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06/08/11	Vascular readmission	<p>We are home health company focused on home infusion. We have a location in Sacramento CA and one in Las Vegas, NV.</p> <p>The issue I see following vascular procedure/discharge are:</p> <ol style="list-style-type: none"> <li>1. Hospital floor nurses lack of knowledge. Often times we receive a patient with double lumen lines. One port is taped and says, "clotted, do not use!" all clotted lines must be cleared in the timely fashion to prevent infection, as we know. Hospital charge nurses should check all central line prior to discharge</li> <li>2. Hospitals do not choose home health agency carefully. Many home health agencies do NOT have certified infusion nurses, nor PICC certified nurses to deal with complications. They will send the patient back to ER for even the simplest complications, such as clotted lines. Home health agencies like ours who have certified infusion nurses on staff would simply trouble shoot (de clot, repair or replace lines) right at patient homes.</li> </ol> <p>These just I can think of right now.</p> <p>Thanks!</p>	Angela Sehr, RN, PHN, CRNI Advanced Home Health Inc.	ASehr@ahhsac.com	Home Health Care Agency
06/10/11	Vascular readmission	<p>Vascular re-admission may be reduced by the implementation of best practices which utilize patient education on vascular disease processes by vascular health educator, routine follow-up with vascular testing to monitor vascular intervention function, life style modification and follow-up by vascular case management to monitor compliance with life style modification and assist with patient education after release from hospital. A support group for those individuals with vascular disease may also assist vascular re-admission by creating a more informed patient population which are able to identify vascular health issues prior to requiring additional intervention.</p>	R. Jeanne Patton RVT  Technical Director/Manager Vascular UTMB Hospitals and Clinics  University of Texas Medical Branch	rjpatton@UTMB.EDU	Academic Medical Center
06/26/11	Vascular readmission	<p>I applaud CMS for attempting to develop an assessment of readmissions following revascularization procedures. However, CMS and the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHC/CORE) have missed an important opportunity to promote appropriateness of care, while also assessing the efficacy and safety of revascularization.</p> <p>When considering the readmission rate following arterial and venous revascularization procedures, there is no attempt to determine the appropriateness of the procedure that resulted in the revascularization. Intervention for venous thromboembolism remains controversial and unproven. Many patients with intermittent claudication, for example, note significant improvement in their pain-free walking distance with exercise therapy and aggressive risk factor intervention. The proportion of patients who actually fail exercise therapy, thereby requiring revascularization for peripheral artery disease of the lower extremities is certainly less than 50%, and readmission following vascular intervention in a patient who was not given</p>	Michael R. Jaff, DO, FACC, FAHA Associate Professor of Medicine Harvard Medical School Medical Director, Vascular Center Vascular Diagnostic Laboratory Vascular Ultrasound Core Laboratory Massachusetts General	MJAFF@PARTNERS.ORG	Academic Medical Center

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		<p>the optimal medical therapy is important to identify.</p> <p>I am surprised that CMS and YNHSC cite a publication from 1994 as the rationale for this “measure”. I certainly agree that the quality of inpatient and outpatient care play a critical role in the likelihood of readmission. However, the “bed capacity of the local health care system” is not nearly the factor on readmission as is the acuity of the illness requiring revascularization. This holds true for patients who present with a symptomatic thoracic or abdominal aortic dissection; ruptured vs unruptured aortic aneurysm; critical limb ischemia vs stable intermittent claudication due to peripheral artery disease of the lower extremity; or acute vs chronic mesenteric ischemia. In addition, in 1994, endovascular therapy was in its’ infancy, so quoting this as a rationale for this “measure” seems incongruous.</p> <p>Regarding specific issues in this report, there is no identification of patients who undergo ultrasound-guided thrombin injection for pseudoaneurysms.</p> <p>I cannot locate codes in your list for patients who undergo catheter-based thrombolytic therapy for deep venous thrombosis or pulmonary embolus.</p> <p>Given the number of complications that have been reported with vena cava filters, why aren’t these procedures included in this cohort?</p> <p>When a patient undergoes revascularization at multiple levels, either arterial or venous, how will that patient be categorized in your system? For example, would catheter-directed thrombolytic therapy with pharmacomechanical thrombectomy of acute deep venous thrombosis of the femoral and iliac veins and inferior vena cava be categorized as lower extremity endovascular, thoracic and abdominal endovascular, or both??</p> <p>I am not sure I understand why you have chosen not to include 39.79, “other endovascular repair (of aneurysm) of other vessels)? Consider, for example, a popliteal artery aneurysm. Whether this is treated with ligation of the aneurysm and surgical bypass grafting, or endovascular stent-graft exclusion, this patient is also at risk of complications within 30 days of the aneurysm exclusion. Many patients with aneurysms of the thoracic and abdominal aorta are also “heterogeneous”, and yet you opted to include them.</p> <p>In your categorization scheme, you may wish to consider (specifically in the limb categories) specifying whether the revascularization was performed for limb threatening ischemia or not? Clearly, the risks of the revascularization are greater</p>	Hospital		

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		<p>Finally, you mention that the primary reason for hospitalization is the “central” cause. How would the YNHHC/CORE and CMS classify this patient: a 60 year old man with 20 years of poorly controlled diabetes mellitus (associated with retinopathy, nephropathy, and peripheral neuropathy) who is admitted for a deep foot infection. The patient requires urgent incision and drainage of a foot abscess. Subsequent to this, while the patient is receiving intravenous antimicrobial therapy, it is determined that the surgical wound is not going to heal due to previously undiagnosed peripheral artery disease. The patient undergoes successful revascularization (the method does not matter), and the patient is discharged with outpatient parenteral antimicrobial therapy and wound care. Within 30 days, the patient is readmitted for worsening tissue necrosis and infection, resulting in a Syme’s foot amputation. Would this meet your definition of a readmission following a vascular procedure? It would not have been a planned readmission, but clearly, this patient did not suffer a complication of the revascularization, but rather, complications of the underlying diabetes and soft tissue infection.</p> <p>Thank you, once again, for the opportunity to provide comments.</p> <p>Michael R. Jaff, DO June 27, 2011</p>			
06/28/11	Vascular Readmission	I think it is important to hold the patient accountable for following the plan of care and not just always penalizing the organization. I would like to have exclusion criteria added related to noncompliance with the plan of care. If a patient does not comply with the plan of care and it is documented by the MD, the patient should be excluded for patient reasons.	Karrie Cleveland Billings Clinic	kcleveland@billingsclinic.org	Healthcare Organization
06/29/11	Vascular Readmission	<p>To Whom It May Concern:</p> <p>RE: 30-day All Cause Readmission Following Vascular Procedures</p> <p>Mayo Clinic appreciates the opportunity to comment on the Vascular Readmission Measure that the Yale-New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) has developed on behalf of the Centers for Medicare &amp; Medicaid Services (CMS) as a claims-based, risk-adjusted hospital readmission measure.</p> <p>Mayo Clinic is concerned with the risk adjustment component. At a minimum, the risk model should differentiate ruptured from unruptured aneurysm. Patients with ruptured aneurysm (e.g., ICD-9 diagnosis code 441.3) should be contained in separate strata, if not excluded from the analysis. The clinical classification diagnosis grouping proposed for use does not differentiate these types of patients. Also, the clinical classification categories proposed as adjustment factors do not correspond with the current</p>	Teresa Beard Regulatory & Reimbursement Process Manager Mayo Clinic Rochester	Beard.Teresa@mayo.edu	Hospital

