFI), CMS needs to create an identification option where physicians can "split TIN or group" for the purposes of identifying 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 most physicians will have no meaningful experience under MIPS. Large groups will select measures that are non-specialty specific, they will not select CPIA 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 nothing to do with the care they have provided to Medicare beneficiaries.

MACRA was created with the intent of physicians being compared to their peers and to those that perform a similar case mix. Large group reporting does not support that premise.

Also, the large groups will be heavily favored to receive the bonus versus small to medium-sized practices or individual reporting because they will all receive the same performance score regardless of whether they contributed to any of the activities or measures reported.

#### SVS believes this is a fundamental and very important element of the Quality Payment Program under MACRA and that it needs to be corrected such that specialty specific sub-groups under a larger TIN can be identified as a group for the purposes of reporting and receiving a composite score before the start of the first reporting period in 2017.

## MIPS Performance Period

MIPS applies to payments for items and services furnished on or after January 1, 2019. Section 1848(q) (4) of the Act requires the Secretary to establish a performance period (or periods) for a year (beginning with 2019). Such performance period (or periods) must begin and end prior to such year and be as close as possible to such year. CMS is proposing that for 2019 and subsequent years, the performance period under MIPS would be the calendar year (January 1 through December 31) two years prior to the year in which the MIPS adjustment is applied.

SVS joins with its fellow medical societies in urging CMS to establish an initial transitional reporting period from July 1, 2017 – December 31, 2017 for the 2019 payment period. MACRA is very clear that the reporting period should be as close to the performance period as possible and CMS needs to use this flexibility to delay the start of the 2017 reporting period. SVS believes it is necessary for CMS to recognize the fundamental changes enacted as part of MACRA and treat the first year as a transitional period that allows physicians to move away from the existing Medicare reporting requirements, learn about MIPS and implement workflow and system changes to become successful MACRA participants.

Specifically, we urge CMS in the first six months of 2017 to offer opportunities for physician practices to meet in person or via teleconference with CMS officials or with those that CMS has contracted with for technical assistance and present their plans for reporting and receive verification that they are not making any operational mistakes.

CMS states that it intends to develop a validation process to review and endorse a MIPS Eligible Clinician's ability or inability to report on the quality performance requirements, and that the process will function similar to the Measure Applicability Validation process under the PQRS program. This validation process needs to be ready by January 1, 2017 and available to physicians to use as part of their technical assistance from CMS prior to this new July 1, 2017 start date.

As a practical matter, starting MIPS on July 1, 2017 rather than January 1, 2017 provides additional time between the issuance of the MACRA Final Rule and the start of the reporting period specifically for practice. Physicians need to be educated about the new requirements and change their practices to accommodate the MIPS program. The Final Rule on MACRA implementation will not be released before the fall of this year, leaving participants with only a few months before the proposed start date. Without adequate notice of final program requirements, CMS is setting up the program for potential failure.

# **MIPS Category Measures and Activities**

# Performance Category Measures and Reporting

CMS is proposing to allow MIPS eligible clinicians and groups to submit data for different performance categories via multiple submission mechanisms. However, CMS is encouraging MIPS eligible clinicians to submit MIPS information for the CPIA and Advancing Care Information performance categories through the same reporting mechanism that is used for quality reporting.

SVS appreciates that CMS has agreed with our comments on the RFI regarding retaining all of the various reporting options for submitting data and information under the MIPS program. While we understand CMS' interest in trying to move the reporting to a "one stop" method, it is not easy or without financial implications for a registry to add all the data fields to allow for its members to be able to report their CPIA and their Advancing Care Information elements via a QCDR registry. **SVS would ask that CMS make some of the \$15 million per year in quality measure resources available via contract to physician society-led registries to enable the addition of the data elements that would be needed to allow for CPIA and Advancing Care Information to be reported via specialty society owned registries.** 

# Submission Criteria for Quality Measures Excluding CMS Web Interface and CAHPS for MIPS

CMS is proposing that for the applicable 12-month performance period, the MIPS eligible clinician or group would report at least six measures including one cross-cutting measure (if patient-facing) and including at least one outcome measure. If an applicable outcome measure is not available, CMS is proposing that the MIPS eligible clinician or group would be required to report one other high priority measure (appropriate use, patient safety, efficiency, patient experience, and care coordination measures) in lieu of an outcome measure. If fewer than six measures apply to the individual MIPS eligible clinician or group, then we propose that the MIPS eligible clinician or group would be required to report one other high priority descent that is applicable.

Again, **the SVS appreciates CMS taking our comments on the RFI into consideration and reducing the number of quality measures required for reporting.** However, we still do not agree that specialty physicians need to report a cross-cutting measure as these measures are all primary care activities. We also recommend that CMS support the reporting of new quality measures by physicians by creating a safe-harbor for the scoring of the performance on these measures.

