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Association

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June 20, 2013

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1599-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Medicare Program; Proposed Rule (Vol. 78, No. 91), May 10, 2013

Dear Ms. Tavenner:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital inpatient prospective payment system (PPS) proposed rule for fiscal year (FY) 2014. We have submitted comments separately on CMS's proposed changes to admission and medical review criteria for hospital inpatient services, as well as its proposed changes to the long-term care hospital (LTCH) PPS.

While we support a number of the proposed rule's provisions, we have serious concerns about certain aspects of the disproportionate share hospital (DSH) and Hospital-acquired Condition (HAC) Reduction Program proposals, as well as the proposed handling of electronic quality measure data collection within the Inpatient Quality Reporting (IQR) program.

CHANGES TO DSH PAYMENT METHODOLOGY

The *Patient Protection and Affordable Care Act of 2010* (ACA) requires that, beginning in FY 2014, hospitals initially receive 25 percent of the DSH funds they would have received under the current formula, with the remaining 75 percent flowing into a separate funding pool for DSH hospitals. This pool would be reduced as the percentage of uninsured individuals declines, and would be distributed based on the proportion of total uncompensated care each Medicare DSH hospital provides.



To implement the law, CMS proposes to use Congressional Budget Office estimates to determine the change in the percentage of uninsured. The agency had considered using charity care, bad debt and other data from the hospital cost report worksheet S-10 to measure uncompensated care, but because that worksheet is relatively new and has only been used for payment purposes in relatively restricted ways, CMS instead proposed to use hospitals' Medicaid and Medicare Supplemental Security Income patient days as a proxy for the amount of uncompensated care they provide. **The AHA supports these proposals. However, we note that, if reported in an accurate and consistent manner, the S-10 data have the potential to serve as a more exact measure of the treatment costs of uninsured patients.** We urge the agency to take action to revise and improve both the form and the instructions so that these data could be potentially used as soon as possible.

In addition, CMS's proposal to distribute DSH payments from the pool on a periodic interim, rather than per-discharge, basis presents serious concerns. Distributing these additional DSH payments on a periodic interim basis would have two significant unintended consequences for hospitals. First, we are concerned about how a Medicare Advantage plan can calculate appropriate payment amounts for a hospital if the additional DSH payment is not included in the per-claim payment amount. In addition, distributing these payments on a periodic interim basis would arbitrarily impose payment cuts on certain sole community hospitals (SCHs) because these payments would not be accounted for in determining whether SCHs are paid the federal rate or their hospital-specific rate. **To ensure accurate and appropriate payments and avoid unintentional payment cuts to hospitals, the AHA strongly urges CMS to distribute the additional DSH payments on a per-discharge basis and not on a periodic interim basis.**

HAC REDUCTION PROGRAM

Beginning in FY 2015, the ACA requires CMS to impose a 1-percent reduction in Medicare payments for hospitals in the top quartile of risk-adjusted national HAC rates. **The AHA urges CMS to reconsider its proposed approach to the HAC Reduction Program due to significant concerns about the measures and scoring methodology CMS proposes in the rule.** First, the selected measures inappropriately overlap with the value-based purchasing program, sending conflicting signals to patients and hospitals about the true state of hospital performance. Second, many of the proposed measures were selected using a flawed process and have significant methodological problems. Third, the proposed scoring methodology would not meaningfully differentiate hospital performance. Finally, the inadequate risk adjustment for certain measures would disproportionately harm teaching hospitals and large hospitals (400 beds and over) that tend to care for sicker patients.

USING E-MEASURES IN THE INPATIENT QUALITY REPORTING PROGRAM (IQR)

We are concerned about CMS's proposal to allow hospitals to meet their IQR program requirements for 16 measures by submitting the data for one quarter's patients using electronic measure specifications and pulling the data directly from the hospital's certified electronic health record (EHR). CMS is aware that the measure specifications and data abstraction methods used with EHRs do not result in accurate representations of hospital performance. For this and several other reasons, CMS proposes to simply not display data for these measures on *Hospital Compare* for any hospital that chooses to submit its information in this manner – at least as we understand

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the language of the proposed rule. We believe this proposal undermines the intent of the IQR program and would fail to provide consumers with reliable data for quality measures related to stroke, venous thromboembolism and early elective deliveries for some hospitals. The AHA urges CMS instead to allow the electronic submission of data collected in accordance with the specifications used for hand abstraction of the measures, and for any hospital choosing to submit data in this manner, allow successful reporting to count for both the IQR program and for Meaningful Use measure submission.

Our detailed comments are attached. If you have any questions, please feel free to contact me or Joanna Hiatt Kim, vice president of payment policy, at (202) 626-2340 or jkim@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

**American Hospital Association
Detailed Comments on the Inpatient Prospective Payment System
Proposed Rule for FY 2014**

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CHANGES TO MS-DRG CLASSIFICATIONS AND RELATIVE WEIGHTS

MS-DRG DOCUMENTATION AND CODING ADJUSTMENT

The Centers for Medicare & Medicaid Services (CMS) proposes a cut of 0.8 percent in fiscal year (FY) 2014 that would fulfill part of the *American Taxpayer Relief Act of 2012* (ATRA) requirement that CMS recoup what the agency claims is the effect of documentation and coding changes from FYs 2010, 2011 and 2012 that CMS says do not reflect real changes in case-mix. We agree with CMS that this proposal helps mitigate extreme annual fluctuations in payment rates. **While we continue to believe these congressionally mandated adjustments are not warranted, we appreciate that the agency's proposal has provided hospitals with additional time to manage these sizeable cuts.**

In addition, in the FY 2013 inpatient prospective payment system (PPS) rulemaking cycle, CMS proposed, but did not finalize, a prospective cut of 0.8 percent related to hospitals' documentation and coding in FY 2010. The agency stated that it did not finalize this cut because it needed to further analyze the AHA's assertion that the 0.8 percent figure was overstated. In this FY 2014 proposed rule, the agency agrees with AHA that the 0.8 percent figure is overstated and that a cut of 0.55 percent would be more appropriate. While we appreciate the agency's acknowledgement that its proposed documentation and coding cut from FY 2013 was overstated, we note that our previous assertion that CMS's coding cuts are overstated is not limited to only the 0.8 percent cut related to FY 2010 – it also applies to the recoupment cuts the agency made related to FYs 2008 and 2009. The Medicare Payment Advisory Commission (MedPAC) found that CMS could have overstated these cuts by cumulatively as much as 0.36 percent in FY 2008 and 0.36 percent in FY 2009 – or by a total of 0.72 percent.

In addition, CMS solicits comments on whether any portion of the 0.8 percent proposed recoupment should be applied on a prospective basis to help satisfy the need for a prospective adjustment. CMS notes that doing so would require relatively larger adjustments for FYs 2015, 2016 and 2017, but would eliminate the need for a future prospective adjustment. As we previously have noted, we are troubled that CMS continues to compare hospitals' documentation and coding practices in FY 2010 to their documentation and coding practices under an entirely different system in FY 2007. We also are concerned that necessitating larger adjustments in the future would be contrary to the agency's stated goal of mitigating extreme annual fluctuations in payment rates. **For these reasons, we urge CMS not to apply any portion of the 0.8 percent proposed recoupment on a prospective basis.**

MS-DRG RECLASSIFICATIONS

In general, the AHA has no objections to CMS's proposed changes to the Medicare Severity Diagnosis-related Group (MS-DRG) classifications and the Medicare Code Editor, which seem reasonable given the data and information provided.

Code Freeze. The AHA continues to support CMS's recommendations to continue limited code updates to ICD-10-CM/PCS to capture new technologies and diseases through FY 2014.

However, we recommend that no updates occur during the first year of ICD-10 implementation, FY 2015. If new codes can still be introduced into ICD-10-CM/PCS in FY

2015, it will make the resolution of any issues all the more complex and costly. Specifically, successful implementation of ICD-10-CM/PCS will require significant planning, education and systems modifications. While the adoption of ICD-10-CM/PCS is welcome and long overdue, implementation of the new system must be carefully orchestrated to minimize the administrative burden on providers. At a time when the health care field, all payers and other stakeholders are struggling to meet deadlines to change their systems and test their changes with all their trading partners, we believe it would be catastrophic to have to make additional changes during nationwide implementation of ICD-10. For example, it would make the implementation of these new code sets more costly and complex, requiring repeated changes to systems and educational training materials.

ICD-10 MS-DRGs. We compliment CMS on making available the Version 30.0 ICD-10 MS-DRGs software and Definitions Manual. These tools will be useful as hospitals prepare for ICD-10 implementation. However, such information should not be limited to the inpatient PPS, but also should address other payment systems, such as those for critical access hospitals (CAHs), inpatient psychiatric facilities and inpatient rehabilitation facilities. Detailed information on how other payment systems will be affected should be made available at least one year prior to ICD-10-CM/PCS implementation in order for providers to be able to analyze the impact of these changes, including thorough financial analysis and modeling, and to allow for hands-on training of medical coders. CMS should direct its contractors to have all policies and edits related to systems referencing diagnosis and procedure codes ready at least six months prior to ICD-10-CM/PCS implementation (April 1, 2014).

RECALIBRATION OF MS-DRG RELATIVE WEIGHTS

In the FY 2009 inpatient PPS final rule, CMS split the medical supplies cost center into two – one for relatively inexpensive medical supplies and another for more expensive devices (such as pacemakers and other implantable devices). Accordingly, CMS proposes, beginning in FY 2014, to calculate the MS-DRG relative weights using one cost-to-charge ratio (CCR) for relatively inexpensive medical supplies and one for implantable devices. **The AHA supports this proposal.** We agree that this approach may help address the issue of charge compression in setting cost-based weights for MS-DRGs that contain medical supplies.

In addition, in the FY 2011 inpatient PPS final rule, CMS split the general radiology cost center into three – one for general radiology, one for MRI scans and another for CT scans. CMS now proposes, beginning in FY 2014, to calculate the MS-DRG relative weights using one CCR for general radiology, one for MRI scans and another for CT scans. These new CCRs would also apply when calculating the ambulatory payment classification relative weights under the outpatient PPS.

When CMS initially proposed to split the general radiology cost center into three, the AHA requested that the agency further consider the impact of adopting those cost centers before finalizing its decision. We expressed concerns that “adopting these cost centers would implausibly reduce the CCRs for these services – so much so, that, in the outpatient setting, it may result in a CT of the chest being reimbursed at a similar level to a routine chest X-ray.” Our concerns have now proven to be valid – CMS states in the proposed rule that if it maintained one

CCR for general radiology, it would be 0.128. However, if it uses three CCRs (one for each of general radiology, MRI scans and CT scans), general radiology would be 0.170, but MRI and CT scan CCRs would be reduced to the implausibly low levels of 0.091 and 0.045, respectively. These new CCRs would dramatically lower reimbursement for MRI and CT scans; as predicted, in the outpatient setting, we believe it will result in a CT of the abdomen or of the head being reimbursed at a similar level to a routine chest X-ray. This inaccurately reflects the resources used for each of these technologies and is inappropriate.

We believe these CCR reductions are occurring because cost reporting requirements do not ensure hospitals capture cost information for capital-intensive services consistently. Specifically, they do not require hospitals to allocate radiology overhead to specific imaging items. Accordingly, much of the overhead belonging to MRI and CT scans remains in the general radiology cost center and is not allocated to the MRI and CT scan cost centers, causing them to be inaccurate. **Therefore, we urge CMS to re-consider the impact of these new radiology CCRs (including in the outpatient setting) before adopting them.** Although a respectable number of hospitals are reporting the new cost centers, we are concerned they are not allocating costs among them consistently and that MRI and CT scans will be paid inaccurately if the detailed cost centers are used.

DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENT CHANGES

MANDATED CHANGES TO DSH PAYMENT METHODOLOGY

The Patient Protection and Affordable Care Act (ACA) requires that, beginning in FY 2014, hospitals initially receive 25 percent of the DSH funds they would have received under the current formula – “empirically justified DSH payments” – with the remaining 75 percent flowing into a separate funding pool for DSH hospitals – “additional DSH payments.” This pool will be reduced as the percentage of uninsured individuals declines and will be distributed based on the proportion of total uncompensated care each Medicare DSH hospital provides relative to the national total.

In recognition of the potential for redistribution under these changes, the AHA convened a Medicare DSH Advisory Committee to discuss the agency’s specific proposals for implementing changes to the DSH program. Our comments below reflect the work of this committee, as well as our members at large.

Eligibility for DSH Payments. CMS proposes that Puerto Rico hospitals and hospitals participating in the Bundled Payments for Care Improvement Initiative are eligible for payments under the revised DSH payment methodology. It also proposes that Maryland hospitals and hospitals participating in the Rural Community Hospital Program are not eligible to receive DSH payments under the revised methodology. **The AHA supports these proposals.**

With regard to sole community hospitals (SCHs), which are paid the higher of the federal PPS rate or their hospital-specific rate, CMS proposes that the additional DSH payments would not be accounted for in determining which of these rates the SCH is paid because the agency proposes to make the payments on a periodic interim basis, rather than a per-discharge basis. **The AHA**

opposes this proposal, which arbitrarily and unfairly imposes payment cuts on certain SCHs. As also discussed below, we urge CMS to make the additional DSH payments from the new pool on a per-discharge, rather than periodic interim basis and, accordingly, account for these payments in determining whether to pay an SCH its federal PPS amount or its hospital-specific rate.

Empirically Justified DSH Payments. CMS proposes to distribute empirically justified DSH payments in the exact manner in which DSH payments are currently distributed, but at 25 percent of the amount of what otherwise would have been paid. Regarding settlement of these payments on the cost report, the agency states that it will provide more detailed instructions following issuance of the final inpatient PPS rule. **The AHA supports these proposals.**

Determining the Size of the Additional DSH Payment Pool. As a first step in determining hospitals' additional DSH payments, CMS must determine the initial size of the 75-percent pool. The agency proposes to use the most recently available projections of Medicare DSH payments to estimate the final size of this pool prior to the beginning of the fiscal year. That is, CMS proposes to set the size of the pool prospectively, based on estimated Medicare DSH payments for the year, and would not settle the size of the pool based on actual Medicare DSH payments for the year. **The AHA supports these proposals.**

For this proposed rule, CMS used the Office of the Actuary's (OACT) February 2013 estimate of what FY 2014 Medicare DSH payments otherwise would have been – \$12.338 billion. Therefore, the initial size of the 75-percent pool would be \$9.2535 billion. The agency provided the assumptions behind this estimate, one of which is that there will be a 2.0 percent documentation and coding cut in FY 2014. However, CMS proposed a 0.8 percent, not a 2.0 percent, documentation and coding cut. **We urge CMS to correct this assumption.**

Change in the Percentage of Uninsured. As the next step in determining hospitals' additional DSH payments, CMS must determine how much the 75-percent pool will be reduced as a result of the decline in the uninsured population. CMS proposes to use the Congressional Budget Office (CBO) estimate from March 20, 2010, which is 18 percent, as the number of uninsured in 2013. It proposes to use the CBO estimate from Feb. 5, 2013, which is 16 percent, as the most recent estimate of the number of uninsured that will remain in 2014. Both of these numbers include all U.S. residents, including unauthorized immigrants. When the statutory formula for calculating the change in the uninsured is applied to these numbers, it results in 88.8 percent of the 75-percent pool being retained. **The AHA supports these proposals.**

Determining Hospitals' Additional DSH Payments. CMS's proposed formula would use inpatient days of Medicaid beneficiaries plus inpatient days of Medicare supplemental security income (SSI) beneficiaries as a proxy for measuring the amount of uncompensated care each hospital provides. CMS proposes to obtain these data from hospitals' most recently available cost report; for FY 2014, this is hospitals' FY 2010 or 2011 cost report (including the FY 2011 SSI ratios or, if not yet available, the FY 2010 ratios). The agency would calculate the percentage of total Medicaid and Medicare SSI days among DSH hospitals that each DSH hospital accounts for. Hospitals would then receive this same percentage of what remains of the

75-percent pool as their additional DSH payment. **The AHA supports CMS's proposal to use data on Medicaid inpatient days and Medicare SSI inpatient days as a proxy for the treatment costs of uninsured patients and the respective allocation of the additional DSH payments until better data sources become available.** However, we note that this proposal results in a significant redistribution of DSH funds among hospitals. Therefore, we urge the agency to consider implementing a stop-loss and stop-gain policy that would limit the amount by which a hospital's DSH payments could change in a single year. In addition, in the inpatient PPS final rule, we urge CMS to update the cost report data used to calculate the additional DSH payments using the latest available cost report information. Finally, we urge the agency to allow hospitals 30 days after publication of the final rule to submit corrections for any errors made in extracting data from the cost report.

CMS had considered using charity care, bad debt and other data from the hospital cost report worksheet S-10 to measure uncompensated care. However, it states that this worksheet is relatively new and has only been used for payment purposes in relatively restricted ways, such as to provide a source of charity care charges in computing electronic health record incentives. In addition, stakeholders have asserted that hospitals have not had enough time to learn how to submit accurate and consistent data through this form, and that the instructions are confusing. Because of these concerns about the S-10 data, the agency decided that its use was not appropriate at this time. CMS does expect reporting on the S-10 to improve over time and may propose to use these data in the future. **The AHA agrees that the S-10 uncompensated care data are not appropriate for use at this time. However, we note that, if reported in an accurate and consistent manner, these data have the potential to serve as a more exact measure of the treatment costs of uninsured patients.** We have communicated our major concerns and suggestions regarding the S-10 to CMS. **We urge the agency to take action to revise and improve both the form and the instructions and, once stakeholders have had an opportunity to weigh in on the proposed changes, educate both the field and CMS's contractors about the form so that these data could be potentially used as soon as possible.**

The agency proposes to distribute the additional DSH payments on a periodic interim, rather than per-discharge basis. **Distributing these additional DSH payments on a periodic interim basis would have two significant unintended consequences for hospitals that raise serious concerns.** First, we are concerned about whether Medicare Advantage plans can calculate appropriate payment amounts for hospitals if the additional DSH payment is not included in the PPS PRICER because it is not paid on a per-claim basis. Although most Medicare Advantage plans do not pay directly from the PRICER, they do use software that extracts data from the PRICER.