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		<p>classification software released by Agency for Healthcare Research and Quality (AHRQ) through Healthcare Cost and Utilization Project (HCUP).</p> <p>Thank you for the opportunity to share our concerns and comments.</p> <p>Sincerely,</p>			
06/29/11	Vascular Readmission	<p>Re: Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Vascular Procedures: Summary of Technical Expert Panel Evaluation of Measures</p> <p>Dear Dr. Krumholz:</p> <p>On behalf of our 13,000 physicians and scientists, the American Society of Nephrology (ASN) appreciates the opportunity to provide comments on “Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Vascular Procedures: Summary of Technical Expert Panel Evaluation of Measures.” ASN is a not-for-profit organization dedicated to promoting excellence in the care of patients with kidney disease. Foremost among ASN’s concerns is ensuring equitable patient access to the highest quality of dialysis care.</p> <p>ASN applauds CMS’ efforts to improve and guarantee the quality of care for all patients undergoing vascular procedures, and appreciates the opportunity to review and comment on the Summary of Technical Expert Panel (TEP) Evaluation of Measures for Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Vascular Procedures. ASN is supportive of the intention to exclude the renal dialysis patient population from the measure. ASN appreciates that CMS and the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation recognize the unique needs and significant diversity of the vulnerable dialysis patient population. Patients on dialysis have unique care needs and vulnerabilities distinct from the general patient population to whom this measure would apply. ASN concurs with CMS that excluding the renal dialysis patient population from the measure is the appropriate course of action.</p> <p>On behalf of ASN, thank you for your willingness to consider these comments about the Summary of TEP Evaluation of Measures at this time. To discuss ASN’s comments, please contact ASN director of policy and public affairs,</p> <p>Paul C. Smedberg, at [REDACTED] or at psmedberg@asn-online.org.</p> <p>Sincerely,</p>	<p>Rachel Nell Shaffer</p> <p>Policy Associate</p> <p>American Society of Nephrology</p>	<p>rshaffer@asn-online.org</p>	<p>Medical Professional Society</p>

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		Joseph V. Bonventre, MD, PhD, FASN President, American Society of Nephrology			
06/29/11	Vascular Readmission	<p>Dear Colleagues:</p> <p>We appreciate the opportunity to comment on the draft Hospital-level 30-day All-Cause Risk standardized Readmission Rate following Vascular Procedures measure. We recognize the importance of promoting high quality and better-coordinated care for patients undergoing vascular procedures and applaud your efforts in this regard.</p> <p>The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have for many years taken a leadership role in promoting high-quality, evidence-based, patient-centered care for cardiovascular disease, including the development of clinical practice guidelines and performance measures that address the management of the most common forms of cardiovascular disease, including coronary artery disease, congestive heart failure and peripheral arterial disease. We recognize that patient outcomes may serve as aggregate markers of quality, integrating both structural aspects and clinical processes of care that could not otherwise be measured. In addition, outcomes are the most important measures from a patient perspective. On the other hand, outcomes may be difficult to report in ways that allow fair comparisons among providers without creating or exacerbating disparities in care. We have reviewed the Measure Information Form (MIF), the TEP Summary Report and the Measure Calculation Algorithm that are posted for review. On behalf of our joint ACCF/AHA Task Force on Performance Measures we respectfully offer the comments below for your consideration.</p> <p><b>Planned Readmissions</b></p> <p>While we agree that these should be excluded from the numerator, we are quite concerned that the current approach will not accurately identify planned readmissions, which are very common in patients undergoing vascular procedures. In our opinion, this weakness relates to the inherent limitations of claims data, some of which are acknowledged in the TEP Summary Report. We are concerned that many readmissions which are planned, or at least recognized as potentially necessary, at the time of discharge will not be identified as such. We believe the proposed approach may identify only a minority of planned readmissions. For example, neither a patient having a carotid endarterectomy followed three weeks later by a hernia repair nor a patient with a lower extremity bypass for an ischemic foot wound who is readmitted three weeks later for split thickness skin graft would be accurately identified as planned readmissions.</p> <p>Conversely, a number of the ICD-9 codes, which are proposed to identify planned admissions do not necessarily represent planned admissions. For example, procedure code 39.56 (repair blood vessels with tissue patch graft) could very well represent an unplanned admission with a subsequent need for</p>	Melanie Shahriary, RN, BSN Director, Performance Measures and Data Standards American College of Cardiology	mshahria@acc.org	Medical Professional Society

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		<p>additional arterial reconstruction, which was not anticipated.</p> <p>A note in the TEP Summary Report indicates that this is a preliminary and evolving approach to identifying planned readmissions. Given that it will be changing, we hope that YNHSC/CORE and CMS will provide the opportunity to review the model when it is further refined and before it is implemented in a public reporting program.</p> <p>Risk Adjustment Methodology:  We are also concerned that claims data are not reliable or complete enough to adequately risk adjust. The model will suffer from the inaccuracies and omissions of claims data, some of which are acknowledged in the TEP Summary Report. The potential for unintended consequences must be considered, especially if this measure is to be publicly reported. Implementing this measure may discourage physicians and hospitals from offering vascular procedures to very difficult or sick patients who might benefit from them most and significantly risk creating or exacerbating disparities in care. For example, it might seem less risky to simply amputate a limb than to perform a complex angioplasty on a very sick patient. In general, we believe that it would be preferable to use a clinical registry to capture the required data. This would provide the robust, granular data needed to adequately risk adjust this measure.</p> <p>The TEP Summary Report notes that the indicator for elective vs. urgent admissions is not uniformly coded. There also does not appear to be anything in the proposed 48-variable risk model that addresses procedural acuity (elective vs. urgent vs. emergent procedures). Procedural acuity also does not seem to be accounted for in the anatomic groupings, but should be captured somehow. It is not clear how the model will account for the greater risk of emergent procedures such as for acute limb ischemia, aortic dissection or ruptured abdominal aortic aneurysm.</p> <p>Although it seems reasonable to include vascular procedures performed as a hospital outpatient, it is unclear whether the setting in which the procedure was performed factors into the risk adjustment model or should be reported separately. Intuitively, it would seem that procedures performed as an inpatient might have a higher risk of readmission than those deemed safe enough to perform on an outpatient basis and perhaps this should be reflected somehow in the measure.</p> <p>Other Comments  Patients who expire in the hospital are removed from the denominator, but it does not appear that mortality is otherwise factored into the model. Any tabulation of 30-day readmission rates that does not also consider 30-day mortality rates could be misleading, given that patients who might have been readmitted could have died instead.</p>			

