SOCIETY FOR VASCULAR SURGERY

September 2, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1612-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-1612-P – Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models and Other Revisions to Part B for Calendar Year 2015

Dear Administrator Tavenner:

The Society for Vascular Surgery (SVS), a professional medical society composed of over 4,800 specialty-trained vascular surgeons and other medical professions who are dedicated to the prevention and cure of vascular disease, offers the following comments on the Centers for Medicare and Medicaid Services' (CMS) Medicare Physician Fee Schedule (MPFS) Proposed Rule for Calendar Year (CY) 2015:

Non-facility Direct PE Inputs for Intravascular Ultrasound

SVS is aware of the interest in establishing non-facility Practice Expense (PE) Relative Value Units (RVUs) for Current Procedural Terminology (CPT) codes 37250 – Intravascular Ultrasound (IVUS); Initial Non-Coronary Vessel/Vein Treated and 37251 – Additional Non-Coronary Vessel/Vein Treated.

SVS, in cooperation with American College of Cardiology, Society for Cardiac Angiography and Interventions, American College of Radiology and Society of Interventional Radiology, has already submitted a CPT code change proposal for presentation at the October 2014 CPT Panel meeting that will delete the four existing codes (37250, 37251, 75945, and 75946) and create two new CPT codes in their place which bundle the procedure and the radiology supervision and interpretation. As part of this process, SVS agrees that IVUS should be priced in the non-facility setting. If approved at the October CPT panel meeting, these codes will be surveyed for physician work and PE in the facility and non-facility settings for presentation at the January 2015 RUC meeting. SVS supports this initiative and will help lead the multiple society effort.

Using OPPS and ASC Data in Developing PE RVUs

SVS thanks CMS for withdrawing the non-facility cap proposal in the CY 2014 MPFS Proposed Rule and for acknowledging that "the comparison of OPPS or ASC payment amounts to PFS payment amounts for particular procedures is not the most appropriate or effective approach to ensuring that PFS payment rates are based on accurate cost assumptions". We also support CMS exploring ways of collecting better and updated resource data from physician practices, including those that are non-facility entities paid through the PFS and increasing the number of invoices required to set PE inputs.

We continue to have concerns about using Medicare Hospital Outpatient Prospective Payment System (OPPS) cost data for potential revisions of the PFS PE methodology. Non-facility methodology considers each CPT code individually and focuses on specific identification of direct inputs, thus creating codes based on actual costs. In contrast, OPPS methodology is a blunt approach that bundles services together in an Ambulatory Payment Classification and determines weighting by aggregated facility cost-to-charge ratios that may be totally inaccurate for specific procedures. Since the creation of the OPPS, the averaging mechanism that is used has consistently resulted in charge compression, which undervalues high-cost items and overvalues low-cost items.

Also, the OPPS fails to reimburse for valid nursing time and room and board. For example, the payment system does not capture costs of nursing care that is required to sustain the patient for a device-dependent service, which is often delivered by vascular surgeons. The MPFS expense data used to calculate the direct PE RVUs for these services contain the costs for nursing care pre-, intra- and post-procedure when performed in a non-facility setting. This lack of nursing cost alone makes the data used to set Medicare PFS PE RVUs more accurate than OPPS data.

In conclusion, we do not support using Medicare hospital outpatient cost data in potential revisions of PFS PE methodology.

Improving the Valuation and Coding of the Global Package

SVS urges CMS to not implement its proposal to transition all 10- and 90-day global bundles to 0-day global codes with medically reasonable and necessary visits billed separately during the pre- and post-operative periods outside the day for the surgical procedure.

Our mission as surgeons is quality patient care first and foremost. To be true to such a mission, we must come to an agreement on a set of principles that guide our work and decisions if CMS moves forward with its proposal to disaggregate the global surgical periods. Principles must include:

- Focusing on a care delivery model and then determining a payment model
- Paying fairly for honest work
- Creating coordinated team-based care, with surgeons being the "captain" for most of their patients
- Not financially disadvantaging patients with more co-pays
- Recognizing that surgeons provide value in pre- and post-operative care
- Creating a fair system for all stakeholders.

Operationalize the best we can by:

- Avoiding reverse building block calculations
- Fairly valuing pre- and post-operative work
- Creating the expectation that if you do not do post-operative work, you will not be paid for it.

SVS believes that CMS' concerns regarding the accuracy of PFS payments for global surgical bundles will not be addressed by its proposal. In fact, CMS acknowledges that it would need to estimate the values for all 4,246 affected codes. Given the proposed timeline, this process of estimation would result in numerous errors. CMS would be operationalizing this policy using a "reverse building block" method and SVS is strongly opposed to that action. Also, determining a "typical," patient from CMS' claims data if the agency establishes future global payment bundles would be challenging and difficult to achieve with this proposal. Many global surgical procedures have been re-surveyed for accuracy through the misvalued services review process. If CMS has specific concerns with particular codes, those procedures should be nominated and then be handled through the Relative Value Update Committee (RUC) process.