And, we urge CMS to create a process in the first six months of 2017, during the transition period, that would allow physicians to submit the list of measures they are or their group is going to report on for 2017 and receive a written reply from CMS that those are acceptable measures.

In addition to the six quality measures selected by the physician, CMS is also proposing to potentially assess a physician on three population health measures (acute and chronic composites and all-cause hospital readmission measure). The SVS is very concerned with the transparency of these measures, including their specifications and scoring methodology.

## Data Completeness Criteria

To ensure completeness for the broadest group of patients, CMS is proposing individual MIPS eligible clinicians or groups submitting data on quality measures using QCDRs, qualified registries, or via EHR need to report on at least 90 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the performance period. For Individual MIPS eligible clinicians submitting data on quality measures data using Medicare Part B claims, they would report on at least 80 percent of the Medicare Part B patients seen during the performance period to which the measures applies.

CMS is proposing to include all-payer data for the QCDR, qualified registry, and EHR submission mechanisms because we believe this approach provides a more complete picture of each MIPS eligible clinician's scope of practice and provides more access to data about specialties and subspecialties not currently captured in PQRS.

**SVS is very concerned regarding this proposed increase in data completeness requirements compared to the current PQRS program**. We understand that CMS believes it would be easier if physicians just reported on everything from a workflow perspective, but this is not the case and the personnel requirement to capture and report all of this data is very cost prohibitive. Creating these high thresholds causes an environment with little room for error and it will mean more errors and more possibility for the failure of many participants.

The large administrative cost and burden with collecting this amount of information, especially when coupled with the new requirement of reporting on "all-payer" data using a QCDR, registry, EHR, or web-interface is not practical. CMS states that it wants to incentivize electronic reporting, especially registries and QCDRs; however, its proposal does the opposite—by placing the highest thresholds for these data submission methods, physicians will be deterred from using them and may prefer to stay with claims and other types of reporting mechanisms.

Also, SVS is concerned with what CMS is planning to do with the all-payer data and what obligation SVS members have with their private insurance contracts to safeguard this data that would now be in CMS' hands. SVS believes that Medicare should only collect and make payment decisions on Medicare data.

A 50 percent threshold is simply a more realistic reporting level that acknowledges potential problems, such as a vendor not updating measure specifications at the start of the reporting period, a practice

switching EHR vendors, power outages, inaccurate coding or natural disaster. Therefore, **SVS urges CMS to reduce the quality reporting threshold back to 50 percent.** 

#### Resource Use Performance Category

CMS is proposing to start with existing condition and episode-based measures, and the total per capita costs for all attributed beneficiaries measure (total per capita cost measure). All resource use measures would be adjusted for geographic payment rate adjustments and beneficiary risk factors. In addition, a specialty adjustment would be applied to the total per capita cost measure.

The SVS believes the proposed resources use category of MIPS carries over many of the problematic areas of the Value-based Modifier, including using measures that use hospital costs that physicians have no control over and have no say in how they are set by the hospital. The proposal also fails to make needed improvements in several key areas, such as attribution and risk adjustment, which are necessary to make this category valid for physicians and to delete total per capita cost measures and Medicare spending per beneficiary, unless they are physician Part B costs only.

# In light of these shortcomings, the SVS urges CMS to use the discretion in the MACRA law to reduce the percentage on the resource category in year one, 2017 performance for 2019 payment to five percent, with the remaining five percent being re-attributed to CPIA.

#### Episode-Based Measures Proposed for the MIPS Resource Use Performance Category

CMS is proposing to calculate several episode-based measures for inclusion in the resource use performance category for a variety of conditions and procedures that are high cost, have high variability in resource use, or are for high impact conditions.

SVS is concerned that CMS is proposing to use untested episode measures that attribute cost and that for the vascular surgery-related episodes, the comments are not even due until August 15. More time is needed to fine-tune and test the proposed episodes prior to their implementation.

Also, to achieve true transparency, there needs to be more specific information shared with clinicians on the risk adjustment methodology and on the concept of the specialty specific adjustment. **SVS urges CMS to hold town hall meetings this summer where it showcases several scenarios and receives feedback from the medical society community.** While only a small section in the MACRA law, the concept of risk adjustment was a major tenet of this new program and so far it has received very little attention from CMS.

MACRA specifically requires that measures of resource use "shall include results from the methodology to develop Care Episode Groups, Patient Condition Groups, and Patient Relationship Categories". We strongly urge CMS to use this opportunity to work with medical specialties to identify and refine those episodes that seem most promising and then pilot-test them with groups or individual physicians. Again, this would be another opportunity for face-to-face meetings this summer between CMS staff and medical society leadership.