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		<p>We agree with the proposal to report this measure only at the facility level. Given the complexity of the outcome and the many contributing circumstances that may influence readmission, it should not be reported at the individual provider level. Measures must be reported at the appropriate level of accountability to avoid incriminating providers or institutions for adverse outcomes which are only minimally or partially under their control.</p> <p>Thank you for your consideration of the comments above. We strongly support the efforts of YNHHS/CORE and CMS improve the treatment of patients undergoing vascular procedures and would be happy to discuss our concerns with you directly at any time.</p> <p>Very truly yours, Eric D. Peterson, M.D., M.P.H., F.A.C.C. F.A.H.A. Chair, ACCF/AHA Task Force on Performance Measures</p>			
06/29/11	Vascular Readmission	<p>There may be planned surgeries that have different ICD 9 codes than the index hospital stay and therefore limiting the exclusion to only include the "same" surgery will not exclude other "planned" surgeries from being counted from readmissions. CMS should reconsider expanding the exclusion list to include Arteriograms followed by a vascular procedure, lower extremity revascularization followed by amputation.</p> <p>Thank you for this opportunity to comment on the developing measure.</p>	Teresa Beard Medicare Strategy Unit Mayo Clinic	Beard.Teresa@mayo.edu	Hospital
06/29/11	Vascular Readmission	<p><b>Comments On The Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Vascular Procedures From Emory Healthcare, Atlanta, GA</b></p> <p>We appreciate the opportunity to comment on this draft measure 30-day RSRR following Vascular Surgery procedures. We agree that understanding hospital readmission rates after complex surgical procedures is an important area of focus. Furthermore, this attempt at developing methodology to help identify preventable readmissions after complex vascular procedures is a necessary first step that we would envision should be applied to other surgical subspecialties. Finally, we would like to acknowledge the incredible amount of work that all involved have put into developing this draft readmission measure. We have divided our comments into 4 general areas.</p> <p><b>Technical Expert Panel (TEP) Composition</b></p> <p>The majority of the "vascular specialists" on each of the three panels are from Yale University School of Medicine. We would recommend the inclusion of 1-2 nationally recognized senior Vascular Surgeons with expertise in Health Services Research (e.g.: ██████████, MD, Dartmouth University). Our fear is that limited geographic <b>and</b> surgical expertise on the panels associated with developing the</p>	John Sweeney, MD Chief Quality Officer, Department of Surgery Chief, Division of General and GI Surgery Emory University School of Medicine	JFSWEEN@emory.edu	Academic Medical Center

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		<p>measure, might limit acceptance of the final measure by vascular specialists.</p> <p><b>Definition of the Cohort</b>  We agree with the revisions to the cohort suggested by the TEP creating 8 groups of patients that have undergone a specific catheter based (endovascular) or open vascular procedure. We also agree with the inclusion of patients who undergo an outpatient vascular procedure into the cohort.  The YNHSC/CORE and TEP spent a considerable amount of time attempting to create a methodology to identify patients that had a planned readmission within 30 days of the index vascular admission. We would recommend a pilot study using this methodology to determine how well it actually identifies planned readmissions. Going forward it will likely be more appropriate to approach this problem with a change in coding criteria to clearly capture planned hospital readmissions rather than “infer” planned readmissions from a strategy like that outlined by the YNHSC/CORE and TEP.</p> <p><b>Definition of the Outcome</b>  We agree with the outcome as defined. It is unclear in reading the measure how it will be enacted and what the consequences of a higher than expected 30-day readmission rate will be for vascular providers and for hospitals.</p> <p><b>Risk Adjustment Methodology</b>  This may be the largest area for concern. We feel that not adjusting for patient admission source, discharge disposition, socioeconomic status, race or ethnicity is flawed. There is ample evidence suggesting that these factors do play a role in hospital readmission (e.g. Joynt et al. JAMA 2011;305:675-681).  Take for example vascular surgery transfers from one hospital to another. The vascular surgeons at our institution (Emory University Hospital) frequently accept transfers for “second opinions” on patients that have undergone a lower extremity procedure (revascularization and/or amputation) that has not gone well (i.e.: failed bypass, necrotic amputation wound). These patients are very resource intensive and are at significant risk for readmission. Unless the transfer status was somehow risk adjusted or risk shared (with the referring institution) in this population of patients, the accepting institution will be negatively impacted.  It is vital to come up with a methodology that takes this demographic information into account. Otherwise inner city hospitals and tertiary care referral centers may be at a disadvantage compared to other institutions. This may lead to a selection bias where institutions and health systems may avoid these potentially high risk patients that have complex vascular disorders. While we agree that discharging institutions should take demographic factors into account in the discharge and follow up processes and attune these efforts to the special needs of the populations being served, some of the burden of extra resources needed to prevent readmissions in disadvantaged populations are societal and should be shared</p>			

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		<p>by the communities. We disagree with the statement in the TEP summary that adjusting for such factors would "...hold hospitals to different standards of care..." In fact different standards of care are required based on case mix and the explicit recognition and adjustment for such factors can recognize the shared responsibility and help avoid unintended consequences.</p> <p>William A. Bornstein, MD, PhD Chief Quality and Medical Officer, Emory Healthcare</p> <p>Matthew A. Corriere, MD, MS Chief Quality Officer, Division of Vascular Surgery</p> <p>Thomas F. Dodson, MD Chief, Division of Vascular Surgery</p> <p>Robert A. Guyton, MD Chief, Division of Cardiothoracic Surgery</p> <p>Christian P. Larsen, MD, DPhil Surgeon-in-Chief, Emory Healthcare Chairman, Department of Surgery</p> <p>John F. Sweeney, MD Chief, Division of General and GI Surgery Chief Quality Officer, Department of Surgery</p>			
06/30/11	Vascular Readmission	<p>Dear Dr. Krumholz:</p> <p>The Federation of American Hospitals (FAH) is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay rehabilitation, and long-term care hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services. On behalf of our member hospitals, we are pleased to offer the following comments on the "Hospital Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Vascular Procedures" measure currently in development under contract with CMS.</p> <p><b>General Comments</b></p>	<p>Samantha Burch</p> <p>Director, Healthcare Policy &amp; Research</p> <p>Federation of American Hospitals</p>	SBurch@FAH.org	Hospital Association

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		<p>The FAH has serious concerns with the use of a 30-day timeframe for this measure and for outcomes measures generally. We believe that clinically, a 15-day timeframe for measuring readmissions is more reflective of the quality of care a patient received during the index hospital stay. By measuring beyond 15 days, CMS is potentially holding hospitals accountable for a range of circumstances, including poor community infrastructure and natural progression of disease, which are not within the institution's control.</p> <p>Similarly, we have concerns with the continued focus on "all-cause" readmissions. Measuring all readmissions regardless of whether there is any clinical relationship between the initial admission and the subsequent readmission does not help hospitals meaningfully assess where process improvements can be made to achieve better outcomes for patients. For this to happen, we need to develop measures that look at related readmissions using a methodology that can be replicated by hospitals. As with the three readmissions measures (for HF, AMI, and PN) currently posted on <i>Hospital Compare</i>, hospitals will have to wait for CMS to calculate this measure utilizing data (such as Part B data) the hospital cannot access and then inform hospitals of their rate which currently occurs only once a year. This data lag, resulting from hospitals' inability to replicate the readmissions measure calculation in-house, does not lend itself to continuous tracking and rapid-cycle improvement.</p> <p>The development of new readmissions measures for consideration for public reporting and/or eventual inclusion in the Hospital Readmissions Reduction Program presents an opportunity to look at methodologies beyond the 30-day, all-cause methodology used in the current condition-specific readmission measures. We believe that this represents a missed opportunity to test the effectiveness of other measure constructs in driving improvements in hospital readmission rates.</p> <p><b>Specific Comments</b></p> <p>In general, the FAH believes that expanding the portfolio of readmissions measures to assess readmissions following procedures is a reasonable approach. However, as described in more detail above, we have serious concerns about the 30-day timeframe for this measure and would ask CMS and the measure developers to strongly consider a 15-day timeframe instead, which we believe is far more appropriate for assessing hospital quality and performance.</p> <p>While we support the inclusion of outpatient vascular procedures in the measure calculation, we believe that labeling these as readmissions in the context of this measure is potentially misleading. We believe the intent of the measure with this inclusion is to more broadly assess "admissions" resulting from an "event" (<i>i.e.</i>, the vascular procedure). We believe that from a quality perspective, including all outpatient vascular procedures is the right approach, but given that the procedure may be performed in an independent Ambulatory Surgery Center (ASC) and not an ASC owed by a hospital, we would like to see quality measures for ASCs that address these procedures, especially in light of the fact that the admission following the vascular procedure would count against the hospital should this measure be adopted for</p>			