Also, many of the post-operative activities performed in a global surgical period in the days immediately following surgery do not have CPT codes to bill separately for those services, such as removal of a Foley catheter or a breathing or feeding tube, or change of dressings. So, there would be no opportunity under this proposal for data to be collected regarding these types of activities and surgeons would no longer be reimbursed for these activities. This is another reason that the proposal is premature and not well thought out. In addition, those pre- and post-operative activities that do have codes are inappropriately low for surgical procedures.

We understand that CMS wants to avoid potentially duplicative or unwarranted payments when a beneficiary receives post-operative care from a different practitioner during the global period. However, there are other ways to accomplish this goal that do not involve the disruption of dismantling the 10- and 90-day global periods. CMS, its contractors, and physicians have successfully used modifiers on claims to notify the contractor when an assistant is utilized during a surgical procedure or when two surgeons are working together as co-surgeons in a complicated case. There are rules for when to bill these modifiers and rules for how much the reimbursement will be for the entire case and for each surgeon.

SVS believes modifiers also exist for use in the avoidance of duplicative post-operative care from a different practitioner during the global period as is done with co-surgeons during the procedure itself. This could be helpful to patients that live in a rural area and need to go to an academic medical center in the city for their surgery and then return home for follow-up care. This practice would also test whether using modifiers for the purpose of attribution for separating a longer term episodic payment can work. And, this could provide a step forward in testing a concept for use in attribution of payments under future alternative payment models.

In addition, this proposal would create burdens for all, including physicians, CMS and Medicare beneficiaries. SVS is concerned about the administrative burden to both SVS members and their practices and for CMS and its contractors. We also feel it is not appropriate for CMS to make a proposal such as this where the basic intent is the collection of data, while the proposal has the potential to increase an individual Medicare beneficiary's co-payments.

The American Medical Association estimates that the elimination of the global period will result in 63 million additional claims being filed with Medicare contractors to account for post-surgical evaluation and management services. The increase in costs to Medicare to pay the contractors to process these claims and the appeals that may occur do not seem to have been taken into consideration when CMS was deciding to propose this policy. There is also the additional administrative burden on the practice to submit all these additional claims. Driving up the cost of healthcare in this fashion is not a good use of physician and staff time resources.

And, SVS is concerned that this proposal will potentially increase the amount a patient has to pay, in total, for an episode of care. 10- and 90-day global surgical packages shift the risk of managing a patient's care to the surgeon, which SVS members have agreed to accept. This mechanism of payment promotes high quality, efficient care that does not create incentives for increases in volume, which could happen by eliminating the global bundles. Global surgical bundles are good for the patient as they have a predictable, guaranteed co-payment for that surgical procedure and all of its follow-up care. Also, this proposal is counter to CMS' support for bundling of payments.

Finally, SVS believes CMS' proposal to deconstruct the global surgical packages will have a negative, and for the purposes of longitudinal research, a devastating impact on our Vascular Quality Initiative (VQI) with regard to data capture and our ability to track patients during a 90-day global period. Also, a change in the global period will not allow for patient data to be pooled from this time period and have their outcomes evaluated against patients that did not have care as part of a 90-day global period because there would be a lack of a control element that could potentially bias or influence research.

<u>For all of these reasons, SVS urges CMS to not implement its proposal in the CY 2015 MPFS Proposed Rule to transition all 10- and 90-day global bundles to 0-day global codes</u>.

Need for Physician Fee Schedule Modifiers Indicators for CPT Codes 34841 – 34848

SVS requests that CMS review the modifier indications assigned to CPT codes 34841 – 34848 and assign these codes an indicator of "2" versus an indicator of "0" for the categories of multiple procedure, assistant at surgery, and co-surgeon. New for 2014 and also contractor-priced, SVS believes these codes may have been overlooked when modifier indicators were assigned.

