



June 18, 2010

Ms. Marilyn Tavenner  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1498-P  
P.O. Box 8011  
Baltimore, MD 21244-8050

**RE: CMS-1498-P - Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2011 Rates**

Dear Acting Administrator Tavenner:

The Society for Vascular Surgery (SVS), representing over 3,000 practicing vascular surgeons in the United States, offers the following comments on the Centers for Medicare & Medicaid Services' (CMS) Medicare hospital inpatient prospective payment system (IPPS) proposed rule for fiscal year (FY) 2011.

SVS supports CMS's intent of working to ensure that Medicare payments for inpatient services are accurate and reflect the cost to the hospital of providing high quality care. However, we are very concerned with the Agency for Healthcare Research and Quality (AHRQ) Inpatient Quality Indicator (IQI) for abdominal aortic aneurysm (AAA) mortality rate for FY 2011 and the proposed hospital-acquired conditions (HACs) quality measures for FY 2012. Therefore, SVS would offer the following recommendations and comments for consideration on these two issues:

Reporting of Hospital Quality Data for Annual Hospital Payment Update (RHQDAPU) – Abdominal Aortic Aneurysm (AAA) Mortality Rate Measure

- **In order to be scientifically valid and accurate, the AAA mortality measure must be separated into one measure for those patients undergoing elective repair and a second measure for those undergoing emergent or urgent repair. The differences in patient profile and perioperative mortality in these two subsets are so great (as much as a 20-fold mortality difference) that they cannot be risk stratified accurately in a single measure.**
- **The AAA mortality measure should be stratified by open surgical vs. endovascular repair because the expected mortality of the former is twice that of the latter.**
- **The AAA mortality risk adjustment model should be tested prospectively for accuracy.**

Despite numerous conversations undertaken by SVS with the AHRQ regarding its IQI measure entitled, “Abdominal Aortic Aneurysm (AAA) Mortality Rate (With or Without Volume)”, we continue to have serious misgivings regarding the validity and accuracy of this mortality indicator as it is currently written. Additionally, we are troubled by the process with which it was developed and we have voiced these concerns to AHRQ and the National Quality Forum (NQF) on numerous occasions.

SVS strongly recommends that mortality measures regarding the repair of ruptured AAAs should not be bundled with that of elective AAAs because the disadvantages to overall accuracy of such a measure vastly outweigh any theoretical advantages associated with obtaining a larger sample size. Thus, we recommend development of separate measures, one for elective AAA repairs and one for emergent ruptured AAA repairs. Separating these surgical events into two separate measures will provide data that are more accurate and more valuable to consumers and purchasers than a single combined measure.

SVS believes the evidence AHRQ used to justify creation of a single combined AAA mortality measure fails on many counts. In our discussions with AHRQ, we were told that their primary reason for bundling these events into a single measure was that using a broad denominator increases the reliability of the indicator (i.e., the probability that differences in indicator reflect true differences in performance) and that a bundled indicator provides a better decision-making tool for consumers and purchasers “since they do not know what type of AAA they will have prior to the event-this is basically a Bayesian decision-making framework”. Furthermore, AHRQ conveyed to SVS that it believes that surgeons with clinical experience in treating ruptured aneurysms would likely carry over that skill to elective aneurysm repair. Finally, it was stated that the risk adjustment in the AAA Mortality Indicator adequately accounts for ruptures’ status. While these issues may seem intuitively correct, when applied to AAA repair SVS believes each point to be inaccurate.

SVS supports the general principle that the denominator of a quality measure should be as broad as reasonably possible. However, in proposing to bundle mortality for elective and ruptured AAA repair, the AHRQ is attempting to force a combination for which there is little natural synergy. First, there exists an overt clinical difference and a major disparity in mortality between these two procedures. The established mortality for elective AAA repair is 1-5%, while that of emergent ruptured AAA repair is greater than 40-50%. Ruptured AAA outcomes depend on different pre-operative clinical variables and on the clinical excellence of various different departments within the hospital. Elective AAA repair outcome depends primarily on the surgical and anesthesia teams, while survival of the ruptured AAA patient is additionally dependent on pre-hospital Emergency Response Teams, the Emergency Department staff and postoperative Critical Care. Ruptured AAA repair is more similar to the triage and care of a major trauma victim than it is to elective AAA repair.