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		<p>public reporting and/or use in the Hospital Readmissions Reduction Program.</p> <p>The FAH was pleased to see a robust discussion in the Technical Expert Panel (TEP) report around identification of planned readmissions. Ensuring appropriate exclusions for planned readmissions within 30 days is important not only to ensure fair assessment of the hospital, but also to avoid unintended consequences for patients. To that end, we would generally support broader exclusions for “readmissions” within 30 days that are almost always planned (<i>e.g.</i>, chemotherapy) to avoid any incentive to delay planned care. Specifically for this measure, we believe that ultimately physician documentation at the time of the first procedure is the best method for determining exclusions for staging of vascular procedures or other planned readmissions. This could be achieved by instituting a coded flag in the patient’s record to indicate that a planned readmission for follow-up care has been scheduled.</p> <p>Finally, the FAH would like to briefly comment on the risk adjustment methodology for this measure. The question of whether to adjust for Socio-Economic Status (SES) has been a topic of great debate within the health care community for some time. While the FAH recognizes there is currently no standard, valid methodology for adjusting for SES, we believe this is an area that warrants continued attention and analysis to determine whether there is a set of SES indicators that should be adjusted for to capture certain characteristics, such as the patient’s ability to comply with discharge/post-procedure instructions, or community infrastructure to support the patient after discharge, while balancing the critical need to avoid unintended consequences.</p> <p>****</p> <p>Again, we appreciate the opportunity to comment on this new readmissions measure in development and look forward to continuing to work with CMS and its contractors to develop additional outcomes measures that will drive meaningful improvements in hospital performance. If you have questions regarding our comments please do not hesitate to contact me or Samantha Burch of my staff at [REDACTED].</p> <p>Sincerely,</p>			
06/30/11	Vascular Readmission	<p>On behalf of the Premier healthcare alliance serving more than 2,500 leading hospitals and health systems and 75,000-plus other healthcare sites, we appreciate the opportunity to comment on the measure currently in development, titled “Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Vascular Procedures.” The documentation and report was prepared by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE). Premier, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in the development of</p>	Christine L. Van Dusen Senior Consultant Clinical Standards and Quality	christinevan_dusen@premierinc.com	Healthcare Association

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		<p>quality measures by the Centers for Medicare &amp; Medicaid Services (CMS).</p> <p>CMS is specifically interested in receiving feedback for the areas of definition of the cohort, definition of the outcome, risk adjustment and the Technical Expert Panel (TEP) comments.</p> <p><b>Definition of the cohort</b></p> <p>The cohort definition consists of inpatient and outpatient vascular procedures. Premier does not agree with including outpatient episodes for the vascular measure cohort definition. We question the rationale for defining an inpatient admission after an outpatient episode as a readmission. An inpatient admission following an outpatient episode may not be due to a quality of care issue and should not be attributed to the hospital alone. As this measure will likely be used for the inpatient prospective payment system penalties, it is not appropriate to include outpatients. We recommend that the cohort definition be revised and exclude outpatient episodes as the index “admission.”</p> <p>Premier agrees with the refinement of the categorization of the procedures into eight groups. However, we are concerned with the impact of the upcoming implementation of the International Classification of Diseases 10th Revision Procedure Classification System (ICD-10-PCS) on the cohort definition. The specificity of ICD-10-PCS codes may result in a new categorization method for the procedures. Premier recommends modeling the cohort definition using the latest ICD-10-PCS version. The results of this modeling will be beneficial to assess the impact of ICD-10-PCS on this measure.</p> <p><b>Definition of the outcome</b></p> <p>The readmission is defined as a subsequent hospital inpatient admission within 30 days of an inpatient stay or outpatient episode in which a qualifying vascular procedure was performed. Additionally, the outcome definition includes criteria to identify planned admissions which would exclude the visit from consideration as a readmission. Premier concurs with the development of a definition for planned admissions. As noted in the report, there are certain procedures that can be staged and it would be inappropriate to assign staged procedures as a readmission. Again we recommend that this planned admission definition be modeled using ICD-10-PCS to determine if any revisions are required.</p> <p>In addition, we also urge CMS to exclude conditions that may result in readmissions that are not “preventable” including trauma, psychoses, substance use, maternity and neonatal, and end-stage renal disease. CMS should actively and quickly work with the National Uniform Billing Committee to enable CMS,</p>			

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		<p>and other payors, to track planned readmissions through claims and alter the measure specifications to exclude additional cases for which the hospital should not be held accountable in this measure.</p> <p><b>Risk adjustment</b></p> <p>The risk adjustment methodology is the same model as the current AMI, Heart Failure and Pneumonia 30 day readmission measures. The intent of the following statement is unclear: “the model does not adjust for the patients’ admission source and discharge disposition because these factors are associated with the structure of the healthcare system and not solely patients’ clinical risk factors.” This statement seems to imply that because these factors cannot be attributed to the patient, the admission source and disposition are within the hospital’s control which may not be true in all cases. We realize this statement is consistent with the NQF guidelines and the admission source and discharge disposition will not be used in the risk model. However these are valid factors that may be outside the control of the hospital and should be considered even if they cannot be directly attributed to the patient.</p> <p>Additionally, socioeconomic status may be an important factor for risk adjustment for this measure. Patients may have underlying conditions that if not managed at home, can result in readmissions. An example is a diabetic patient that cannot cover the cost to manage their diabetes and recover from surgery. Vascular deficiency that resulted in a digit amputation if not managed can lead to further amputations even though the hospital provided the appropriate care and services.</p> <p><b>Technical Expert Panel (TEP) comments</b></p> <p>Premier appreciates the ongoing work of the TEP. One of the TEP’s concerns regarding the cohort definition is the assignment to the group with the highest risk of readmission when the index admission has procedures in more than one of the defined groups with the exception of the unspecified groups. Premier agrees with this concern and is pleased that additional analyses will be performed.</p> <p>The TEP also commented on amputations and whether these should be considered a planned readmission. There was a suggestion to consider the principal diagnosis associated with the amputation following a vascular procedure to determine if this was a planned readmission or a complication. YNNHSC/CORE agreed to perform additional analyses on amputations to refine indentifying planned readmissions. Premier agrees with this approach.</p>			