Second, as noted above, making DSH payments on a periodic interim basis would arbitrarily impose payment cuts on certain SCHs. Specifically, CMS proposes that the additional DSH payments would not be accounted for in determining whether SCHs' federal PPS rate or their hospital-specific rate is higher because the agency proposes to make the payments on a periodic interim, rather than per-discharge, basis. This would result in the federal PPS amount being lower than it otherwise would have been. In turn, certain SCHs would be paid under their hospital-specific rates when they otherwise would have been paid higher federal PPS rates.

When the other payers informally rely upon a data resource provided by CMS, such as the PPS PRICER, and when CMS is aware of such reliance, we suggest that the agency has a responsibility to avoid implementing its policies in a manner that would lead to such significant disruption and unintended consequences as those described above. **Therefore, the AHA strongly urges CMS to distribute the additional DSH payments on a per-discharge basis, and not on a periodic interim basis.** As currently configured, the CMS PPS PRICER has an option that allows the check of a box to identify whether a claim is paid under Medicare Part A or Medicare Advantage. Consequently, it is reasonably clear that CMS routinely makes changes to the PRICER to allow the efficient administration of payments under Medicare Advantage. We are requesting no more than that with regard to the implementation of the revised DSH methodology.

Specifically, we suggest that immediately below the operating DSH line (“O-DSH” in the PPS PRICER), CMS add a value for additional DSH (“A-DSH”) that would represent the per-discharge interim payment for Medicare Part A and the per-discharge payment for Medicare Advantage paid claims when the Medicare Advantage paid claim option is selected. Making such a change would ensure that these payments flow through the PRICER for both Medicare Part A and Medicare Advantage claims and that all significant components of the Medicare rate continue to be accurately reflected. It also would ensure that the revised DSH payment policy does not disrupt the current Medicare Advantage Plan/provider relationships and the resulting Medicare Advantage provider networks that beneficiaries depend upon. Finally, it would ensure that CMS accounts for these additional DSH payments when determining whether SCHs’ federal PPS amount or their hospital-specific amount is higher, thereby avoiding unintended cuts to these vulnerable hospitals.

In proposing the periodic interim payment approach, CMS notes that the statute includes no information from which it would be possible to infer that the additional DSH payments should be made on a per-discharge basis. However, the opposite is also true: the statute includes no information from which it would be possible to infer that these payments should *not* be made on a per-discharge basis. The only DSH change that the Congress intended was clearly spelled out in the law – the reduction that CMS proposes to make related to the decline in the percentage of uninsured. The statute does not include any information that would lead to the conclusion that the Congress intended to risk further cuts to hospitals that care for low-income Americans by distributing the additional DSH payments on a periodic interim basis. We have estimated that the impact of not including the additional DSH payments in the PRICER could result in a cut of at least \$3 billion annually in Medicare Advantage payments to hospitals. This is clearly inappropriate and not sustainable.

Finally, CMS states that if it were to make the additional DSH payments on a per-discharge basis, unless a hospital’s Medicare utilization was identical to the period used to determine the per-discharge payment level, it is certain that Medicare would overpay or underpay, necessitating a reconciliation of the hospital’s prospectively determined additional DSH payments to account for the difference between actual and estimated Medicare utilization. That is certainly true. However, CMS already proposed to conduct reconciliations for the empirically justified DSH

payments. A simple process that reconciles the amount of a hospital's actual additional DSH payments to its prospectively determined additional DSH payments would be a small step on top of the agency's already proposed reconciliation – not a reconciliation where none would have occurred otherwise.

Cost Settlement. Although CMS proposes to settle the empirically justified DSH payments as is done with current DSH payments, the only aspect of the additional DSH payments that the agency proposes to settle is whether or not a hospital is eligible or ineligible. **Notwithstanding our above request to make the additional DSH payments on a per-discharge basis, the AHA generally supports this proposal.** However, we note that inadvertent cost report errors can and do occur. An error in a hospital's Medicaid or Medicare SSI days would now affect not only that individual hospital's additional DSH payments, but also all DSH hospitals' additional DSH payments. **Because of this, we urge CMS to implement a system of "reasonability" edits to these fields on the cost report before distributing the additional DSH payments for a given year.** For example, CMS could implement a check that flags hospitals that have reported Medicaid or Medicare SSI days on past cost reports, but that have not reported such days on their most recent cost report, or that flags Medicaid and Medicare SSI days that are outside the range of plausibility.

In addition, if CMS has projected that a hospital will be ineligible for DSH payments in a given year, but more recent data become available that indicate the hospital will be eligible for empirically justified payments, we ask that CMS allow the hospital to work with its fiscal intermediary/Medicare Administrative Contractor to be able to receive interim DSH payments, including the additional DSH payments. Otherwise, the hospital would not receive any additional DSH payments until its cost report from a given year is settled; settlement could be years into the future and the hospital may experience cash-flow issues in the meantime.

COUNTING MEDICARE ADVANTAGE DAYS IN THE DSH CALCULATION

CMS proposes to readopt the policy of counting Medicare Advantage patient days in the Medicare fraction of the DSH calculation. This proposal responds, in part, to the Federal District Court for the District of Columbia's recent ruling in *Allina Health Services v. Sebelius*. **The AHA strongly opposes CMS's proposal and urges the agency to continue to exclude Medicare Advantage patient days from the Medicare fraction of the DSH calculation.**

Under the statute, the Medicare fraction of the DSH calculation includes only individuals "entitled" to benefits under Part A. CMS states that individuals enrolled in Medicare Advantage are entitled to benefits under Part A because, in order to enroll in Medicare Advantage, a beneficiary must be entitled to the benefits under Part A. The agency also states that once enrolled in Medicare Advantage, the plan must provide the benefits the beneficiary is entitled to under Part A, and that under certain circumstances and for certain beneficiaries, Part A pays for care furnished to individuals enrolled in Medicare Advantage.

We disagree that individuals enrolled in Medicare Advantage are "entitled" to benefits under Part A. In examining the statute and CMS's own regulations, it is clear that Medicare Advantage enrollees are *not* entitled to benefits under Part A and, thus, should continue to be excluded from

the Medicare fraction of the DSH calculation. First, § 226(c)(1) of the *Social Security Act* states that “entitlement of an individual to hospital insurance benefits for a month [under Part A] shall consist of entitlement to have payment made under, and subject to the limitations in, [P]art A.” In addition, § 1851(a)(1) of the *Social Security Act* states that persons eligible for Medicare Advantage are “entitled to elect to receive benefits” either “through the original [M]edicare fee-for-service program under [P]arts A and B. or through enrollment in a [Medicare Advantage] plan under [Part C].” Finally, § 1851(i)(1) states that “payments under a contract with a [Medicare Advantage] organization...with respect to an individual electing a [Medicare Advantage] plan...shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under [P]arts A and B...”

Individuals who enroll in a Medicare Advantage plan do not receive benefits under Part A; rather, they receive benefits under Part C. Thus, Medicare Advantage enrollees cannot be “entitled” to benefits under Part A, because they can no longer receive benefits under Part A. Rather, they can receive benefits under only Part C. Medicare beneficiaries are not “entitled” to benefits that the law denies them, and CMS’s contrary interpretation of the statute frustrates a principal purpose of the Medicare DSH statute and is, therefore, unreasonable. Further, the policy is unreasonable because it is inconsistent with legislative intent and inconsistently interprets the same term “entitled to benefits” in a single sentence of the DSH provision.

In addition, as mentioned above, this proposal responds, in part, to the Federal District Court for the District of Columbia’s recent ruling in *Allina Health Services v. Sebelius*, which invalidated CMS’s attempt in the FY 2005 inpatient PPS final rule to adopt the very policy it is proposing in this rule. According to the court, CMS acted in an arbitrary and capricious manner in violation of the *Administrative Procedure Act* when it stated that it would begin including Medicare Advantage days in the Medicare fraction of the DSH calculation.

In *Allina*, the court found that CMS’s explanation of its new policy in the FY 2005 rule was flawed in two ways: It failed to acknowledge that the policy was a complete reversal of the agency’s prior interpretation of the statutory provision, and it failed to give a sufficient explanation for that reversal in interpretation. Yet, the agency does not correct either of these deficiencies in the FY 2014 proposed rule. First, as the *Allina* opinion makes clear, the court had previously ruled that CMS’s policy was a reversal, not a clarification, and CMS “is not free to pretend otherwise.” Yet, the agency still does not discuss that including Medicare Advantage days in the Medicare fraction would actually be a reversal of its prior position. Instead, it states that it “continues” to believe that individuals enrolled in Medicare Advantage plans are entitled to benefits under Part A and, therefore, should be included in the Medicare fraction under the statute.

In addition, CMS does not include a reasoned explanation for the reversal. The agency itself, in both the FY 2004 proposed and FY 2005 final inpatient PPS rules, acknowledged that the statute is susceptible to multiple interpretations, including the agency’s own previous position that individuals enrolled in Medicare Advantage plans should not be included in the Medicare fraction. For its FY 2014 proposal, the agency only slightly elaborates on its assertion in the FY 2005 rule that individuals enrolled in Medicare Advantage plans “are still, in some sense entitled

to benefits under Medicare Part A,” an argument that the *Allina* plaintiffs characterized as a “vacuous utterance [that] explains nothing” and is “entirely devoid of genuine reasoning.”

Such a thorough and complete discussion is critical in this case because, as the court affirmed in *Allina*, quoting its earlier decision in *FCC v. Fox Television Stations*, when stakeholders have come to rely on a certain policy, as is the case here, an agency must give a more detailed explanation for changing its policy than would be necessary for a policy created on a blank slate. Although the AHA strongly urges CMS not to finalize its proposal, if it does choose to move forward, the agency must set out such a discussion and allow stakeholder comment on it *before* deciding whether to finalize its proposal. **With regard to the forthcoming FY 2014 final rule, because CMS has corrected neither of the deficiencies cited by the court in rejecting the agency’s prior attempt to include Medicare patient days in the Medicare fraction of the DSH calculation, the agency should not – and cannot – finalize its new proposed policy. By doing so, it again would be acting in an arbitrary and capricious manner in violation of the *Administrative Procedure Act*.**

OUTLIER PAYMENTS

CMS proposes to make two changes to its outlier methodology for FY 2014. First, as it has done in the past, to calculate the proposed FY 2014 outlier threshold, CMS simulates payments by applying the proposed FY 2014 payment rates and policies to cases from the FY 2012 Medicare Provider Analysis and Review (MedPAR) file. Since FY 2005, it has used the same methodology to inflate the MedPAR charges by two years. Specifically, to compute the one-year average annualized rate-of-change in charges per case, CMS previously compared the average charge per case from the most recent six-month period of charge data to the average charge per case from the same six-month period in the prior year.

The agency now proposes to use one-year rather than six-month comparison periods. In addition, rather than estimating the rate of change in cost-to-charge ratios (CCRs) by assuming the relationship between actual costs and the hospital market basket stays constant over time, CMS proposes to use historical data to adjust the CCRs. It states this method is simpler and consistent with CMS’s estimation of charge inflation. **The AHA supports these proposals.**

GRADUATE MEDICAL EDUCATION (GME)

Treatment of Labor and Delivery Beds in GME Payments. In the FY 2013 inpatient PPS final rule, CMS finalized its proposal to include labor and delivery bed days as available bed days for indirect medical education (IME) payment adjustment purposes. CMS now proposes to include labor and delivery inpatient days in the “Medicare utilization ratio.” The Medicare utilization ratio impacts all Medicare policies where either the number of inpatient days or a ratio of Medicare inpatient days to total inpatient days is used, such as in calculating direct GME payments. **The AHA continues to oppose the agency’s rationale for its recent policy changes regarding labor and delivery beds and days, particularly absent any direction from Congress, for the reasons discussed below.**

Including labor and delivery patient days for purposes of allocating direct GME payments is inappropriate given that these services typically are not covered by the Medicare program. Specifically, including labor and delivery beds in this Medicare adjustment is unreasonable because Medicare pays for very few births: In 2011, it paid for about 14,000 births, or approximately 0.35 percent of all births in the United States.

In addition, CMS's proposal to reduce direct GME payments is particularly inappropriate given that direct GME payments already cover only a fraction of the direct costs of training medical residents. Specifically, Medicare direct GME payments are about \$3.2 billion, but according to data from the Association of American Medical Colleges, the annual cost of direct GME to hospitals is \$15.4 billion. As the ACA's marketplace reforms are implemented and we face looming physician shortages, it is critical to protect GME and the health care professional pipeline to ensure that expanded coverage does not outpace access. Further, this proposal could have the unintended consequence of incentivizing hospitals to eliminate labor and delivery beds and days, potentially jeopardizing access for non-Medicare populations. **We remain fundamentally opposed to the proposed policy change and continue to believe that CMS should exclude labor and delivery costs, days and beds for both direct GME and IME payment purposes, because the Medicare program does not generally cover services for labor and delivery.**

Medical Resident Training at CAHs. Under existing payment policies, an inpatient PPS teaching hospital that rotates residents to a CAH may count the time the residents spend in the CAH for either IME or direct GME purposes if the PPS hospital pays the residents' salaries and benefits for the time they spend training at the CAH and complies with other "nonhospital" requirements set forth in 42 CFR §413.78(d)-(f). If the CAH itself incurs the costs of training these residents when they are rotated to the CAH, then the CAH may receive 101 percent of the reasonable costs it incurred for the training. In adopting its existing policy, CMS stated that CAHs are unique facilities that generally are not considered "hospitals" under the *Social Security Act*. However, in light of Section 5504 of the ACA, which allows hospitals to count resident time in "nonprovider" settings, the agency is re-evaluating the policy. CMS states that CAHs, although not considered "hospitals," are included in the definition of "providers" in the *Social Security Act*. Therefore, the agency proposes that teaching hospitals would no longer be permitted to count the time residents spend rotating to CAHs for either IME or direct GME purposes.

CMS itself, however, has created the common understanding among policymakers and hospitals that the two terms "nonhospital" and "nonprovider" are interchangeable. The agency explicitly acknowledges in the proposed rule that prior to the effective date of Section 5504, it employed in the preamble of rules and in other policy discussions, these two terms interchangeably when talking about whether a hospital is allowed to count residents training at locations outside the hospital. The agency's sudden and abrupt decision to now attribute distinct and different meanings to terms it previously suggested were synonyms is inappropriate; the agency cannot pretend that the difference between these two terms and the precise consequences of using one versus the other has been clear and apparent all along. **It also casts some doubt on the agency's conclusion as part of the proposed rule that the Congress intended to exclude**

residents' rotation to CAHs by choosing to use the term "nonprovider" rather than "nonhospital" in section 5504.

CMS's interpretation of Section 5504 seemingly leads to the exactly opposite objective than that intended by Congress in enacting such section. The intent of Section 5504 was to remove obstacles and to allow a flexible interpretation of GME rules that particularly advantage implementation of primary care training programs and community-based training outside of the metropolitan teaching hospital. CAHs are critical part of this effort. They are absolutely essential in meeting the health care needs of rural America. The geographic isolation and large coverage area means that they are *the* medical center for, in some cases, hundreds of miles. Yet, rural areas in general, and CAHs specifically, face ongoing difficulty recruiting and retaining physicians, in large part because of their low volume and geographic isolation. The Congress clearly recognizes the importance of ensuring the availability of physician services in rural and underserved areas and did not use the term "nonprovider" with the intent of excluding CAHs.

CMS's proposal would likely chill such efforts to advantage implementation of primary care training programs and community-based training outside of the metropolitan teaching hospital. It also is contrary to the articulated need for and existing policies designed to promote more primary care physicians. The proposed rule would significantly harm the many community-based resident training programs – almost all such programs are family medicine residencies, and all of them are likely to have specific missions to train residents to serve the rural and underserved populations for which the CAHs are precisely intended to serve. **The AHA strongly urges CMS not to finalize this policy, and to instead continue to allow teaching hospitals to count the time residents spend rotating to CAHs for both IME and direct GME purposes.**

HOSPITAL SERVICES FURNISHED UNDER ARRANGEMENTS

In the FY 2012 inpatient PPS final rule, CMS adopted a new policy, effective Oct. 1, 2011, to preclude a hospital from providing certain services to its patients "under arrangements" with another hospital. The effective date of this policy was then delayed until Oct. 1, 2012, and subsequently until Oct. 1, 2013, to give hospitals additional time to make the changes necessary to comply with the new policy. In this rule, CMS proposes to delay the implementation date of the "under arrangements" policy again, to Jan. 1, 2015, give hospitals additional time to comply.

The AHA continues to believe that CMS should rescind the revised policy or, at the very least, grandfather in hospitals that, prior to publication of the FY 2012 proposed rule, provided "routine services" under arrangements with other hospitals for the reasons we have previously articulated. If these approaches are not feasible at this time, we request that CMS delay the effective date of this requirement to Jan. 1, 2016 (at the earliest) to provide adequate time for the agency to work through this issue with the affected hospitals. As CMS recognizes, achieving compliance with the under arrangements policy will, in some cases, require major building construction, in addition to restructuring existing arrangements and establishing operational protocols that CMS had previously approved with these hospitals. The delay until Jan. 1, 2016 is needed to provide affected hospitals with the time necessary to come

into compliance with the under arrangements policy. The AHA strongly encourages CMS to continue to work with affected hospitals and to consider alternative proposals to comply with this policy.

HOSPITAL-ACQUIRED CONDITION (HAC) REDUCTION PROGRAM

Beginning in FY 2015, the ACA requires CMS to impose a 1 percent reduction in Medicare payments for all MS-DRGs for hospitals in the top quartile of risk-adjusted national HAC rates. In this rule, CMS proposes eligibility requirements and the basic payment adjustment methodology. The agency also proposes the specific measures the program would include, as well as a scoring methodology to determine which hospitals are in the top quartile for HAC rates.

While we certainly support programs to eliminate patient harm from hospital-acquired conditions, this ACA provision is not well conceived or designed for a number of reasons.

The AHA strongly opposed the inclusion of the HAC Reduction Program in the ACA. We believe it is arbitrary to assess penalties on hospitals regardless of the overall progress the field has made in improving performance on measures. In addition, the HAC Reduction Program's mandate constrains it solely to assessing penalties based on hospital performance, and we are concerned that CMS has proposed measures that do not appropriately assess hospital performance. Specifically, because the HAC Reduction Program is a penalty program with only downside risk to hospitals, we believe the measures selected for such a program should have generally strong performance, with a limited performance gap to close.