#### Attribution for Individual and Groups

CMS is proposing to evaluate performance at the individual and group levels. For MIPS eligible clinicians who are reporting as individuals, CMS proposes to attribute resource use measures using

TIN/NPI rather than TIN. For those reporting as a group, CMS is proposing to attribute resource use measures at the TIN level – i.e. the group TIN under which they report.

# SVS believes that physicians should be compared to their peers both on quality and on resource use. And, we believe that a peer should be defined as any physician that is performing the same types of procedures with a similar patient /case-mix in the same region of the country.

As stated above, we have concerns regarding the inflexible nature of group reporting at the TIN level and the ability of a department or smaller group of physicians within a large TIN identified group to report together and be compared to their same specialty groups that treat the same type of patients. Under the proposed attribution model for groups, physicians reporting as a group could be measured on resource use that has nothing to do with the care they provide and we do not believe that is very meaningful to physicians. Nor do we believe it will help to lower overall healthcare costs through better clinical choices.

# Clinical Practice Improvement Activity (CPIA) Category

#### Submissions Mechanisms

For the purpose of submitting under the CPIA performance category, CMS is proposing to allow for submission of data for the CPIA performance category using the qualified registry, EHR, QCDR, CMS Web Interface and attestation data submission mechanisms. Regardless of the data submission method, all MIPS eligible clinicians or groups must select activities from the CPIA Inventory provided in this Proposed Rule.

The SVS appreciates the long list of CPIAs included in the Proposed Rule and is pleased that physicians can select from any of the identified activities. However, we are concerned that many of the activities on the list are primary care focused versus specialty care focused and we would ask that CMS be aware of this and take it into account in the annual process it will be putting in place to add additional CPIAs in the future.

We support the shorter, 90-day performance period that will allow physicians to become accustomed to reporting on these activities. And, we encourage CMS to make it a simple web-based attestation process where it is a list of the activities which physicians can select that they have been doing for at least 90 days and what the time frame for those 90 days was.

Finally, SVS reiterates its comments from the RFI that all Continuing Medical Education (CME) activities should be included on the list of acceptable CPIA for the 2017 reporting year. These activities are about life-long learning and providing better patient care and should be included in the first year of this program.

#### Weighted Scoring

CMS is proposing a differentially weighted model for the CPIA performance category with two categories: Medium and High.

CMS is also proposing to set the CPIA submission criteria under MIPS, in order to achieve the highest potential score of 100 percent, at three high-weighted CPIAs (20 points each) or six medium-weighted CPIAs (10 points each), or some combination of high and medium-weighted CPIAs.

**SVS urges CMS to reduce the number of activities required for reporting in year one of this CPIA program.** The cost to a practice of increasing or adding six new activities, including possibly participation in a QCDR is very expensive and time consuming for a practice. A maximum of three **CPIA activities should be the bar set by CMS in year one.** Also, participating in the quality **improvement activities of a QCDR should be seen as adequate to achieve the entire year one reporting score.** 

The SVS urges CMS to make all QCDR related CPIA activities as rated "High", given the resources needed by a practice to participate in a QCDR and also the impact that registry participation can have on a practice's quality of care.

The SVS also asks that CMS include specialty society CME related activities on the list of acceptable CPIAs. These activities take up considerable time for physicians but ensure patient care is of the highest quality and reflects the latest medical knowledge and innovations. While some proposed CPIA activities could be satisfied through CME, we believe a more explicit recognition would help physicians understand whether all CME will count under the CPIA component of MIPS.

CMS needs to take into consideration the fact that the CPIA category will typically only count for 15 percent of the overall MIPS composite score and should not require the same level of reporting and expense (e.g., six measures) as the quality component, which is weighted at a much higher 50 percent.

Also, the amount of effort required for APM participation is the reason that Congress put into MACRA that it earns *a minimum* one half of the highest potential score for the CPIA performance category (emphasis added). Many APMs already include requirements that are similar to the activities listed as CPIAs. **CMS should finalize for 2017 that any APM participation would be sufficient to earn the full category score for CPIA.** 

# Advancing Care Information (ACI) Performance Category

Under MIPS, CMS is proposing to align the performance period for the ACI performance category with the proposed MIPS performance period of one full calendar year. Under this proposal, MIPS eligible clinicians would need to submit data based on a performance period starting January 1, 2017, and ending December 31, 2017, would need to possess certified EHR technology and report on the objectives and measures. CMS recognizes that stakeholders may still have concerns related to a full year performance period.

The SVS is confused by CMS' proposal for ACI given its statements regarding its desire to simplify the reporting requirements relative to the overly burdensome requirements under Meaningful Use Stage 3. In many instances, the ACI category is largely unchanged from MU Stage 3—for example, it remains a pass-fail program and retains the same prescriptive measures.

