



August 22, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1403-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: CMS-1403-P – Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2009

Dear Administrator Weems:

The Society for Vascular Surgery (SVS), representing over 2400 practicing vascular surgeons in the United States, offers the following comments on the Centers for Medicare and Medicare Services' (CMS) Medicare Physician Fee Schedule Proposed Rule for Fiscal Year 2009.

Malpractice RVUs for TC Component Services

- **SVS could not identify specific additional PLI premiums related to provision of technical-only services.**
- **SVS supports the concept that CMS retain an outside contractor to assess the issue of PLI relative values for technical-only services.**

SVS understands CMS' concern regarding the need to develop resource-based methodology that could be used to assign malpractice RVUs to technical component-only services. In a review of the malpractice premiums that SVS members pay, we did not find any specific additional premiums or "tags" that could be directly applied to malpractice coverage of technical component-only services, which in the case of our specialty, would predominantly relate to provision of non-invasive vascular diagnostic studies.

An element that increases a practitioner's risk regarding malpractice exposure is the time involved in that procedure. Therefore, SVS requests that CMS consider using methodology for the allocation of malpractice RVUs for the TC component based on clinical staff time in the CMS database as determined originally by the CPEPs and refined by the PEAC.

Application of the Hospital-Acquired Conditions (HACs) to Other Settings

- **SVS strongly supports quality initiatives, but we believe application of the HACs concept to the non-facility setting would be impossible to administer fairly.**

SVS understands both CMS and Congress' interest in not having the Medicare program reimburse physicians for low quality or error-ridden care. We expressed concerns about applying the HACs payment policy to IPPS hospitals, mostly because the Agency has associated this effort with the term "never events", when for several of the HACs it is impossible for the incidence to be reduced to zero. We believe it would be even more difficult to apply this policy to the physician office practice setting.

First, there is the "free will" factor in the office setting, meaning that no matter how hard a physician tries to follow scientific guidelines in providing the best possible care, some patients may later behave in such a way that adverse events occur. In other situations certain conditions may lay dormant and not be discernible in the physician practice setting, only for problems to occur after patients leave the office setting.

For example, a patient undergoing a surgical procedure in the office may ignore all instructions regarding post-operative wound care. Vascular surgeons oftentimes operate on lower extremities, areas that may be subject to major lapses in hygiene. If a patient were to return with a lower extremity surgical wound infection it would be impossible to determine whether the "fault" lay with the surgeon's lack of sterile surgical technique or the patient's refusal to follow postoperative wound care instructions.

Second, SVS has concerns about which conditions would be selected by CMS. Most of the conditions selected in the IPPS Proposed Rule do not fulfill the statutory requirement that they be completely preventable through evidence-based guidelines. There should be solid evidence, published in peer-reviewed literature, that by following certain guidelines, the occurrence of an event can be reduced to zero, or near zero, among a typically broad and diverse patient population. Inherent in this proposal would likely be the de-selection of patients based on high risk – presently, vascular surgeons care for patients with some of the most severe and complicated conditions.

Finally, increased utilization of tests and screenings would be necessary that may or may not improve the overall value of health care services provided under Medicare, but would certainly increase Medicare spending. These would also be necessary to avoid unfounded malpractice suits.

Therefore, while the provisions in this proposed rule regarding application of the HACs payment policy to physicians are well-intentioned, they would present confusion, higher costs and many unintended consequences for both the beneficiary and Medicare program as a whole.

Independent Diagnostic Testing Facilities (IDTFs)

- **SVS commends CMS for addressing quality issues in diagnostic testing, however, for reasons cited herein we strongly urge that the Agency NOT adopt its proposal requiring that IDTF standards apply to physicians.**
- **SVS urges CMS to require facility certification or technologist credentialing as a more reasonable and effective means to achieve uniformly high quality testing in the physicians' office setting.**

The CMS proposal would create a significant change to the supervision requirement already present for diagnostic testing services under 410.32(b) of the CMS Code of Federal Regulations. This provision states that diagnostic testing services “must be furnished under the appropriate level of supervision by a physician”. Because IDTFs have been historically independent from provider entities such as hospitals and physician offices, they have required greater specificity regarding the physician supervision requirement. The extension of that requirement to the physician office setting would create a “privileging” program for office-based imaging based upon a physician’s medical specialty rather than the physician’s training, experience and competence. For example, under the current Carrier implementation of the IDTF regulations, vascular surgeons are deemed not capable of supervising ultrasound screening for abdominal aortic aneurysms. The Medicare Payment Advisory Commission (MedPAC) specifically cautioned against privileging based on specialty in its March 2005 report on imaging: “Medicare should not limit payment to specific specialties...The practice of medicine is evolving quickly and specialty training may change over time. Thus, CMS should develop criteria...based on some combination of physician training, experience and continuing education”.

