



1949 - 2009

AMERICAN COLLEGE
OF CARDIOLOGY
FOUNDATION

Helping Cardiovascular Professionals
Learn. Advance. Heal.

Heart House

2400 N Street, NW
Washington, DC 20037-1153
USA

202.375.6000
800.253.4636
Fax: 202.375.7000
www.acc.org

President

Alfred A. Bove, M.D., Ph.D., F.A.C.C.

President-Elect

Ralph G. Brindis, M.D., M.P.H., F.A.C.C.

Immediate Past President

W. Douglas Weaver, M.D., M.A.C.C.

Vice President

David R. Holmes, Jr., M.D., F.A.C.C.

Secretary

John G. Harold, M.D., F.A.C.C.

Treasurer

Richard A. Chazal, M.D., F.A.C.C.

Chair, Board of Governors

John G. Harold, M.D., F.A.C.C.

Trustees

Elliott M. Antman, M.D., F.A.C.C.
Eric R. Bates, M.D., F.A.C.C.
Alfred A. Bove, M.D., Ph.D., F.A.C.C.
Ralph G. Brindis, M.D., M.P.H., F.A.C.C.
A. John Camm, M.D., F.A.C.C.
Richard A. Chazal, M.D., F.A.C.C.
Gregory J. Dehmer, M.D., F.A.C.C.
Paul L. Douglass, M.D., F.A.C.C.
James T. Dove, M.D., M.A.C.C.
Robert A. Guyton, M.D., F.A.C.C.
John G. Harold, M.D., F.A.C.C.*
Robert A. Harrington, M.D., F.A.C.C.
David R. Holmes, Jr., M.D., F.A.C.C.
Jerry D. Kennett, M.D., F.A.C.C.
Richard J. Kovacs, M.D., F.A.C.C.*
Gerard R. Martin, M.D., F.A.C.C.
Charles R. McKay, M.D., F.A.C.C.
Rick A. Nishimura, M.D., F.A.C.C.
Steven E. Nissen, M.D., M.A.C.C.
Patrick T. O'Gara, M.D., F.A.C.C.
George P. Rodgers, M.D., F.A.C.C.
John S. Rumsfeld, M.D., Ph.D., F.A.C.C.
Jane E. Schauer, M.D., Ph.D., F.A.C.C.*
James E. Udelson, M.D., F.A.C.C.
C. Michael Valentine, M.D., F.A.C.C.
Mary Norine Walsh, M.D., F.A.C.C.
Carol A. Warnes, M.D., F.A.C.C.
W. Douglas Weaver, M.D., M.A.C.C.
Kim Allan Williams, M.D., F.A.C.C.
Stuart A. Winston, D.O., F.A.C.C.

*ex officio

Chief Executive Officer

John C. Lewin, M.D.

June 30, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8011
Baltimore, MD 21244-8018

ATTENTION: CMS-1406-P

Dear Ms. Frizzera:

The American College of Cardiology (ACC) is pleased to offer our comments on the notice of proposed rulemaking **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates and to the Long-Term Care Hospital Prospective Payment System and Rate Year 2010 Rates (CMS-1406-P)** as published in the Federal Register on May 22, 2009.

The ACC is a professional medical society and teaching institution made up of 37,000 cardiovascular professionals from around the world – including 90 percent of practicing cardiologists in the United States and a growing number of registered nurses, clinical nurse specialists, nurse practitioners, physician assistants, and clinical pharmacists. Our goal in commenting on these policy changes is to assure access to quality cardiovascular care for all Americans.

The ACC has been a leader in advancing the reporting of quality data in both the inpatient and outpatient arenas. Our comments on this rule will focus on the quality measures that hospitals report on as part of the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program and other issues related to the quality of care provided to hospitalized patients.

Preventable Hospital-Acquired Conditions (HACs), Including Infections
ACC is pleased that the Centers for Medicare and Medicaid Services (CMS) have not proposed additional hospital-acquired conditions that must be reported as present on admission. However, we repeat our concerns about the program detailed in the College's previous comments on the proposed rule for the FY 2009 IPPS. The Deficit Reduction Act (DRA) requires that CMS establish at least two preventable Hospital-Acquired Conditions for which a higher diagnosis-related group (DRG) payment will not be made. The program's current eleven measures include several that are not always preventable and can develop in a patient who receives best-practice, evidence-based care. The College urges CMS to monitor the impact of this program on patients and providers to ensure that patients at high risk of complications continue to have access to high quality care and that physicians do not have undue administrative burden. The ACC remains committed to improving the care of patients in the hospital and looks forward to continuing work with CMS on this issue through a variety of methods.

Reporting of Hospital Quality Data for Annual Hospital Payment Update

Retirement of Measures

The ACC strongly supports the retirement of RHQDAPU measure AMI-6, used to report the administration of a beta blocker upon arrival in the hospital for an acute myocardial infarction. As stated in the proposed rule, the ACC/AHA guidelines for ST-segment elevation myocardial infarction (STEMI) and non-ST segment elevation myocardial infarction (NSTEMI) on this issue have been updated to indicate that this therapy is not always appropriate in all patients. Requiring a hospital to report on a measure that may be contraindicated is not appropriate and the ACC supports the permanent retirement proposed in the rule. Furthermore, the ACC appreciates the action CMS took to immediately retire the measure in December of 2008 upon the guideline's publication rather than waiting for the rulemaking process. While it is usually preferable to allow full public comment on proposed changes of this magnitude, the safety of patients must be the most important consideration at all times. We fully support CMS's decision to take prompt action in this instance.

