American Heart Association | American Stroke Association

June 25, 2013

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Docket No. CMS-1599-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 2014 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 Hospital Inpatient Quality Reporting (IQR) Program, including highlighting our serious concerns with the Agency's proposed 30-day stroke readmission and 30-day stroke mortality measures. We also provide feedback on the proposed changes to the Medicare Severity Diagnosis-Related Groups (MS-DRG) for tissue plasminogen activator.

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

Proposed Additional Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years

Proposed 30-Day Stroke Readmission and 30-Day Stroke Mortality Measures

CMS plans to include two stroke outcome measures in the Hospital IQR Program for fiscal year 2016. Both measures were developed by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) as part of a contract with CMS. The measures are:

- Hospital 30-day, All-Cause Risk-Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke (Stroke Mortality) Measure; and
- Hospital 30-day, All-Cause Risk-Standardized Rate of Readmission Following Acute Ischemic Stroke (Stroke Readmission) Measure.

CMS proposes adopting the measures even though they are not endorsed by the National Quality Forum (NQF) and are not recommended by the Measures Application Partnership (MAP). According to the proposed rule, CMS believes it is imperative to adopt these measures as they aim to address a prevalent and costly health problem in the nation; and the measures align with the Agency's priority objectives to promote quality improvements leading to successful transition of care for patients from acute care to outpatient settings, and to reduce short term, preventable readmission and mortality rates.

We agree that stroke is a significant health problem and we are committed to preventing and improving the treatment of stroke. As part of our efforts, we strongly support the creation and implementation of measures that lead to quality improvement. However, it is critical to ensure such measures are properly constructed and do not result in unintended consequences. Unfortunately, the proposed stroke mortality and readmission measures are not appropriately risk-adjusted and will not accurately measure the quality of care. Instead, the measures could mischaracterize hospital performance, worsen health disparities, and ultimately harm patient care by undermining stroke systems of care. Therefore, we again urge CMS to not adopt these measures for inclusion in the IQR. Our concerns are detailed below.

<u>The proposed measures are not adequately risk-adjusted and may mischaracterize hospital performance, worsen health disparities, and harm patient care</u>

The proposed measures are not adequately risk-adjusted and may mischaracterize hospital performance, worsen health disparities, and harm patient care. The proposed stroke mortality and readmission measures do not account for stroke severity, and therefore, do not appropriately account for risk. Any outcome measure that does not adequately adjust for initial stroke severity is not suitable for use.

In the case of the 30-day stroke mortality measure, there is compelling scientific evidence that stroke severity, as measured by the National Institutes of Health Stroke Scale (NIHSS), is the single most important determinate of 30-day outcomes for acute ischemic stroke, having more discriminatory power than all other variables combined. It has also been established that risk models based on administrative data or clinical data, that do not include stroke severity, have inferior discrimination, substantial unaccounted for variance, and result in marked misclassification of hospital performance for 30-day mortality. The recently published JAMA[1] article demonstrates the importance of including the NIHSS. In a risk model nearly identical to the proposed stroke mortality measure, we found that more than half of hospitals would be misclassified; 58% of hospitals identified as having "better than" or "worse than" expected risk-standardized mortality would be reclassified to "as expected mortality" if risk-adjustment does not include an adjustment for stroke severity with the NIHSS. For example, stroke centers, which are the most qualified to treat patients with severe strokes and treat more of these patients than other facilities, may appear to have a low performance rating simply because patients with severe strokes are more likely to die.

A recent analysis of Get With The Guidelines (GWTG) data found that hospitals treating patients with significantly greater stroke severity are more likely to have their performance misclassified as inappropriately high mortality using 30-day risk models that do not adjust for stroke severity.

[1] Fonarow et al. Comparison of 30-Day Mortality Models for Profiling Hospital Performance in Acute Ischemic Stroke With versus Without Adjustment for Stroke Severity. JAMA. 2012;308(3):257-264. Available at: http://jama.jamanetwork.com/article.aspx?articleid=1217240.

According to the analysis, hospitals treating patients with greater stroke severity are substantially more likely to provide care for patients who are black or Hispanic, or transported by EMS. These hospitals are larger, teaching hospitals, having higher volume of stroke patients, and treat more patients with tPA. Hospitals treating patients with higher stroke severity, as expected, have higher unadjusted in-hospital mortality rates.