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		<p><b>Conclusion</b></p> <p>In closing, Premier appreciates the opportunity to provide comments. As the measure development work by YNHSC/CORE and the TEP is not completed, CMS should provide another public comment period when the measure specifications are refined or before finalized. Premier recommends that the information for a public comment period include the measure specifications, the risk adjustment methodology and results of all analyses.</p>			
06/30/11	Vascular Readmission	<p>Dear Dr. Berwick:</p> <p>On behalf of Partners HealthCare and its acute member hospitals, we appreciate the opportunity to offer comments on the proposed methodology for the 30-day All Cause Readmission Following Vascular Procedures measure.</p> <p>Partners’ surgeons bring decades of experience in Academic Medical Centers and the VA Healthcare System. We appreciate the value of thoughtfully constructed performance measures for bringing out improved patient care quality and offer the following observations on CMS’ proposed readmission methodology following vascular procedures.</p> <ol style="list-style-type: none"> <li>Partners is concerned about the ability to identify planned readmission from the administrative databases available.</li> </ol> <p>The proposed Vascular readmissions methodology lists a number of ICD-9 codes which will constitute planned readmission largely based on the supposition that they represent repetitive procedures done in other extremities or other vessels. This approach only identifies a small number of plan B admissions. For example, a patient having a carotid endarterectomy, followed three weeks later by a hernia repair would not be identified. Similarly, a patient with a lower extremity bypass for an ischemic foot wound, who was readmitted three weeks later for a split-thickness skin graft would not be identified as a planned re-admission. In vascular care, readmissions for secondary procedures (e.g. skin grafts, forefoot amputations after lower extremity revascularization) is frequently a week to week clinical decision, and delineation of what is planned vs unplanned based on coding data seems tenuous.</p> <p>As noted in the TEP discussion, the coding for planned readmissions and elective versus urgent admissions is not reliable. Thus, we believe a large number of readmission which are planned or at least recognized as potentially necessary at the time of discharge will not be identified as such.</p> <p>Conversely, a number of the ICD-9 codes, which appear in Appendix E, which would identify patients as being planned admissions do not necessarily represent planned admissions. For example, code number 39.56, which represents “repair blood vessels with tissue patch graft” could very well represent an unplanned admission with a subsequent need for additional arterial reconstruction, which was not anticipated. The inability to accurately identify planned readmissions, which are very common in vascular surgery, represents a major weakness to this administrative database approach.</p> <ol style="list-style-type: none"> <li>As part of the risk adjustment, the authors of the proposed methodology have distributed</li> </ol>	Diane O'Connor Partners HealthCare, Clinical Affairs, Project Manager	dgoconnor@partners.org	Hospital

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		<p>vascular procedures into six defined anatomic groups and two unspecified groups. The authors then link patients who have multiple qualifying procedures into the one anatomic group which may represent the highest risk for readmission. Our vascular surgeons believe that this represents a potential problem. Patients, who have multiple anatomic areas operated on, may be at an especially high risk for readmission within the risk adjusted model. As such, we believe that multiple anatomic areas of reconstruction should be considered a risk factor to be evaluated in the model.</p> <ol style="list-style-type: none"> <li>3. Regarding comorbidities, which are entered into the model, the author s have included “chronic ulcerations of the skin, except decubitus”. Are there more descriptive diagnoses available which could identify increased risk such as gangrene or infected wounds (beyond cellulitis, which is listed as comorbidity)?</li> <li>4. The “Transfer-out patient” denominator exclusion tends to favor primary and secondary care facilities that (usually appropriately) send cases that are not faring well to tertiary referral centers. We wish to point out this bias to see if the authors might address it in the final methodology. Further, our surgeons would like the authors to review inclusion of CPT code 35800 (exploration for postoperative hemorrhage, thrombosis or infection; neck) CPT Code 35860 in the denominator.</li> <li>5. We seek clarification on how the risk-adjusted model will be employed. Will each hospital be assigned an observed versus expected readmission rate based on the risk-adjusted model?</li> <li>6. Finally, there are many gray areas where the best surgical judgment may allow for subsequent readmission for a patient, which would unfortunately be identified as an unnecessary readmission” within the proposed model. For example, a patient who has an infrainguinal arterial reconstruction for ischemic gangrene and undergoes debridement of a foot wound may be eventually discharged to an outpatient facility with antibiotics and wound dressings with the understanding that a subsequent additional debridement might be necessary. Keeping a patient hospitalized for an additional two weeks until that procedure becomes necessary, would not necessarily represent cost effective or optimal care.</li> </ol> <p>We appreciate CMS’s effort to develop thoughtful measures and methodology. As with all measures, our surgeons seek a methodology that encourages quality care and hopes the final approach will be structured in such a way that extension of hospital stays (to avoid readmission for a possible second procedure), or delays of medically appropriate readmissions, are discouraged. If you have an questions about our responses, please feel free to contact Diane O’ Connor, Project Manager, Clinical Affairs at [REDACTED] or <a href="mailto:dgoconnor@partners.org">dgoconnor@partners.org</a></p> <p>Sincerely,</p>			

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		<p>Thomas H. Lee, MD  Network President  Partners HealthCare System, Inc.  Chief Executive Officer  Partners Community HealthCare, Inc.</p>			
06/30/11	Vascular Readmission	<p>Dear Administrator,</p> <p>The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the measures currently in development by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) regarding 30-Day All Cause Readmission Following Vascular Procedures.</p> <p>AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members produce the majority of the health care technology purchased annually in the United States and a significant share purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies, including those that detect and treat vascular conditions worldwide.</p> <p>AdvaMed supports the development of relevant hospital-level quality outcome measures related to vascular procedures and understands the potential problems and complex issues involved in meaningful development and data collection/analysis concerning these measures. While we support this effort, we have several concerns with both the proposed measures and several statements in the Technical Expert Panel (TEP). Therefore,</p> <p><b>AdvaMed strongly recommends that CMS publish the measure with another 30 day comment period to include the remaining TEP-convened review (July 2011), and to address the results of the preliminary model, detailed processes for determining “planned” readmissions, methods to determine adverse events or complications of care from the complications and co-morbidities (CCs) and alternative measures rather than a single measure for vascular procedures.</b></p> <p>Our detailed comments address the following key issues:</p> <ul style="list-style-type: none"> <li>• Risk Adjustment, including Socio-Economic Status, Discharge Destination, Coding Issues, and Use of Administrative Claims Data for Risk Adjustment</li> <li>• Planned Readmissions</li> <li>• Cohort for Inclusion in the Measure</li> <li>• Validity of the Measure</li> </ul> <p><b>I. Risk Adjustment</b></p>	<p><b>Mandy Wall</b>  Research Associate  AdvaMed</p>	AWall@advamed.org	Medical Device Company

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		<p>AdvaMed recognizes the importance of risk adjustment factors in the development and implementation of quality measurement. In the proposed measure set for Vascular procedures, CMS is proposing to use variables derived from Medicare administrative claims data submitted by hospitals to CMS for payment purposes to create “clinical” risk adjusters. Risk adjusters must be valid, reproducible, sensitive and specific. Any flaws that may be present in the methodology to examine risk adjustment can potentially lead to flawed conclusions and therefore compromise the validity of the resultant conclusions. Thus it is important to consider many relevant variables in developing these models.</p> <p>In addition to age, sex, race, other variables should be used. These include severity of illness and clinical covariates, socioeconomic status, other concurrent treatments/interventions and their associated intensity/complexity and sources of co-morbidity. The potential side effects and adverse reactions associated with the different therapies and interventions that may occur to patients may also need to be considered. And, notably absent from discussions on determination of risk stratification factors are functional status and other individual patient measures can play a very significant role in contributing to outcome measurement and potential readmissions, especially in the post-surgical/procedural setting.  <b>Therefore, AdvaMed recommends that CMS examine additional variables including patient-specific factors in the risk adjustment methodology.</b></p> <p><b>a) Socio-Economic Status (SES)</b>  The TEP Summary Report (Posted June 1, 2011) notes that the risk adjustment methodology was discussed and “the model does not adjust for socioeconomic status (SES), race, or ethnicity because risk-adjusting for these factors would hold hospitals to different standards of care depending on their case mix.” AdvaMed recognizes that SES-based information, for example, educational level, literacy and language skills/abilities, can potentially alter the process of care of patients undergoing diagnosis and treatment for vascular disease and thus confound the results and conclusions in these measure sets. For example, some patients, while they may be literate, may not understand the complexity of their health condition and their care and treatment. This may influence their compliance and ultimately impact the quality of care that they receive which, in turn, will affect the outcome data. Additionally, there may be some hospitals where SES would have a significantly different impact on complication/mortality or readmission rates (e.g., hospitals in regions for which patient SES is incongruent with the average of all U.S. hospital regions). While this information may be difficult to elicit and collect, its omission could have a significant impact on the validity of these measures.</p> <p><b>AdvaMed recommends that the YNHSC/CORE team perform additional analyses to determine the potential impact of SES status on this measure set and consider stratifying the measure by SES; and AdvaMed Recommends that risk stratification should take into account a patient’s socioeconomic</b></p>			