Primary risk factors for mortality after elective AAA repair include pre-operative renal insufficiency and a history of congestive heart failure, among others, and the vascular surgeon considers these carefully in deciding whether to recommend surgery. In so doing, the surgeon has a major opportunity to influence the hospital’s elective AAA results. In contrast, the major risk factors for mortality after a ruptured AAA include pre-hospital arrest, shock, and anuria. Although the surgeon is well aware of these, the decision to offer surgical repair is not something that is customarily withheld for concern over potentially poor outcomes, and most patients confronting immediate death will request potentially life-saving therapy. In summary, elective and emergent AAA repairs have vastly different mortality profiles, involve different resources within the hospital, and there exists a major difference in the ability of providers to influence

outcomes by patient selection. SVS believes these differences are not reconcilable and should not be bundled in a single outcome measure simply to broaden the denominator.

To address the assumption that a bundled indicator provides a better decision-making tool for consumers and purchasers “since they do not know what type of AAA they will have prior to the event”, SVS would point out that only the consumers and purchasers of elective AAA repair have the luxury of time to consider which surgeon and which hospital should provide their care. In stark contrast, when a patient’s AAA ruptures at home or in the supermarket, he or she is usually in shock, unconscious, or both. The decision regarding hospital choice usually lies within pre-existing algorithms within the emergency transport system. SVS therefore contends that the value of an AAA mortality measure for the typical consumer lies exclusively in the results of elective AAA repair. Inclusion of ruptured AAA repair results only serves to confound this measure.

We are also concerned about the AHRQ contention that a surgeon’s experience and skill with ruptured AAA repair confers an outcomes benefit to that surgeon’s elective AAA experience. It is an intriguing hypothesis, but we know of no peer-reviewed published evidence in support thereof.

SVS disagrees with the AHRQ assumption that ruptured AAAs are distributed equally and randomly among hospitals and are therefore unlikely to systematically affect outcomes. We believe this is not true in the U.S. because many EMT services have specific algorithms regarding triage of suspected ruptured AAAs. In Seattle, WA, for instance, most ruptured AAA patients are transported to Harborview Hospital even if the events occur close to another facility. Additional systematic events that are completely out of hospital or surgeon’s control affect mortality from ruptured AAAs. For instance, in metropolitan areas where EMT services have “scoop and run” policies, the unstable ruptured AAA patient is more likely to arrive at the hospital alive only to then die in the operating suite. In rural areas, where it may take several hours to transport the typical patient to a hospital capable of treating ruptured AAAs, a greater proportion of victims will die in transport. Those who arrive alive may therefore comprise a pre-selected “survivor” subset with a lower operative mortality than in metropolitan regions. Thus, SVS believes that inclusion of ruptured AAA in the mortality index is not random and very likely will result in a systematic bias.

Regarding risk adjustment, SVS believes that data from field use of this measure demonstrate the risk adjustment to be inaccurate. We reviewed University Healthcare Consortium (UHC) use of the AHRQ AAA mortality measure. Although unobserved mortality in the UHC system for ruptured aneurysms has been 40-42% over the last three years, expected mortality using the AHRQ model is only 17-22%. The model does not risk adjust adequately within the large UHC system.

This major disparity between the mortality rate predicted by the AHRQ model and that observed in the UHC database raises important questions about the manner in which the model was developed and tested. Since mortality indicators are critically important, testing transparency will be a key to the development of measures that are appropriate for the provider community. An important step in the development of a successful model for risk stratification is validation of the model in an external database. We suggest that objective criteria by which risk stratification models are tested and implemented be transparent and subject to a well defined peer review process.