African-American race and Hispanic ethnicity both are associated with higher hospital level stroke severity. Therefore, the nation's safety net hospitals that care for these disadvantaged groups are most likely to be unfairly penalized by risk-standardized mortality rates measures that do not take stroke severity into account, depriving them of needed resources and unduly causing concerns in these communities of substandard care. As patients transported by EMS also have greater stroke severity, hospitals which participate in stroke systems of care with EMS diversion are also most likely to be unfairly penalized by measures that do not take stroke severity into account, providing perverse incentives to discourage hospitals from participating in stroke systems of care.

The analysis also found that there were little differences in the demographics and comorbid conditions that are used in CMS risk adjustment models among hospitals treating patients with greater or lesser stroke severity, suggesting that the hospital level variation in case mix could not be captured by current comorbidity codes and requires a direct measure of stroke severity. Given the results from the JAMA paper, and this recent analysis of GWTG data, we strongly oppose the use of any model that has been demonstrated to so severely mischaracterize hospital performance.

It is feasible to collect NIHSS in all acute ischemic stroke patients without any missing data at the hospital system and entire community level. Many hospitals already collect and voluntarily report NIHSS scores to patient registries, including 74% of hospitals that participate in Get With The Guidelines-Stroke. A similar proportion of Medicare beneficiaries with acute ischemic stroke have NIHSS information documented. NIHSS training and certification modules are also available online and widely used. Therefore, a stroke severity variable can be reliably abstracted and reported via registries, and can be required by CMS for all stroke admissions by creating a new coded variable for this value. As we have stated previously in other letters, we strongly urge CMS to begin collecting stroke severity in the form of the NIHSS score and work to revise this measure to include adjustment for stroke severity, prior to implementation in the IQR.

With regards to the proposed stroke readmission measure, there is a growing body of evidence which suggest the primary drivers of variation in 30-day readmission rates involve variables which are not included in this model nor captured in administrative claims data, including poor social supports, poverty, and inadequate community resources, which are all factors that are beyond a hospital's control. Thus, this measure will not identify higher or lower quality of care per se, but will instead reflect unaccounted variability in case mix and other unmeasured factors. We are concerned that this may worsen health disparities by unintentionally penalizing hospitals that care for populations in low-income areas. According to a recent study, patients living in impoverished areas have more severe strokes; in fact, they are twice as likely to have a severe stroke.[2] Safety-net hospitals that care for significantly larger numbers of poor stroke patients are at risk of being disproportionally impacted if CMS imposes financial penalties on hospitals that have high readmission rates.

[2] Kleindorfer, et al. Patients living in impoverished areas have more severe ischemic stroke. Stroke. 2012;43:2055-2059.

The readmission measure also does not account for the fact the patients who die post discharge cannot be re-hospitalized. Hospitals with a low readmission rate could have a high mortality rate or vice versa. Prior studies with similar measures for heart failure patients have suggested that hospitals classified as having higher than expected readmission rates are in fact the ones with the lowest mortality rates. In our review of this measure we found that the readmission model has very poor discrimination in its current form (c-statistic 0.60). This demonstrates that most of the variances in hospital 30-day readmission rates are not captured by variables included in the Yale CORE/CMS model.

In addition, there are no peer-reviewed articles or published data to support these two measures or to delineate what limitations, if any, were identified through data analysis. As a result, we are concerned that there is no way to substantiate that the measure models will provide adequate discrimination and prevent unintended consequences if implemented. We are particularly concerned that the measures may harm patient care by undermining stroke systems of care. Stroke systems of care are designed to ensure that stroke patients get the timely, appropriate treatment they require by transporting patients to the hospital or stroke center best equipped to care for the patient. However, the measures may encourage hospitals to select or "cherry pick" stroke patients with mild or moderate strokes, and discourage hospitals from accepting patients via transfer who have the most severe strokes. "Cherry picking" patients may allow hospitals to improve their performance rating, which is a concern since hospitals are aware that the mortality and readmissions data may be publicly available on the Hospital Compare website (without the benefit of an adequate risk adjustment) and may eventually impact payment amounts.

We have previously communicated these concerns to Yale CORE, CMS, and NQF. For your convenience, we are including copies of these comment letters as attachments. The letters provide a very detailed accounting as to why these measures should not be adopted.