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		<p><b>status, as this information potentially affects all aspects of health care delivery.</b></p> <p><b>b) Discharge Destination</b>            AdvaMed is also concerned that the proposed readmission measure set is not risk adjusted for a patient’s discharge destination after the index event. Post-acute services provided to the patient, such as skilled nursing facility care, may significantly impact the mortality and readmission rates. Therefore, <b>AdvaMed recommends that CMS risk adjust the readmission measure set to reflect a patient’s discharge destination.</b></p> <p><b>c) Coding Issues</b>            Changes in coding may impact the validity of the claims data and should be carefully considered. A recent TEP evaluation on a proposed stroke measure set by CMS (YNHHSC/CORE) highlighted this issue. The authors noted that recent change in the definition of stroke vs. transient ischemic attack (“TIA”) based on imaging results, could be leading to a miscoding of some patients who actually experienced a TIA, but were coded as “stroke” instead. The TIA patients (who had been miscoded as “stroke”) were highly likely to experience better outcomes than those patients with a more severe stroke, thus introducing a significant source of unintentional bias into the outcome measure results. Therefore, <b>AdvaMed recommends that CMS monitor the impact that any ICD-9 coding definition changes could have on these measures.</b></p> <p><b>d) Using Administrative Claims Data for Risk Adjustment</b>            The proposed measure uses administrative claims data to develop risk adjusted outcome measures for calculating readmission rates. AdvaMed has serious concerns regarding the use of solely administrative claims data in setting these quality measures. Administrative claims data lacks robust clinical information and other pertinent patient data—such as those contained in medical records — which are necessary to assess details related to patient complications and other variables that are used in determinations of these measures.</p> <p>In the Stratification of Risk Adjustment section (Page 12, <i>Measure Information Forms - MIF</i>) CMS states that condition categories (CC’s) -- or groupings of ICD-9-CM codes -- will be used to adjust for case mix differences based on the clinical status of the patient at the time of the hospital stay. However, CMS does not plan to risk-adjust for complications and comorbidities (CC’s) that are possible adverse events of care or include complications that arise during the course of the hospital stay in the determination of the risk adjustment. Without these adjustments, a significant amount of unintentional bias could be introduced into the measure set. Therefore, <b>AdvaMed strongly recommends that adverse events and complications of care be factored-in as part of the planned risk adjustment analyses in this measure and requests clarification from CMS on how these will be included.</b></p>			

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		<p><b>II. Planned Readmissions</b>  There are several issues related to the proposed planned readmissions that are of concerns to AdvaMed. These are highlighted below.</p> <p><b>a) Definition of “Planned Readmission”</b>  Planned readmissions are defined in the proposed measure set as admissions <i>following</i> the index hospital stay or “central” treatment. It is important to note that planned treatment strategies can also involve a “pre-index” intervention, preparing the patient for a subsequent “central” or index treatment. (See comment below regarding “Procedure Pair” Exclusions which notes that Endovascular Repair 39.71 pairs is an example of this circumstance). In light of these concerns,  <b>AdvaMed recommends that the YNHHS/CORE consider that planned/phased treatments can also involve treatment delivered prior to an index admission and in such instances, they should not be considered “readmission” events.</b></p> <p><b>b) Definition of “Index Procedure”</b>  The proposed vascular readmission measure set defines “index” procedure as either an inpatient or outpatient procedure. However, the proposal limits “readmissions” to only include inpatient admissions. In other words, the measure as proposed includes as a “readmission” either an index outpatient procedure with subsequent inpatient <u>admission</u>, or as an index inpatient procedure with subsequent inpatient <u>readmission</u>. In contrast, an index outpatient treatment with a subsequent outpatient event/re-visit is not considered a “readmission” for purposes of this quality measure. We question whether procedures performed in an outpatient setting with subsequent inpatient admission should represent a “readmission.”</p> <p>The proposed methodology would implement this quality measure reflecting only inpatient readmissions while not reflecting repeat outpatient treatments. Readmission following an index procedure should include any required follow-up treatment encounter, whether inpatient or outpatient (planned/phased or non-treatment service not included). YNHHS/CORE should consider addressing index inpatient or outpatient treatment separately so that patients can more accurately gauge the likelihood of their outcome in regards to repeat visits.</p> <p><b>c) “Procedure pair” exclusions proposed to recognize “planned/phased” treatments involving different therapies</b>  Assessment of the correlation between patient risk factors and suggested procedure pairs may help to distinguish planned from unplanned readmissions. Excluding these treatments from the measure relies on</p>			

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		<p>prescribing representative “clinically coherent” coding circumstances. For example, the TEP proposes that some types of amputation might represent a part of a phased treatment plan, while others might not – these might be “unplanned”, or perhaps part of a conservative “wait and see” strategy.</p> <p>The YNHSC/CORE decision to conduct further analysis for amputation reflects the inherent challenge in distinguishing purposefully “phased” treatments from unplanned readmissions. Therefore,</p> <p><b>AdvaMed recommends that the YNHSC/CORE consider an assessment of the net impact of proposed exclusions from the measure, and point impact on individual institutions.</b></p> <p>Such assessment may indicate how meaningful these exclusions would be, and may also suggest that some of these cases should be adjusted on the basis of risk, without exclusion.</p> <p><b>d) “Procedure pair” exclusions not currently proposed as “planned/phased” treatment: “Aortic debranching”</b></p> <p>The potential “procedure pairs” represent “clinically coherent” circumstances where a planned/phased treatment is reasonably inferred (although not absolute solely on the basis of coding). Endovascular repairs of the aorta represent major surgical procedures which can involve a planned adjunctive surgical treatment provided outside the index admission. These potential “pairs” should be considered in similar fashion as other procedure pair exclusions. For example: Index procedure: 39.73; most likely planned pre or post (inpatient) surgical procedure: 39.22, 39.23 (CPT-4 35694, 35509, 35601) or; Index procedure: 39.71; most likely planned pre (inpatient) surgical procedure: 39.24, 39.26 (CPT-4 35631).</p> <p><b>e) “Same Procedure” exclusions to recognize “planned/phased” treatments involving the same therapy</b></p> <p>Significant repeat procedures signals a need to better understand the underlying clinical circumstances so that the utility of the measure can be optimized, rather than diminished, by eliminating a large segment of data. On the other hand, if repeat procedures are relatively uncommon and have little impact on 30 day readmission, the need for these exclusions is challenged. The performance measure could potentially be simplified by reducing/eliminating one more variable. Therefore,</p> <p><b>AdvaMed recommends that the impact of excluding “planned readmissions” (as defined by Appendix E “same procedure” tentative list) on the current 30 day readmission rate (Appendix D) should be assessed by the YNHSC/CORE before excluding these from the measure set.</b></p> <p><b>III. Cohort for Inclusion in the Measure</b></p> <p>In the “Numerator Details” section (page 10 of the “<i>Measures Information Form (MIF)</i>”), it is noted that the list of ICD-9 procedures (page 11, <i>MIF</i>) will be considered “planned” readmissions and excluded if the same procedure is performed in the index hospital stay and the readmission. Some of those procedures</p>			