We urge CMS to delay finalizing the HAC program, as we have significant concerns about the measures and scoring methodology proposed in the rule. First, the selected measures inappropriately overlap with the value-based purchasing (VBP) program, creating the potential for double payment penalties, as well as sending conflicting signals to patients and hospitals about the true state of hospital performance. Second, many of the proposed measures were selected using a flawed process and have significant methodological shortcomings. Third, the proposed scoring methodology will not meaningfully differentiate hospital performance, and finally, the inadequate risk adjustment for certain measures would disproportionately penalize teaching hospitals and larger hospitals (400 beds and over) that tend to care for sicker patients.

The AHA welcomes the opportunity to work with CMS, as well as other stakeholders from the provider and consumer communities to identify better measures for the program, and to improve the fairness of the scoring methodology. Given that the program is not required to be implemented until FY 2015, we believe CMS could delay finalizing any proposals until the outpatient PPS rule is finalized, providing additional time for CMS to enhance the program.

We first comment on the proposed measures, then the proposed scoring methodology, and finally on CMS's administrative proposals related to eligible hospitals and data review.

Proposed Measures. CMS proposes to use up to eight quality measures grouped into two domains to determine payment penalties for FY 2015. Domain 1 consists of claims-based Patient Safety Indicators (PSIs) developed by the Agency for Healthcare Research and Quality (AHRQ). In Domain 1, CMS proposes to use either six individual PSIs, or a single composite measure of several PSIs. Domain 2, which would be used regardless of the configuration of Domain 1 measures, includes healthcare-associated infection (HAI) measures currently reported in the Inpatient Quality Reporting (IQR) Program. The agency proposes to use two HAI measures for FY 2015, to add one more for FY 2016 and to add two more for FY 2017. The measures proposed for the HAC Reduction Program for FY 2015 through FY 2017 are outlined in Table 1.

Table 1: Proposed Measures and Domains for the HAC Reduction Program, FY 2015 – 2017

Domain 1, Option 1: Individual PSIs	Domain 1, Option 2: PSI 90 (Composite PSI)	Domain 2: HAI Measures
<ul style="list-style-type: none"> • Pressure ulcer rate (PSI 3)# * • Volume of foreign object left in the body (PSI 5) • Iatrogenic Pneumothorax rate (PSI 6)* • Postoperative physiologic and metabolic derangement rate (PSI 10)# * • Postoperative pulmonary embolism (PE) or deep vein thrombosis rate (DVT) (PSI 12) • Accidental puncture and laceration rate (PSI 15) 	<p>PSI 90 (PSI Composite), comprised of the following 8 PSIs:</p> <ul style="list-style-type: none"> • Pressure ulcer rate (PSI 3)# * • Iatrogenic Pneumothorax rate (PSI 6)* • Central venous catheter-related blood stream infection rate (PSI 7)# * • Postoperative hip fracture rate (PSI 8)# * • Postoperative pulmonary embolism (PE) or deep vein thrombosis rate (DVT) (PSI 12) • Postoperative sepsis rate (PSI 13)# * • Wound dehiscence rate (PSI 14)# * • Accidental puncture and laceration rate (PSI 15) 	<ul style="list-style-type: none"> • Central Line-associated Blood Stream Infection (CLABSI) (FY 2015 onward) • Catheter-associated Urinary Tract Infection (CAUTI) (FY 2015 onward) • Surgical Site Infection (SSI) (FY 2016 onward): • SSI Following Colon Surgery • SSI Following Abdominal Hysterectomy • Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia (FY 2017 onward) • <i>Clostridium difficile</i> (<i>C. Diff</i>) (FY 2017 onward)

#Not National Quality Forum (NQF)-endorsed *Not reviewed by the Measure Applications Partnership (MAP)

Measure Overlap with Value-Based Purchasing. CMS proposes to use several HAI measures that also will be used in future years of the hospital VBP program, including CLABSI, CAUTI, SSI, MRSA and *C. Diff*. If CMS opts to use the composite PSI (PSI 90) to calculate a Domain 1 measure score, that measure also would overlap with VBP.

Many stakeholders have commented that using the same measures in multiple programs is desirable because it aligns measures across programs, and creates increased emphasis on a particular quality or safety issue. **However, the AHA does not support using the same measures in both the HAC and the VBP programs because the programs use disparate ways to identify good versus bad performance. This could send conflicting signals about the true state of performance on these measures to hospitals and patients.**

As currently constructed, it is entirely possible that performance in the one program could appear acceptable or even good, but may lead to a payment penalty in the other program. As outlined in Table 2 below, the proposed measurement and performance periods of two of the potentially overlapping measures – CAUTI and PSI 90 – differ significantly. This alone may cause differences in measure performance. Moreover, the scoring methodologies of the two programs are vastly different, which could lead to hospitals having disparate scores for the same measure, as well as disparate payment incentives. In the VBP program, a portion of hospital reimbursement is withheld, with hospitals having an opportunity to earn incentive payments back based either on how well the hospitals perform on certain quality measures or how much the hospitals' performance improves from a baseline period. The HAC Reduction Program, by contrast, assesses penalties based on scoring in the top quartile of HAC measures.

Table 2: Comparison of HAC Reduction and VBP Baseline and Performance Periods, FY 2015

Measure	VBP Baseline Period	VBP Performance Period	HAC Measurement Period
CLABSI	Jan. 26, 2011 – Dec. 31, 2011	Jan. 26, 2013 – Dec. 31, 2013	Jan. 1, 2012 – Dec. 31, 2013
PSI 90	Oct. 15, 2010 – Jun. 30, 2011	Oct. 15, 2012 – Jun. 30, 2013	Jul. 1, 2011 – Jun. 30, 2013

These differences in measurement periods and scoring methodologies highlight important philosophical differences between the programs. VBP, we believe, is geared toward encouraging hospital improvement on measures where there is still variability and a gap in performance. The HAC program, by contrast, is a penalty program, with only downside risk to hospitals. Therefore, we believe the measures selected for such a program should have generally strong performance, with a limited performance gap to close, which would indicate that the strategies for preventing the harm to patients were known, effective and able to be implemented in various hospitals. In such instances, failure to prevent such harm could represent a system failure for which a payment penalty would be a reasonable public policy options rather than an occurrence of patient harm that may not have been preventable.

Using these principles, we recommend that CMS retain CLABSI and CAUTI in the HAC Reduction Program, while retiring both measures from the VBP program. CLABSI and CAUTI are well-established HAI measures on which hospitals have been focused for several years. The Centers for Disease Control and Prevention's (CDC) 2011 annual report on HAI measures reported into National Healthcare Safety Network (NHSN) notes that CLABSI rates have dropped 41 percent since 2008. While the rates of CAUTI have not dropped as dramatically as CLABSI, the scores have continued to improve over time, dropping by 7 percent since 2009.¹

We also recommend that CMS not finalize SSI, MRSA and *C. Diff* for the HAC program until performance on those measures has improved. We believe SSI, MRSA and *C. Diff*

could be made part of the VBP program and monitored to determine if or when they should be included the HAC program. The rates of SSI have declined, but there remains considerable variability in rates across surgical procedure types. Similarly, while hospitals have focused on reducing MRSA and *C. Diff* rates, these measures were not part of federal quality reporting programs until they were finalized for the hospital IQR program for the FY 2015 payment determination. The data collection and submission began only in January 2013, meaning there has been limited experience with using the measure in a public reporting application.

Measure Applications Partnership (MAP) Review. The AHA is concerned that the agency has ignored Congress's intent to use the MAP to obtain multi-stakeholder input on measures being considered for all federal programs *before* those measures are formally proposed in rulemaking. Specifically, three of the Domain 1, Option 1 proposed measures – PSI 3, PSI 6 and PSI 10 – have not yet undergone MAP review. **We urge CMS not to finalize these three measures until the MAP has had an opportunity to fully vet them as part of its normal pre-rulemaking input activities.**

As mandated by the ACA, the National Quality Forum (NQF) convenes the multi-stakeholder Measure Applications Partnership (MAP) to provide input on measures being considered for federal quality measurement and reporting programs in advance of formal rulemaking. By Dec. 1 of each year, the ACA requires the Secretary of Health and Human Services (HHS) to provide the MAP a list of measures – known as the Measures Under Consideration (MUC) list – that it is considering for future use in its programs. By Feb. 1 of each year, the MAP must provide its report detailing its recommendation for each measure on the MUC list.

As noted in Table 1 above, however, several Domain 1 measures were not on the MUC list transmitted to the MAP on Nov. 30, 2012, and hence, were not part of the MAP's subsequent review in December 2012 and January 2013.ⁱⁱ In the proposed rule, the agency provides no explanation of why the measures did not receive MAP review. **Moreover, while PSIs 3 and 6 are part of the PSI 90 composite measure, the MAP evaluated the composite measure as a whole. The MAP's review of PSI 90 did not constitute a review of PSI 3, PSI 6 or any of the individual PSIs that make up the composite score.**

In May 2013, the AHA and other members of the MAP were informed that the MAP Hospital Workgroup was being reconvened on June 10, 2013 to review the proposed PSI measures that were not included on the MUC list. **However, the MAP's review process operates under the premise that input is provided on measures *before* any rule is proposed or finalized. Reconvening the MAP on a *post hoc* basis is not consistent with currently established MAP processes, or the intent of the ACA.** To date, the MAP's formal review of measures has taken place between December and February. MAP workgroups have met between February and December of each year to provide strategic advice and input to HHS about measurement gaps, as well as to identify NQF-endorsed measures that may address specific programmatic needs. None of these supplemental activities, however, included a formal review of a MUC list with measures CMS wishes to propose for future programs. We also are unaware of any proposal from CMS or the MAP to alter the timing of the formal review of the MUC list.

In fact, the proposed rule itself was the first indication from CMS that PSIs 3, 6 and 10 were being considered for the program. Proposing measures in a rule, and subsequently having them reviewed by the MAP, undermines the consistency and credibility of the MAP process. The AHA strongly supports the premise of the MAP's work; that is, improvement in our nation's health care system can be catalyzed by selecting rigorous quality measures in federal reporting and payment programs focused on aspects of care that a broad array of stakeholders believe to be important. We believe that CMS intended to obtain meaningful input on the three PSI measures by reconvening the MAP. In practice, however, this *post hoc* review prevented MAP members from evaluating the three PSI measures against other options. It also created the appearance that CMS is trying to bypass the MAP process rather than fully engage it.

If CMS wishes to use PSIs 3, 6 and 10 in the HAC program, then it should include them on a future MUC list so they can be reviewed through the MAP's regular pre-rulemaking review process. The agency should then re-propose the measures in future rules. These steps will ensure that the MAP has the opportunity to fully vet these measures, and compare them to any alternatives CMS is proposing. It also would ensure that the MAP uses a consistent process to review measures prior to their inclusion in rulemaking.

***PSI Measure Issues.* The AHA does not support the use of the proposed PSI measures in the HAC program. We believe these measures have a number of critical flaws rendering them unsuitable for use in a public reporting or pay-for-performance application:**

- ***Lack of NQF Endorsement.* We are disappointed that CMS has selected two measures – PSI 3 and PSI 10 – that are not endorsed by the NQF.** Quality reporting programs – especially those with a significant payment penalty associated with them – require rigorous measures. NQF's multi-stakeholder measure endorsement process provides an opportunity to examine the strength of the evidence base supporting the use of a measure, as well as the ability of the measure to generate accurate performance results.
- ***Removal from the IQR program.* We are concerned that several of the PSI measures proposed for the HAC program – including PSI 6, PSI 12 and PSI 15 – were finalized for removal from the IQR program after FY 2014 in last year's inpatient PPS rule.** We believe that if the agency has deemed these measures unfit for use in a public reporting application, they are equally unsuitable for use in a payment penalty program.
- ***Proposed data source and measure reliability.*** In calculating the scores on the PSI measures, CMS proposes to use Medicare claims data. However, all PSI measures – including those that are NQF-endorsed – were specified and tested for reliability and validity using an all-payer data source. We believe the PSI measures have the potential to lose reliability and validity when not used as originally intended.

In 2012, CMS tested the reliability of claims-based measures used in its programs using Medicare-only data. Included in that analysis were several, though not all, of the PSI

measures proposed for the HAC program.ⁱⁱⁱ In the report, CMS's contractor states that "the statistical concept of reliability (R) used to determine the minimum case size for a particular measure is whether a hospital's ranking on that measure, compared to its performance in other periods or compared to other hospitals, is likely to be the same if we take repeated samples of the hospital's own cases. R depends on the rate's variance between hospitals, the variance of the rate within a hospital's own cases, and the number of discharges from a given hospital." The CMS study indicates that "R = 0.4 is considered to be the lower limit of 'moderate' reliability."

We do not believe that the "lower limit of moderate reliability" is sufficient for a pay-for-performance program. We believe a more appropriate reliability threshold is the CMS benchmark of R=0.75 used for chart-abstracted measures. While some of the proposed PSI measures tested in the CMS-commissioned study score reasonably well using Medicare-only claims data, others fare poorly. For example, PSI-6's median reliability is R=0.47 using 24 months of data, the same amount of data as CMS proposes to use for the HAC program. The reliability scores of several of the PSI-90 component measures are particularly low. For example, PSI-8 scores at R = 0.02, and PSI-14 at R=0.09 with 24 months of data. We are troubled that CMS would use a measure with individual components that demonstrate such poor reliability.

- *Limitations of claims-based measures.* The use of claims-based quality measures has been identified as a way to reduce the burden of data collection on hospitals. However, such measures are highly dependent upon a coding processes, as well as physician documentation. This limits the ability of claims-based measures to generate accurate results. For example, with regard to PSI-3 (pressure ulcers), our members have noted that nurses typically review patient skin condition, and are best positioned to document pressure ulcers. PSI-3 may not capture complete data on patients with pressure ulcers because the coding of it is based on physician documentation.

In other cases, claims-based measures may be able capture a particular event, but have numerators and denominators that do not fully account for patient risk factors. For example, PSI-6 (iatrogenic pneumothorax rate) would be most likely to occur during a hospitalization. However, as currently constructed, the measure includes all medical and surgical patients, and not just those with risk factors predisposing them to having such an event.

- *Bias toward surgical care.* The AHA also is concerned that many of the proposed PSI measures are focused predominately on surgical care. For example, retained foreign objects (PSI-5), post-operative metabolic derangement (PSI-10), post-operative deep vein thrombosis (DVT) (PSI-12), and accidental puncture/laceration (PSI-15), are all more likely to occur in the context of surgical care. We agree that improving surgical safety is a laudable and important goal for hospitals. However, hospitals with a range of clinical services will be subject to the HAC reduction program, and some may have significantly higher surgical volumes than others. **As discussed in the next section, we are very concerned that hospitals may receive HAC penalties simply because they care for**

more surgical patients. Moreover, it appears that the PSI measures' risk-adjustment approach is not sufficient to mitigate this bias.

Proposed Scoring Methodology. Using a hospital's performance on the measures in Table 1 above, CMS proposes to calculate a "Total HAC Score," with higher scores indicating worse performance. Under its proposed methodology, the two domains of measures would be equally weighted, and hospitals in the highest quartile of Total HAC Scores would be subject to the payment penalty. Assuming that a hospital can be scored on both domains, the formula CMS proposes is: Total HAC Score = 50% x (Domain 1 Score) + 50% x (Domain 2 Score).

To determine the domain and total HAC scores, CMS proposes to calculate scores on applicable measures for each hospital. The top quartile of scores would be further subdivided into deciles. If a hospital's score on an individual measure falls in the top quartile of scores, then the hospital would be given between one and 10 points, depending on the decile in which its performance falls. However, for PSI-5, CMS proposes that if a hospital has one or more event it will be assigned 10 points because the agency considers a retained foreign object a "never event."

In addition to its formal proposal, CMS describes two additional alternative HAC scoring methodologies. In the first option, instead of assigning points to hospitals with measure scores in the top quartile, CMS would assign points to hospitals scoring above the median. The second proposed option scoring methodology would assign points to all hospitals. That is, the calculated scores on each measure would be divided into deciles, with hospitals receiving between one and 10 points on a given measure depending on the decile.

We appreciate the basic assumption behind the agency's proposed scoring methodology. That is, by selecting multiple measures, and assigning a range of points based on hospital performance on each measure, hospitals have opportunities to score well in some areas even if they score poorly in others. This principle is important because several of the PSI measures, such as iatrogenic pneumothorax, are rarely occurring events. The proposed scoring mechanism, we believe, is intended to ensure that hospitals that have just one or two such events within the measured timeframe do not automatically receive payment penalties.

In practice, unfortunately, the proposed scoring methodology, when coupled with the proposed measures in the program, disproportionately penalizes teaching hospitals and large hospitals (i.e., hospitals with 400 or more beds). Therefore, the AHA cannot support any of CMS's proposed scoring methodologies for the HAC Reduction Program.

While CMS provides an estimate of the number of hospitals that would be penalized under the program in the proposed rule, the agency does not provide the underlying data used to derive those calculations. In the absence of such data in the rule, the AHA contracted with KNG Health Consulting to model the impact of each of CMS's proposed scoring methodologies. The results of their analysis by teaching status and hospital size are presented in Tables 3 and 4 below.^{iv} We note that the proportion of large hospitals and teaching hospitals penalized under the program varies somewhat by whether the PSI-90 composite measure is used, and by how points are assigned. Specifically, teaching hospitals and/or large hospitals were less likely to receive

penalties if PSI-90 is used to calculate a Domain 1 score. Additionally, if points are assigned to all hospitals for each measure, rather than only to hospitals scoring in the top quartile, large hospitals and teaching hospitals were less likely to receive penalties.