HCPCS	Short Descriptor	MULT PROC	BILAT SURG	ASST SURG	CO-SURG	TEAM SURG
34841	Endovasc visc aorta 1 graft	0	0	0	0	0
34842	Endovasc visc aorta 2 graft	0	0	0	0	0
34843	Endovasc visc aorta 3 graft	0	0	0	0	0
34844	Endovasc visc aorta 4 graft	0	0	0	0	0
34845	Visc & infraren abd 1 prosth	0	0	0	0	0
34846	Visc & infraren abd 2 prosth	0	0	0	0	0
34847	Visc & infraren abd 3 prosth	0	0	0	0	0
34848	Visc & infraren abd 4+ prost	0	0	0	0	0

Potentially Misvalued Services under the Physician Fee Schedule

CMS is proposing 65 CPT codes, listed in Table 10, as potentially misvalued codes. SVS recommends that CMS remove the following vascular codes from this new screen, based on the details outlined below:

RUC Recommendations Already Submitted for CPT 2015

- 36475 Endovenous radiofrequency 1st vein
- 36478 Endovenous laser 1st vein
- 93978 Vascular study

36215 Place Catheter in Artery

As outlined by a multi-specialty panel in April 2012, CPT code 36215 will be greatly impacted by the new cervicocerebral angiography codes, which bundle 36215 (and the associated S&I code). At that time, the multispecialty group requested that 36215 be maintained until three years of utilization data are available and the specialties can determine the typical vignette and dominant specialty. 2013 is the first year for which data under the new cervicocerebral angiography coding system is available, and significant trends are already evident in the data. The utilization of 36215 has dropped dramatically from 78,041 (2012) to 44,623 (2013). We continue to recommend this code be maintained until three years of utilization data are available for review.

36870 Percutaneous, Thrombectomy AV Fistula
This procedure has been referred to CPT "to bundle the appropriate services". A Code Change Proposal will be submitted for the 2017 RUC/CPT cycle.

Transcatheter Placement Intravascular Stent (CPT codes 37236 and 37237)
A multispecialty group requested that CMS correct a PE problem with CPT codes 37236 and 37237. The group submitted PE recommendations on four new stent CPT codes in April 2013. A "new item" for a stent system was submitted for CPT codes 37236 and 37237. Proper documentation indicating a price of $1500 was included. When CMS implemented the codes, they replaced the new item with an existing code – SD152 a balloon catheter for $243. The issue was not included in the CY 2015 MPFS Proposed Rule; CMS' 2015 direct practice input files still include SD152 for CPT codes 37236 and 37237. SVS urges CMS to correct this error in the 2015 fee schedule

Abdominal Aortic Aneurysm (AAA) Ultrasound Screening – G0389

SVS appreciates CMS including AAA ultrasound screening in the CY 2015 MPFS Proposed Rule following our meeting with CMS staff in May regarding its reimbursement. We support CMS maintaining the work RVU for G0389 and proposing to revert back for CY 2015 to the PE RVUs that were assigned to the procedure in CY 2013.

As we discussed, cross-walking this code to CPT code 76775 (retroperitoneal ultrasound) no longer accurately reflects the resources involved in furnishing AAA ultrasound screening, due to changes in CPT 76775 PE direct cost inputs. Specifically, the type of equipment used in furnishing G0389 is different, the time involved is greater and the specialty that furnishes this screening (vascular surgery) is different than for CPT code 76775 (urology). As a result, for CY 2014, G0389 has an undervalued Technical Component of $36.90, which creates a disincentive to provide this important screening.

CMS modified AAA screening in the CY 2014 MPFS Final Rule consistent with the United States Preventive Services Task Force by eliminating the one-year time limit with respect to a referral as part of the Initial Preventive Physical Examination for male-ever smokers ages 65-75 and for men and women ages 65-75 with a family history of AAA. This will likely expand the number of at-risk Medicare beneficiaries who will get screened for this deadly disease. These beneficiaries need easy access to this life-saving preventive screening.

We strongly agree with CMS' proposal to maintain the work RVU for this code and revert back to the same PE RVUs that CMS used for CY 2013. SVS supports designating G0389 as a potentially misvalued code and having it reviewed. A multi-specialty recommendation has already been submitted to the RUC recommending referral of this code to the CPT panel for the possible creation of a Category I code for the 2017 RUC/CPT cycle. We will look forward to participating in the RUC review of this issue.

Malpractice RVUs

For CY 2015, CMS is proposing to implement the third comprehensive review and update of the Malpractice RVUs. SVS understands that as part of that process CMS is calculating a specialty specific risk factor by taking a national average premium for each specialty and dividing it by the national average premium data for the specialty with the lowest premiums.

SVS submitted detailed comments to the RUC to re-assign the dominant provider for low volume CPT codes (PLI). SVS urges CMS to implement these RUC recommendations in the CY 2015 Final Rule.

Valuing New, Revised and Potentially Misvalued Codes

SVS appreciates CMS' proposal regarding a new timeline and process for the publication and implementation of changes to physician codes and relative values. The current process in which changes for new, revised and misvalued codes are first announced at the beginning of November and implemented on January 1 of the following year, does not allow adequate public comment or sufficient time for physicians to prepare for the changes, including how the revisions might impact their practices and patients.