<u>The stroke mortality measure was voluntarily withdrawn from NQF endorsement to re-evaluate the risk adjustment model</u>

In October 2012, CMS voluntarily opted to withdraw the proposed stroke mortality measure from NQF consideration. As noted in the NQF *Neurology Endorsement Maintenance Phase I* report, "the developer withdrew this measure in order to reevaluate their approach to risk adjustment."[3] Given that Yale CORE/CMS voluntarily withdrew the measure after reviewing the public comments received, it seems counterintuitive to adopt this measure for FY 2016. It does not appear that Yale CORE or CMS have modified the measure since withdrawing it from NQF consideration. In fact, the measure posted on the CMS website includes the identical language that was proposed in the measure specifications submitted to NQF for consideration.[4]

We do not understand why CMS would propose adopting this measure after voluntarily withdrawing the measure from NQF consideration. Instead, we invite the Agency to work with AHA/ASA and

[3] Neurology Endorsement Maintenance Phase I, National Quality Forum. Page 98, 2012. Available at: http://www.qualityforum.org/Projects/n-r/Neurology_Endorsement_Maintenance/Neurology_Endorsement_Maintenance.aspx

[4] CMS Measure Specification for Stroke 30 Day Morality and 30 Day Readmission Measures; Available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html

professional societies to develop an appropriately risk-adjusted 30-day mortality measure that could be included in the IQR.

The stroke readmission measure was not endorsed by NQF

As CMS acknowledges, the proposed stroke readmission measure was not endorsed by NQF. By proposing to include this measure in the IQR, CMS appears to ignore the observations that were made by the NQF Stroke Technical Advisory Panel. The panel stated that there was a lack of information regarding the extent to which hospital level factors influence readmission rates, and noted concerns related to the risk-adjustment strategy, the importance of readmissions, and the potential for unintended consequences. However, it appears that the concerns voiced by the Technical Advisory Panel were not considered by CMS. CMS should not adopt measures that NQF declined to endorse because of substantial concerns.

CMS has previously stated that it wants to adopt measures that are endorsed by NQF and MAP

In past IPPS proposed rules, CMS has clearly moved towards adoption of measures that are NQF endorsed to ensure that the measures are consensus based, are widely supported, and, where possible, to reduce administrative burden. We understand that some measures have been adopted by CMS without NQF endorsement, using its exception authority under section 1886(b)(3)(B)(IX)(bb) of the Act; however, we do not believe it is appropriate to use this authority in the case of outcome measures. And it is our understanding that CMS has never adopted an outcome measure that was not first endorsed by NQF, or that was not pending NQF endorsement.

Outcome measures warrant higher scrutiny because of the potential benefit and harm that can result. It is incumbent to ensure that outcome measures will not result in potential harm. Ensuring that outcome measures are consensus based and endorsed by organizations such as NQF lends validity to the measures, as they have been reviewed by an expert panel. We also note that when CMS has used its discretionary authority in the past, the Agency has adopted measures that were currently under consideration by NQF or were scheduled to be submitted by the measure developer to NQF for consideration during the next review cycle. It appears that CMS may have adopted those measures believing that they would soon be NQF endorsed. Yet, in this case, CMS is proposing to adopt two measures that were unable to successfully complete the NQF process – one measure was voluntarily withdrawn from consideration and the other measure was voted down by NQF.

Furthermore, while CMS intends to only use these measures for pay for reporting initially, it is very likely that data on these two measures will eventually be included on the Agency's Hospital Compare website. Currently, all outcome measures that are reported on Hospital Compare are NQF endorsed; the two stroke measures are not. Because patients, caregivers, and health professionals may use the data posted on Hospital Compare to evaluate and select a hospital, the measures included on the website must be shown to be valid. It would be counter to CMS practice to start adopting measures that are not NQF endorsed or currently under review by NQF and where stakeholders have raised significant concerns, especially when the measures will likely be used for public reporting. In addition, these measures may eventually be included in the hospital readmission reduction program. Any measure that may potentially be used for value based purchasing or to meet the intent of the readmission reduction act must be held up to rigorous standards in terms of scientific acceptability, reliability and feasibility.

Additionally, the Measures Application Partnership did not endorse either of these measures. The MAP's primary purpose is to provide input to the Department of Health and Human Services on selecting performance measures for quality reporting programs and pay for reporting programs. Yet it does not appear that the MAP was even consulted prior to the decision.

Finally, as noted above, safety-net hospitals care for a disproportionate number of poor or minority patients and tertiary care hospitals care for the sickest stroke patients. These hospitals are the most likely to be mislabeled as providing poor quality stroke care by measures that do not adjust for stroke severity. If information about these measures is posted on the Hospital Compare website, it could send a confusing and misleading message to consumers and have the perverse effect of deterring patients from seeking care at those hospitals.