Table 3: Estimated Percentages of HAC Reduction Program-Eligible Hospitals Receiving Penalties in FY 2015, by Teaching Status

Teaching Status	Using Six PSI Measures in Domain 1			Using PSI 90 Composite		
	CMS Proposal: Assign Points to Top Quartile	CMS Alternative: Assign Points Above Median	CMS Alternative: Assign Points to All Hospitals	CMS Proposal: Assign Points to Top Quartile	CMS Alternative: Assign Points Above Median	CMS Alternative: Assign Points to All Hospitals
Major Teaching	54%	51%	52%	53%	50%	50%
Other Teaching	35%	30%	28%	31%	25%	24%
Non-Teaching	18%	19%	18%	18%	19%	18%
Total	25%	25%	23%	24%	23%	22%

Table 4: Estimated Percentages of HAC Reduction Program-Eligible Hospitals Receiving Penalties in FY 2015, by Bed Size

Bed Size	Using Six PSI Measures in Domain 1			Using PSI 90 Composite		
	CMS Proposal: Assign Points to Top Quartile	CMS Alternative: Assign Points Above Median	CMS Alternative: Assign Points to All Hospitals	CMS Proposal: Assign Points to Top Quartile	CMS Alternative: Assign Points Above Median	CMS Alternative: Assign Points to All Hospitals
<100	9%	15%	15%	11%	19%	18%
100-399	31%	28%	24%	29%	22%	21%
400 and over	51%	44%	43%	43%	38%	38%
Total	25%	25%	23%	24%	23%	22%

However, regardless of the option selected, at least half of teaching hospitals and at least 38 percent of large hospitals would receive a penalty in the HAC program. This situation may be tenable if it could be demonstrated that such hospitals actually deliver lower quality, less safe care. We do not believe this is the case. Rather, large hospitals and teaching hospitals offer an array of services, and often care for the most medically complex patients. Such hospitals are often referral centers, and are more likely to have a higher volume of surgical procedures. We believe that because the PSI measures are biased towards surgical procedures, hospitals that have higher volumes of such procedures are more likely to receive penalties. This bias is further reinforced by modeling the proportion of hospitals that would be penalized if only Domain 1

measures were used in the program. As shown in Table 5, roughly 60 percent of teaching hospitals and large hospitals would receive a penalty. We also believe that the risk-adjustment methodology used in the HAC measures is simply not sufficient to blunt the effect of using measures biased towards surgical care.

Table 5: Distribution of Hospitals Affected by HAC Penalty if only Domain 1 Score* is used

	Number of Affected Hospitals	Total Number of Hospitals	Percent Affected
<i>By Teaching Status</i>			
Major Teaching	167	282	59%
Other Teaching	275	733	38%
Non-Teaching	355	2351	15%
<i>By Bed Size</i>			
<100	81	1290	6%
100-399	493	1708	29%
400 and over	223	368	61%

*Note—The analysis in this table assumes that Domain 1, Option 1 is used (i.e., using the six individual PSI measures).

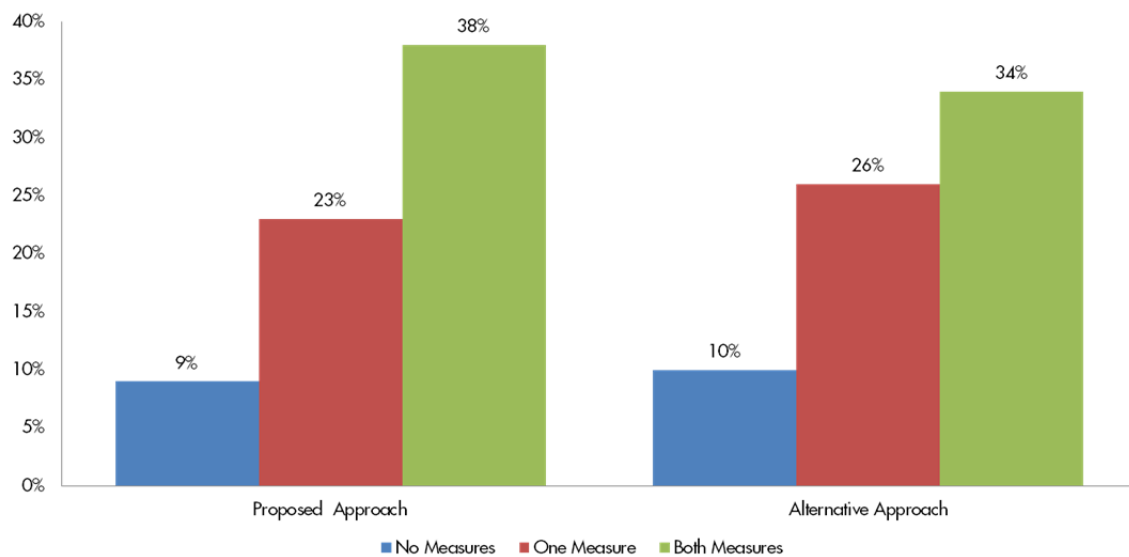
Given the financial and reputational impact of the HAC Reduction Program, patients, hospitals and policymakers must have confidence that the program fairly assesses penalties based on meaningful differences in hospital performance. Unfortunately, given the proposed measures and scoring methodologies, the HAC program falls well short of this ideal.

Alternative Approaches to Measurement and Scoring. Using the results of our modeling exercise, the AHA explored short-term fixes to the program that would improve its fairness. Given the inherent flaws in the PSI measures, the AHA considered whether basing the total HAC score solely on HAI measure performance (i.e., the CLABSI and CAUTI measures in Domain 2) would improve the fairness of the scoring approach. Unfortunately, this approach has two significant drawbacks. First, not all hospitals report on each of the HAI measures. Indeed, hospitals that do not have ICUs currently do not report the measure. According to the KNG Health Consulting analysis, out of the approximately 3,300 hospital estimated to be eligible for the HAC Reduction Program, 1,927 have sufficient CLABSI data, and 1,754 have sufficient CAUTI data. CMS does propose to expand CAUTI and CLABSI reporting into non-ICU areas, but this will not have taken effect by FY 2015. Using only HAI measures would exclude a large number of hospitals from the program.

Second, there is indirect, but compelling evidence that the same bias against large hospitals and/or teaching hospitals is still present when only HAI measures are used. Figure 1 shows that hospitals reporting one or more HAI measures are significantly more likely to receive a penalty

under the HAC program using either proposed approach for Domain 1 (i.e., six individual PSIs, or the PSI-90 composite). While we do not have data on whether those hospitals with more HAI measures are indeed teaching and/or large hospitals, large hospitals and teaching hospitals are generally more likely to have ICU capacity. This increases the likelihood that they would receive a score on HAI measures. Thus, while we believe the HAI measures are far more reliable and valid than the PSIs, using HAI measures alone does not improve the fairness of the program.

Figure 1: Percentage of Hospitals Penalized by Number of Domain 2 HAI measures reported



We believe that the CAUTI and CLABSI measures could be part of the HAC Reduction Program. However, we urge CMS to identify additional measures superior to the PSIs that more meaningfully and accurately assess hospital performance. CMS should then seek formal MAP review of these measures through its regular pre-rulemaking review process, and include them in future IQR programs to allow the field to obtain experience with public reporting before they are proposed for the HAC program. Many of the proposed PSI measures assess important patient safety topics, but as noted in the previous section, they are simply not robust enough for use in a pay-for-performance program. One potential source of stronger measures is the portfolio of NQF-endorsed measures. While not all NQF-endorsed measures are suitable for a pay-for-performance application, CMS should review the NQF portfolio to identify measures it could substitute for the existing PSI measures.

The MAP has provided a useful starting point by assembling a patient safety “Family of Measures” that identifies measures that may be suitable for use in federal programs.^v A review of available measures may yield measures that could be implemented in the short term. For example, there is an NQF-endorsed pressure ulcer prevalence measure (NQF #0201) in which

hospitals conduct quarterly, one-day studies of the number of patients with pressure ulcers in their facilities. While this measure is not perfect, we believe it is better than PSI-3. CMS should seek formal MAP pre-rulemaking review of NQF #0201, and any other measure it identifies through this review process.

In other cases, CMS may need to embark upon longer-term measure retooling and development efforts to obtain measures suitable for the HAC program. For example, the MAP Safety Family includes several measures of medication safety, a topic that is largely not covered in the current HAC program. CMS should explore whether these measures can be re-specified and tested for use in a hospital reporting program. The updated measures should then be re-reviewed by the NQF, and reviewed by the MAP during its formal pre-rulemaking review process.

Applicable Measurement Time Period. CMS proposes to define the measurement timeframe for measures in the FY 2015 HAC Reduction Program, and in subsequent fiscal years, as a two-year period from which data are collected to determine a “Total HAC Score.” **Given our concerns with the proposed scoring methodology, the AHA does not support CMS’s proposed definition of applicable period.** Moreover, we believe that as the measures in the program evolve, CMS will need to revisit and update the applicable time period to ensure measure reliability and validity are not adversely affected.

Applicable Hospitals. Under the statute, subsection (d) hospitals are subject to the HAC Reduction Program. The statute defines subsection (d) hospitals as hospitals located in the 50 states or the District of Columbia. Therefore, hospitals located in the territories or Puerto Rico are *not* subject to the HAC Reduction Program. Also excluded from the definition of a subsection (d) hospital are long-term care hospitals, cancer hospitals, children’s hospitals, CAHs, inpatient rehabilitation facilities and inpatient psychiatric facilities. However, Indian Health Services hospitals, SCHs and Medicare-dependent hospitals (MDHs) (if the MDH program is extended) are considered subsection (d) hospitals. **The AHA supports CMS’s proposed definition of “applicable hospital.”**

Maryland Hospitals. Under the statute, Maryland hospitals are subject to the HAC Reduction Program; however, the statute also allows CMS to exempt these hospitals from the program if certain parameters are met. CMS proposes that Maryland hospitals may receive an exemption if the state submits an annual report to CMS describing how a similar state program to reduce HACs achieves or surpasses the federal program’s results in terms of health outcomes or cost savings. **The AHA supports CMS’s proposed process for exempting Maryland hospitals from the HAC Reduction Program.**

Basic Payment Adjustment. CMS proposes a basic payment adjustment methodology for hospitals that score in the top quartile of risk-adjusted national HAC rates that is consistent with the statute. Specifically, as required under the ACA, penalized hospitals will receive a per-discharge payment equal to 99 percent of the payment that would otherwise have applied to such discharges. Moreover, this payment adjustment must be applied after payment adjustments for the Hospital Readmission Reduction Program (HRRP) and the VBP program. **The AHA supports CMS’s proposed basic HAC payment adjustment methodology, but asks the**

agency to specify that it will apply the adjustment to base operating MS-DRG amounts (inclusive of HRRP and VBP adjustments), in order to be as consistent as possible with how payment adjustments are administered under the HRRP and VBP program.

Review and Corrections Process. For the HAI measures in Domain 2, CMS proposes that hospitals use the review and corrections process currently available to review HAI data submitted for the IQR program. CMS believes this provides a more timely way to identify inaccuracies in the data. For the PSI measures in Domain 1, CMS proposes to deliver confidential “discharge-level data,” including information about the risk factors used to calculate the PSIs, via hospital QualityNet accounts. The data would be calculated using claims information available approximately 90 days after the end of the applicable measurement period. Concurrent with the posting of the data for Domain 1, CMS also proposes to make hospitals’ Total HAC Scores available, and provide 30 days to review and submit corrections to the data. **The AHA supports these proposals.**

Disaster Waiver. **The AHA urges CMS to develop a HAC Reduction Program waiver process for hospitals that face natural disasters or extenuating circumstances.** Natural disasters and other circumstances have a profound impact on both hospitals’ ability to collect measure data and their performance on those measures. As we noted in a letter to the agency on May 20, 2013, hospitals affected by Superstorm Sandy in October 2012 have experienced meaningful differences in their performance on a variety of quality measures. Without a waiver mechanism, we are concerned that hospitals will face an undue burden of data reporting and collection, as well as the potential for their performance to be unfairly reported and penalized. We believe that the ACA provides enough flexibility for CMS to adjust the time periods used for reporting and penalty calculations in the HAC program under such a waiver: Section 3008 of the ACA states that the “the term ‘applicable period’ means, with respect to a fiscal year, *such period as the Secretary shall specify.*”^{vi}

HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP)

The HRRP assesses penalties on hospitals for having “excess” readmission rates when compared to expected rates. For FY 2014, CMS proposes to increase the maximum payment penalty to 2 percent of Medicare base operating payments, as required by the ACA. CMS also proposes to exclude planned readmissions from the three readmissions measures that are included in the FY 2014 program – acute myocardial infarction (AMI), heart failure (HF) and pneumonia.

While the AHA welcomes the planned readmissions exclusions, we are disappointed that CMS has not yet excluded readmissions unrelated to the initial reason for admission, as required by the ACA. In addition to incorporating an exclusion for unrelated readmissions, we also urge the agency to incorporate an adjustment to account for socioeconomic factors using the proportion of dual-eligible patients that hospitals serve. We believe such an adjustment can be readily implemented by CMS, and is likely to be budget neutral.

Planned Readmissions Algorithm. To exclude planned readmissions from the readmissions calculations for FY 2014, the agency proposes to incorporate an algorithm that was endorsed by the NQF, and supported by the MAP. The algorithm always excludes readmissions for obstetrical delivery, transplant surgery, maintenance chemotherapy and rehabilitation. Non-acute readmissions for certain procedures that are typically considered “scheduled” also may be excluded. However, admissions for acute diagnoses or complications of care are always considered “unplanned” and, therefore, are included in the measure calculations.

We are pleased that the agency has responded to stakeholder concerns by incorporating exclusions for planned readmissions. However, we urge CMS to continually assess the algorithm to determine whether additional diagnoses or procedures should be counted as “planned.” CMS’s latest readmissions measure technical report shows that the algorithm identifies a small number of readmissions as “planned” for all three measures. In the case of the pneumonia measure, only 7,526 readmissions are identified as “planned” out of 1,089,758 index pneumonia admissions, or less than 1 percent, from July 2009 to June 2012. The ratios of planned readmissions to index admissions are similarly small for AMI and HF.^{vii} While the lists of diagnoses and procedures deemed as “planned” or “potentially planned” reflect the current judgment of the measure developer’s technical experts, there is an opportunity to use the field experience gained with these measures to determine whether additional changes are warranted. Indeed, a recent study from the *Journal of the American Association* indicates that there is an ongoing need to understand the difference between planned and unplanned readmissions. The study authors analyzed both emergency department visits and all-cause readmissions 30 days after hospital discharge using data from hospitals in California, Nebraska and Florida. Of the readmitted patients identified in the study, 57 percent were readmitted to hospitals from the emergency department.^[iii] This means that 43 percent of patients readmitted via another pathway, such as being directly admitted to the hospital. Direct admissions to the hospital are often, though not always, planned events. To the extent that readmissions through the emergency department are a proxy for acute, unplanned complications post hospital discharge, the study suggests that a large minority of readmissions may be planned. While we may not ever know the exact, “right” proportion of planned readmissions in the measures, we believe the proportion may be significantly higher than indicated by the current measures.

Applying an Adjustment for Socioeconomic Factors. **The AHA continues to urge CMS to incorporate an adjustment for socioeconomic factors into the HRRP.** All hospitals, regardless of the circumstances they face, aim to provide the highest quality of care to the patients and families that rely on them. Applying an appropriate adjustment for socioeconomic factors would acknowledge the reality that hospitals cannot always control or change structural barriers to accessing resources that can help prevent readmissions. **Rather, hospital readmissions are affected by a variety of factors, many of which are beyond the control of hospitals.** The health care infrastructure of a community greatly impacts readmissions rates. A lack of access to primary care, mental health services, physical therapy and other rehabilitative support can increase the likelihood of readmission. Other factors can include lack of public transportation (which can affect access to medical care), and inconsistent access to appropriate foods to aid in patient recovery. While hospitals should do all within their power to care for and

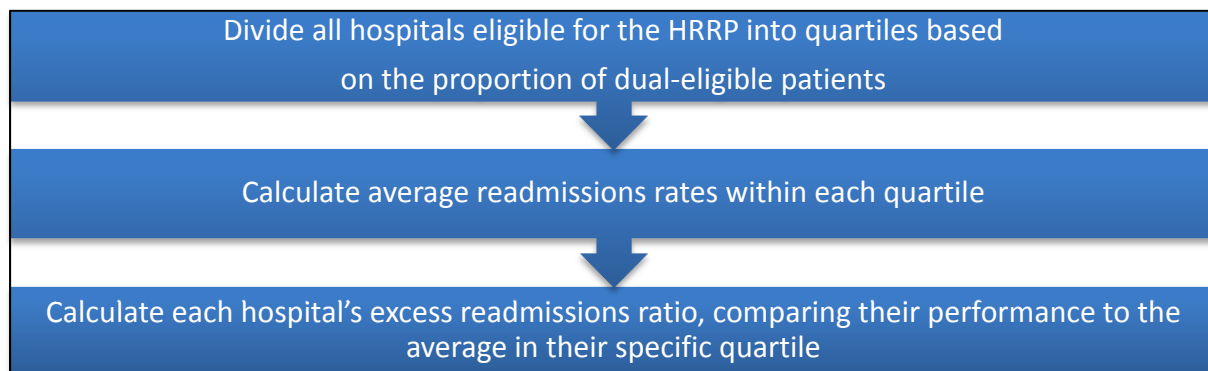
assist the patients in challenging circumstances, they should not suffer financial penalties due to community issues.

Early experience from the implementation of the HRRP suggests that hospitals caring for the most economically disadvantaged patients were most likely to receive readmissions penalties. A recent Commonwealth Fund analysis found that hospitals in the top 25 percent of the DSH patient percentage have 30-day hospital readmission rates that are approximately 30 percent above the national average for AMI, HF and pneumonia.^{viii} As a result of this phenomenon, Kaiser Health News found that 12 percent of hospitals that fall into the top quartile of the DSH patient percentage were scheduled to receive the maximum readmissions penalty from CMS starting in FY 2013. In contrast, only 7 percent of hospitals in the bottom quartile of the DSH patient percentage were projected to receive the maximum penalty.^{ix}

Dual-eligible status is a powerful predictor of readmission risk and is a factor that is readily available to CMS. It should be used as an adjustment factor to account for socioeconomic difference in communities. A hospital's proportion of dual-eligible patients reflects that hospital's share of impoverished *Medicare* patients, and since the readmission measures include only Medicare beneficiaries, an adjustment based on hospitals' proportion of dual-eligible beneficiaries is appropriate and will enable fairer comparisons of performance among hospitals.

To improve the fairness of the HRRP, the AHA proposes that CMS separate HRRP-eligible hospitals into quartiles based on the proportion of their patients that are dually eligible. Our proposed adjustment approach is outlined in Figure 2. Once all eligible hospitals are divided into quartiles based on the proportion of dual-eligible patients, CMS would then determine the average readmissions rate within each quartile. Finally, CMS would calculate an excess readmissions ratio for hospitals using the existing readmissions measures. However, those measures would use each quartile's average readmissions rate, rather than the average readmissions rate of all hospitals in the program. Thus, readmissions penalties would then be dependent on how hospitals perform compared to hospitals with a similar proportion of duals.