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		<p>may or may not be performed on different anatomic parts. Those procedures performed on the same anatomic part should be included in the numerator while procedures performed on different anatomic parts should not be included in the numerator. However, there is no mention of a method to distinguish and capture this difference for the numerator calculation.</p> <p><b>AdvaMed recommends that CMS develop a method to identify those procedures that are performed in the index hospital stay and the readmission performed on different anatomic parts that will be excluded from the numerator.</b></p> <p><b>VI. Validity of the Measure</b>  It is difficult to assess the validity of the measure for 30-Day All Cause Readmission Following Vascular Procedures due to incomplete TEP review and the measure complexity. The measure methodology incorporates significantly diverse types of diseases, procedures, providers, and treatment settings. Moreover, it is unclear how this measure will provide valid information on readmissions to patients, physicians or hospitals. <b>Therefore, AdvaMed strongly recommends that this measure be thoroughly researched and modeled before finalized.</b></p> <p>Additionally, given the numerous diverse factors and settings that CMS wishes to include in this measure, AdvaMed believes that development of a <i>single</i> measure for readmissions of vascular procedures may be unrealistic. Rather, CMS should consider creating multiple vascular readmission measures which could be segmented by, for example, factors such as treatment setting, procedure type, anatomic area or combinations of these.</p> <p>As listed in the “<i>Summary of the TEP Evaluation</i>”, the TEP is still discussing and must review two items; the risk adjustment methodology and the preliminary model. Therefore, it is difficult to perform a comprehensive meaningful assessment of this measure calculation since these two components are still under development. AdvaMed believes that neither the TEP, nor the public, are able to appropriately assess the validity of this measure without proper vetting and evaluation of these two components. Therefore,  <b>AdvaMed strongly recommends that CMS publish the details of this vascular readmission measure again for public comment after the TEP has finalized their assessment and recommendations.</b></p> <p>AdvaMed greatly appreciates the opportunity to provide these comments to CMS. We would be pleased to answer any questions regarding these comments. Please contact Steven Brotman, MD, JD, Senior Vice President, Payment and Health Care Delivery Policy, at [REDACTED] or via e-mail at <a href="mailto:SBrotman@AdvaMed.org">SBrotman@AdvaMed.org</a>, if we can be of further assistance.</p>			

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		<p>Sincerely,</p> <p>Steven Brotman, M.D., J.D.  Senior Vice President,  Payment and Health Care Delivery Policy  The Advanced Medical Technology Association (AdvaMed)</p>			
06/30/2011	Vascular Readmission	<p><b><u>Surgical site infection occurring within 90-days following implantation of a Cardiovascular Implantable Electronic Device (CIED)</u></b> should be identified as a readmission measure for the following reasons:</p> <ol style="list-style-type: none"> <li>1. The rate of CIED infection is out of proportion to the rate of CIED implantation.</li> <li>2. CIED infections are associated with substantial morbidity and mortality in Medicare beneficiaries.</li> <li>3. CMS has expressed an interest in CIED infections for many years in both proposed and final IPPS payment rules, but not yet identified as a quality measure.</li> <li>4. Any patient re-admitted within 90-days following CIED implantation with a CIED-related infection, especially one associated with methicillin-resistant <i>Staphylococcus aureus</i> (MRSA), should be identified as a readmission measure.</li> <li>5. A substantial body of peer-reviewed evidence is available that objectively quantifies the morbidity, mortality and cost associated with CEID infection in older adults. Evidence in support of CMS adding surgical site infection following CIED implantation as a readmission measure includes the following citations: <ul style="list-style-type: none"> <li>• Baddour L <i>et al.</i> <b>AHA Scientific Statement.</b> Update on Cardiovascular electronic device infections and their management. <i>Circulation</i> 2010;121:458-477.</li> <li>• Cabell <i>et al.</i> Increasing rates of cardiac device infections among Medicare beneficiaries: 1990-1999. <i>Am Heart J</i> 2004; 147:582-6.</li> <li>• Voigt <i>et al.</i> Rising rates of cardiac rhythm management device infections in the United States: 1996-2003. <i>J Am Coll Cardiol</i> 2006; 48:590-591.</li> <li>• Voigt <i>et al.</i> Continued rise in rates of cardiovascular implantable electronic device infections in the United States: Temporal trends and causative insights. <i>PACE</i> 2010; 33:414-419.</li> <li>• Most recently, Sohail <i>et al.</i> presented “Financial cost and mortality associated with CIED infection in a contemporary cohort of Medicare beneficiaries” at the American College of Cardiology</li> </ul> </li> </ol>	KATHRYN BARRY, MPH, MSN, RN	kathryn.barry@metallc.com	Medical Sales and Marketing Company

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		<p>(ACC)'s 60<sup>th</sup> Annual Scientific Session in New Orleans on April 4, 2011. Using ICD-9-CM codes to screen the 2007 Inpatient Medicare Standard Analytic File, a total of 200,219 admissions for CIED generator implantation, replacement, or revision were identified, including 5,817 with infection and 194,402 without an infection. For admissions with an infection, the mean hospital length of stay (LOS) was 14.4-19.6 days and the mean total cost was \$31,149-\$55,003, depending on the CIED type. This corresponds to incremental increases of 9.6-15.0 days and \$16,851-\$25,582 per admission, compared to admissions without infection. Three cost centers accounted for two-thirds of this incremental cost: Intensive care, Routine care, and Pharmacy. The in-hospital mortality with infection was 4.7-11.5%, depending on the CIED type, which was 8.4- to 11.6-fold the mortality without infection. Mortality during the admission quarter and following year was 24-33% for infected patients, depending on the CIED type, which was approximately 2-fold the mortality for non-infected patients. More than one-third of this excess mortality occurred after hospital discharge. A copy of this abstract is available upon request. In addition, a manuscript is under final review by a peer-reviewed journal, soon to be available for public distribution. Sohail <i>et al.</i> concluded, hospitalization for CIED procedures with infection is associated with significant, device-dependent, incremental increases in LOS, cost, in-hospital mortality, and longer-term mortality, compared to admissions for similar CIED procedures without infection. Surprisingly, more than one third of the excess mortality occurs after hospital discharge. The manuscript for this presentation is pending peer-reviewed publication.</p> <ul style="list-style-type: none"> <li>• Sohail <i>et al's</i> most recent publication, "Risk factors associated with early versus late-onset implantable cardioverter-defibrillator infections", <i>J Interv Card Electrophysiology</i>, 2011 March 2 [epub ahead of print], further supports making surgical site infection following CIED implantation a readmission measure. It concludes that "chances of pocket contamination in the <b>perioperative period</b> are more likely to be associated with early-onset ICD infection".</li> </ul> <p><b><u>Definition of the cohort would be as follows:</u></b></p> <ul style="list-style-type: none"> <li>• Primary Diagnosis of Cardiac Device Infection (996.61)</li> <li>• Implantation of a Pacemaker (37.80-37.83, 37.85-37.87)</li> <li>• Implantation of Cardiac Resynchronization Therapy Device with Pacemaker (CRT-P) (0.50)</li> <li>• Implantation of an Implantable Cardioverter-Defibrillator (ICD) (37.94, 37.98)</li> <li>• Implantation of a Cardiac Resynchronization Device with Defibrillator (CRT-D) (00.51).</li> </ul> <p><b><u>Definition of the outcome would be:</u></b></p>			