A privileging program would result in a physician’s inability to supervise imaging services for their own patients, having to hire a radiologist instead. To require a physician with responsibility for patients to hire another physician to supervise imaging is incompatible with the prevailing model for ultrasound, in which the use of technology is deeply integrated into the care that physicians provide to their patients.

For vascular surgeons this would be particularly ironic and inappropriate. Vascular surgeons basically invented the entire discipline of noninvasive vascular testing, a methodology that allows accurate assessment of a patient’s arterial and venous system without costly and invasive techniques such as contrast arteriography or venography. Vascular surgeons have refined the techniques,

participated in development of quality standards, and helped develop programs to assess and accredit noninvasive vascular testing programs. Yet, this IDTF proposal would potentially exclude vascular surgeons from serving as medical directors of noninvasive vascular laboratories.

Congressional authority would likely be needed to place additional standards on physicians for the performance of imaging studies. Judging physician competence based upon clinical specialty would be a significant departure from Medicare's historic practice of paying for all medically necessary services provided by physicians operating in their scope of practice in the state in which they are located. In the same MedPAC study referenced above, the following was also included: "To ensure that CMS is able to implement national standards in all settings, Congress should provide the Secretary with specific statutory authority to do so. Although CMS has set quality standards for various types of facilities (hospitals and skilled nursing facilities), there are very few examples of federal standards for physician offices".

This proposal also conflicts with the newly enacted Medicare Improvements for Patients and Providers Act of 2008. This law requires accreditation for imaging services based upon the certification of third party accreditation bodies, which determine physician qualifications by using experience, training and competence. Although this only applies to advanced diagnostic imaging services, SVS has always been supportive of accreditation standards for vascular ultrasound. We applaud those Carriers, such as Trailblazer, that require either non-physician providers to hold a vascular sonography credential or the vascular lab to be accredited by a third party accreditation organization.

Finally, the proposal will impose significant, unfunded administrative burden on providers, Carriers and CMS. Expanding the IDTF program to physician offices would impose an enormous administrative burden on providers, Carriers and CMS. Already struggling with payment reductions resulting from the Deficit Reduction Act of 2005 – reimbursement for non-invasive vascular diagnostic studies has been reduced on average 32 percent, with some vascular labs forced to close – providers do not have funding to cover the administrative costs of complying with IDTF standards. Because of poor compliance within the existing IDTF program, with only one-fifth of IDTFs complying with participation and enrollment standards, the Office of Inspector General recommended in 2006 that CMS increase inspections by Carriers to monitor compliance with standards. CMS responded that the Carriers do not have the resources to conduct such inspections. Adding physician offices to these inspections will further cripple the ability of the program to ensure compliance with standards and appropriate billing for services.

As a designated health service (DHS), ultrasound is performed in physician offices largely as a result of the in-office ancillary services' exception to the Stark regulations. This exception allows physicians to self-refer for DHS they provide

in their own offices that are necessary for the diagnosis or treatment of the medical condition of patients in the physician's office. Because of its immediate bearing on patient management decisions, in-office ultrasound conforms to the intent of the in-office ancillary services exception as well as the technical requirements.

Although SVS appreciates the recognition that physician organizations already meet or exceed some of the IDTF standards, we believe that there will be many negative consequences created by this proposal as delineated above. If vascular surgeons are unable to continue using ultrasound, diagnoses will be delayed, office visits will increase because it will no longer be possible to review imaging findings and create a treatment plan in the initial visit and more expensive diagnostics and treatment will likely increase because of the reduced availability of in-office ultrasound.

For many years, SVS has pleaded with CMS to mandate quality requirements for providers of noninvasive vascular diagnostic testing. We were disappointed that MIPAA excluded ultrasound in the sections mandating that advanced imaging facilities undergo facility accreditation. We strongly urge CMS to require – instead of IDTF standards – the much more appropriate mandate for either 1) vascular ultrasound facility accreditation, or 2) technologist credentialing (e.g. Registered Vascular Technologist).

Physician and Non-Physician Practitioner Enrollment Issues

- **SVS requests that CMS continue to allow physicians to bill the Medicare program retroactively for up to 27 months prior to the physician receiving approval from the Medicare program on their enrollment application, as long as physicians meet Medicare's program requirements for the services at the time they were rendered.**

SVS supports current enrollment provisions for the Medicare program which allow physicians that are establishing or changing a practice location to be able to bill retroactively for the services they have been providing to Medicare patients prior to the date of filing or receiving Medicare billing privileges, as long as the physician rendering the services is meeting Medicare's program requirements for these services. If a Medicare contractor is not able to provide verification that program requirements and qualifications are being met or process a physician's Medicare enrollment application in a timely manner, it should not be the physician or Medicare beneficiary who should be penalized. We believe this is even truer now that CMS had moved to a web-based PECOS enrollment application system.