Figure 2: Proposed Process for Applying a Socioeconomic Adjustment Based on a Hospital's Proportion of Dual-Eligible Patients



The goal of the dual-eligible quartile adjustment is to ensure that hospitals with higher proportions of dually-eligible patients are not disproportionately penalized. To ensure this is the case, the AHA contracted with KNG Health Consulting to model the potential impact of applying the dual-eligible adjustment in the HRRP. The results of their analysis are provided in Table 6.^x Under the current CMS model, hospitals with the two highest shares of dual-eligible patients had higher penalties than those in the lowest two. Under the AHA’s proposed adjustment model, the penalties for hospitals in the top two dual-share quartiles drop significantly.

Table 6: Impact of Applying Dual Eligible Quartile Model – Estimated HRRP Payment Penalty as a Percentage of Base Operating MS-DRG Payment

Quartile of Hospital Dual-Eligible Proportion	Percent Penalty Under Current CMS Model	Percent Penalty under Hospital Dual-Eligible Proportion Adjustment Model
Lowest	0.84%	0.90%
2nd	0.85%	0.89%
3rd	1.00%	0.98%
Highest	1.08%	0.91%
Total	0.92%	0.92%

Moreover, the overall payment penalty under the dual-eligible quartile model is comparable to the current CMS program, suggesting that such an adjustment would likely be budget neutral. Given the feasibility and affordability of the approach, we urge CMS to implement it in the FY 2014 program and beyond. We believe CMS has the regulatory flexibility to implement this change. Under the ACA, CMS must use NQF-endorsed measures in the HRRP program. Incorporating the dual-eligible quartile model would not require a change to the underlying measures. Rather, it would change the comparison group of hospitals scored on that measure.

FY 2015 Measure Expansion. Under the ACA, beginning in FY 2015, CMS may expand the HRRP to include additional disease conditions. To that end, CMS proposes to include readmissions measures for chronic obstructive pulmonary disease (COPD) and total hip and total knee arthroplasties (THA/TKA) in the FY 2015 payment penalty calculation. Both measures are NQF-endorsed, and include the same planned readmissions algorithm incorporated into the AMI, HF and pneumonia measures currently in the program. In addition, the MAP supported the use of the THA/TKA measure in the HRRP.

The AHA continues to be concerned about the reliability of the measures in the HRRP program. Before finalizing any additional measures for the program, we urge CMS to improve readmission measure reliability. Adequate measure reliability ensures that differences in performance scores across hospitals are, in fact, due to underlying differences in quality and not just random variations in patient populations. CMS has yet to conduct a

reliability analysis of the readmissions measures, but the AHA contracted with KNG Health Consulting to assess the reliability of the current and proposed measures in the HRRP (Table 7).^{xi} The median reliability using CMS's current minimum case threshold of 25 cases ranges from 0.41 to 0.56. This reliability threshold is significantly lower than the R=0.75 reliability threshold that is CMS's standard for chart-abstracted measures.

Table 7: Median Reliability of Current and Proposed Readmissions Measures

Condition	Median Reliability (R) Using Current CMS Case Threshold of 25	Cases Needed to Achieve Reliability of R=0.7	Cases Needed to Achieve Reliability of R=0.8
AMI	0.45	369	631
HF	0.56	450	772
Pneumonia	0.53	421	722
COPD	0.46	537	920
THA/TKA	0.41	682	1,169

The AHA believes that this level of reliability is unacceptable for a payment penalty program. To improve reliability, CMS should significantly raise the minimum case threshold required for hospitals to qualify for the HRRP. As Table 7 demonstrates, achieving a higher level of reliability on the measures will require a minimum case threshold much higher than 25 cases.

Payment Adjustment Factor. Under the statute, the adjustment factor that will be used to penalize hospitals under the HRRP is one minus the ratio of the hospital's aggregate payments for excess readmissions for applicable conditions to the hospital's aggregate payments for all discharges for applicable conditions. An applicable condition is one that falls under one of the previously finalized three readmissions measures. Any penalties would be applied to each Medicare discharge during the fiscal year.

For FY 2014, CMS again proposes to determine the hospital's aggregate payments for all discharges for applicable conditions using MedPAR claims data. It would use claims with discharge dates on or after July 1, 2009, and no later than June 30, 2012. CMS also proposes to link the MedPAR data with the Medicare Enrollment Database to make additional exclusions to the admissions used to calculate aggregate payments for excess readmissions. These exclusions include admissions for patients who did not have Medicare Parts A and B fee-for-service (FFS) enrollment in the 12 months prior to the index admission, patients without at least 30 days post-discharge enrollment in Medicare Parts A and B FFS, and multiple admissions within 30 days of a prior index admission. **The AHA supports these proposals.**

Maryland Hospitals. CMS proposes that the state of Maryland submit a report by January 15 of each year to maintain Maryland hospitals' current exemption from the HRRP. This report must describe how a similar state program to reduce hospital readmissions achieves or surpasses the federal program's results in terms of health outcomes and cost savings. Additionally, because Maryland hospitals are not paid under the inpatient PPS, but are instead paid under a special

waiver, CMS proposes an alternate definition of “base operating MS-DRG payment amount” in the event the current HRRP exemption is revoked. CMS proposes to create an estimate of what Maryland hospitals’ base operating MS-DRG payments would have been if they had been paid under the inpatient PPS. This estimate would then be used to calculate readmissions penalties for Maryland hospitals. **The AHA supports these proposals.**

HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM

As required by the ACA, CMS proposes to fund the FY 2014 VBP program by reducing base operating MS-DRG payment amounts to participating hospitals by 1.25 percent in FY 2014. The VBP program is budget neutral; all funds withheld must be paid out to hospitals.

FY 2016 Measure Removal Proposals. **The AHA supports CMS’s proposal to remove the following three measures from the FY 2016 VBP program:**

- AMI-8a (primary PCI within 90 minutes of hospital arrival): We agree with CMS’s assessment that measure performance has “topped out.”
- PN-3b (blood cultures performed in the emergency department prior to initial antibiotic received in hospital): This measure is no longer NQF-endorsed, and was not recommended by the MAP.
- HF-1 (discharge instructions): This measure also no longer has NQF endorsement, and was not recommended by the MAP.

FY 2016 New Measure Proposals. **The AHA supports CMS’s proposal to add the IMM-2 (Influenza Vaccination for inpatients 6 months and older) to the FY 2016 VBP program.** This measure is NQF-endorsed and was supported by the MAP for inclusion in the program.

The agency also proposes two additional HAI measures – CAUTI and SSI, which are both NQF-endorsed and MAP-supported. **However, the agency did not propose FY 2016 baseline or performance periods for CAUTI or SSI measures, or for the previously finalized CLABSI measure. As noted below, we urge CMS to defer finalizing these three measures until it has issued a proposed rule that includes baseline and performance periods.** We believe all three measures focus on important issues. We also believe the agency intended to include the baseline and performance periods in the rule, as evidenced by the proposed data benchmarks; however, we cannot conduct a complete evaluation without information on the measure reporting periods.

FY 2017 New Measure Proposals. **The AHA does not support CMS’s proposals to add MRSA bacteremia and *C. Diff* measures to the FY 2017 VBP program.** The AHA agrees that hospitals must continue to focus on reducing HAIs, and that MRSA and *C. Diff* are important measurement areas. However, both measures are new to public reporting programs, and their collection for the IQR program began in January 2013, for FY 2015 payment determination. We urge CMS to gain additional experience with collecting and reporting the measure before adding it to the VBP program. The MAP concurred with this assessment during its most recent pre-rulemaking review of VBP measures, voting only to “support direction” on MRSA and *C. Diff*.

Baseline and Performance Periods.

CAUTI, CLABSI and SSI Baseline and Performance Periods. As noted above, CMS did not propose baseline and performance periods for these measures for the FY 2016 program. **We request that the agency propose baseline and performance periods for these measures so that we may evaluate them.**

Mortality Measures. **The AHA does not support the proposed baseline and periods for the three mortality measures (PN, AMI and HF) for FYs 2017 through 2019. We continue to believe these measures do not have adequate reliability and should be removed from the program all together.** CMS proposes to increase the timeframes of both the baseline and reporting periods for the mortality measures to three years of data, and to align the performance periods with the Hospital IQR program.

In 2012, CMS commissioned an analysis of claims-based measures used in its programs that demonstrated that many of them have poor reliability.^{xii} In that report, CMS's contractor states that "the statistical concept of reliability (R) used to determine the minimum case size for a particular measure is whether a hospital's ranking on that measure, compared to its performance in other periods or compared to other hospitals, is likely to be the same if we take repeated samples of the hospital's own cases. R depends on the rate's variance between hospitals, the variance of the rate within a hospital's own cases, and the number of discharges from a given hospital." The CMS study indicates that "R = 0.4 is considered to be the lower limit of 'moderate' reliability."

None of the mortality measures meet this "lower limit of moderate reliability," and achieving a "lower limit of moderate reliability is not sufficient for a pay-for-performance program in the first place. In last year's inpatient PPS rule, CMS finalized its proposal to use only nine months of data to calculate the baseline period, and 21 months of data for the performance period. However, even with 24 months, none of the measures meets the reliability threshold of R = 0.4. Moreover, CMS uses a much higher reliability threshold of R=0.75 for chart-abstracted measures. We believe all measures in CMS quality reporting and payment programs should be held to at least that standard. Table 8 below includes the data on the mortality measures from the study.

Table 8: Reliability of Mortality Measures in the VBP Program

Measure	6 Months		12 Months		18 Months		24 Months	
	Median* Reliability	% of Hospitals R \geq 0.4**	Median* Reliability	% of Hospitals R \geq 0.4**	Median* Reliability	% of Hospitals R \geq 0.4**	Median* Reliability	% of Hospitals R \geq 0.4**
Pneumonia Mortality (R = 0.4 with 211 cases)	0.11	1	0.19	8	0.27	22	0.32	35
HF Mortality (R=0.4 with 196 cases)	0.11	2	0.20	14	0.27	28	0.33	40
AMI Mortality (R=0.4 with 2011 cases)	0.09	2	0.17	12	0.23	24	0.29	33

* Reliability of measure of hospital median case size
 **Proportion of hospitals with case size large enough that $R \geq 0.4$

With respect to the FYs 2017 through 2019 proposed baseline and performance periods, we appreciate that CMS has increased the data collection period to 36 months in an effort to increase measure reliability. However, the agency has not provided an updated reliability analysis that demonstrates measure reliability is improved. Given the results of CMS’s existing analysis in Table 8 above, we do not believe any of the measures will approach the chart-abstracted measure reliability threshold of $R = 0.75$. We urge the agency to explore outcomes measures with better reliability, and propose them in subsequent rulemaking.

PSI Composite Measure. **The AHA supports the proposed baseline and performance periods for the PSI composite in FYs 2017 through 2019. However, the AHA does not support the baseline and performance periods proposed for the PSI composite measure in FY 2016.** The same CMS-commissioned reliability study showed that the PSI composite measure needed a minimum of 24 months of data to attain reliability of $R = 0.89$, a reliability level that would surpass CMS’s benchmark for chart-abstracted measures. However, the proposed periods are much less than that. In addition, as currently proposed, there is a mismatch between the length of the baseline period (Oct. 15, 2010 through June 30, 2011) and the performance period (Oct. 1, 2012 through Jun. 30, 2014). CMS should ensure the baseline and reporting periods are at least 24 months long and both capture the same number of months of data to enable a fairer comparison of hospital progress from the baseline level.

Medicare Spending per Beneficiary (MSPB). We note that the MSPB measure is currently undergoing NQF-endorsement review. **While we applaud the agency for submitting the measure for NQF review, we recommend that CMS await final endorsement before finalizing baseline and performance periods for the measure.** This will ensure that any changes are incorporated into the measure and the resulting performance benchmarks.

Measurement Domains. For FY 2016, CMS proposes to increase the weights of the outcomes and efficiency domains, while decreasing the weights of the patient experience and process

domains. Moreover, CMS also proposes to realign the measurement domains with the priority areas of the National Quality Strategy.

FY 2016 Proposed Domain Weights. **The AHA does not support CMS's proposed domain weights for FY 2016.** Given the reliability concerns with the mortality measures, it is inappropriate to place such a heavy emphasis on these outcomes measures. We believe CMS should not use the mortality measures to determine FY 2016 VBP scores. As noted above, we also urge CMS to remove the mortality measures from the VBP program because they are unreliable.

Moreover, while the AHA supports the need to adopt outcomes measures, we believe that CMS must use an appropriate mix of measures in the VBP program tailored to fit the field's placement on the continuum of quality improvement. It is helpful to think of these quality measurement needs as evolving over several phases. In the initial "Development Phase," measures are needed to ascertain whether providers are executing on the care interventions that can lead to better outcomes. At this phase, there must be a mix of both process measures and outcomes measures so that process impediments to improving care are identified. The concurrent use of an outcomes measure enables hospitals to assess the effectiveness of the interventions in improving care.

The next phase of evolution in hospital quality measurement needs is the Performance Phase. During this phase, the interventions to improving outcomes have been well established. While performance is better, there is still opportunity to close a performance gap. Generally, outcomes measures, along with a limited number of process measures, are appropriate for use.

At the final "Sustaining Phase," performance across hospitals is universally high. It is appropriate to use only outcomes measures at this phase. It also would be appropriate to consider those outcomes for either incentive programs like VBP, or programs where there is only a penalty for poor performance (e.g., the HAC Reduction Program).

The need for process and/or outcomes measures for a given measurement area should be driven by the extent of hospital progress in that area. Our members have noted that that solely focusing on outcome measures – and placing such a great emphasis on performance results – does not create the right incentives for hospitals to improve. Thus, we recommend that the agency apply this concept of phased measurement in identifying the correct mix of measures for the VBP program.

FY 2017 Domain Realignment. CMS proposes to realign the measurement domains of VBP so that they are consistent with the priority areas of the National Quality Strategy. Specifically, the agency proposes to create four measurement domains with newly associated weights – Safety (15 percent), Efficiency and Cost Reduction (25 percent), Patient and Caregiver Centered Experience of Care/Care Coordination (25 percent), and Clinical Care (35 percent). The clinical care bucket is further subdivided into Outcomes (25 percent), and Process (10 percent). Previously finalized and proposed measures are then mapped to each of these areas.

The AHA supports several aspects of CMS's proposed realignment. However, we recommend the following changes:

- *Clinical Care:* **We continue to believe that CMS has placed too great an emphasis on deeply flawed mortality measures for the outcomes domain.** Until CMS puts higher reliability outcomes measures into the VBP program, we recommend the agency assign a weight of zero to the outcomes portion of the Clinical Process domain.

Moreover, as noted above, CMS should use a balanced mix of process and outcomes measures in the VBP program. Once CMS has identified rigorous and reliable outcomes measures, we recommend that the Clinical Care domain weightings change to 20 percent process, and 15 percent outcomes.

- *Patient Experience/Care Coordination:* We agree that patient experience and care coordination are related topics. Currently, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey is the only measure in this domain. **As CMS moves to include care coordination measures, it must focus on those measures that assess the *hospital's* role in ensuring successful care coordination and transitions.** Care coordination often involves multiple parts of the health care system, but the VBP program is used to assess *hospital* penalties, and should use measures focused on hospital performance.

HCAHPS Measures. **The AHA continues to urge CMS to reassess how it adjusts HCAHPS survey scores for the severity of patient illness to ensure that accurate, meaningful comparisons of measure results can be made.** We previously have highlighted emerging research suggesting that patient characteristics may affect scores more than previously thought. For example, an analysis by the Cleveland Clinic has shown that as patients' severity of illness worsens, HCAHPS scores decline in a statistically significant manner. The same relationship was observed when the researchers examined the relationship between patients' symptoms of depression and responses to HCAHPS – as symptoms of depression worsened, HCAHPS scores declined. These findings indicate that hospitals that treat the most severely ill patients may have systematically lower scores. We encourage CMS to conduct an analysis that assesses the extent of the issue, and identifies potential mechanisms for enhancing how HCAHPS scores are adjusted for patient factors.

Future Efficiency Domain Measures. While CMS does not propose any specific measures, it solicits comment on two measure concepts.

Appropriateness of Inpatient versus Outpatient Treatment. CMS states it is considering constructing a measure to assess the rate and/or dollar amount of billing hospital inpatient services to Medicare Part B, subsequent to the denial of a Part A hospital inpatient claim. Under such a measure, higher rates and/or dollar amounts would indicate worse performance. CMS states that this concept stems from its recent proposal to permit hospitals to rebill certain services under Part B after a Medicare contractor determines that hospital inpatient services should have been provided in an outpatient setting.

The AHA is strongly opposed to such a measure because it would offer a grossly inaccurate picture of the degree to which hospitals “appropriately” assign patient status. The Recovery Audit Contractors (RACs) chronically make improper denials, including denying inpatient status for patients with MS-DRGs that are on the inpatient-only list, denying cases that meet Interqual or Milliman admission criteria, and basing denials on details that were not available when the physician was assessing the patient’s medical necessity for an admission. This is because the RACs have a strong financial incentive to deny claims – the more claims the RAC denies, the more the RAC is paid, and denying payment for an entire inpatient stay is far more lucrative than identifying an incorrect payment amount or an unnecessary medical service. The provider can challenge the RAC’s finding, but the multi-level appeal process is expensive and cumbersome for both hospitals and the agency. Moreover, obtaining a favorable decision on appeal has little to no precedential value: RACs continue to review and deny substantially similar claims, forcing hospitals to engage continually in the same cumbersome and expensive appeals process on a claim-by-claim basis. Yet, in order to improve performance on a given measure, a health care organization must be able to exert reasonable control over the factors (e.g., internal policies and processes, personnel, material resources, etc.) that contribute to measure performance results. This guiding principle enables the assignment of accountability to the correct entity, and it facilitates a fair assessment of the performance of that entity by patients, payers and policymakers. Given that hospitals cannot control how many and which of their claims RACs audit and how little influence they have over the chronically improper RAC decisions, the proposed measure is entirely unsuitable as a hospital performance measure.