For all of the reasons above, we strongly urge CMS to drop its proposal to adopt the stroke mortality and stroke readmission measures. The Agency should not adopt measures that have the potential to cause unintended harm. Instead, we recommend that CMS and Yale CORE work with AHA/ASA to create stroke mortality and readmission measures that are properly developed, tested, and appropriately risk-adjusted using the NIH Stroke Scale. We believe that a properly risk-adjusted measure could be ready for field testing and use within 1-2 years if the decision were made by CMS to pursue this opportunity.

Hospital Value-Based Purchasing Program

In the proposed rule, CMS delineates a number of measures that it plans to include in the FY 2014 Hospital Value-Based Purchasing Program.

HF-1 Discharge Instructions

According to the rule, CMS will include "HF-1 Discharge Instructions" in both the FY 2014 and FY 2015 program, but plans to remove it in FY 2016.

We agree with CMS that the "HF-1 Discharge Instructions" measure has been invalidated. NQF has not endorsed this measure because additional evidence is needed. We recommend however that CMS replace the HF-1 measure with another measure. Specifically, CMS should consider adopting the ACCF/AHA/AMA PCPI measure entitled "post-discharge appointment for heart failure patients."[5] This measure addresses transition in care for heart failure patients and was developed with the intent of having a greater impact on morbidity and readmission. We plan to submit this measure to NQF during its next call for cardiovascular measures. We therefore 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.

NQF #0083 Beta Blocker Therapy

We also recommend that CMS consider adding additional measures that are endorsed by NQF, including "NQF Measure #0083 – beta-blocker therapy for left ventricular systolic dysfunction (PCPI)", which was endorsed in 2009. The use of beta-blockers is well supported by science and evidence-based guidelines. The recently released 2013 Heart Failure Guidelines state that the "use of 1 of the 3 beta blockers proven to reduce mortality (i.e., bisoprolol, carvedilol, and sustained-release

[5] 2011 Heart Failure Measures. ACC/AHA/AMA PCPI. http://www.ama-assn.org/ama1/pub/upload/mm/pcpi/hfset-12-5.pdf

metoprolol succinate) is recommended for all patients with current or prior symptoms of HF*r*EF, unless contraindicated, to reduce morbidity and mortality." (Class A: Level of Evidence: A).[6]

Long-term treatment with beta blockers can lessen the symptoms of heart failure, improve the patient's clinical status, and enhance the patient's overall sense of well-being.[7,8,9,10,11,12,13,14] In addition, like ACE inhibitors, beta blockers can reduce the risk of death and the combined risk of death or hospitalization.[15,16,17,18,19] These benefits of beta blockers were seen in patients with or without coronary artery disease and in patients with or without diabetes mellitus, as well as in women and blacks. The favorable effects of beta blockers were also observed in patients already taking ACE inhibitors. And as noted it the guidelines, three beta blockers have been shown to be effective in reducing the risk of death in patients with chronic heart failure reduced ejection fraction: bisoprolol and sustained-release metoprolol (succinate), which selectively block beta-1-receptors; and carvedilol, which blocks alpha-1–, beta-1–, and beta-2–receptors. Furthermore, this measure is currently e-measure specified and could potentially be used in the Agency's continued effort to further meaningful use.

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[6] Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH, Fonarow GC, Geraci SA, Horwich T, Januzzi JL, Johnson MR, Kasper EK, Levy WC, Masoudi FA, McBride PE, McMurray JJ, Mitchell JE, Peterson PN, Riegel B, Sam F, Stevenson LW, Tang WH, Tsai EJ, Wilkoff BL. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013 Jun 5.

[7] Fisher ML, Gottlieb SS, Plotnick GD, et al. Beneficial effects of metoprolol in heart failure associated with coronary artery disease: a randomized trial. J Am Coll Cardiol. 1994;23:943-50.

[8] Metra M, Nardi M, Giubbini R, et al. Effects of short- and long-term carvedilol administration on rest and exercise hemodynamic variables, exercise capacity and clinical conditions in patients with idiopathic dilated cardiomyopathy. J Am Coll Cardiol. 1994;24:1678-87.

[9] Olsen SL, Gilbert EM, Renlund DG, et al. Carvedilol improves left ventricular function and symptoms inchronicheart failure: a double-blind randomized study. J Am Coll Cardiol. 1995;25:1225-31.

[10] Krum H, Sackner-Bernstein JD, Goldsmith RL, et al. Double-blind, placebo-controlled study of the long-term efficacy of carvedilol in patients with severe chronic heart failure. Circulation. 1995;92:1499-506.

[11] Waagstein F, Bristow MR, Swedberg K, et al. Beneficial effects of metoprolol in idiopathic dilated cardiomyopathy. Metoprolol in Dilated Cardiomyopathy (MDC) Trial Study Group. Lancet. 1993;342:1441-6.