We find the ACI performance category to be confusing and compliance-driven rather than physician and patient-centric. The SVS believes that it should be a simple program where a physician attests to 3-4

main elements – like protocols in place to protect patient PHI and ability to share data with the hospital and other providers. **CMS should take immediate action to reduce the overall complexity of the ACI category**.

The SVS urges CMS to continue to provide for the existing hardship exceptions and to have a 90-day reporting period. Also, all elements of the program should be graded based on where the physician's practice is in adopting the measure or needed EHR activity, not the proposed binary, pass/fail system.

#### Base Score

To earn points toward the base score, a MIPS eligible clinician must report the numerator and denominator of certain measures specified for the ACI performance category, which are based on the measures adopted by the EHR Incentive Programs for Stage 3 in the 2015 EHR Incentive Programs Final Rule, to account for 50 percent (out of a total 100 percent) of the ACI performance category score.

As proposed, the base score carries over the problematic all-or-nothing structure of the current MU program: if a physician fails to report/attest to just one requirement, the physician earns a zero for not only the base category, but the *entire* ACI category. Missing one base measure earns a zero score regardless of whether that physician achieved 100 percent on every other ACI requirement. CMS' justification for retaining this approach is that the base score only requires simple yes/no or one patient reporting for each measure. Yet, by using this scoring, CMS maintains a structure where failure to report does not simply harm your performance but renders all of your other efforts meaningless. The potential for complete failure due to inadvertent error or mistake continues to dominate the program, and the incentive to try is diminished. **The SVS absolutely opposes this all-or-nothing scoring system.** 

To correct this proposal, CMS should award credit for each measure reported under the base score, and make clear that physicians will not fail the entire ACI category if they fail to report all base measures. This allows the base score to reflect a physician's actual progress in achieving the objectives.

#### Performance Score

Similar to the Quality score and the Resource Use score, the SVS believes the proposed performance score for ACI is extremely complex and creates significant barriers to achieving CMS' goals of a program that is simplified, allows flexibility in selecting measures, and encourages innovation. As such, we believe this portion of the ACI category requires significant changes and should not be finalized in its current form.

As proposed, the ACI category adopts the same flawed EHR Stage 3 measures opposed by the majority of physician societies and does not provide a clear path away from process measures. EHR developers will continue to rely on these requirements as a roadmap for product design that hindere usability, and certain specialties will continue to have no relevant technology measures for their practice. Physicians are not computer programmers and thus are unable to identify how systems designed to meet proposed ACI measures will be able to support their needs as they transition to new payment models.

At least for the 2017 reporting and 2019 payment year, CMS should finalize the base score performance, with the suggested changes by the SVS, as the entire ACI program. This will allow CMS to work with specialty societies to develop proposals for more relevant measures and then count these measures as part of the performance category in 2018. Mirroring the quality category, specialties could identify a group of ACI measures that are more relevant for their practices. CMS could also leverage the proposed CPIA and utilize existing but relevant ACI measures or adopt new ones to facilitate reporting on these activities, including activities related to closing the referral loop, timely communication of test results, and updating plans of care. This would not only improve the relevance of measures, but would help bridge the different MIPS components, creating a more integrated program.

SVS understands that this approach is a major shift from the proposed ACI structure. At a minimum, we request that CMS outline a process for simplifying the ACI program for 2017 reporting and a process for considering new ACI measures. In every other MIPS category, CMS has defined a way for stakeholders to propose new measures or activities to include in future years; yet, this opportunity is completely missing from the ACI category.

# MIPS Composite Performance Score (CPS) Methodology

CMS is proposing a scoring methodology that allows for accountability and alignment across the performance categories that the agency believes minimizes burden on MIPS eligible clinicians. CMS' rationale for the proposed scoring methodology is grounded in the understanding that the MIPS scoring system is a complex system with numerous moving parts. MIPS eligible clinicians should know the actual performance standards in advance of the performance period, when possible.

The SVS believes that the calculation of the composite score is much too complicated and not transparent. We believe that CMS must provide clarification in order for physicians to understand the numerous point systems and how CMS came to their final score under the proposed methodology. For example, the quality performance category by itself has four different point calculations for the measures, ranging from 80 to 210 points. Physicians must then further understand how bonus points are determined within the quality component and factor in how benchmarks impact this final quality score (which vary based on how the data is submitted).