Physician Services. **The AHA is concerned about a potential measure assessing Medicare spending measures specific to physician services – such as radiology, anesthesia and pathology – that are provided during a hospitalization.** In many cases, the appropriate level of utilization for such types of services is simply not yet known. Moreover, this measure is being proposed as a *hospital* performance measure even though it reflects the performance of physicians. We believe that the accountability for physician service measures is shared between physicians and hospitals, and should not be solely attributed to hospitals. Some hospitals directly employ physicians; it may be reasonable to measure such hospitals on a physician services measure. Other hospitals, however, contract with individual physicians or physician groups. Such physicians operate with a greater level of independence from hospitals, making it more difficult to assign accountability for a physician services measure solely to hospitals. Finally, we caution that such measures should not be used to push only toward the lowest possible cost. In some cases, that low cost may be achieved when the patient does not get needed services. **The objective of cost and efficiency measurement is to improve the value of health care, that is, lower cost with equal or better outcomes.** For that reason, any measures of physician services must be appropriately coupled with related quality measures to mitigate any unintended consequences of measurement.

Disaster/Extraordinary Circumstances VBP Waiver. **We applaud CMS for proposing a waiver process for natural disasters and extenuating circumstances.** We greatly appreciate the agency’s recognition of the effects of these circumstances on hospital quality measure performance. Currently, disaster-affected hospitals can be waived only from being scored on

specific measures in the VBP program. This measure-specific waiver occurs only if a hospital receives a waiver from IQR data submission requirements and, as a result, cannot report the minimum required cases for a measure. If a hospital cannot submit the minimum-required cases for multiple measures, then this may cause a hospital to be waived from the VBP program.

Under the newly proposed waiver process, CMS could waive a hospital from the VBP program for the fiscal year in which the hospital's VBP performance period data are affected by a disaster or other extenuating circumstance. Hospitals would submit waiver requests to CMS describing how their performance on VBP measures was adversely affected within 30 days of the occurrence of the extraordinary circumstance. This request would be made simultaneously with a waiver request for the IQR program.

We support nearly all of the agency's VBP waiver proposals, but urge the agency to lengthen the amount of time hospitals have to submit the VBP waiver to 60 days, and to decouple the VBP waiver request from the IQR waiver request. We appreciate that the agency wishes to maintain a fair process and does not want hospitals to seek an advantage on their VBP scores long after the disaster period has ended. However, in the midst of disaster recovery, it may take longer than 30 days to fully assess the impact of the disaster to a hospital and its normal processes to ensure quality of care. We believe it is generally easier to know whether *data submission* will be compromised than it is to assess whether *measure performance* is affected. We believe adding 30 additional days to the timeframe gives hospitals a better sense of how and whether their performance might be affected.

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

Updates to Previously Finalized Measures. CMS proposes refinements to four measures that have already been finalized for the hospital IQR program.

Readmissions Measures. CMS proposes to incorporate a "planned readmissions algorithm" into the 30-day readmissions measures finalized for the FY 2014 and FY 2015 IQR programs. This is the same algorithm that CMS has proposed to incorporate for calculating excess readmissions in the HRRP. The affected measures include readmissions for AMI, HF, PN and THA/TKA, as well as the hospital-wide readmissions measure.

The AHA supports the inclusion of the planned readmissions algorithm. However, as we noted in our comments on the HRRP, we urge the agency to continuously evaluate the planned readmissions algorithm to ensure the list of diagnoses and procedures is adequate. Moreover, we strongly urge the agency to exclude readmissions unrelated to the initial reason for admission. Unrelated readmissions do not meaningfully reflect quality of care.

Finally, the agency should adjust the measures for the proportion of dual-eligible patients that each hospital treats. We have provided additional details on this proposed adjustment in our comments on the HRRP. Preventing readmissions involves a variety of resources and interventions, many of which are outside of hospitals' control. We believe this adjustment will

ensure that hospitals treating patients with lower socioeconomic status do not receive poorer scores on the measures due to health care infrastructure barriers in their communities.

Expansion of CLABSI and CAUTI Measures into Non-ICU Locations. Currently, these measures are collected for ICU locations. CMS proposes that beginning with discharges on or after Jan. 1, 2014, hospitals will also be asked to collect CAUTI and CLABSI data for medical wards, surgical wards, and medical/surgical wards. NQF recently endorsed the expansion of these measures into non-ICU settings.

The AHA believes that expanding the measure into non-ICU locations is the right goal in the long term. However, we recommend the agency defer the collection of data for non-ICU settings until discharges on or after Jul. 1, 2014. Collecting these HAI measures in additional settings is a major process change for hospitals, and one that will likely require either the reconfiguration or addition of resources to collect the data appropriately. Assuming that the measure is finalized in the rule by August 2013, hospitals would have only five months to identify appropriate staff resources to collect data, and hone their collection processes.

By deferring the collection of the data for an additional six months, hospitals will have nearly a year from the time the rule is finalized until the data collection begins. Given that the scores from these measures will be publicly reported, and potentially used in pay-for-performance programs, hospitals must have adequate time to prepare so that they can collect reliable, accurate data.

SCIP-4, Controlled 6 AM Glucose for Cardiac Surgery Patients. CMS proposes to adopt updated measure specifications that were endorsed by the NQF beginning with discharges on or after Jan. 1, 2014. **The AHA supports this proposal.**

Medicare Spending Per Beneficiary (MSPB). CMS proposes to include Railroad Retirement Board beneficiaries for the measure in the FY 2016 IQR program. CMS states that it now has available complete claims data to include the beneficiaries in the measure. The MSPB measure is currently undergoing review to receive NQF endorsement. **While the AHA supports the proposal to add Railroad Retirement Board beneficiaries to the measure, we also urge the agency to ensure that the measure specifications used for the MSPB measure are consistent with any version of the measure endorsed by NQF.**

Removal of Measures for FY 2016. **The AHA supports CMS's proposed removal of eight measures from the IQR program.** Specifically, the agency proposes to remove seven chart-abstracted process measures assessing aspects of AMI, pneumonia and heart failure care. The agency also proposes to remove a measure assessing perioperative temperature management for surgical patients, and a pneumonia vaccination measure. Finally, the agency proposes to remove a structural measure – participation in a systematic stroke database – since it adopted process measures for stroke in previous rulemaking.

We also urge the agency to remove these measures from the program, as well as *Hospital Compare*, as soon as possible. Since CMS has concluded that these measures are no longer

appropriate for the program, we believe they should be removed from the program as soon as the beginning of FY 2014.

New Additional Measures for FY 2016. CMS proposes to add five measures to the FY 2016 IQR program. **The AHA is concerned that three of these measures are not NQF-endorsed. While CMS has the authority to include non-endorsed measures in the IQR, we do not believe these measures are appropriate for inclusion in a public quality reporting program.**

30-day Risk Standardized COPD Readmission Rate. This measure also has been proposed for the HRRP program for FY 2015 and assesses 30-day readmissions rates for patients hospitalized with an acute exacerbation of COPD. **The AHA does not support the addition of this measure to the IQR program. As noted in our comments on the HRRP, CMS must improve measure reliability, adjust for socioeconomic factors, and exclude unrelated readmissions before we can offer our support.**

30-day Risk-Standardized COPD Mortality Rate. **The AHA does not support the inclusion of the COPD mortality measure because it has not yet demonstrated adequate measure reliability.** The underlying methodology of this measure is very similar to that of the PN, HF and AMI mortality measures that are currently part of the IQR and VBP programs. As noted in our comments on CMS's VBP proposals, those measures demonstrated poor reliability in a CMS-commissioned analysis. Moreover, CMS has not yet conducted a reliability analysis on the COPD measure. Given that the underlying measure constructions are the same, we do not believe the COPD measure will score any better.

30-day risk Standardized Stroke Readmission Rate. **The AHA does not support the inclusion of the stroke readmissions measure.** This measure assesses the readmissions rate for patients hospitalized for an acute ischemic stroke. It uses a data reporting and risk adjustment methodology similar to the existing readmissions measures in the IQR program. This measure was reviewed by the NQF Neurology Steering Committee in 2012, and failed to receive endorsement. However, CMS still proposes to include it in the IQR because it believes it addresses a prevalent and costly health problem.

We believe this measure shares all of the same problems as the other readmissions measures currently in the IQR program. Specifically, it has poor reliability, fails to adjust for socioeconomic factors outside the control of hospitals, and fails to exclude unrelated readmissions. This measure must undergo substantial changes to improve its rigor, as well as receive NQF endorsement, before it should be considered for the IQR.

30-day Risk Standardized Stroke Mortality. **We do not support the inclusion of the stroke mortality measure in the IQR program, and have significant concerns about its use in a public reporting application.** This measure assesses the 30-day mortality rate for patients hospitalized with acute ischemic stroke. Similar to the 30-day stroke readmissions measure, the NQF Neurology Steering Committee reviewed this measure in 2012 and did not endorse it.

In evaluating the measure, the NQF Neurology Steering Committee noted that the severity of stroke is closely tied to clinical outcomes. Stroke severity can be measured using the National Institutes of Health Stroke Scale (NIHSS). However, the measure does not incorporate an adjustment based on the NIHSS, or any other indicator that differentiates stroke severity. Because of this, the measure simply cannot be depended upon to yield accurate and valid results.

Indeed, a recently published Journal of the American Medical Association article re-modeled the stroke readmission measure by incorporating the NIHSS into the measure risk adjustment model.^{xiii} Nearly 58 percent of the hospitals identified as having “better than” or “worse than” expected risk-standardized mortality using the measure with stroke severity adjustment would be reclassified to “as expected mortality” using CMS’s non-stroke severity adjusted measure. **This troubling result underscores the inability of the proposed measure to differentiate meaningfully hospital performance, and demonstrates that it is not appropriate for a national reporting program.**

AMI Payment Per Episode of Care. This proposed measure calculates total payments for Medicare FFS patients with a primary discharge diagnosis of AMI from the date of the initial hospital admission through 30 days post-admission. Payments for the initial hospitalization are included in the measure, as are payments for a broad range of subsequent care, including inpatient, outpatient, physician, laboratory and post-acute care services. The measure also includes a risk adjustment methodology to account for patient characteristics, such as age, prior procedures and co-morbid conditions, all of which influence resource use and, therefore, payment.

Resource use and efficiency measures, when coupled with information about quality, can help improve healthcare “value” – that is, the same or better outcomes at lower costs. **However, the AHA does not support the inclusion of the AMI payment-per-episode measure. We believe this measure should not be proposed for any federal quality reporting program until it has received NQF endorsement.** This measure is still under development, and has yet to be submitted to the NQF for review. The public comment period on the proposed measure closed only on Jan. 31, 2013.

Furthermore, this measure is being proposed as a hospital measure, even though it reflects the actions of a multitude of health care entities, many of which are often not within hospitals’ direct control. Data clearly demonstrate that costs within a 30-day episode of AMI care cannot be attributed solely to hospitals. An analysis of the costs of various episodes of care commissioned by the AHA and the Association of American Medical Colleges (AAMC) demonstrates that on average, AMI patients discharged alive have nearly three “sequence stops” in their care pathway during a 30-day episode of care (Table 9).^{xiv} These sequence stops ranged from inpatient care to inpatient rehabilitation facilities, to outpatient care provided by physicians.

Table 9: Total Medicare Paid, Average Medicare Paid, and Average Sequence Stops for AMI Patients Discharged Alive

Number of episodes	Total Medicare Paid	Average Medicare Paid	Average Sequence Stops	Average Facility-based Sequence Stops	Average Ambulatory-based Sequence Stops
383,720	\$6,694,001,200	\$17,445	2.96	1.87	1.09
KEY					
Facility-based Sequence Stops			Ambulatory-Based Sequence Stops		
Index hospital Stay			Community (includes Physician and Outpatient)		
Home Health Agency			Emergency Room		
Inpatient Rehabilitation Facility			Outpatient Therapy		
Long-Term Care Facility			Hospice		
Skilled Nursing Facility			Other		

Source: The AHA and AAMC commissioned study of bundled payments by Dobson | Davanzo using a 5% sample of Medicare claims data from 2007-2009. Includes MS-DRGs 280, 281, 282. Indirect medical education (IME), disproportionate share hospital (DSH), copay, capital and other third-party payments have been removed. All episodes have been extrapolated to reflect the universe of Medicare beneficiaries. Payments have been standardized to 2009 dollars and to account for the wage index.

Measures selected for a hospital accountability program must appropriately reflect hospital care. To improve performance on a given measure, any health care organization must be able to reasonably control the factors (e.g., internal policies and processes, personnel, material resources, etc.) that contribute to measure performance results. This guiding principle enables the assignment of accountability to the correct entity, and it facilitates a fair assessment of the performance of that entity by patients, payers and policymakers. In the case of the proposed AMI episode of care measure, it would be unfair to hold hospitals solely accountable for the costs incurred by entities they do not always control.

Electronic Clinical Quality Measures (eCOM). With a stated goal of enhancing the alignment of the IQR with the Medicare Electronic Health Record (EHR) Incentive Program, CMS proposes to allow hospitals to report one quarter of data for 16 IQR quality measures using EHRs certified in the meaningful use program. The electronic reporting option would allow hospitals to meet both their FY 2016 IQR reporting requirement for those 16 measures, as well as fulfill the electronic quality measure reporting requirements in the meaningful use program in calendar year (CY) 2014. The agency strongly encourages participation in the voluntary election as a precursor to a required electronic reporting requirement of measures in the future.

The AHA strongly supports the long-term goal of using EHRs to streamline and reduce the burden of quality reporting while increasing access to real-time information to improve care. However, we believe the current proposal by CMS would undermine the intent of the IQR Program and provide little insight into whether EHRs can be used to effectively report comparable data for purposes of public reporting in the future. As an alternative, the AHA recommends that CMS allow hospitals to electronically report data gathered according to the IQR specifications, and thereby receive credit for both the IQR and Medicare EHR Incentive Program.

An Alternative Approach to Electronic Reporting. The IQR program is intended to provide the public with *useful* and *comparable* information about hospitals across the country. The IQR program also provides important information to hospitals striving to understand where their performance can be improved and whether performance is improving over time. Hospitals were the first provider group to actively seek credible public reporting on important quality metrics to foster improvement and inform the public. We continue to believe that this is an incredibly important activity. As we understand CMS’s proposal, it would allow hospitals to choose to report just one quarter of data directly from their EHRs using the e-measure specifications mandated in the Meaningful Use program for the 16 important measures of stroke, venous thromboembolism (VTE), and early elective delivery. This reporting would count in fulfillment of the hospital’s required reporting of those measures for IQR (but not others) and all of the eCQM reporting for the Meaningful Use program. However, because one quarter’s worth of data usually does not provide a statistically valid sample, and because CMS has heard from AHA and its member hospitals that electronic data capture using certified products has significant problems that result in inaccurate assessments of a hospital’s performance, CMS has indicated that it will not publicly report the data that is submitted in this manner.

We concur with CMS that the data generated from EHRs using the e-specifications is unlikely to result in valid, reliable and comparable data at this juncture, much to everyone’s dismay. Table 10 below illustrates some of the significant differences between the e-specified measures and the hand-abstracted measures – differences that mean the data are not comparable.

Table 10: Significant Differences between the e-Specified Measures and the Hand-abstracted Measures

	Specifications for IQR Measures	e-Specifications for eQMs
Specification Development	Generated and maintained by the original measure developer	Generated by unspecified contractors based on manual specifications developed by the original measure developer
Specification Maintenance	Updated over time to reflect changes in science, with strict version control to ensure comparability of data gathered	No clear plan for maintenance Some already out of date with scientific changes. Multiple versions in use at the same time (vendors certified to either December 2012 release and April 2013 without requirement to stay up to date).
NQF Endorsement	Fully reviewed by NQF and endorsed using standard process	E-specified measure uses same NQF ID number, but not the same specifications. Limited review of e-specifications. Measure endorsement decision not contingent on review of e-specifications

	Specifications for IQR Measures	e-Specifications for eQMs
		Provisional endorsement that “rides the coattails” of original measure endorsement.
User Support	Supported by detailed manuals that are updated regularly and disseminated through established communication channels.	Originally posted to the website of a defunct organization (HITSP); now accessible via the CMS website. Limited support for vendors and providers with questions.
Data Extraction / Collection process	Relevant data extracted by experienced clinical staff who can exercise judgment and query physician and other clinicians to clarify documentation	Measure relies on highly specified data fields, with little ability to extract relevant data from other systems (such as lab information systems)
Data Reporting	Reports generated each quarter, based on a sampling algorithm for the applicable patient population	One quarter of reporting with no sampling within applicable patient population.

However, we do not believe that the most appropriate response to this dilemma is to accept the erroneous data generated directly from the EHR in fulfillment of the IQR and Meaningful Use requirements and not publicly report them. This would simply deprive the public and hospitals of access to data for those hospitals that choose to submit in this manner. To do so would impair the continued success of the IQR program, create a significant impediment to moving any of these important stroke and VTE measures deemed appropriate into the VBP program over the next few years, and not advance the work to elicit meaningful quality metrics from EHRs.

Instead, we urge CMS to allow hospitals to voluntarily generate data using the specifications in the joint CMS/Joint Commission measure manual, and report it to CMS using the electronic submission mechanism. These data would be submitted in conformance with the requirements of the IQR program, and if submitted through the electronic submission mechanism for at least one quarter, would count as fulfilling the Meaningful Use requirements for clinical data submission. This would achieve improved alignment between the programs without curtailing the information available to the public and providers.

We believe that the stroke and VTE measures being requested are important indicators of quality, and that the public deserves to see reliable information on hospital performance on these measures. We believe the public reporting of such data is a more important goal than testing whether some hospitals would choose to submit data derived from their EHR for quality improvement.

Technical Elements of the Electronic Reporting Option. CMS proposes that hospitals using the electronic reporting option do so using the QRDA-III data standard. This data standard allows only for reporting of patient-level data. Reporting of patient-level data creates a separation between the provision of care and the calculation of measurement data that runs counter to the promise of EHRs to provide close to real-time data for use in quality improvement. By contrast, the QRDA-I standard transmits aggregate measure data (numerator, denominator, exclusions).