We agree with CMS in the CY 2015 MPFS Proposed Rule that if the agency followed a process that involved proposing values for codes in proposed rules, CMS would be able to consider additional information contained in these comments prior to making final decisions on revised payments for services. SVS strongly supported the letters to CMS from the House of Representatives and Senate that recommended this process change in order to provide sufficient transparency.

We agree with CMS' observation in the proposed rule that "the RUC recommendations are an essential element that we consider when valuing codes. Likewise, we recognize the significant contribution that the CPT Editorial Panel makes to the success of the potentially misvalued code initiative through its consideration and adoption of coding changes." Also, "for many codes, the surveys conducted by specialty societies as part of the RUC process are the best data that we have regarding the time and intensity of work. The RUC determines the criteria and the methodology for these surveys. It also reviews the survey results. This process allows for the development of survey data that are reliable and comparable across specialties and services than would be possible without having the RUC at the center of the survey vetting process. In addition, the debate and discussion of the services at the RUC meetings in which CMS staff participate provides a good understanding of what a service entails and how it compares to other services in the family, and to services furnished by other specialties. The debate among the specialties is also an important part of the process."

However, starting this process in 2016 has major ramifications for the CPT and RUC process. There would be a January 15, 2015 deadline for RUC recommendations, meaning that no recommendations after that date would be part of the payment process. Although this increases CMS' review time, it leaves only the May 2014 CPT Panel meeting and the September 2014 RUC meeting for input into the 2016 payment schedule. The result is that none of the codes and RVUs from the current cycle beyond those coming from the May 2014 CPT meeting would be part of the 2016 fee schedule.

To accommodate the proposed process for new, revised and potentially misvalued services, we believe the current meeting infrastructure for both CPT and RUC should be maintained, but the workflow should be shifted to review the commonly performed services at the May CPT/October RUC and October CPT/January RUC meetings.

The February CPT meeting should predominately address editorial changes and new services with expected low volume and the April RUC meeting should be utilized to review new low volume services and to discuss methodological and process issues. Since this is a lighter schedule compared with the other meetings, we believe that the April meeting provides enough time to get these low volume services into the July proposed rule.

In order to effectively implement the revised process, SVS recommends delaying the new timeline and process until 2017.

Also, CMS has proposed creating HCPCS G codes to cover new and revised codes until the 2017 payment schedule. Unfortunately, this would create administrative burdens for physicians who would be required to maintain one coding system utilizing G codes for Medicare and another for payers using the new and revised CPT codes.

In addition, SVS recommends that CMS review the Refinement Panel process, particularly since in the past few years CMS typically chose to accept original proposed values for vascular surgery even if the Panels supported RUC recommendations and our commenters' requests. We believe the Refinement Panels should be kept in place until CMS can create an alternative appeals process that is fair, objective and consistently applied and would be open to any commenting organization.

Chronic Care Management (CCM)

SVS agrees care management is a critical component of advanced primary care that contributes to better health for individuals and reduced expenditure growth. We support development and implementation of initiatives designed to improve payment for and encourage long-term investment in care management services, particularly for optimizing health and quality of life for individuals with multiple chronic conditions.

Also, we support the policy to pay separately for care management services furnished to Medicare beneficiaries with two or more chronic conditions beginning in 2015. But,

because of the budget neutrality issue, one of our concerns continues to be that funding for this would result in further dilution of payments for high resource intensity specialty services.

In addition, we are disappointed that CMS has decided not to propose an additional set of standards that must be met in order for practitioners to furnish and bill for CCM services. We believe that there needs to be an accountability mechanism for CCM which goes beyond "standards", such as quality measures that demonstrate improved outcomes and benefits for relevant patients.

We do support CMS' proposal for a new scope of service requirement in this year's proposed rule: CCM services must be furnished with the use of electronic health records (EHR) or other health IT or health information exchange platform that includes an electronic care plan that is accessible to all providers within the practice, including those furnishing care outside of normal business hours and is available to be shared electronically with care team members outside of the practice. We believe this proposal would provide more continuity of care.

Reports of Payments or Other Transfers of Value to Covered Recipients

SVS is concerned about CMS' proposal that would revoke the existing Sunshine Act exclusion for Continuing Medical Education activities, mainly due to requests from other accrediting bodies that they be added to the list of exempt organization covered by the exclusion. The proposal would exempt third party transfers to Continuing Education (CE) only where an industry donor is unaware of the recipients/beneficiaries before and after the funds are transferred. However, industry could learn the identities of speakers/faculty and even attendees after the funds have been transferred through brochures of programs and other publications or through their physician-employees' participation in CE activities. This could have a chilling effect on CE, which runs counter to public interest.