For the first year, the CPS needs to be a simple score that is easy to following for each program element, similar to the scoring system for the CPIA. This will make it easier for CMS to meet the requirements of the MACRA law regarding publishing the benchmarks and thresholds for each element of MIPS prior to the performance period. **SVS urges CMS to provide all the information to physicians on all elements of the scoring system prior to the start of the 2017 reporting period.** 

# **MIPS Payment Adjustments**

In general, CMS proposes to use the CPS associated with the TIN/NPI combination in the performance period in making payment adjustments. For groups submitting data using the TIN identifier, the SVS proposes to apply the group CPS to all the TIN/NPI combinations that bill under that TIN during the performance period. For individual MIPS eligible clinicians submitting data using TIN/NPI, we propose to use the CPS associated with the TIN/NPI that is used during the performance period.

CMS' analysis proves that this proposed payment attribution system will be very negative for medium and small practices because so many physicians in large groups will have the same score, regardless of whether any of their actions or activities accounted for said score. This is a fundamental problem with the proposal to use one CPS and attribute it to all physicians in the group versus having there be at least some individual level of comparison. The SVS urges CMS to consider the implications of the score attribution model to the validity of the MIPS program and work with specialty societies to make it more meaningful in future years.

## **Performance Feedback**

Under MACRA, CMS is at a minimum required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and resource use performance categories beginning July 1, 2017, and it has discretion to provide such feedback regarding the CPIA and ACI performance categories. The first performance feedback is due on July 1, 2017. At a minimum for the first year, CMS proposes to provide performance feedback on an annual basis.

The SVS has joined many in the physician community in past comment letters, stressing the problems with the lack of timely feedback to physicians and calling for improved performance reports that provide more understandable information. We urge CMS to ask Congress for the resources needed to update Medicare's antiquated data systems to allow for real-time feedback. Physicians lack the data and the information used to arrive at the benchmarks and other calculations made under current reporting programs, which limits their ability to successfully participate.

The SVS is also concerned with the timeliness of the release of feedback reports and benchmarking information. CMS should consult with stakeholder groups to determine the best presentation and most meaningful format for sharing ongoing, actionable performance feedback with physicians and practices. At the very least, CMS must produce quarterly reports on a physician's resource use/cost information compared to other MIPS EC's since the information is based on claims' submission. CMS needs to devote the necessary resources, including dedicated CMS staff, to help physicians and administrators interpret the feedback reports, and include explanation of the various measure methodologies, attribution rules, scoring and benchmarks. In cases where different attribution methods or other methodological variance creates mismatched data within a physician's report, the report should include an explanation rather than expecting physicians to search for and read detailed documents on the CMS web site.

Finally, SVS urges CMS to release the reports as early as possible, so that physicians are not well into the next reporting cycle before they learn of their MIPS results and performance and have the opportunity to institute workflow changes to ensure success under MIPS. At a mínimum, CMS needs to follow the MACRA recommendation that data be available on a quarterly basis.

#### **Public Reporting on Physician Compare**

MACRA requires that CMS publicly report on Physician Compare the composite score for each MIPS eligible clinician, performance of each MIPS eligible clinician for each performance category and periodically post aggregate information on MIPS, including the range of composite scores for all MIPS eligible clinicians and the range of performance of all MIPS eligible clinicians for each performance category.

The SVS has repeatedly urged CMS to extend the preview period from 30-days to 90-days in order for physicians to review and ensure the accuracy of their information. It currently takes practices several weeks or months to request, obtain, and review information such as a QRUR report. To expect physicians to access, review, and contest their Physician Compare data in 30 days ignores the demands of patient care and competing priorities physicians face on a daily basis, especially when there have been numerous inaccuracies in previous data sets CMS has released. In addition, data under appeal should not be publically reported. If at any time a physician files an appeal and flags information as problematic, CMS should postpone posting the information until all issues are resolved.

**Finally, CMS needs to make it clear on Physician Compare if the information being reported on a physician is based on group reported data or individual physician reported data** and what quality measures were reported by the group and what episodes of care were used in the resource use measurements. Patients need to be able to distinguish if the information being reported on Physician Compare is related to the specialty of the physician they are inquiring about.

# <u>APMs</u>

# With the complexity of the MACRA Proposed Rule, a "look back" period of two years beginning January 1, 2017 for incentive payments in 2019 is unrealistic.

With a start date for APM participation of January 1, 2017, physicians would need to already be participating in an APM before the Final Rule is published. The Final Rule will actually help to define whether the APM being considered will qualify under MACRA as a MIPS APM or Advanced APM. Since the identification of APM-participating physicians will be based on participant lists as of December 31, 2017, **there is no justification for requiring that eligible APMs be implemented and physicians be participating in them on January 1, 2017**. At present, NO APMs qualify as Advanced or MIPS APMs under the Proposed Rule, which makes it impossible for all but a handful of physicians to meet the proposed January 1, 2017 deadline. This is particularly problematic for specialty physicians.