Under the 2014 certification rules from ONC, vendors must be able to generate reports using both the QRDA-III and QRDA-I standards. In addition, CMS will allow Medicare physicians to use either standard in their voluntary electronic reporting program in 2014. **The AHA recommends that CMS allow hospitals to use either the QRDA-I or QRDA-III standard for the electronic reporting option. This approach will fully leverage the certified technology and be consistent with the physician electronic reporting option, which permits use of either standard.**

Limiting Choice in Meaningful Use. As proposed, the electronic reporting option would limit hospitals' choice in fulfilling meaningful use requirements. Most obviously, by naming a specific set of 16 eCQMs, CMS has taken away the choice hospitals currently have of reporting any 16 of 29 eCQMs. As noted below, vendors are not required to support all 29 measures, and may not, in fact, support these specific 16 measures. In addition, the Stage 2 meaningful use rules require hospitals to implement at least five clinical decision support (CDS) tools in their EHRs that are related to the eCQMs that they report for meaningful use. Thus, by limiting the eCQMs reported, CMS would also constrain the choice of CDS tools to only three clinical domains (stroke, VTE, and delivery). **The AHA recommends that CMS rectify this problem by eliminating the requirement that CDS tools be related to eCQMs. Hospitals should be free to choose the CDS tools that best help them achieve their individual quality improvement strategies and goals.**

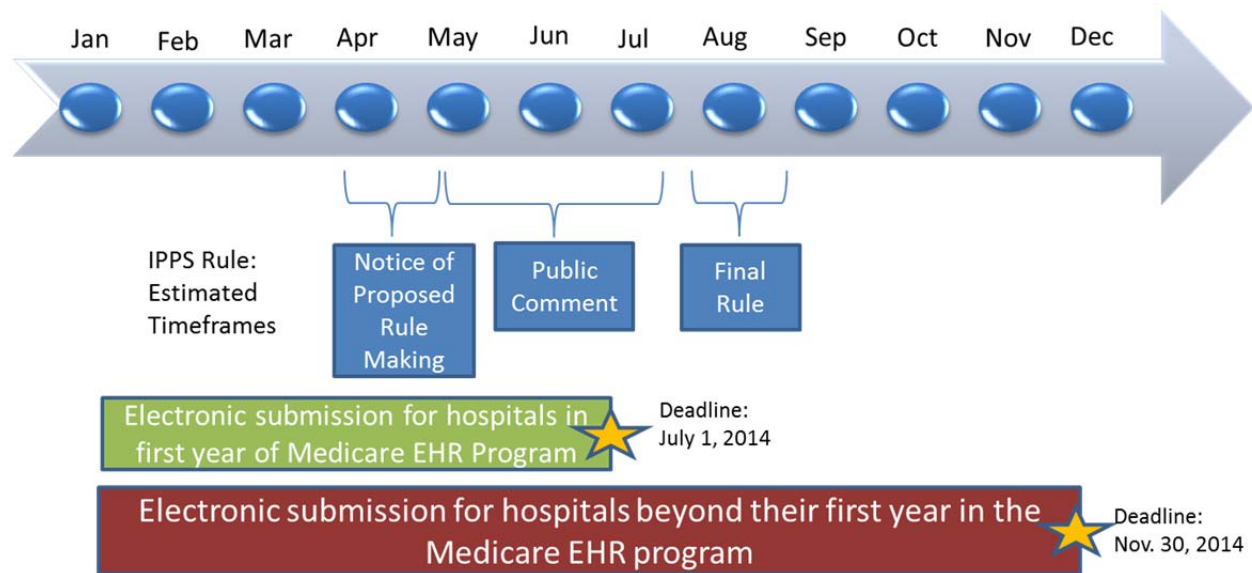
Electronic Reporting Pilot. Over the past two years, CMS has conducted an EHR Incentive Program Reporting Pilot that requires the reporting of eCQMs, and therefore offers a valuable source of insight on eCQMs. However, written findings and evaluation of the pilot results to date are not available. Based on statements made in public forums where the pilot was discussed, it is our understanding that only four hospitals are pilot participants and each hospital utilizes the same health information technology (HIT) vendor for the reporting of eCQMs. **The AHA recommends that CMS evaluate and report the results of the Electronic Reporting Pilot and extend the pilot to include additional HIT vendors so that the findings can inform all stakeholders about successes and challenges of eCQM reporting.**

The Need to Maintain Voluntary Electronic Submission. In the proposed rule, CMS notes that it is considering making electronic submission of the 16 IQR quality measures a requirement as soon as CY 2015. However, the agency also notes that it may use the results of the voluntary reporting option to inform its decisions about when to require electronic submission, and when to publicly report the measure results from electronic submission.

The AHA does not support requiring the electronic submission of IQR measures in 2015. Instead, we recommend that CMS continue a voluntary electronic reporting option in IQR in order to fully inform future decision-making about the timetable for required electronic reporting of measures in the IQR. We do not believe that CMS will have a sufficient amount of evidence from the voluntary reporting option in 2014 to specify a date certain for the start of required eCQM reporting in IQR. In general, IQR requirements are set forth in each year's inpatient PPS rule. With respect to 2015, as the timeline in Figure 3 below illustrates, both electronic submission deadlines for the proposed voluntary reporting option would come after

CMS generally issues the Notice of Proposed Rulemaking for the inpatient PPS. The rule would also be finalized before the second submission deadline of Nov. 30, 2014. CMS would, in short, propose required reporting without the benefit of experience from the field. Figure 3 also demonstrates a lack of alignment between the timeframes of electronic reporting option, and established timelines for rulemaking. We urge the agency to align these timeframes in the future.

Figure 3: Comparison of Timeframes for IPPS Rulemaking and Proposed IQR Electronic Data Submission in 2014



Moreover, the experience of Stage 1 of the EHR Incentive Program indicates that a rushed timeline and insufficient testing of certified EHRs led to an inability to generate useable, accurate clinical quality data out of EHRs certified to meet the Stage 1 requirements. Stage 1 of the EHR Incentive Program includes 15 of the 16 measures in CMS's proposal. Hospitals participating in that program are best positioned to assess their readiness to generate accurate CQMs, and the challenges they have faced are numerous. For example, electronic specifications (e-specifications) are meant to provide guidance on how measures can be generated from the EHR. However, there are known errors in e-specifications of the measures. Additionally, vendor products supporting Stage 1 met very light testing requirements before receiving certification that they could report eCQMs. Rigorous testing before certification occurs is essential to ensuring needed data are routinely captured by the EHR.

In practice, hospitals found that much of the needed data was not captured without extensive additional effort, counter to the idea that electronic reporting would reduce measure burden. In recognition of these issues, CMS in the fall of 2011 provided sub-regulatory guidance stating **that the EHR Incentive Program requires providers only to attest that eCQMs were generated as output from the certified EHR in order to successfully demonstrate for**

meaningful use. The program does not currently require data accuracy for eCQMs because hospitals have found that their certified EHRs generally cannot generate accurate data.

Therefore, hospitals in the EHR Incentive Program have had very limited experience with generating and attesting to the accuracy of electronic quality measures in the Medicare EHR Incentive Program.

In addition, given the implementation timeframe for Stage 2 of the Medicare EHR Incentive Program, it is not yet known which quality measures EHR vendors will support.

As outlined in the final rule for Stage 2 of the EHRs Incentive program, electronic CQM requirements will move from simply attesting to obtaining the results from a certified EHR, to reporting of the actual results. Vendors also will be permitted to select which eCQMs they will support under the “modular certification” construct in the EHR Incentive Program. They will not be required to support all eCQMs. Therefore, we recommend that CMS study the experience of hospitals reporting eCQMs in the EHR Incentive Program after the start of FY 2014 for additional insight on the timing of required eCQM reporting in IQR.

Electronically Reported Measures and VBP. **The AHA also is concerned about the future implications of CMS’s proposed electronic reporting process for the VBP program.**

Measures must be reported in the IQR for at least one year before they can be selected for VBP. None of the measures proposed for the electronic reporting option is currently proposed for inclusion in VBP. However, the reporting timeframes of the electronic reporting option and the regular IQR program are not the same. In the electronic reporting option, hospitals would report only one quarter of data for each measure. In the existing IQR program, hospitals are required to submit a full year of data. Moreover, VBP program also generally uses one year of data for both the baseline and performance periods. **Combining data from two different time periods in the VBP program is not appropriate. Given our concerns about the accuracy and validity of measures reported using existing electronic specifications, we do not recommend that CMS create baseline and performance periods that blend the results of both reporting modes until the reliability and accuracy of measures reporting using electronic specifications has improved.**

A Path Forward. Notwithstanding our concerns about the accuracy of the electronically reported quality measures, the AHA continues to believe electronically-reported quality measures hold the potential to decrease provider burden, and capture quality information in a more timely fashion. Thus, we recommend CMS pursue the process below to advance electronic reporting of clinical quality measures:

1. Maintain the clinical utility of quality measures while transitioning to electronic reporting of quality measures. The AHA recommends that CMS purposefully engage all stakeholders involved in quality measure development to develop feasible, accurate and reliable quality measures that can be reported electronically before moving forward with required electronic reporting. The transition to routine electronic reporting of quality data must build from adherence to accuracy and clinical utility. Experience under the IQR demonstrates that quality measures built upon clinical evidence derived from adherence to a clinical protocol can be successfully adopted by hospitals. Therefore,

eCQM development and validation should include a full range of stakeholders – quality measure developers, professionals engaged in the manual calculation of quality measures clinicians, electronic measure developers, HIT vendors and measure endorsers. Evidence from rigorous field-testing will inform feasibility. Additional time for the engagement of stakeholders with multiple areas of expertise will result in valid data that can be used to improve care, educate consumers and assess performance.

2. Assess the readiness to use specific vocabularies and the burden associated with their use. Starting in FY 2014, hospitals will be required to use specific standards to capture data used in calculating eCQMs. These vocabulary standards include SNOMED for the problem list and LOINC for laboratory data. Consistent use of standards is challenging; it requires providers to change information technology systems, change how care is provided, and conduct extensive – and ongoing – training of staff. All of this happens in a fast-paced, rapidly changing health care system where there is a strong emphasis on reducing costs. Based on experience to date in Stage 1 of Meaningful Use, more work needs to be done.

Steps taken by the National Library of Medicine in providing a Value Set Authority Center for some of the required vocabulary standards is a good start. However, an effective transition to standards adoption needs to be supported by educational resources that are easy to find and understand. The educational efforts CMS has undertaken to support the overlapping transition to ICD-10 serve as an example. **The AHA urges CMS to re-double its efforts to educate providers on the new standards embedded in meaningful use and how they are best used in support of accurate eCQM reporting. CMS also should conduct a cost-benefit analysis for adoption of these standards.**

3. Tools supporting successful eCQM development must be reviewed and tested prior to inclusion in electronic quality measure reporting. ONC created the Data Element Catalog (DEC) to provide clarity on the data elements expected to be captured in support of 2014 CQM electronic specifications and to support the testing of EHR products that will be certified for use in 2014. However, we remain concerned that the DEC was included in the 2014 standards final rule, but was not specifically described in the 2014 standards proposed rule and was not therefore subject to public comment.

The task of reviewing the DEC and other tools that support successful quality measure reporting should be undertaken prior to a determination that EHRs can support hospital IQR program requirements. Given the explosion of quality measure reporting requirements, it is essential that there be transparency in HHS programs supporting electronic measure reporting and collaboration with providers who will report the quality measures. We recommend that CMS create a process that engages multi-stakeholder participation in the process of updating and maintaining the DEC. Health care providers also need clarity on the requirements for their EHR vendors to update their products as inputs like the DEC will change over time.

4. Electronic specification stability is needed before EHRs can support accurate IQR reporting. E-specifications are relied upon by hospitals and EHR vendors to identify specific locations in EHRs for data elements necessary to calculate eCQMs. If the data element location is incorrect, then the eCQM lacks complete information for reporting. Most hospitals have found the initial implementation of e-specifications to be highly complex and time-consuming, often taking up to a full year. Updating e-specifications after they have been implemented is possible, but also requires time and resources. Unfortunately, experience by hospitals in the EHR Incentive Program suggests that the e-specifications in the program were implemented on a rushed timeline, and subjected to frequent changes. These timeframes have impeded the ability of hospitals to generate performance data from a single version of eCQM specifications. Indeed, the timeline below (Table 11) illustrates that e-specifications often changed month-to-month.

Table 11: Electronic Specifications Supporting Hospital and CAH CQMs Reported under Meaningful Use

9/4/2012	Stage 2 meaningful use final rule published, including CQMs reported starting in 2014
10/24/2012	Final CQM electronic specifications published
11/2/2012	Draft test procedures for the 2014 Edition EHR certification criteria released
12/7/2012	Interim final rule announcing changes to electronic specifications published
12/14/2012	Final test procedures for the 2014 Edition EHR certification criteria released
12/21/2012	Updated electronic specifications for CQMs published (Dec. 2012 edition)
4/1/2013	Updated electronic specifications for CQMs published (April 2013 edition)

CMS and ONC are to be commended for undertaking a review of the eCQM process for Stage 1 and developing a process to identify problems with e-specifications. The creation of a tool that lists problems identified with e-specifications and is transparent to stakeholders is a positive step. We are concerned, however, that two different sets of e-specifications are currently available for use by vendors – the December 2012 and April 2013 versions. It is difficult to imagine that the data coming from systems that support different e-specifications would be comparable.

Furthermore, AHA members have attempted to validate the Stage 1 Meaningful Use eCQMs against the data generated through the IQR manual chart abstraction process. Hospitals expect quality measures with identical measure titles to yield similar results regardless of the measure calculation method. However, to date these efforts have required hospitals to expend considerable effort to modify how data are captured, and generally do not lead to comparable results across measurement methodologies. The AHA is concerned that a premature requirement for electronic reporting of quality measures places at risk the longitudinal trend analysis central to quality reporting and ultimately value-based purchasing. Given the turbulence within one set of e-specifications, the AHA also is concerned that the availability of two sets of e-specifications to support eCQM reporting amplifies this concern. **The AHA urges CMS**

to establish a clear process to manage updates to e-specifications prior to their publication for use in any program. Vendors should be required to support only the latest version of e-specifications to facilitate comparability of results.

5. *Field test measures prior to including them in a reporting program.* **The AHA recommends that CMS modify the EHR Incentive Reporting Pilot Program to include field testing of eCQMs.** The process of testing and evaluation of measures in a pilot environment provides assurance of the feasibility, reliability and validity of the measure for use in a reporting program. CMS should consider testing a subset of measures in the IQR program in the pilot. This would provide a rigorous review of the electronic submission of those measures before expanding electronic reporting to include a larger set of IQR measures.

Other Data Submission Proposals. CMS proposes a number of minor modifications to the data submission requirements for selected IQR measures. For example, the agency proposes to change the submission dates for FY 2015 IQR structural measures from Apr. 1 - May 15, 2014 to Jan. 1 – Feb. 15, 2014 in order to provide a more timely determination of whether hospitals have met all IQR requirements and, therefore, qualify to receive a full annual payment update. **The AHA supports these proposals.**

CMS makes two additional proposals related to the submission of HAI measures in the FY 2016 program. First, it proposes that the deadline for the submission of the healthcare provider flu vaccination measure will be May 15 of the calendar year for which a flu season ends. This proposal would affect the submission of flu vaccination data for the flu season from Oct. 1, 2013 – Mar. 31, 2014. Second, CMS proposes to require hospitals to submit Health Insurance Claim numbers for those patients that have them in order to enhance future data validation efforts. **The AHA supports these proposals.**

Validation. CMS proposes changes to the timing, scope and process of validating IQR measures.

Number and Timing of Quarters Included in Validation. **The AHA supports CMS's proposals to alter the timing of the quarters included in chart validation.** CMS proposes to change the timing of the quarters of measure data it validates, as well as the number of quarters included in order to make all annual payment update determinations by July 1 of each year. For the FY 2015 annual payment update determination, CMS proposes to include three quarters of data in its validation process – the fourth quarter of the calendar year that occurs two years before the payment determination, and the first two calendar quarters (January through June) of the following calendar year. Beginning in FY 2016, CMS would include one additional quarter of data in the validation. Thus, validated data would be from the third and fourth quarters of the year occurring two years before the annual payment update determination, and the first and second quarters of the subsequent year. For example, in FY 2016, the validated quarters would be July – December 2013 and January – June 2014.

Selection of the Measures and Sampling of Charts in Validation. CMS proposes to validate 12 clinical process of care measures, and suspend the validation of nine other clinical process

measures. The validated IQR clinical process measures are those for AMI, HF, PN, surgical care improvement project (SCIP) and immunizations. **The AHA supports these proposals.**

The AHA also supports CMS's proposed changes to the HAI validation process. CMS currently validates CLABSI, CAUTI and SSI in up to 600 hospitals, requesting 12 records per reporting quarter for each measure. CMS proposes to add *MRSA* and *C. Difficile* to its validation program for FY 2016, reflecting their proposed addition to the IQR program. Instead of continuing to validate all measures for selected hospitals, CMS will randomly assign half of the 600 hospitals selected for validation to either CAUTI and CLABSI, or C Diff and MRSA. CMS would use 15 records per year, instead of 48. For SSI, CMS would continue to conduct validation on 600 hospitals, but lower the number of records per hospital to six to maintain an adequate sample size.

***Electronic submission of records selected for validation.* The AHA supports CMS's proposal to allow hospitals to transmit electronically medical records selected for validation.**

Hospitals will have the option of placing patient charts and other requested information onto CDs, DVDs and flash drives and mailing them to CMS. While we welcome this approach, we also encourage CMS to continue exploring additional means of electronically transmitting records selected for validation to help mitigate the burden of transmission.

PPS-EXEMPT CANCER HOSPITAL QUALITY REPORTING PROGRAM (PCHQR)

The ACA mandates a quality reporting program for PPS-exempt cancer hospitals. Failure to meet the data submission requirements of the program will subject cancer hospitals to a two-percentage point reduction to their annual market basket update, beginning in FY 2014. CMS proposes one new measure for the PCHQR for FY 2015 and 13 new measures for FY 2016.

FY 2015 Proposed Measure. **The AHA supports CMS's proposed addition of the SSI measure to the PCHQR program.** This measure is reported in several other federal programs, is NQF-endorsed and supported by the MAP. **However, we also urge CMS to exercise care in publicly reporting the measure in the future.** Reporting the measure for cancer patients presents different challenges than reporting the measure for general acute care hospital patients. For example, many cancer patients are immune-compromised because of their disease, making them more susceptible to infections. This may, in turn, lead to higher than expected infection rates.