SVS recommends that CMS slightly modify the proposal to add the language that the exemption applies under section 403.904(g)(1)(i) when an applicable manufacturer provides funding to a CE provider, but does not select or pay the covered recipient/speaker/faculty directly or provide the CE provider with a distinct, identifiable set of covered recipients to be considered as speakers/faculty for the CE program. The agency should provide guidance in a regulation to achieve the aforementioned to ensure that the industry donor is unaware of the speakers/faculty and other participants before committing to fund the activity. This accomplishes CMS' goal while eliminating the potential negative impact to CE. To allow CE providers time to ensure that their processes comply with the modified exemption, we urge CMS to make this change effective six months after the Final Rule is issued.

Also, when Congress enacted the Sunshine Act, 12 specific exclusions from the reporting requirements were outlined, including "educational materials that directly benefit patients

or are intended for patient use". CMS concluded that medical textbooks, reprints of peer-reviewed scientific clinical journal articles and other services used to educate physicians were not covered by this exclusion even though these clearly have a direct benefit for patient medical care. CMS' decision to not cover these materials under the educational materials' exemption is inconsistent with congressional intent. We urge CMS to reconsider its decision to not cover medical textbooks and journal articles within the existing statutory exclusion for educational materials that directly benefit patients.

In addition, there are widespread concerns that the implementation of the Open Payments system for data collection will not be ready and will likely lead to the release of inaccurate, misleading and false information. CMS has already taken the Open Payments system offline for almost two weeks because of technical problems. As previously recommended, there should be a minimum of six months to upload the data, process registrations, generate aggregated individualized reports and manage the dispute communications and process. CMS has also not provided effective notification to the vast majority of physicians nor provided SVS a reasonable amount of time to educate its members on the registration and dispute process. Thus, it is extremely likely that many vascular surgeons impacted by Sunshine Act reporting are not aware of the requirements. And, there is frustration at the overly complex, 11 step registration process. For these reasons, SVS urges CMS and the Office of Management and Budget to postpone for six months, until March 31, 2015, the publication of the information collected in the Open Payments System.

Finally, the May 5, 2014 Federal Register supplementary document entitled "Agency Information Collection Activities; Submission for OMB Review" relating to dispute of Open Payments information stated that manufacturers "after reviewing the disputed information, if they determine that no change is required to the data, may dismiss the dispute or request that physician or teaching hospital who initiated the dispute to withdraw it". The February 2013 Sunshine Act Final Rule does not authorize manufacturers to dismiss disputes without both parties agreeing that the dispute is resolved. We understand that CMS officials have stated their intent to issue clarifying guidance that manufacturers are not authorized to unilaterally dismiss disputes. We would appreciate receiving this guidance in writing.

Physician Compare Website

As SVS expressed in last year's comments on the CY 2014 MPFS Proposed Rule, we have concerns with the accuracy of the information that is being used for the Physician Compare Website, particularly since CMS is proposing to expand public reporting of group-level measures by making all 2015 Physician Quality Reporting System (PQRS) Group Practice Reporting Option (GPRO), registry and EHR measures for group practices of two or more Eligible Professionals (EPs) available for public reporting by 2016. CMS is also proposing to expand measures for individual EPs by making all 2015 PQRS individual measures collected by registry, EHR or claims available for public reporting on Physician Compare in late 2016.

CMS states that "consumer testing has shown including too much information and/or measures that are not well understood by consumers on these pages can impact a consumer's ability to make informed decisions". Most consumers are not familiar with PQRS, registry and EHR measures, so using these measures without explanation continues to be problematic. Benchmarks using percentiles will also be difficult for consumers to understand. Testing consumers to determine how well they understand each measure may begin to remedy this problem.

We do appreciate that CMS will continue to reach out to specialty societies to ensure that the measures under consideration for public reporting remain clinically relevant and accurate and will link to their websites for information on non-PQRS measures.

More relevant for consumers is patient experience data collected via a certified Consumer Assessment of Healthcare Providers and Systems vendor that includes: getting timely care, appointments and information; patient's rating of provider; access to specialists, etc. SVS supports making these measures available for public reporting for all group practices.

We also support processes for physicians whose information is being publically reported to have a reasonable opportunity to review their results before these are posted in Physician Compare, although a 30-day preview period is a relatively short time for physicians to review their data as it will appear in the website.

In addition, we supported a full redesign of the underlying database and a new Intelligence Search feature. However, the continued use of the American Board of Medical Specialties' information is problematic; it is not an accurate list as it contains specialty-designation errors. SVS members have reported that their information is still incorrect which includes the designation of their specialty.