The ACC appreciates the general discussion of the retirement of performance measures in the proposed rule. This is particularly important given the costs of routine data collection and analysis and the need to insure these efforts are offset by meaningful improvement in outcomes associated with greater adherence. As stated above, the ACC believes that measures that are no longer supported by evidence should be retired. In addition, the ACC agrees with the CMS statement that performance measures ought to be retired when a certain threshold of consistent performance has been met throughout the measured entities. In fact, there is evidence that the abstraction of data from charts, even in the best of circumstances, is associated with some error rate of 3-4%, such that when performance is above 90-95% that any observed differences between providers is more likely to be due to errors in abstraction, rather than true performance. In addition, CMS may wish to consider retiring measures that are infeasible for collection by the measured agency in a way that was not anticipated at the time of the measure creation. Finally, there may emerge evidence that there are unintended consequences that result from the use of a performance measure and this would also constitute grounds for retirement. The ACC is currently working on a policy statement that will explore this issue in depth and will share it with CMS when it is released. As the science of performance measurement matures, the issue of retirement will be one of increasing importance and ACC looks forward to working with CMS on the continual evolution of relevant and appropriate performance measures.

Measures Proposed for RHQDAPU for FY 2012

The revised ACC/AHA STEMI/NSTEMI guidelines referenced above created a new measure for the care of myocardial infarction patients that should be added as a hospital quality measure – statin on discharge after STEMI and NSTEMI. This measure is included in the proposed rule as being considered for implementation in 2012. ACC recommends that this measure be implemented as soon as possible. . This therapy has proven to be efficacious, clinically effective, and broadly applicable in reducing recurrent cardiovascular events and deaths. Nationally clinically relevant gaps, variations, and

disparities in the use of this evidence-based, life prolonging therapy persist. The experience with other core measure therapies for AMI suggests that including the statin on discharge after STEMI and NSTEMI measure in RHQDAPU would result in substantially more patients receiving appropriate treatment, thus preventing thousands of recurrent events and cardiovascular deaths.

The ACC examined the long list of potential quality measures for future years. There are a number of cardiovascular measures included in this list and CMS should carefully consider each of these measures and their impact on the quality of care for future rulemaking cycles. In addition to the statin at discharge for AMI measure that is discussed above, the ACC supports the inclusion of the two measures related to percutaneous cardiovascular intervention – one used to track readmission and the other used to track mortality. There are a number of measures that may be appropriate for inclusion as well and ACC looks forward to commenting on those when they are proposed in the future.

Structural Measures and Registries

The ACC is pleased that CMS recognizes the potential for clinical registries to enable and support systematic quality improvement. The ACC supports the inclusion of registry participation as structural measures of quality. The Society of Thoracic Surgeons (STS) database, for examples, includes data on the majority of thoracic surgery cases performed in the United States and this data will contribute considerably to future developments in surgical cardiovascular care. The use of the STS database is already a structural measure for RHQDAPU. CMS proposes to add two additional measures of registry use for 2010. The ACC supports this proposal and recommends that CMS actively seek to expand the list of structural measures to encompass additional registries. Several registries that are part of the ACC's National Cardiovascular Data Registry's (NCDR)[®] suite of seven registries would be strong candidates for structural measures. The ACC believes that hospitals that participate in these registries are demonstrating a commitment to quality.

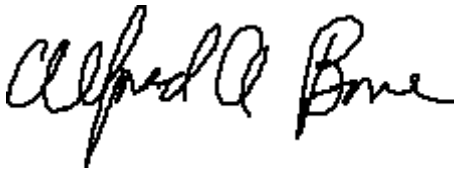
The ACC's Acute Coronary Treatment and Intervention Outcomes Network (ACTION) registry is an outcomes-based quality improvement program that helps participating facilities measure and improve care for high-risk myocardial infarction patients with STEMI or NSTEMI. In addition to its clinical registry functions, the ACTION Registry [®] - GWTG[™](Get With The Guidelines) program provides hospitals with benchmarking capabilities, decision support, and other performance improvement methodologies that encourage adherence to ACC/AHA STEMI and NSTEMI guidelines based on scientific evidence. The clinical literature demonstrates the positive effects of this multi-pronged strategy for AMI care. Acute coronary syndrome (ACS) results in a high burden of morbidity and mortality in the Medicare patient population, treatment of ACS is of extraordinary cost to Medicare and there are significant variations in care of ACS patients. The ACC recommends that a new structural measure for participation in a registry on acute coronary syndrome patients be considered for future years.

As CMS considers more structural measures for participation in registries, we urge the agency to consider harnessing the full power of these registries for reporting the data now

required to be reported directly to CMS under the current RHQDAPU. For example, the ACTION registry captures many of the measures that hospitals now report to CMS on acute myocardial infarction. The registry has the advantage of capturing all patients rather than just Medicare patients and gives participating hospitals a feedback report on a regular basis. Requiring that this data be entered twice seems needlessly burdensome. Moreover, we believe that CMS should do as much as possible to encourage hospitals to participate in registries that improve the care of patients in a more meaningful way than the chart abstraction methods used in today's RHQDAPU program. Adopting additional registries, such as the ACTION registry, for data reporting will greatly improve the agency's ability to monitor the quality of patient care and facilities' commitment to improved outcomes.

The ACC appreciates the opportunity to comment on this proposed rule. The members of the ACC remain dedicated to improving the cardiovascular care for all by cooperating with hospitals to provide quality care. If you have any questions or wish to discuss this further, please contact Brian Whitman, Associate Director of Regulatory Affairs at bwhitman@acc.org or (202) 375-6396.

Sincerely,

A handwritten signature in black ink that reads "Alfred A. Bove". The signature is written in a cursive, flowing style.

Alfred A. Bove, MD, PhD, FACC
President