[12] A randomized trial of beta-blockade in heart failure. The Cardiac Insufficiency Bisoprolol Study (CIBIS). CIBIS Investigators and Committees. Circulation. 1994;90:1765-73.

[13] Packer M, Colucci WS, Sackner-Bernstein JD, et al. Double-blind, placebo-controlled study of the effects of carvedilol in patients with moderate to severe heart failure. The PRECISE Trial. Prospective Randomized Evaluation of Carvedilol on Symptoms and Exercise. Circulation. 1996;94:2793-9.

[14] Colucci WS, Packer M, Bristow MR, et al. Carvedilol inhibits clinical progression in patients with mild symptoms of heart failure. US Carvedilol Heart Failure Study Group. Circulation. 1996;94:2800-6.

[15] CBIS II Authors. The Cardiac Insufficiency Bisoprolol Study II (CIBIS-II): a randomised trial. Lancet. 1999;353:9-13.

[16] Packer M, Coats AJ, Fowler MB, et al. Effect of carvedilol on survival in severe chronic heart failure. N Engl J Med. 2001;344:1651-8.

[17] Effect of metoprolol CR/XL in chronic heart failure: Metoprolol CR/XL Randomised Intervention Trial in Congestive Heart Failure (MERIT-HF). Lancet. 1999;353:2001-7.

[18] Packer M, Bristow MR, Cohn JN, et al. The effect of carvedilol on morbidity and mortality in patients with chronic heart failure. U.S. Carvedilol Heart Failure Study Group. N Engl J Med. 1996;334:1349-55.

[19] Randomised, placebo-controlled trial of carvedilol in patients with congestive heart failure due to ischaemic heart disease. Australia/New Zealand Heart Failure Research Collaborative Group. Lancet. 1997;349:375-80.

We strongly believe that the evidence base for this measure shows that there are no issues remaining regarding safety and that beta blocker use in heart failure is cost effective, saves lives and reduces hospitalizations. Therefore, we urge CMS to include this measure as it could help reduce the number of hospital readmissions and deaths. If CMS has concerns about adopting the heart failure/beta blocker measure, we request that you explain what would be required to include 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.

NQF #1952 Time to Intravenous Thrombolytic Therapy

We also recommend that CMS add measure 1952 "time to intravenous thrombolytic therapy" which was endorsed by NQF last year. This measure has the potential to significantly impact stroke patient outcomes. Despite its effectiveness in improving neurological outcomes, many patients with ischemic stroke are not treated with rt-PA, because they arrive too late or because of delays in assessment/administration of intravenous rt-PA. Earlier administration of intravenous rt-PA after the onset of stroke symptoms is associated with greater functional recovery. One of the potential approaches to increase treatment opportunities and improve stroke outcomes is to provide this treatment in a more timely fashion after patient arrival (reducing the door to needle time for intravenous rt-PA).

Results from clinical trials and registries have encouraged multiple organizations to set targets for timely initiation of thrombolytic therapy after hospital arrival. A National Institute of Neurological Disorders and Stroke national symposium on the rapid identification and treatment of acute stroke recommended a door-to-needle target time of 60 minutes.

Despite the clinical trial evidence for better functional outcomes with early treatment with IV rt-PA and guideline recommendations,[20] there remain a substantial portion of patients where treatment is delayed. In a recent analysis of Get With The Guidelines–Stroke, only one quarter of patients with acute ischemic stroke treated with tPA within 3 hours of symptom onset had door-to-needle times within 60 minutes, and overall median door-to-needle time for the entire cohort of patients was 78 minutes.[21] This suggests that there are substantial opportunities to improve the timeliness of reperfusion therapy. While a number of hospitals currently report on this measure via Get With The Guidelines—Stroke and the Coverdell Registry, we believe that systematic implementation through all hospitals participating in the IQR, would significantly improve patient outcomes. Therefore, we urge CMS to adopt this measure in future years of the IQR.

Removal and Suspension of Hospital IQR Program Measures

In the proposed rule, CMS discusses several measures that it intends to remove from the IQR program.

Stroke Structural Measure

CMS has proposed removing the "systemic clinical database registry for stroke care" structural measure. This measure was adopted by CMS for the Hospital IQR Program for the FY 2013 payment determination beginning with January 1, 2011 discharges. CMS intends to remove this measure

[20] Adams HP Jr., del Zoppo G, Alberts MJ, Bhatt DL, Brass L, Furlan A, et al. Guidelines for the early management of adults with ischemic stroke. Circulation. 2007;115:e478–534.

