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June 25, 2012

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1588-P  
PO Box 8011  
Baltimore, MD 21244-1850

Re: CMS-1588-P

Dear Sir/Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million volunteers and supporters, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed changes to the Hospital Inpatient Prospective Payment System for Acute Care and Long-Term Care Hospitals and Fiscal Year 2013 Rates.

The proposed rule addresses a wide range of reimbursement and operating issues for acute care and long-term care hospitals. However, in this letter, AHA/ASA limits its comments to the quality data reporting requirements.

### ***Quality Data Reporting Requirements***

#### ***Suspension of Data Collection for the FY 2014 Payment Determination and Subsequent Years***

Last year, CMS decided to suspend data collection for four measures beginning with January 1, 2012 discharges, affecting the FY 2014 payment determination and subsequent years. Three of the suspended measures are of interest to AHA/ASA:

- AMI-1 Aspirin at arrival
- AMI-3 ACEI/ARB for left ventricular systolic dysfunction
- AMI-5 Beta-blocker prescribed at discharge

According to the proposed rule, CMS intends to continue the measure suspension unless it sees evidence that performance on the measures is in danger of declining. If hospital adherence to these practices declines, CMS will resume data collection.

We believe that it is appropriate for CMS to suspend measures prior to retiring them, as the Agency has done with these measures. However, we urge CMS to work with organizations like AHA to first assess which measures should be

considered for suspension *before* adding them to future lists of suspended measures. AHA and other stakeholders can work with the Agency to avoid any potential unintended consequences that may adversely affect patient care.

*Proposed Measures for the FY 2015 Payment Determination*

In the proposed rule, CMS delineates a number of measures that it plans to include for FY 2015. Many of the measures are of interest to AHA including:

- AMI–2 Aspirin prescribed at discharge
- AMI–7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival
- AMI–8a Timing of receipt of primary percutaneous coronary intervention (PCI)
- AMI–10 Statin prescribed at discharge
- HF–1 Discharge instructions
- HF–2 Evaluation of left ventricular systolic function
- HF–3 Angiotensin Converting Enzyme Inhibitor (ACE–I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction
- STK–1 VTE prophylaxis
- STK–2 Antithrombotic therapy for ischemic stroke
- STK–3 Anticoagulation therapy for Afib/flutter
- STK–4 Thrombolytic therapy for acute ischemic stroke
- STK–5 Antithrombotic therapy by the end of hospital day 2
- STK–6 Discharged on statin
- STK–8 Stroke education
- STK–10 Assessed for rehab
- Acute myocardial infarction (AMI) 30-day mortality rate
- Heart failure (HF) 30-day mortality rate
- Acute myocardial infarction 30-day risk standardized readmission measure
- Heart failure 30-day risk standardized readmission measure

We generally support these measures, but offer the following comments.

We recommend that CMS consider adding additional measures that are endorsed by the National Quality Forum (NQF), including NQF Measure #0083 – beta-blocker therapy for left ventricular systolic dysfunction (PCPI). Beta blockers have been shown to be an effective treatment for heart failure; practice guidelines support prescribing beta blockers for appropriate patients; and this practice has been endorsed by NQF. The evidence base for this measure shows that there are no issues remaining regarding safety; the evidence shows that beta blocker use in heart failure is cost-effective, saves lives and reduces hospitalizations. In fact, the data show that eligible patients who are not started on beta blockers prior to discharge have a higher likelihood of not being placed on beta blockers in follow up. AHA urges CMS to include this measure; it could help reduce the number of hospital readmissions and deaths.

If CMS has concerns about adopting the heart failure/beta blocker measure, please explain what evidence is needed to support inclusion of this measure in future years. If the Agency requires additional data to validate the inclusion of this measure, AHA can provide data collected via our *Get With The Guidelines—Heart Failure* registry.

With respect to the other proposed measures, we strongly urge CMS to replace “HF-1 Discharge Instructions”; HF-1 has been demonstrated to have no process outcome link and has been invalidated. In addition, NQF does not endorse heart failure discharge instructions as a measure, due to a need for additional evidence. A better measure is the “Post-discharge appointment for heart failure patients”<sup>1</sup> which was developed by the ACCF/AHA/AMA PCPI and addresses transition in care for heart failure patients. This measure was developed with the intent of having a greater impact on morbidity and readmission. We recommend that CMS adopt the “Post-discharge appointment for heart failure patients” measure in future fiscal years, as we understand that this change is unlikely to occur for the upcoming fiscal year.

For “Heart Failure-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction”, we agree that this is an important measure. There would, however, be additional benefit to also capturing data on the *amount* of ACEI/ARB prescribed. Appropriate dosing of ACE inhibitors continues to be a problem. Collecting information on ACEI/ARB dose could provide valuable data to the Agency on best practices that may need to be instituted to address this gap.