When a physician decides to establish a practice or move his/her practice to a given area, that decision is usually heavily influenced by the amount of need by the patients living in that community. Specifically for vascular surgery, many of

these patients waiting for care are Medicare beneficiaries living in rural or underserved areas. If CMS increases the time and barriers that a practice must go through prior to providing care, this will result in more physicians being unwilling to go to these areas to set up practices, thus delaying access for appropriate medical care for Medicare beneficiaries who need it the most. Therefore, we request that CMS continue its current practice.

Physician Quality Reporting Initiative (PQRI)

- **SVS commends CMS for including the NQF-approved dialysis fistula measure that we developed in the 2009 PQRI quality measures.**

SVS has supported the PQRI program since its inception, and we also support the risk-adjusted outcomes measures currently under development. SVS is pleased that registries are recognized as an instrument to support and leverage existing voluntary clinical data collection efforts, and we intend to explore the possibility that the SVS carotid stent and carotid endarterectomy vascular registry may be used for this purpose in the future.

SVS also supports the venous ulcer compression and diabetic foot ulcer offloading wound care measures that are under consideration by NQF.

Potentially Misvalued Services Under the Physician Fee Schedule

- **SVS supports updating high cost supplies on an every two year basis.**

The SVS does not oppose CMS' request for an update of high cost supplies every other year and we have attached a chart to our comment letter of those supplies used in vascular surgery procedures with updated unit prices and quantities per procedure and invoices documenting this information. However, we would encourage CMS to review the timing for these high cost supply updates and the statutorily-mandated five-year review of practice expense inputs such that high cost supplies are not updated one year and then re-updated again the following year as part of the overall five year review.

- **SVS recommends that the threshold for services billed together should remain at 90%.**

SVS urges CMS to rely on the work that is already being done in this area by the RUC. We believe the work RUC is doing will be extremely informative to CMS regarding which services it may consider in the future for the purposes of bundling or multiple services reduction. We feel that the RUC's criteria for services having to be billed together 90 percent of the time on the same day for the same patients for the same indication to be considered for some type of payment efficiency policy, is more appropriate. CMS' proposed lower thresholds

of 60-70 percent would be impossible to adjudicate, and more importantly would be impossible to determine situations in which payment reduction would, or would not be, appropriate.

- **SVS urges consideration of patient and disease related issues when conducting review of rapidly growing procedure frequency.**

SVS encourages CMS to allow RUC to do the screens concerning identification of the fastest growing CPT codes and for RUC to then work with the physician community regarding the clinical evidence needed for determining why certain procedures are growing and others are not. Furthermore, we would ask that any analysis done by CMS about the growth in CPT codes be normalized by both beneficiary growth and the amount of disease burden in the Medicare program. SVS expects there to be growth in the CPT codes that are used to identify services provided to Medicare beneficiaries, with at least 75 percent of these beneficiaries being diagnosed and treated for some form of vascular disease and/or its complications some time during their lifetime. Therefore, as the number of beneficiaries in the Medicare program increases, so do the services provided by vascular surgeons. Thus, with the Medicare program having more beneficiaries over the age of 80 in the program than ever before, the volume of services to diagnose and treat is going to increase, as it should to be able to provide them with high quality, appropriate health care.

- **SVS urges objectivity when considering services originally valued by Harvard.**

CMS states in the NPRM that Harvard-valued codes that have never been reviewed by the RUC may be potentially misvalued. First, we believe the value of such an endeavor is questionable as the vast majority of these services are infrequently performed. More importantly, no a-priori assumptions can be made regarding potential over-valuation of codes that retain Harvard inputs. In fact, since several thousand “potentially misvalued” Harvard codes have been carried through the RUC process during three 5-year reviews, it may be predicted that the majority of codes with retained Harvard inputs have relative work values that are close to correct. Evaluating these codes with the RUC process will identify some codes that are currently overvalued and some that are undervalued. Therefore, if CMS determines that Harvard valuation alone constitutes sufficient compelling evidence to reconsider a code’s work value, the Agency must be willing to consider, in an unbiased and objective manner, the possibility that a Harvard code’s work value may increase or decrease after undergoing reconsideration.

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 Health Policy and Government Relations at pPhillips@vascularsociety.org or 703-573-7894.

Sincerely,

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