Also, "Advanced APMs" are not in statute – they are referred to as "Eligible APMs" in MACRA, CMS needs to further define Advanced APMs to determine if these meet Congressional intent. The SVS is aware of Congressional members who have the same statutory concerns as we do about Advanced APMs. We strongly urge CMS to delay APMs for one year, so the look-back period would begin on January 1, 2018 and the incentive payments would begin on January 1, 2020.

We do appreciate that there is no mínimum number of measures or domain requirements, except that an Advanced APM must have at least one outcome measure. We also support measures being evidence-based, reliable and valid.

# Physician-Focused Payment Models (PFPMs)

In its comments on the 2015 MACRA RFI, the SVS stated its support for PFPMs, particularly since specialty physicians were specifically mentioned. Vascular surgeons have had difficulty participating in Accountable Care Organizations' (ACO) models and thus have been unable to share in any savings. These models have not adequately acknowledged and accounted for the importance of specialists who

are crucial in the delivery of quality care and long-term care, particularly since the quality measures that must be met for shared savings do not reflect a continuum of care for patients.

An example is Dartmouth-Hitchcock Health System, which left the Pioneer ACO program because the financial penalties and performance goals were "unsustainable". One of the problems is that benchmarks were set that penalized participants who had already reduced utilization before the program began and more significantly, those who performed well in their first year.

Geisinger, which has extensive experience with quality measurement, has stated that maintaining ideal care over time is a significant challenge. The SVS continues to be concerned about what kind of impact this would have on vascular surgeons who are already high quality providers. Would they be required to maintain the same level of care or suffer penalties even if they treat patients with more acute conditions the following year and for a level which is above the average for most providers?

**CMS must establish an easy pathway for PFPMs to be proposed to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and adopted by the agency as Advanced APMs that focus on specialty physicians; this is not in the Proposed Rule**. The PFPM pathway should include: outlining criteria that will be used to evaluate proposals (which will be available this fall), working collaboratively with specialty societies during the development of proposals, providing feedback on drafts and providing data up-front to help in modeling. SVS representatives have attended PTAC meetings and are encouraged by its discussions and the inclusion of CMS staff as presenters.

The Final Rule should establish a timely and predictable CMS review process for stakeholder APM proposals, including models for specialists and those recommended by PTAC in order to increase MACRA APM opportunities. Physicians are expecially concerned by comments from some CMS officials that stakeholder models proposed by PTAC, which was established by Congress, will need to go through the entire CMS model review process, suggesting that it could be years before APMs are finalized. The SVS does not believe that this long process was the intent of Congress.

We have many resources, such as the Vascular Quality Initiative that is a Qualified Clinical Data Registry, which makes it easier to follow longitudinal care of patients and should be used to report quality measures for participating in PFPMs. Vascular surgeons also have many skills including open and endovascular techniques that are unique to vascular surgery. The SVS is already working with the American College of Surgeons on APMs for vascular surgery procedures, which we believe will improve patient outcomes and reduce spending. These include: carotid endarterectomy, endovascular aneurysm repair, arteriovenous fistulas and endovascular leg revascularization. It is important that speciality societies be given the opportunity to create PFPMs that highlight their expertise. In addition, we believe other physician societies could endorse PFPMs if they typically work with vascular surgeons.

However, as described in the Proposed Rule, PFPMs that are reviewed by PTAC and could be led by specialty physicians may not be considered Advanced APMs, so they would not qualify for the five percent bonuses. **The Final Rule needs to provide more opportunities for specialists who are not primary care physicians to participate in MIPS APMs and Advanced APMs**. Based on the APMs listed in Table 32 that would currently qualify as MIP APMs or Advanced APMs, the only specialty physicians who would have access to an eligible APM are oncologists and nephrologists.

Even though there are presently no existing APMs for vascular surgery, one solution would be a straightforward means of modifying existing APMs so that they could quality as MIPS APMs or Advanced APMs. The statute authorizing the Centers for Medicare and Medicaid Innovation (CMMI) directs the HHS Secretary to "focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under this title". This makes it difficult to understand how CMMI models listed in Table 32 of the Proposed Rule could have been implemented without means of measuring quality. Likewise, the Comprehensive Care for Joint Replacement model was developed after MACRA was enacted, so it should have been structured to meet the requirements for an Advanced APM. Whether there is a need for a participant list, a quality measure or some measurable financial risk, there should be an expeditious way of modifying the agreements between APM entities and CMS to allow more APMs to qualify as MIPS APMs or Advanced APMs.

#### **Technical Assistance/Education**

More technical assistance/education is needed from CMS to help physician societies create payment models, particularly since MACRA completely changes the way Medicare will pay physicians. Two areas that societies especially need help with are data mining and modeling. Not only are these two activities cost-prohibitive, essentially becoming "unfunded mandates" for physicians who create and participate in APMs, but also physicians lack the expertise in modeling APMs.