Physician Payment, Efficiency and Quality Improvements – Physician Quality Reporting System (PQRS)

SVS has supported the PQRS since its inception and has been an active participant and measure developer of consensus-based quality measures that have been approved by the National Quality Forum (NQF) and/or chosen for PQRS measure inclusion. SVS continues to support a better alignment of quality reporting programs such as PQRS, the eRx Incentive Program, and EHR program to reduce the reporting burden on physicians. Compliance with the many quality reporting programs is an administrative burden for many vascular surgery practices and could result in substantial loss of reimbursement for non-compliance.

<u>Implementation of PQRS Penalties</u>

SVS continues to be very concerned with the payment adjustments for PQRS that will begin in 2015, with a two percent penalty on the estimated Medicare Part B allowed charges for all covered services if quality measures are not successfully reported. SVS strongly supports easing the penalties for unsuccessful reporters until PQRS has a higher percentage of EPs participating.

SVS does appreciate CMS' request for comment regarding a registry participating in PQRS being able to report PQRS data more frequently during the reporting year. Flexibility in reporting data to CMS is always appreciated given the amount of reporting required under current quality improvement programs. SVS would support such an option in future reporting years.

SVS does not support CMS's proposal to require PQRS-reporting registries to also be capable of reporting on all 18 cross-cutting measures. The listed measures are extremely problematic for surgical specialties, and are not representative of measures that are meaningful to vascular surgery. They also present an additional reporting burden on top of an increasingly high threshold of reporting for PQRS. We urge CMS to reconsider this requirement or at least to consider an exemption from the requirement when an overwhelming majority of the cross-cutting measures listed are not applicable to a given specialty.

Qualified Clinical Data Registries

As SVS prepares to apply to the CMS Qualified Clinical Data Registry Program (QCDR), it still proves to be a challenge to meet many of the additional provisions in order for a registry to participate in the QCDR program. SVS would urge CMS to continue to refine the program to account for the challenges faced by smaller registries.

SVS also strongly objects to the proposed requirement to publically report data received by a QCDR in order to remain in the QCDR program. SVS feels that the requirement to public report data discourages the voluntary and honest reporting of quality measures by EPs. The concerns that surround public reporting make the requirement contradictory to the purpose of quality reporting and will negatively affect the data needed for true quality improvement. Thus, we believe that the public reporting requirement is premature and does not give EPs participating in the QCDR program ample time to assess the data from their participation in previous years to see if performance improvement is needed, nor the time to make those improvements if necessary prior to that data being made public. We urge CMS to reconsider this requirement because of the negative impact it will have on quality improvement.

Measure Reporting Requirement

In reference to both the QCDR program, as well as the traditional PQRS program, SVS continues to find the requirement of reporting nine measures across three National Quality Strategy (NQS) domains challenging. The jump from three to nine measures was extreme, and when coupled with the requirement that the measures cover three of the six

NQS domains the requirement has created a complex and burdensome reporting requirement for providers. It is important to note that not all of the six NQS domains have what SVS feels is a sufficient number of measures. We believe that each domain should contain a diverse and high quantity of measures to choose from if a requirement to cover three of the domains is to stay in place. We hope CMS will also consider that despite reporting requirements increasing from year to year, there is still a large amount of measures removed from the PQRS program every year. This inconsistency in available measures only adds to the burden of more challenging reporting requirements. Although SVS appreciates the lowering of the patient population threshold to 50 percent of patients if less than nine measure are reported, SVS strongly urges CMS to be mindful of the burden that reporting nine measures presents, and that the requirement to cover multiple NQS domains be considered through a lens of how many measures are currently available within each of those domains.

In addition, SVS has concerns about the lack of transparency provided thus far in regard to the Measures Application Validity process for those EPs who do not meet the nine measure/three domain threshold. A more transparent process, particularly when so many measures are removed from the program every year, is an important step in assuring providers that they can meet the requirements of the PQRS program and not incur unnecessary penalties.

Changes in NQS Domains for SVS Measures

SVS very strongly objects to the change in the NQS domain for four SVS-owned measures. It is proposed that four SVS measures be stripped of their current NQS domains and all placed in the Patient Safety domain. Not only does this change not improve care or the effectiveness of the measures, it makes the burden of reaching the three domain requirement under PQRS extremely burdensome. We feel the only thing this change accomplishes is an increased reporting obstacle for vascular surgery, with absolutely no improvement of care or effectiveness.

