



August 22, 2008

Kerry N. Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1404-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

**RE: CMS-1404-P – Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rules; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rules**

Dear Administrator Weems:

The Society for Vascular Surgery (SVS), representing over 2,400 practicing vascular surgeons in the United States, offers the following comments on the Centers for Medicare and Medicaid Services' (CMS) Medicare hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for fiscal year 2009.

Background for the OPPS – SVS Emphasis on Prevention

The Initial Preventive Physical Examination (IPPE, G0344, APC 605) is referenced in the NPRM as an outpatient service payable under the OPPS. SVS continues to be disappointed with the low number of Medicare beneficiaries who have taken advantage of the IPPE. Early 2007 data suggest that G0344 may have been reported as a HOPPS service less than 7,000 times, representing a miniscule percentage of the new beneficiaries who qualify for this valuable service. SVS is concerned about the IPPE not only on its own merit, but also because another important preventive service, screening for abdominal aortic aneurysm (AAA, G0389, APC 266) is available only to at-risk beneficiaries who have undergone the IPPE. Early 2007 data suggest that AAA screening may have been claimed less than 5,000 times in the HOPPS, again just a fraction of individuals at risk for death from ruptured AAA. This is a sad note since ruptured AAA carries an 85% mortality, while death following elective AAA repair is only 2-3%. In order to reduce the 85% mortality of ruptured AAA to a 2-3% mortality, all we need to do is find the AAAs before they rupture.

SVS urges CMS to use all available financial resources for the education and promotion of these important benefits in the manner and degree of the Agency's successful effort to

promote the Part D prescription drug benefit. On April 16, 2008, the original U.S. House of Representatives sponsors of the AAA screening bill sent a letter to CMS regarding the low utilization rates for both of these preventive benefits. Their concern was that CMS's effort to promote IPPE and AAA screening to physicians and Medicare beneficiaries has been insufficient. SVS agrees entirely with these Representatives. Our Medicare program needs to shift a degree of emphasis from treatment of advanced acute disorders to disease prevention, and the IPPE and AAA screening are appropriate targets for this emphasis. MIPAA extends the opportunity for a new beneficiary to undergo the IPPE from six months to twelve. CMS could use this change as a catalyst for a reinvigorated preventive campaign.

### SVS Urges CMS Not to Enact OPPTS Healthcare-Associated Conditions (HACs)

SVS understands CMS and Congress' interest in not having the Medicare program reimburse physicians for low quality or error-ridden care. However, we expressed concerns about applying the HACs payment policy to the IPPS and physician practice setting. We also have apprehension about the HACs listed for occurrences during hospital-outpatient department (HOPD) encounters, particularly conditions resulting from trauma or falls. No matter how hard a physician tries to follow the scientific guidelines in providing the best possible care, in the end the patient may behave in such a way that an event such as trauma or fall may occur.

Also, SVS is concerned that additional conditions that were included for the IPPS may be applied to the OPPTS. Most of those conditions do not fulfill the statutory requirement that they can be reasonably prevented through application of evidence-based guidelines. To be reasonably preventable, 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, including high-risk patients. Vascular surgeons care for patients with some of the most severe and complicated conditions, and the best possible care will not result in a "0" incidence of several of the disorders that have been mentioned in prior CMS publications as possible HACs. Inherent in this proposal is also the unintended likelihood of de-selection of some patients based on their high risk status.

In addition, CMS is proposing the requirement of present on admission (POA) indicator information for the OPPTS, yet some conditions lay dormant or are not discernible on admission. Increased utilization of preoperative tests and screenings would be considered necessary by providers should this program be implemented, and while these extra tests may not improve the overall value of health care, they will certainly increase the cost of providing care. Performance of these pre-operative tests and screenings would be driven by avoidance of unfounded malpractice suits since the sense of the community is that plaintiff's attorneys are salivating over the concept of "never events".

Therefore, while the provisions in this proposed rule regarding application of HACs to OPPTS and particularly to surgical procedures are well-intentioned, they would present an

undue burden to surgeons, higher costs, and many unintended consequences for the beneficiary and the Medicare program.

### SVS Urges CMS to Un-package IVUS

For CY 2009, CMS is proposing to maintain the packaged status of CPT codes 37250 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel); and 37251 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel). These services were newly packaged for CY 2008 because they were members of the intraoperative category of services that were included in the CY 2008 packaging approach. The intraoperative category includes those codes that are reported for supportive dependent diagnostic testing or other minor procedures performed during surgical or other independent procedures. CMS packaged the IVUS payment because IVUS supports the performance of an independent procedure and is provided in the same operative session as the independent procedure.

Although SVS supports the concept of packaging as a means to encourage cost containment, we believe that IVUS should NOT be packaged. IVUS falls into the category of a rarely performed, yet significantly expensive ancillary procedure that serves to improve the quality and limit the complication rate of percutaneous vascular intervention. The IVUS literature is compelling in situations where exact real time assessment of arterial or venous status is mandatory, or when the use of iodinated contrast material is contraindicated. However, since these situations are uncommon, the modality will likely never proliferate to the point where it will influence the relevant packaged APC payments. If IVUS payments remain packaged, facilities that employ IVUS will be substantially under-reimbursed for every case in which an IVUS catheter is used, but facilities that never use IVUS will be rewarded by the small increment that IVUS contributes in the HOPPS packaged methodology. Continued packaging may result in elimination of availability of this important albeit niche device. Please un-package IVUS.

### Proposed Quality Measures for CY 2010 and Proposed Process to Update Measures

SVS is concerned with the lack of process being used to create four new OPSS imaging quality measures for 2010. Even though CMS has submitted these measures to the National Quality Forum (NQF), they have not received NQF endorsement nor have they been considered for adoption by the Hospital Quality Alliance (HQA). Adoption of appropriate quality measures and continued progress in improving quality of care also requires “public” comment following adoption by the HQA and endorsement by the NQF. None of this has been completed for the four new OPSS measures.

These new imaging quality measures are directly related to the practice of physicians, so SVS recommends they be reviewed by the AMA Physician Consortium for Performance

Improvement as well, which is best qualified to consider the appropriateness of the measures for numerous health care conditions. In addition, OPSS measures that relate to physician performance should be aligned with physician measures utilized in the Physician Quality Reporting Initiative. Finally, since the imaging measures are still in the developmental process, CMS is unable to include such critical information as measure specifications, rationales and evidence or an explanation of the expected value of these measures in the proposed rule.

MIPAA calls for the HHS Secretary to contract with consensus-based organizations such as the NQF to develop and report annually to the Secretary and Congress on goals and priorities and specific measures and for the Secretary to then set national goals. We believe this process needs to be completed before any new measures are included in proposed rules.

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](mailto:pPhillips@vascularsociety.org) or 703-573-7894.

Sincerely,

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