Specifically regarding data, societies will need baseline data and original benchmarks of costs along with present imaging rates from CMS. They will also need technical assistance from CMS with data runs and education on data sets, such as how they can be used and what are their limitations. **This data should be free-of-charge for each society**.

As mentioned above, the SVS is encouraged that PTAC will be working collaboratively with specialty societies and encourages CMS to do the same. If CMS continues its current approach to defining "more than nominal financial risk" (discussed below) and fails to provide a path to guide the development and implementation of physician-focused APMs, it will preclude many promising APMs that are under development from qualifying under MACRA. Without significant changes to the APM policies in the Final Rule, it will be difficult for many proposed APMs to be implemented and for Medicare beneficiaries to benefit from these care improvements.

#### More than Nominal Financial Risk

The Final Rule should define "more than nominal financial risk" for all Advanced APMs similar to the currently proposed risk standards for medical homes, which means that the potential loss of guaranteed payments should count as a loss and the amount of losses should be tied to physician revenues, not APM expenditures. This definition needs to be simplified and set at a level that is more realistic, appropriate and attainable. With multiple components including total risk, marginal risk and mínimum loss rate, it will be difficult for physicians contemplating participation in Advanced APMs to understand their financial risks or know how much to set aside to cover potential repayments. This will be particularly problematic for small and médium-sized practices. **It is not appropriate to tie nominal risk** 

# requirements to the total cost of care as the Proposed Rule does by linking it to expenditures under APMs.

Also, SVS believes that physicians will be more willing to take accountability for costs that they can affect through their own performance versus taking on risk for the total cost of care for a large patient population. "More than nominal financial risk" should be defined in a way that allows physicians to take accountability for Medicare spending on health services **their patients** receive. Thus, SVS does not support a requirement for reporting quality measures' data based on a certain percentage or number of physicians' patients. In addition, we strongly discourage the development and implementation of a one-size-fits-all data reporting system in any program that is created. The goal should be to provide physicians with greater flexibility to report on and get credit for quality improvement activities relevant to their practice and patients.

The Regulatory Impact Analysis notes that HHS has long **defined "significant" impact as the loss of three percent of physicians' revenue**; more than nominal financial risk should be set to match this amount. It is important for CMS to allow sufficient time to achieve savings' goals and not expect them to be reached in the first year. And, upfront costs that APM participants incur for delivering APM patients' care, such as the capability to gather and analyze data for quality and cost performance improvement, hiring care coordinators and educators, providing non-face-to-face services that cannot be billed, etc. should count as potential losses to APMs. A new National Association of ACOs survey found that the average ACO operating costs are \$1.6 million annually.

For medical homes, the Final Rule should limit required risk for losses to the proposed first year level of 2.5 percent, limit the revenues used to measure these potential losses to revenues for professional services, expand medical homes beyond primary care to include **specialty physicians** and eliminate the proposed requirement that Advanced APM medical homes have fewer than 50 clinicians. MACRA does allow medical homes in a model that is expanded by CMS to count as Advanced APMs without the need to bear more than nominal financial risk.

In summary, SVS urges the following modifications to "more than nominal financial risk":

- 1. **Simplify the definition** it is difficult for physicians contemplating participation in Advanced APMs to anticipate the magnitude of their financial risks and to design care in ways that would avoid excessive losses. Vascular surgeons in small or large medical practices who are thinking of participating in an Advanced APMs need to know how much money they should set aside in the event that repayments or reductions are required. The Final Rule needs to establish the mínimum requirements for financial risk as a known percentage or dollar amount that physicians can calculate and set aside.
- 2. Base risk requirements on physician professional services revenues, not expenditures under APM although the term "APM benchmark" is not defined in the Proposed Rule, the requirement that financial risk be linked to the APM benchmark or episode target price means that the risk to which physicians could be tied would be the total costs of care for the patient's treatment under the APM, which could include: inpatient and outpatient hospital care, post-acute care, drugs and other costs that are beyond the physician's control. As stated above, the SVS supports inclusion of only those services that are provided by vascular surgeons.