If CMS is going to put all specialty measures in the same domain, then we would suggest that CMS reduce or eliminate the requirement that measures span across three domains or create more domains in which specialty measures can be spread across. We would even suggest replacing the NQS domain requirement with a system that classified measures simply as process or outcome, with a set threshold for the number of outcomes measures that would be required to be reported. However, in lieu of an alternative, we strongly urge CMS to assure that vascular-related measures are placed in appropriate and diverse NQS domains in order to meet the PQRS reporting threshold set by CMS.

Concerns over a Future Deeming Authority

SVS supports the freedom provided to entities participating in the QCDR program to use a more populous and diverse universe of measures to meet the QCDR reporting requirements. SVS also appreciates the increase of reportable non-PQRS measures by a QCDR from 20 to 30 measures. Although measures do not have to be PQRS measures,

SVS has concerns about the future of this option, and if there will be any future deeming authority or clearinghouse for measures within the QCDR program. SVS hopes that moving forward the QCDR program will retain its initial level of autonomy for registries to be able to choose which measures are valid and appropriate for reporting through the QCRD program, as opposed to adding an additional burden of some level of deeming authority in the future. SVS believes that registries themselves should serve as the primary determinant of which measures are appropriate for reporting through the QCDR program within a given specialty.

Removal of SVS-Owned Measure from the PQRS program

SVS very strongly opposes the proposed removal of SVS-owned measure #257: Statin Therapy at Discharge after Lower Extremity Bypass (LEB). The rationale given by CMS in the proposed rule to remove the measure is that the "measure represent[s] a clinical concept that is currently accepted standard treatment for patients that receive lower extremity revascularization when clinically indicated". We strongly disagree with CMS's assessment that the measure represents a current standard of care. Although data received through PQRS may justify CMS' rationale, we would like to remind CMS of the incomplete picture the PQRS program creates in reference to a measure's effectiveness. PQRS is far from 100 percent participation by EPs in reporting to PQRS, which creates a large hole in CMS's ability to determine if a measure such as the Statin Therapy measure is indeed being performed at a rate that would constitute an accepted standard of care. As registry data from the SVS Vascular Quality Initiative (VQI) shows below, this measure is far from meeting an accepted standard of care. It is for this reason that we strongly urge CMS to retain this measure within the PQRS program. SVS feels this measure not only fills a need in the quality reporting system, but as more EPs become PQRS successful reporters, the measure will provide a needed assessment of the use of statin therapy after lower extremity bypass.

- SVS VQI analyzed 15,725 lower extremity bypass (infrainguinal) procedures, performed from 2009-2014 at 158 medical centers in 45 states.
- Overall, a statin drug was prescribed at discharge after 76 percent of procedures (25^{th} percentile = 67%, 75^{th} percentile =83%).
- There was no significant improvement over time, comparing the intervals 2009-2011 vs 2012-2014:
    - 2009-2011: 77.5 percent of patients receiving infrainguinal bypass discharged on statin
    - 2012-2014: 76.6 percent of patients receiving infrainguinal bypass discharged on statin (p =.26)
- These data demonstrate substantial opportunity for improvement in the PQRS measure #257: Statin Therapy at Discharge after Lower Extremity Bypass.

New SVS Measures Included in the PQRS Program

Although we greatly appreciate CMS including two new measure concepts from SVS in the proposed rule, we strongly request CMS to remove them from the list of potential measures and not include them in the 2015 measure set. Because these measures were concepts at the time of measure submission, SVS had not yet seen the measures with full PQRS specifications. After receiving the specifications, SVS has multiple concerns regarding the functionality of the specifications. SVS would like time to work out the issues that the specifications present and resubmit more sound measures at a later date. The measures being requested for removal are:

- Recurrence or amputation following endovascular infrainquinal lower extremity revascularization
- Recurrence or amputation following open infrainquinal lower extremity revascularization

Please remove these measures from the PQRS program for the 2015 reporting year. We would greatly appreciate CMS' agreement regarding the removal of these measures, as the specifications for these measures are not yet approved or sanctioned for use by SVS.

PQRS Feedback Reports

Lastly, SVS encourages CMS to continue to work toward more timely feedback reports, as feedback to physicians on their participation and performance in the numerous CMS reporting programs will help physicians to perform more efficiently in future reporting years.

Electronic Health Records Incentive Program

Although SVS appreciates the inclusion of the EHR Incentive program in the streamlined QCDR program, along with SVS' hesitations with the QCDR program, major concerns with the EHR program still exist.

The high cost of the EHR program is of constant concern to SVS. The high cost of EHR remains a burden particularly for private practitioners, as the PQRS program no longer includes any incentive payments for reporting. A study in the March 2011 edition of Health Affairs estimated that the total first-year cost of EHR implementation for a five-physician practice to be $233,297, with average per-physician cost of $46,659 – a large expense for any small business to incur.