With regard to the “Heart Failure 30-day Risk Standardized Readmission” measure, we have several concerns. While we understand why CMS wants to measure 30-day risk standardized readmission, we are concerned that this measure could result in unintended consequences and potential harm to patients; and we do not believe that there is sufficient evidence to demonstrate that the various strategies used to address re-hospitalization are cost-effective. Furthermore, the community environment and socioeconomic status of patients (for example, whether they are insured or uninsured) ultimately influences the readmission rates of heart failure patients. Community environment and socioeconomic status are two factors that cannot easily be adjusted for in a measure. Therefore it is important to develop safeguards to prevent potential harms from this risk adjusted model, given these two external factors. Another potential harm that may result from this measure is a possible increase in 30-day heart failure mortality rates. The original Yale Core model used administrative data and had a c-statistic of ~ 0.69 when compared to clinical databases. Recent evidence shows that there may be issues associated with 30-day readmission that can affect a risk adjusted measure. One study, for example, asserts that the major driver in determining readmission is the patient population and the community from which those patients originate, i.e., the built environment,<sup>2</sup> but the Yale CORE readmission risk model does not adequately capture community metrics. Another study raised the disturbing concern that there is an inverse relationship between 30-day readmission rates and 30-day mortality rates.<sup>3</sup> Therefore, we ask that CMS not implement this measure in FY 2015. We understand that CMS is currently reporting this measure on the Hospital Compare website and that it is included in the hospital readmission reduction program – and we believe this makes our request to reexamine the measure and assess the possible unintended consequences even more important. AHA would like to work with the Agency on this endeavor. We believe that the measure should be modified to account for the concerns raised here. If CMS continues to include the 30-day Risk Standardized Readmission Measure for Heart Failure in the

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<sup>1</sup> 2011 ACCF/AHA/AMA PCPI Heart Failure Measure Set. Available at:  
<http://www.ama-assn.org/ama1/pub/upload/mm/pcpi/hfset-12-5.pdf>.

<sup>2</sup> Joynt KE, Orav EJ, Jha AK. Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA 2011;305:675-81.

<sup>3</sup> Gorodeski EZ, Starling RC, Blackstone EH. Are all readmissions bad readmissions? N Engl J Med. 2010 Jul 15;363(3):297-8.

Inpatient Quality Reporting (IQR) Program, we would still like to work with the Agency and explore how the measure construct could be adjusted to avoid unintended consequences. We are also interested in working with CMS to assess what evidence base may exist to show if there are “best practices” that could universally be used to reduce hospitalizations.

In the case of the eight stroke measures, we support their inclusion. These measures were developed through consensus of the American Stroke Association, the Centers for Disease Control and Prevention, and The Joint Commission. They can significantly increase the quality of care that is provided to stroke patients and reduce readmissions and mortality. Thus, we agree that these measures should be included in FY 2015, FY 2016 and future years.

*Possible New Quality Measures and Measure Topics for Future Years*

In the proposed rule, CMS states that as electronic health record (EHR) technology evolves and more infrastructure is put in place, the Agency will have the capacity to accept electronic reporting of many of the clinical chart-abstracted measures that are currently part of the Hospital IQR Program or have been proposed for adoption into the program. According to the Agency, this will significantly reduce the administrative burden on hospitals. CMS goes on to say that it intends to support the following measure domains in the Hospital IQR measure set in future measurement proposals for the Hospital IQR Program: clinical quality (for example, the AMI, HF, PN, STK, and VTE measures), care coordination (for example, the mortality measures), patient safety, population/community health, and efficiency.

We commend CMS for addressing the topic of future quality measures, however, we are disappointed that the proposed rule only highlights The Joint Commission measures for tobacco and alcohol cessation and only includes a broad description of general measure domains. While we appreciate the inclusion of the general measure domains and the Agency’s efforts to consider recommendations from the Measure Application Partnership (MAP), CMS should provide a comprehensive list of measures that the Agency anticipates adding to the program in future years, as CMS did last year. Including a detailed list provides the public with an opportunity to comment on the proposed measures and to propose additional measures for future consideration. For example, with the physician fee schedule, CMS sends out an email soliciting public feedback on potential measures for inclusion in the Physician Quality Reporting System for future years. We urge CMS to consider doing something similar for the IPPS in addition to considering the measures recommended by the MAP.

Additionally, we agree with CMS that EHRs have the potential to bring about great change in how data is collected and potentially reduce administrative burden. We also take this opportunity to strongly urge CMS to consider utilizing existing data sources for the collection of these measures, such as registries, including *Get With The Guidelines–Stroke*. Currently, over 1,600 hospitals are utilizing this module to improve care for stroke patients and are collecting data on the eight stroke measures that are proposed for inclusion in the FY 2015 payment determinations. Hospitals currently collecting and submitting data via GWTG–Stroke should be able to use this registry to submit data to CMS. We would be happy to discuss any concerns the Agency may have with allowing the submission of data via a registry in place of, or in addition to data collected via an EHR.

*Hospital Value Based Purchasing Program*

AHA supports the addition of “AMI-10 Statin Prescribed at Discharge” as a new clinical process of care measure for the Hospital Value Based Purchasing Program starting in FY 2015. Recognized by the AHA/ACC clinical guidelines and proven by multiple randomized clinical trials, the use of statins reduces the risk of death and recurrent cardiovascular events in patients with prior myocardial infarction. Given this clinical benefit, we support the addition of this measure.

Thank you again for the opportunity to submit comments. If you have any questions or need any additional information, please do not hesitate to contact Penelope Solis, JD, Healthcare Quality Manager, at 202-423-3124 or [penelope.solis@heart.org](mailto:penelope.solis@heart.org).

Sincerely,

A handwritten signature in blue ink, appearing to read 'G. Tomaselli', with a long horizontal flourish extending to the right.

Gordon F. Tomaselli, MD, FAHA  
President  
American Heart Association