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		<ul style="list-style-type: none"> <li>• Reduction in readmissions rates within 90-days of CIED implantation.</li> <li>• Reduction in surgical site infection rates following CIED implantation.</li> <li>• Reduction in CIED-revision and re-implantation re-admission rates.</li> <li>• Reduction in overall costs associated with CIED patient care.</li> <li>• Reduction in CIED-infection related mortality.</li> </ul> <p>In response to the disproportionate rise in CIED infections and mounting peer-reviewed evidence quantifying the morbidity, mortality and cost associated with CIED infections in Medicare beneficiaries, <b><u>surgical site infection within 90-days following implantation of a CIED</u></b> should be identified as a readmission measure as soon as possible. Thank-you very much for your time and consideration.</p> <p>Sincerely,</p> <p>Kathryn</p>			
06/30/2011	Vascular Readmission	<p>To Whom It May Concern:</p> <p>The Society for Vascular Surgery (SVS), a professional medical society composed of 3370 specialty-trained vascular surgeons and other medical professionals who are dedicated to the prevention and cure of vascular disease, respectfully offers the following comments on the Vascular Readmission Measure currently under development by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNNHSC/CORE).</p> <p>The majority of vascular surgeons' patients are Medicare beneficiaries and we are committed to assuring the highest quality of care for our patients, including addressing concerns of readmissions. The following comments are offered in support of making the developing Vascular Readmission Measure a functional and comprehensive measure to address those concerns.</p> <p><b>Patient Risk Factors</b></p> <p>After reviewing the current measure specifications, SVS would like to express concern regarding what will, or will not, be included in the measure as "patient level risk factors". The following list of risk factors is of specific concern to SVS and can affect expected outcomes significantly:</p> <ul style="list-style-type: none"> <li>• Will indication for procedure be included (claudication vs. gangrene, etc.)?</li> <li>• Will emergent procedures vs. elective procedures be addressed (acute vs. chronic ischemia,</li> </ul>	<p><b>Lindsey Adams</b></p> <p>Health Policy Manager</p> <p>Society for Vascular Surgery</p>	ladams@vascularsociety.org	Medical Professional Society

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		<p>ruptured vs. non-ruptured AAAs, etc.)?</p> <ul style="list-style-type: none"> <li>• Will ambulatory status of the patient be considered? Is the patient independent, assisted, or wheelchair bound?</li> <li>• Will a history of the patient’s smoking status be considered?</li> <li>• Will consideration of a patient’s history of infection be addressed? This would include cellulitis and history of infection listed, but not active infection(s).</li> <li>• SVS feels the consideration of the Hgb A1c level is necessary, not just the inclusion of presence or absence of DM.</li> </ul> <p><b>Planned vs. Unplanned Readmissions</b></p> <p>SVS offers the following two concerns regarding how the measure addresses planned versus unplanned readmissions:</p> <ul style="list-style-type: none"> <li>• SVS feels the measure currently assumes same procedures to be contralateral, and we feel this neglects the issue of readmissions due to complications such as thrombosis of a SFA stent within 30 days.</li> <li>• How will the measure address planned readmissions for staged or planned subsequent procedures?</li> </ul> <p><b>Additional Concerns</b></p> <ul style="list-style-type: none"> <li>• The measure excludes admissions to other facilities other than the facility at which the original admission took place. Currently, admissions to other facilities would not count against the physician or hospital to which the original admission was made. SVS is concerned this may encourage the “dumping” of patients on other facilities to avoid readmission penalties.</li> <li>• SVS has concerns about the clarity of the algorithm and the ability for it to be universally understood. In reference to the algorithm, are the outcomes hospital specific? Also, does the algorithm take into account multiple areas of reconstruction? Clarification on these points is needed.</li> </ul> <p>SVS appreciates the opportunity to submit these comments and would be happy to work with Yale and the Technical Expert Panel to improve this proposed readmission measure. Please feel free to contact Lindsey Adams, SVS Health Policy Manager at (202) 787-1231, or ladams@vascularsociety.org, if we can provide further information.</p>			

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization of Commenter	E-Mail Address	Type of Organization
		<p>Sincerely,</p> <p><b>Richard Cambria, M.D.</b> Richard Cambria, M.D. President Society for Vascular Surgery</p> <p><b>Timothy Kresowik, MD</b> Timothy Kresowik, MD Chair, Quality and Performance Measure Committee Society for Vascular Surgery</p>			
06/30/11	Vascular Readmission	<p>Dear Dr. Han,</p> <p>The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) Joint Cerebrovascular Section appreciates the opportunity to comment on the 30-day All Cause Readmission Following Vascular Procedures measure developed by Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) under contract with CMS. We have indentified the following concerns regarding this measure:</p> <ul style="list-style-type: none"> <li>• The mechanisms used to identify planned staged treatments do not appear adequate. One example is a patient that presents with acute stroke and undergoes acute stroke intervention (37184) and later, in a planned readmission, undergoes carotid endarterectomy (35301), carotid stenting (37215) or another revascularization procedure. Furthermore the process for tracking planned readmissions is not clear. For instance, how does the provider or facility correctly document that a readmission is planned, if it is not on the "list?"</li> <li>• Regarding risk adjustment, admission source/discharge disposition and socio-economic status/race are not considered in the model, with the statement that doing so would "hold hospitals to different standards of care depending on their case mix." However, these factors often do independently influence outcome in many disease processes, including vascular disease, and it seems that they should be accounted for in the model. Additionally, "indicators of frailty" are listed as tools used for risk adjustment, but not clearly specified.</li> <li>• The measure specifications state that neurosurgical procedures are excluded. Therefore, we would presume that only head, neck and extracranial vessels are to be included. However, the</li> </ul>	<p>Rachel Groman</p> <p>Senior Manager, Quality Improvement and Research</p> <p>American Association of Neurological Surgeons/Congress of Neurological Surgeons</p>	rgroman@neurosurgery.org	Medical Professional Society

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		<p>basilar artery (an intracranial vessel) is listed along with vertebral and carotid in “Head/Neck Endovascular” code 00.61.</p> <p>We once again appreciate the opportunity to provide CMS and YNHHS/CORE with feedback regarding this measure and encourage the developers to address our comments before finalizing the measure. Should you have any questions, please feel free to contact Rachel Groman, Manager for Quality Improvement and Research, AANS/CNS, at [REDACTED] or rgroman@neurosurgery.org.</p> <p>Sincerely,  E. Sander Connolly, Jr., M.D.  E. Sander Connolly, Jr., MD, Chair  AANS/CNS Joint Cerebrovascular Section</p>			