We ask CMS to keep in mind the combination of the extremely high cost burden of EHR implementation with the multiple reporting penalties physicians are facing. Although we do appreciate CMS removing the requirement that CEHRT products be recertified to the most recent version of the electronic specifications for reporting CQMs, we still strongly support a small practice exemption from the EHR Incentive Program penalty.

Value-Based Payment Modifier (VBPM) and Physician Feedback Program

SVS opposes applying the VBPM to additional physicians before CMS has refined the methodology used in calculating this in order to better identify both high and low performers for upward and downward payment adjustments. Unfortunately, this proposed rule would drastically increase the number of physicians who are subject to the VBPM and would include limited license practitioners. SVS understands that the Affordable Care Act (ACA) requires the VBPM to be phased in over a three-year period beginning in 2015 and ending in 2017 and must now include all physicians; however, SVS feels the doubling of the adjustment percentage from two percent to four percent seems contrary to CMS' stated principle in the proposed rule of a "gradual implementation" of the program.

VBPM Implementation

Again, although SVS understands that the ACA requires the VBPM to be phased in over a three-year period beginning in 2015 and ending in 2017, given that CMS is basing the adjustments in any given year on a "performance year" two years earlier, that means any requirements attached to the 2016 payment adjustment have a two-year "look-back" to 2014; we find this time lag very problematic.

As per the proposed rule, payment for EPs could be cut by four percent in 2017 unless they successfully participate in one of the PQRS group options, or 50 percent of the physicians and other eligible professions in the group successfully participate in the PQRS as individuals. PQRS participation can only be avoided if participation in a QCDR is chosen as the reporting method. Given that QCDRs have not even completed a whole year of reporting, and that many organizations such as SVS have yet to apply to the QCDR program, it seems unrealistic that the QCDR option is the only alternative participation method outside of meeting the PQRS requirements. The negative four percent adjustment, in addition to other reporting penalties like unsatisfactory PQRS reporting, are constantly creating a steeper burden for physicians in relatively new quality improvement programs such as the VBPM.

Quality Tiering

SVS continues to oppose the second "quality tiering" step where groups would be compared nationally on quality and cost and have the potential to earn an unspecified bonus or penalty of up to four percent. SVS opposes any type of tiering where there must be "winners and losers" to ensure budget neutrality. Also, using a methodology that creates the same benchmark for all physicians is a flawed concept. This would only be fair if physicians are compared with their peers by allowing vascular surgeons to select measures that have been developed by SVS and endorsed by the NQF process or are part of the SVS-sponsored VQI registry. SVS supports a scoring methodology that provides an additional upward payment to groups of physicians who care for high-risk patients and

a thorough, transparent review process to enable groups to inquire about the calculation of their VBPM. At least groups of physicians between two and nine, along with solo practitioners, would only be subject to an upward or neutral adjustment in 2017.

Quality and Resource Use Reports

SVS has been generally supportive of the concept of the Quality and Resource Use Reports (QRURs) in the past. We do believe the QRURs will be useful since they will compare quality and resource use among physicians and will provide a preview of how affected groups might fare under the VBPM on a risk-adjusted basis using three factors: patient health status, demographics and beneficiary type. However, as the program moves forward, we also have some concerns that CMS should address. Given the number of changes to programs such as the VBPM and PQRS in the last few years, the feedback a physician will receive in their QRUR could be based on quality and performance for less measures than are required in the current reporting year, or even for measures that are no longer included in the PQRS program due to the large number of measures CMS has chosen to remove. SVS supports feedback to physicians, but worries that given program changes, the usefulness of that feedback may be low given the vast differences in program requirements and measures available from year to year. We urge CMS to reduce the amount of drastic changes in the programs from year to year (such as greatly increasing reporting requirements from three to nine measures), and the yearly removal of large numbers of measures that physicians may have previously reported on or find useful in order to meet the reporting requirements.

Spending Measures

In addition, SVS opposes the inclusion of the Medicare Spending per Beneficiary (MSPB) Measure in the VBPM cost composite for both Parts A and B that spans from three days prior to a hospital admission to 30 days post discharge. Our biggest concern is the proposals for attribution, particularly the proposal that would attribute the MSPB Measure to physician groups when any EP in a group submits a Part B Medicare claim under the group's Tax Identification Number for an inpatient hospital service. We support coordination of care and appreciate that this would be risk-adjusted for age and severity of index. However, we believe this proposal does not promote shared accountability, instead unfairly targeting the surgeon over the hospital and other EPs during the 33 day time period.

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 pphillips@vascularsociety.org or 202-787-1220.

Sincerely,

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