[21] Fonarow GC, Smith EE, Saver JL, Reeves MJ, Bhatt DL, Grau-Sepulveda MV, et al. Timeliness of Tissue-Type Plasminogen Activator Therapy in Acute Ischemic Stroke: Patient Characteristics, Hospital Factors, and Outcomes Associated With Door-to-Needle Times Within 60 Minutes. Circulation. 2011;123:750–758.

because a new STK measure set went into effect beginning with January 1, 2013 discharges. The Agency believes that the new stroke measure set will provide more meaningful and detailed information regarding how well stroke care is being managed in a hospital setting than the current structural measure, which consists of a general yes/no response.

We disagree with the Agency's decision to remove the "systematic clinical database registry for stroke care" measure from the IQR. While we agree that the new STK measures will provide useful data, we believe that participating in a clinical stroke registry is equally important. Registries collect additional data that is not collected via the meaningful use measures. We are concerned that the removal of this stroke registry measure has the potential to make it more difficult for collection of test data on measures not currently in meaningful use, as it may remove the incentive for hospitals to participate in registry data collection, since CMS no longer deems participation in a stroke registry as important. A hospital may shift its resources to another CMS area of interest. Furthermore, we believe that the STK measures that are collected via registries such as GWTG-Stroke and the Paul Coverdell registry can help the Agency assess whether or not the EHR measures are truly equivalent to the predecessor registry based measures. As we have stated in previous comments, we remain concerned that there is not sufficient data to assess whether the meaningful use version of the measures are equivalent. Therefore, testing and validation of these measures against registry based data is important. We recommend that CMS continue to include this measure in future years, in tandem with the collection of the STK measures.

HF-3 ACE-I or ARB for Left Ventricular Systolic Dysfunction

CMS also states that it plans to remove "Heart Failure-3 Angiotensin Converting Enzyme Inhibitor (ACE–I) or Angiotensin II Receptor Blocker (ARB) for Left Ventricular Systolic Dysfunction" from the IQR in FY 2016. We strongly disagree with Agency's decision to remove this measure. We believe that this measure collects valuable data for heart failure patients. In fact, we believe that it is important to go beyond inclusion of this measure, by also capturing data on the appropriate dosing of ACE inhibitors/ARBs which 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.

However, if CMS decides to not include this measure starting in FY 2016, we request that the Agency grant it the status of a "suspended" measure and not a "removed" measure. This would allow AHA and other interested parties to analyze data to assess whether or not the removal of these measures results in any unintended change in the quality of care received by patients.

AMI-2 Aspirin and AMI-10 Statin Prescribed at Discharge

In the case of "AMI-2 Aspirin Prescribed at Discharge" and "AMI-10 Statin Prescribed at Discharge" CMS states that it will continue to categorize these measures as "suspended" and not as "removed". We agree with the Agency's decision to suspend these measures and not to remove them. This will allow organizations such as the AHA/ASA to monitor whether or not there is a decline in these measures. We also urge CMS to work with organizations like the AHA/ASA to first assess whether a measure should be removed from the IQR program. We can work with the Agency to avoid any potential unintended consequences that may adversely affect patient care.

HF-1 Discharge Instructions

As noted earlier in our comments, we believe that "HF-1 Discharge Instructions" should be replaced with the ACCF/AHA/AMA PCPI measure entitled "post-discharge appointment for heart failure patients." If CMS is not willing to adopt the ACCF/AHA/AMA PCPI measure at this time we ask that HF-1 be granted the status of a "suspended" measure and not a "removed" measure.

Previously Adopted and Proposed Hospital IQR Program Measures

In the proposed rule, CMS delineates a number of measures that it plans to include for FY 2015.

Heart Failure 30-day Risk Standardized Readmission Measure

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,[22] 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.[23] 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.

Furthermore, the recently released MedPAC report notes that computation of readmissions rates and of the penalty should be refined to address several issues with the current policy.[24] Specifically, MedPAC advocates for the use of an all-condition readmission measure to increase the number of observations and reduce random variation. MedPAC recommends the use of an all-condition readmission measure to limit the concerns regarding the inverse relationship between heart failure mortality rates and readmission rates.

[22] Joynt KE, Orav EJ, Jha AK. Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA 2011;305:675-81.

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

[24] Medicare and the Health Care Delivery System. MedPAC report. June 14, 2013.

If CMS continues to include the "30-day Risk Standardized Readmission Measure for Heart Failure" in the IQR Program, we would 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.