Regarding open vs. endovascular repair, nearly every peer-reviewed manuscript analyzing recent population-based experience of elective open and endovascular repair reveals lower peri-

operative mortality after endovascular treatment, and the relative risk reduction is approximately 50%. SVS believes there is some logic to creating separate AAA mortality measures for open and endovascular AAA repair, but if the risk adjustment model is created accurately and proves its accuracy in prospective testing, then a combined measure may suffice.

Even less is known at this time about potential risk reduction when endovascular repair is applied to urgent and emergent AAA repair, but initial experience in centers of excellence suggests the endovascular approach may result in lower perioperative mortality in that population as well. Much more experience and analysis is required before any accurate prediction model of endovascular repair for symptomatic or ruptured AAA could be constructed.

In conclusion, SVS strongly supports development of accurate outcomes measures for AAA repair using clinical evidence, but we believe that, unless AHRQ has revised their model recently without notifying SVS, its mortality measure is conceptually flawed and operationally defective. Thus, it should be retired for FY 2011 and not be included in the RHQDAPU program. Instead, SVS recommends development of separate mortality measures for elective and ruptured AAAs, and we are available to work with CMS and AHRQ in the development and field testing of these measures.

#### RHQDAPU – SCIP-Infection-2: Prophylactic Antibiotic Selection for Surgical Patients

We believe that this measure is overly-complicated and confusing. SVS recommends that this measure either be retired or harmonized with the corresponding CMS Physician Quality Reporting Initiative (PQRI) measure. Most of the SVS members who participate in PQRI use this measure and have been able to successfully report it.

#### Claims-based Measures - Hospital Acquired Conditions (HACs)

- **While it is reasonable and appropriate for CMS to encourage hospitals to direct significant effort at reducing HACs, SVS recommends further discussion regarding appropriate risk adjustment, documentation of co-morbid conditions, appropriate exclusion criteria and interpretation of the collected data be undertaken before adopting HAC measures.**
- **Surgical Site Infections cannot be completely eliminated. In vascular surgery the best evidence to the contrary lies in review of the peer-reviewed lower extremity arterial revascularization literature wherein every significant clinical experience documents an incidence of post-operative infection and wound breakdown related to factors of advanced age, obesity, diabetes, requirement for surgical incisions in unhygienic groin areas, and poor pre-operative nutrition. For example, for patients undergoing varicose vein ligation and stripping, factors of advanced skin lipodermatosclerosis, obesity, and venous hypertension auger against primary wound healing in all cases. While a risk-adjusted approach to wound healing issues may be developed, calling surgical site infections “preventable” in all cases is not reasonable.**
- **Trauma or falls also cannot be completely eliminated. No matter how hard a physician tries to follow scientific guidelines in providing the best possible care, the patient may behave in such a way that a trauma or fall may occur.**

SVS understands both CMS and Congress' interest in not having the Medicare program reimburse hospitals for low quality or error-ridden care, but most of the adverse events associated with the proposed HAC quality measures cannot be reduced to zero despite our best efforts. Also, there is the "free will" factor which means that no matter how hard a hospital or 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 events may still occur. We do appreciate that HACs will likely be used in FY 2012 as measures in the RHQDAPU program for data tracking and reporting purposes vs. non-payment if HACS are not documented as present on arrival (POA).

However, most of the HACs do not fulfill the statutory requirement that events be preventable through application of evidenced-based guidelines. To be 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. And, the proposed measures have not been endorsed by an organization such as the NQF.

Also inherent in the proposed HAC measures are the following problems: patient de-selection (especially for high-risk patients), and increased utilization of tests and screenings that may or may not improve the overall value of health care services provided under Medicare, but certainly could increase Medicare spending.

Therefore, the SVS strongly urges CMS to consider our comments and work closely with the physician community to better understand the serious ethical, practical and financial implications surrounding the HAC measures before they are finalized.

SVS appreciates the opportunity to submit these comments and looks forward to working with CMS to implement these recommendations. Please feel free to contact Pamela Phillips, Director of the SVS Washington Office at 202-787-1220 or [pPhillips@vascularsociety.org](mailto:pPhillips@vascularsociety.org), if we can provide further information.

Sincerely,

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