- 3. Reduce the amount of losses defined as "more than nominal" as stated above, losses in excess of three percent is the HHS standard for determining what the agency considers to be "significant" loss. Defining "more than nominal" as four percent of Medicare expenditures rather than a percentage of practices' revenues means that "more than nominal financial risk" would be greater than what HHS has defined as "significant" risk. With medical homes' initial risk standard being 2.5 percent of Medicare revenues, SVS supports changing the "more than nominal financial risk" to 2.5 percent for Advanced APMs for the initial year.
- 4. **Count physicians' uncompensated costs as potential financial losses** there are many costly changes that physicians will need to make in order to initiate and maintain participation in Advanced APMs. Some of the upfront costs are stated above. The ACO Investment Model Request for Applications states it well: "ACOs need a sustained business model as they transition to payment arrangements that reward outcomes rather than volume. Given the time lag between when ACOs begin making investments and when they can realistically expect to receive sufficient shared savings to recoup their investments, organizations with less access to capital may be less likely to enter or sustain participation in Medicare ACO initiatives".
- 5. Count loss of guaranteed payments as losses for all APMs, not just medical homes, as all APM participants should be able to treat repayment of performance-based payments as financial risk MACRA exempts expanded medical home models from the need to meet financial risk criteria and does not require that CMS set a higher definition of nominal risk for other APMs that are not medical homes. Physicians participating in APMs will need to engage in new or expanded activities in order for APMs to meet their quality and financial goals, which are not eligible for payment under the current Medicare Fee Schedule. For example, the CMS Oncology Care Model compensates physicians for monthly care management. If physicians are unable to achieve goals relating to new/expanded activities, physicians will experience financial loss because the payments will be less than the costs that are incurred. These new/expanded activities should be considered a financial loss for all APMs, not just medical homes.

# Certified Electronic Health Records Technology (CEHRT)

The SVS supports the proposal that Advanced APMs require 50 percent of participating clinicians to use CEHRT to "document and/or communicate clinical care to their patients or other health care providers". APM entities should be permitted to exclude from calculations of the 50 percent any clinicians who are lacking face-to-face patient interaction. **CMS should maintain the 50 percent mínimum into the future as more experience is gained with the new MACRA programs**. We oppose the discussion in the Proposed Rule to raise the requirement to 75 percent in year two until experience indicates that it is practical to move to a higher threshold.

CMMI models mentioned earlier, such as Comprehensive Care for Joint Replacement, do not explicitly require the use of CEHRT; this should not preclude participants from being considered part of an Advanced APM. Also, if hospitals participating in bundled payment models are using CEHRT and physicians involved in the models are doing the same, these hospitals and physicians should be able to qualify as Advanced APMs, particularly if there was an explicit requirement to use CEHRT.

The SVS also continues to be concerned with the issue of health information technology interoperability and information blocking. Achieving interoperability will become even more important as CMS begins to rely more on Qualified Clinical Data Registries to support MIPS and APMs. However, some electronic health record vendors are intentionally blocking the exchange of information, including not adopting standards needed to accomplish information exchange in a timely fashion or charging unreasonable fees to exchange clinical data. **These problems must be resolved prior to the 50 percent minimun CEHRT requirement**.

# **Risk Adjustment**

For vascular surgeons, risk adjustment is essential in determining quality since they often treat older, sicker patients compared with other specialties. However, the SVS believes that methods and various models need additional study before this type of measurement can be adopted. This provides another important reason to delay APM implementation. As mentioned in the MIPS section of the comments, we are very concerned that risk adjustment was not even addressed in the MACRA Proposed Rules.

## **Patient Attribution**

**The SVS continues to support a prospective approach to beneficiary assignment**. This would allow active patient involvement and better coordination of care as physicians would have real time data and the incentive to coordinate and collaborate on any changes needed in care delivery. Vascular surgeons provide longitudinal care that follows their patients for months and typically years. To facilitate this, we support models that compensate for the following services:

- Communications between primary care physicians and specialists to coordinate patient care, thus avoiding duplicative tests and conflicting medications.
- Time spent by a physician serving as a leader of a multi-physician care team for patients with complex conditions.
- Time spent in a shared decision-making process with patients and family members when there are multiple treatment options.

Moreover, the SVS does not support assignment of risk or compensation using estimates of the percentage of risk assumed or care provided based on generalized assumptions about the role of the physician. Many specialists, including vascular surgeons, manage both episodic and procedural care, along with chronic care for a range of conditions. It is important that the models of risk assignment and compensation be transparent and reflective of physician responsibilies.

Similarly, as episode- and condition-based payment models are approved as qualified Advanced APMs, achieving accurate attribution may require the development of the ability to "nest" episodic care bundles within broader chronic care or condition-based models. The SVS also strongly encourages CMS to utilize a flexible and patient-centric approach to determining the models which should be applicable to 25 percent of all Medicare payments that are attributable to a certain condition or a certain Advanced APM in the initial year. Thus, **reporting on patients that are being managed within an APM should be a patient-centered approach versus determining revenues from the services physicians provide**.

The SVS appreciates the opportunity to provide comments on this Proposed Rule. If you have any questions or need additional information, please contact Pamela Phillips, Director of the SVS Washington Office at <u>pphillips@vascularsociety.org</u> or 202-787-1220.

Sincerely,

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