STK 1, 2, 3, 4, 5, 6, 8, 10

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.

AMI Payment Per Episode of Care

In the case of the AMI episode of care measure we note that there are concerns that the measure cannot adequately capture case mix or be risk adjusted. The discrimination of these models has not been well validated. Therefore, we believe that this measure should be closely monitored for unintended consequences.

30-Day Stroke Mortality and Readmission

With regards to the stroke 30-day mortality and 30-day readmission measures, as stated earlier, we do not believe that these measures should be adopted; adoption of these two measures could lead to unintended consequences. The 30-day mortality measure was withdrawn from NQF consideration in order to examine the risk adjustment model. Furthermore, we believe that adopting the 30-day stroke readmission measure that has been rejected by NQF, and for which numerous parties have raised concerns, goes against the Agency's efforts to ensure that measures are supported by consensus. Given that neither of these measures was adopted by NQF, and that both are outcome measures, we do not support the inclusion of these measures in the IQR program.

PROPOSED CHANGES TO MEDICARE SEVERITY DIAGNOSIS RELATED GROUP CLASSIFICATIONS

Proposed Changes to Specific MS-DRG Classifications

MDC 1: Tissue Plasminogen Activator (tPA) (rtPA) Administration Within 24 Hours Prior to Admission

In the proposed rule, CMS responds to a request to conduct an analysis of diagnosis code V45.88. This V code is used to identify acute stroke patients who receive tPA in an emergency department and then are subsequently transferred to another hospital's stroke center for admission and subsequent care – commonly referred to as "drip and ship". We appreciate the Agency's willingness to examine the utilization and cost data associated with this V code. We do, however, have questions about the analysis and the conclusions the Agency reached.

First, we are concerned that the analysis compares the number of V code cases with the total number of stroke cases included in each of the MS-DRGs. As we explained in previous comments to CMS,[25] MS-DRG 064, 065, and 066 are utilized for patients with ischemic stroke, intracerebral hemorrhage,

[25] AHA/ASA comments to CMS in response to the IPPS proposed rule for FY 2011; CMS-1498-P. June 18, 2010.

and subarachnoid hemorrhage; however, only patients with ischemic stroke should receive tPA. Therefore, any analysis to determine if "drip and ship" patients have greater lengths of stay and/or greater costs than other similar stroke patients should be limited to ischemic stroke patients. Unfortunately, it appears that the CMS analysis again compared "drip and ship" cases against patients with ischemic and hemorrhagic stroke.

We request that the Agency remove patients with hemorrhagic stroke from the V code analysis. Removing hemorrhagic stroke patients will allow CMS to better examine the differences in length of stay and cost between "drip and ship" patients and other ischemic stroke patients. Including hemorrhagic stroke patients, who, on average, have higher costs than patients with ischemic stroke,[26] may minimize the cost difference between "drip and ship" patients and other stroke patients. For example, the CMS analysis found that the average cost for "all cases" in MS-DRG 064 is $11,654; however, average costs for "drip and ship" patients in MS-DRG 064 are $2,778 higher or $14,432. $2,778 is a sizable difference, yet it may not be an accurate representation of the difference in costs. Removing hemorrhagic stroke patients from the analysis may lower the average cost for "all cases" and result in a higher difference in costs. If hemorrhagic stroke patients are removed and the average cost for "all cases" decreases to, for example, $10,000, the cost difference between "all cases" and "drip and ship" cases grows to $4,432. Thus, removing hemorrhagic stroke cases from the analysis will allow the true cost difference to be apparent. We hope that CMS will take this step, which will better reflect the higher cost to hospitals that receive patients who have already been administered tPA.

Our second concern relates to the Agency's proposal to address the higher costs associated with treating "drip and ship" patients. According to the proposed rule, CMS concluded that the differences in length of stay and costs are too small to warrant moving "drip and ship" patients from MS-DRG 064, 065, and 066 to MS-DRG 061, 062, and 063. However, CMS found that "the data does reflect that the average costs for cases reporting diagnosis code V45.88 as a secondary diagnosis in MS-DRG 066 are more similar to the average costs of higher severity level cases in MS-DRG 065. Therefore… we are proposing to move cases with diagnosis code V45.88 from MS-DRG 066 to MS-DRG 065, and to revise the title of MS-DRG 065 to reflect the patients status post tPA administration within 24 hours." The new title for MS-DRG 065 would be: MS-DRG 065 (intracranial hemorrhage or cerebral infarction with CC or tPA in 24 hours).

We appreciate the Agency's attempt to address the higher costs associated with treating "drip and ship" patients, but it is unclear why CMS has only proposed a change in reimbursement for "drip and ship" patients who currently fall in MS-DRG 066. According to the data provided by CMS and reproduced below, there is a significant cost difference between "all cases" and the subset of "drip and ship" cases for all three of the MS-DRGs – 064, 065, and 066.

[26] Russo, CA and Andrew, RM. Hospital Stays for Stroke and Other Cerebrovascular Diseases, 2005. HCUP Statistical Brief #51. May 2008. Agency for Healthcare Research and Quality.

Intracranial Hemorrhage or Cerebral Infarction				Average Cost Difference
	# of Cases	Average Stay	Average Costs	
MS-DRG 064 – all cases	64,095	6.30	$11,654	**$2,778**
MS-DRG 064 – w/ V45.88	955	7.06	$14,432	
MS-DRG 065 – all cases	101,011	4.29	$7,414	**$2,057**
MS-DRG 065 – w/ V45.88	1,259	4.91	$9,471	
MS-DRG 066 – all cases	56,620	2.92	$5,414	**$1,268**
MS-DRG 066 – w/ V45.88	493	3.28	$6,682	

Based on these data, we do not understand why CMS has only proposed moving "drip and ship" patients in MS-DRG 066 to a higher paying MS-DRG. This is especially confusing because the analysis shows that of the three MS-DRGs, MS-DRG 066 has the smallest difference in costs ($1,268) and affects the smallest number of patients (493).

By proposing to move "drip and ship" patients from MS-DRG 066 to MS-DRG 065, it appears that CMS recognizes that there are higher costs associated with treating "drip and ship" patients. Yet the Agency did not propose any change for "drip and ship" patients coded to MS-DRG 064 or 065 even though these DRGs have significantly higher costs differences ($2,778 and $2,057 respectively). Again, we do not understand why CMS only focused on the one MS-DRG with the smallest difference in costs; CMS should make adjustments for all three.

To address the higher costs associated with treating all "drip and ship" patients, we recommend that CMS do the following:

- Move "drip and ship" patients in MS-DRG 066 to MS-DRG 065 as proposed
- Move "drip and ship" patients in MS-DRG 065 to MS-DRG 063
- Move "drip and ship" patients in MS-DRG 064 to MS-DRG 062

Moving "drip and ship" patients in MS-DRG 064 and 065 to MS-DRG 062 and 063, as illustrated below, follows the same principle advanced by CMS in the proposed rule. CMS proposed moving "drip and ship" patients in MS-DRG 066 to 065 because the costs for MS-DRG 066 "are more similar" to the average costs in 065. In the same manner, the costs for MS-DRG 065 "are more similar" to the costs in 063, and the costs for MS-DRG 064 "are more similar" to the costs in 062. In addition, these changes would better align reimbursement rates with the actual costs to treat "drip and ship" patients.

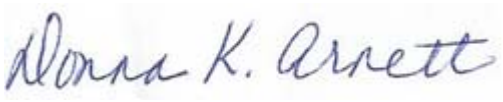
Intracranial Hemorrhage or Cerebral Infarction	
	Average Costs
MS-DRG 064 – all cases	$11,654
MS-DRG 064 – w/ V45.88	$14,432
MS-DRG 065 – all cases	$7,414
MS-DRG 065 – w/ V45.88	$9,471
MS-DRG 066 – all cases	$5,414
MS-DRG 066 – w/ V45.88	$6,682

Acute Ischemic Stroke with Use of tPA	
	Average Costs
MS-DRG 061 – all cases	$18,556
MS-DRG 061 – w/ V45.88	$19,008
MS-DRG 062 – all cases	$12,935
MS-DRG 062 – w/ V45.88	$13,317
MS-DRG 063 – all cases	$10,363
MS-DRG 063 – w/ V45.88	$9,372

Again, we appreciate the Agency's efforts to examine the utilization and cost data associated with "drip and ship" stroke patients. We look forward to working with CMS to make sure stroke centers receive proper reimbursement so that patients continue to have access to these life-improving services.

Thank you again for the opportunity to submit comments. If you have any questions about the Hospital IQR Program, please do not hesitate to contact Penelope Solis, JD, Healthcare Quality Manager, at 202-423-3124 or penelope.solis@heart.org. For questions regarding proposed changes to the MS-DRGs, please contact Susan Bishop, Senior Advisor for Regulatory Affairs, at 202-785-7908 or susan.k.bishop@heart.org.

Sincerely,



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