We also encourage CMS to engage with cancer centers to determine whether stratifying SSI reporting by type of cancer may allow for a more meaningful comparison of rates. Currently, SSI reporting is done on a surgical procedural level – these surgical procedures may not directly tie to the kinds of cancers patients have.

FY 2016 Proposed Measures. CMS proposes to add 13 measures to the FY 2016 PCHQR Program.

SCIP Measures. CMS proposes to add six measures from the SCIP measure set to assess the care of patients receiving surgery in cancer hospitals. All six of the proposed measures are NQF-endorsed, and were supported by the MAP in its 2013 pre-rulemaking report. **The AHA supports these proposals.**

Clinical Process/Oncology Process Measures. The AHA is concerned about the burden of reporting the clinical and oncology process measures CMS has proposed for FY 2016. All of these measures must be reported on an entire patient population because there is no allowance made for sampling. Moreover, in some cases, superior measures that more meaningfully capture cancer quality of care may be preferable to the measures CMS has proposed.

We recommend that CMS not finalize any of these proposed processes for the FY 2016 program. Three of the measures – oncology: radiation dose limits to normal tissues, prostate cancer: adjuvant hormonal therapy for high-risk patients, and prostate cancer: avoidance of overuse of bone scan for staging low-risk patients – are NQF-endorsed and MAP-recommended or supported. The AHA could support these three measures for inclusion in a future program, but only if CMS develops an appropriate sampling methodology. Where appropriate, it also must seek NQF review of the methodology.

The AHA does not support the inclusion of the multiple myeloma: treatment with bisphosphonates measure in the PCHQR program. Bisphosphonates are part of a class of drugs known as “osteoclast inhibitors” which are prescribed to help prevent bone deterioration. As noted by the Alliance of Dedicated Cancer Centers (ADCC) in its comments to the MAP, the use of bisphosphonates for patients with multiple myeloma is generally indicated to help stem bone deterioration. But the drug has substantial side effects, and may not be appropriate for all patients. Emerging studies suggest there may be other drugs that work just as well, if not better. Therefore, we believe it would be inappropriate for CMS to finalize a measure tied solely to bisphosphonates at this time.

Future measure development efforts may yield more meaningful measures in this area. NCQA has just opened an informal public commenting period on a measure that assesses the use of bisphosphonates and other osteoclast inhibitors in a wider range of cancer patients, not just those with multiple myeloma. While it would be premature to lend support to that measure in the absence of full specifications and testing information, we believe that CMS should further explore the potential use of this measure, taking into account feedback from cancer hospitals and other key stakeholders. **No matter what measure CMS selects, it must receive NQF endorsement and be reviewed by the MAP before it is proposed for the program.**

The “oncology: plan of care for pain”, and “oncology: pain intensity quantified” measures are proposed for use as a complementary pair. The “plan of care for pain” measure assesses the percentage of patients who report pain and have a plan to address that pain documented in their medical record. The “pain intensity quantified” measure assesses whether the intensity of pain experienced by patients is actually quantified in the medical record.

Pain management is integral to delivering high-quality cancer care. We also appreciate CMS's intent in pairing these measures. That is, to adequately address patient pain issues, the pain must be systematically assessed, and be followed by an intervention appropriate to the level of pain.

However, we do not support the inclusion of these measures in the PCHQR program because we do not believe they accurately and meaningfully assess pain management in cancer hospitals. We also believe they would be inordinately burdensome to collect.

In addition, the measures offer vague definitions of both “quantification” of pain intensity, and a “plan of care” to manage pain. For example, the pain intensity measure specifications state, “pain intensity should be quantified using a standard instrument, such as a zero to 10 numerical rating scale, a categorical scale, or the pictorial scale.”^{xv} But, the measure fails to point the user to any specific, validated pain measurement tools or scales. We agree that multiple mechanisms to measure pain levels are necessary given the differences in patient types. For example, while some patients are able to provide a zero to 10 rating of their pain, other patients, such as those with communication or cognitive difficulties, may respond better to a pictorial scale. Nevertheless, the listing of instrument in the measure specifications captures just general types of tools that could be used. This introduces far too much subjectivity in interpreting the specifications, thereby undermining efforts to reliably collect the measure across entities.

These vague definitions carry over to the plan of care measure. The measure defines a plan of care as “use of opioids, non-opioid analgesics, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval.”^{xvi} This provides us with only a range of possible interventions; it fails to suggest which intervention is appropriate for a specific patient type or level of pain. Moreover, as the ADCC notes in its comments to the MAP, the pain needs for cancer patients vary over time. The measure does not take these clinical realities into account.

Finally, given the ambiguity in the measure specifications, we believe it would be highly burdensome for cancer hospitals to collect these measures. While the measure specifications suggest that administrative data may be used, there is too much subjectivity in the specifications to generate accurate results. While using chart abstraction is another possible approach, there is no sampling methodology provided for the measure, meaning that cancer hospitals must report on all relevant patients. This would represent a tremendous data collection and reporting burden to hospitals.

HCAHPS. While the AHA supports the goal of rigorously measuring the patient experience, the AHA does not support the inclusion of the HCAHPS measure for the PCHQR program. The HCAHPS tool has not yet been tested nor NQF-endorsed for use in cancer hospitals. Moreover, HCAHPS is an inpatient experience of care measure, but most cancer care is actually delivered on an outpatient basis. By focusing on such a narrow piece of the cancer care continuum, this measure fails to provide a meaningful assessment of the patient experience in cancer hospitals.

In future years, tools that more meaningfully assess the patient experience in cancer settings may become available. For example, the ADCC notes that there is a cancer CAHPS tool under

development. While we believe that having too many CAHPS tools can overwhelm patients with unnecessary surveys, we believe a tool specific to cancer care may be warranted. If deployed correctly, such a tool may be able to encapsulate both outpatient and inpatient care. The agency should consider testing the tool, and submitting it for NQF endorsement. If the cancer CAHPS tool receives endorsement, the agency could consider having it reviewed by the MAP, and subsequently proposed for the PCHQR program.

Data Collection and Reporting. CMS proposes to collect the new SSI measure through the NHSN on a quarterly basis, proposing deadlines for FYs 2015 through 2017. CMS proposes to require cancer hospitals to submit the data for the SCIP and clinical/oncology process measures via QualityNet, beginning with discharges on or after Jan. 1, 2015. **The AHA supports CMS's data collection and reporting proposals for SSI and SCIP. However, we do not support the agency's proposals for the oncology process measures because we do not support the inclusion of those measures in the program.**

CMS proposes that the HCAHPS survey collection requirements and deadlines be the same as those for hospitals in the IQR. Cancer hospitals will either have to contract with an approved HCAHPS vendor or self-administer the survey in accordance with CMS requirements. CMS proposes that data collection begin with discharges on or after April 1, 2014. **Given our concerns about using the HCAHPS measure for cancer hospitals, the AHA does not support the HCAHPS reporting proposals.**

Public Reporting. The ACA requires measures from the PCHQR program to be publicly reported. CMS proposes to defer public reporting of the measures in the program while they continue to test and assess data quality. **The AHA supports this proposal. We also urge CMS to consider carefully how the SSI measure is reported, taking into account the unique patient population of cancer hospitals.**

Reporting Waivers for Disasters or Extenuating Circumstances. **The AHA applauds CMS for recognizing the impact of natural disasters and other extenuating circumstances on the ability of hospitals to collect and report quality data. We support the agency's proposals to develop a waiver process.** Cancer hospitals would submit a waiver request to CMS within 30 days of the occurrence of the extraordinary circumstance, providing evidence of the impact of the extraordinary circumstance and an estimated date when reporting would be able to resume. CMS also proposes to have the option to grant waivers or extensions to a region or locale without hospitals specifically requesting them.

INPATIENT PSYCHIATRIC FACILITY QUALITY REPORTING (IPFQR) PROGRAM

The ACA mandates a quality reporting program for inpatient psychiatric facilities (IPFs) reimbursed under the IPF PPS. Failure to meet the data submission requirements of the program subjects IPFs to a two-percentage point reduction to their annual market basket update, beginning in FY 2014.

FY 2016 Measurement Proposals. CMS proposes no new measures for the IPFQR in FY 2015, but three new measures for FY 2016 – substance abuse screening, alcohol and drug use assessment, and follow-up for mental illness.

SUB-1 – Alcohol Use Screening. **The AHA does not support the inclusion of SUB-1 in the IPFQR program at this time because the measure has not yet obtained NQF endorsement or been reviewed by the MAP.** The proposed measure assesses the percentage of patients 18 years of age and older who are screened during an IPF stay for unhealthy alcohol use. The measure is part of a measure set developed by The Joint Commission, but its reporting is not required. While we agree this is an importance area of measurement, hospitals have had limited experience to date in using SUB-1 for public reporting purposes.

The measure was recently submitted to the NQF Behavioral Health Steering Committee for review, and we expect the committee will make a decision on endorsement during 2013. CMS should re-propose this measure when it receives NQF endorsement and the agency has sought MAP review for any NQF-endorsed version of the measure.

SUB-4 – Alcohol and Drug Use: Assessing Status After Discharge. **The AHA does not support the inclusion of SUB-4 in the IPFQR program at this time because the measure has not yet obtained NQF endorsement or been reviewed by the MAP.** This measure assesses whether discharged patients are contacted between seven and 30 days after hospital discharge to collect information about their alcohol or drug use. The measure is part of the same Joint Commission measure set as SUB-1, and is being reviewed by the NQF Behavioral Health Steering Committee. Similar to SUB-1, CMS should re-propose this measure when it receives NQF endorsement and the agency has sought MAP review for any NQF-endorsed version of the measure.

FUH – Follow-up After Hospitalization for Mental Illness. **The AHA does not support the inclusion of FUH in the IPFQR program, and has significant concerns about the manner in which CMS proposes to implement it. While this measure is NQF-endorsed and supported for use in the IPFQR by the MAP, it is not specified for use as a hospital measure. Rather, it is specified as health plan performance measure. Therefore, we do not believe the measure is appropriate as a hospital accountability measure.**

The proposed measure assesses the percentage of discharges for patients six years of age and older who were admitted to IPFs for treatment of selected mental health disorders, and who subsequently had outpatient treatment from a mental health practitioner, or received partial hospitalization services. Indeed, in the measure specifications submitted to receive NQF endorsement, the measure developer, the National Committee on Quality Assurance (NCQA) explicitly states, “This measure is specified and reported by NCQA at the health plan level. However, some health plans use the data from this measure to identify individual clinician performance. *This measure has been not tested by NCQA to distinguish individual clinician performance*” [emphasis added].^{xvii} The measure submission further notes that to date, the measure has been used only for public reporting and accountability efforts at the health plan

level. For example, NCQA uses the measure in its health plan accreditation program. It also is used in an annual listing of “America’s Best Health Plans.”

Given that the specifications of the measure are geared toward health plans, it is simply not feasible for IPFs to implement the measure. The measure is specified to use billing data to measure follow up care. IPFs do not have full access to billing information for a variety of follow-up services. For example, IPFs would be challenged to use billing data to determine whether a patient has received a follow-up visit within 30 days, especially if the clinicians providing care at the IPF are not the same as the clinicians providing follow-up care. Therefore, CMS proposes to deviate from the specifications and have IPFs use chart abstraction to collect the measure, claiming “this measure is specified by the steward for either collection through chart abstraction or calculation using claims/administrative data.” CMS further proposes that IPFs will not be able to collect data on a sample of patients. Rather, they will be required to report on all discharges captured by the measures.

We are dismayed that the agency proposes to use chart abstraction for this measure. There is no evidence in either the measure submission to NQF or in the specifications posted on the measure developer’s website that this measure was specified, tested or NQF-endorsed for manual chart abstraction. The measure specifications CMS includes in the proposed rule include billing codes, not an algorithm to support manual chart abstraction. Moreover, on both the NQF measure submission form and NQF’s directory of measures, the “data source” for the measure is listed as “administrative claims” and “electronic clinical data: electronic health records.”^{xviii} A paper-based medical record is not listed as a data source for the measure. Moreover, given that not all IPFs have fully implemented EHRs, we believe they would be challenged to collect this measure via that mechanism as well. **Proposing to collect a measure using chart abstraction in the absence of both an appropriate protocol and evidence that the measure can be collected in this fashion is inappropriate.**

As an alternative approach to chart abstraction, CMS has considered using available administrative claims data to compute the measure for each IPF. We do not support this approach either. As noted above, FUH is not appropriate as an accountability measure at the hospital level. Moreover, neither CMS nor the measure developer provides sufficient information to understand what kinds of administrative claims data it used to test the measure on a Medicare population, and therefore, what claims data it would use to collect the measure for IPFs.

Finally, we note that the collection of this measure would be a substantial burden on IPFs. Patient sampling would not be permitted on this measure. Additionally, within the patient population treated by IPFs, treatment adherence and follow-up can be a challenge. For example, as noted by the National Association of Psychiatric Health Systems in their comments on the measure to the MAP, a patient may be scheduled for an appointment, but may not actually show up for the appointment. This would make it unclear whether a patient had received follow-up care within the allotted timeframe or not.

Data Collection and Reporting. **The AHA does not support any of the proposed data collection and reporting mechanisms for SUB-1, SUB-4 and FUH because we do not support the inclusion of those measures in the IPFQR program in the first place.** The agency proposes to allow IPFs to collect data on a sample of their patient population using the sampling methodology in the measure specifications. Similarly, the agency proposes that IPFs use the NCQA's measure specifications for the FUH measure. However, hospitals will be expected to collect and submit all data, and not just a sample.

With respect to the previously finalized measures in the program, CMS proposes to collect four quarters of data for FY 2016. CMS proposes no validation approach for any measures in the FY 2016 program, but urges facilities to develop one in the event the agency begins to conduct validation in future years. **The AHA supports these proposals.**

CMS proposes the same reporting periods for FYs 2015 and 2016 as it proposed in last year's rule. It also proposes the same deadlines for the submission of a Data Accuracy and Completeness Acknowledgement form. However, CMS does propose a minor modification to the timeframes for the public display of IPFQR data and the data preview period for IPFs. Specifically, the agency proposes that IPFQR data would be publicly displayed in April of each calendar year. This proposal aligns the timeframe with the refresh of data on CMS's website. Additionally, the agency proposes that IPFs would have a 30-day period to preview their data approximately twelve weeks before they are publicly displayed. **The AHA supports these proposals.**

ⁱ See 2011 National and State Healthcare-associated Infections Standardized Infection Ratio Report, accessible at: <http://www.cdc.gov/hai/national-annual-sir/>

ⁱⁱ The original Measures Under Consideration list may be accessed at <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72363>. The MAP Final Report issued on Feb. 1, 2013 can be found at <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72746>.

ⁱⁱⁱ See http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf

^{iv} KNG Health Consulting used 100% Medicare Inpatient Claims from July 2009 to June 2011 to estimate PSI rates with the exception of two measures. PSI 10 and 13 are estimated using 2011 full year claims since type of admission is not available on 2009 and 2010 claims. Hospital Compare (April 2013) data are used to obtain estimated rate of two CDC HAI measures: CLABSI and CAUTI. Finally, Hospital Compare (April 2013) data and FY 2011 IPPS Impact File are used to identify hospital characteristics

^v See National Quality Forum, *MAP Families of Measures: Safety, Care Coordination, Cardiovascular Conditions, Diabetes*, available at <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72021>

^{vi} Emphasis added. See Affordable Care Act text at: <http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf>.

^{vii} The measure technical report can be accessed at: https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889985643&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DRmd_AMI-HF-PN_Msrs_Updts_2013.pdf&blobcol=urldata&blobtable=MungoBlobs

^[iii] Vashi AA et al, "Use of Hospital-Based Acute Care Among Patients Recently Discharged from the Hospital." *Journal of the American Medical Association* 309 (4), January 22/30, 2013.

^{viii} Berenson, Julia and Anthony Shih. *Higher Readmissions at Safety-Net Hospitals and Potential Policy Solutions*. The Commonwealth Fund. December 2012.

^{ix} Rau, Jordan. *Hospitals Treating the Poor Hardest Hit by Readmissions Penalties*. Kaiser Health News. August 13, 2012 (Updated October 13, 2012).

^x Analysis based on the 2009 100% inpatient Standard Analytic File. Hospitals with fewer than 8 discharges for any single condition were excluded from the analysis for that condition. This was done to proxy the minimum number of cases used by CMS (25) based on 3-years of data. Exlihauser comorbidity index was used in place of the CMS HCC risk adjustment method because of lack of access to carrier/physician claims. To calculate the excess readmissions ratios (ERR), KNG Health Consulting estimated a single model, with risk-adjusted expected readmissions (denominator in ERR) calculated by quartile of hospital dual share. For a hospital in 4th quartile of dual share: $ERR = \text{Risk-adjusted predicted readmissions} / \text{risk-adjusted expected readmissions}$ for hospitals in quartile 4. A similar calculation done for hospital in quartiles 1, 2 and 3.

^{xi} KNG used 2009 100% Medicare inpatient claims data to identify Medicare beneficiaries admitted to short-term acute care hospitals with principal diagnoses of one of the 3 initial conditions that will be included in the program (acute myocardial infarction, heart failure, and total hip/knee). To develop the analytic sample, we applied inclusion and exclusion criteria consistent with the Medicare readmission measures endorsed by the National Quality Forum and used by CMS. Demographic and other characteristics of Medicare beneficiaries, such as age, sex, race, and dual eligible status were obtained from the 2009 Medicare denominator file. We were unable to use CMS's risk-adjustment methodology because 100% Medicare physician claims were not available to us. Instead, we used the Elixhauser comorbidity index for risk adjustment. The Elixhauser comorbidity measure is widely used in the literature as a risk-adjustment method for its proven predictive power of inpatient mortality. Following the approach used by CMS, we computed risk-standardized readmission rates (RSRRs) for each hospital and condition using a hierarchical regression model (HRM), which included hospital-level random effects.

^{xii} See http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf

^{xiii} 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>. Last accessed: August 13, 2012.

^{xiv} American Hospital Association and Association of American Medical Colleges, 2012. *Medicare Payment Bundling: Insights from Claims Data and Policy Implications*. The report and summary can be accessed at <http://www.aha.org/research/reports/12bundling.shtml>.

^{xv} Measure specifications can be found on the National Quality Forum Quality Positioning System: <http://www.qualityforum.org/QPS/0384>

^{xvi} See <http://www.qualityforum.org/QPS/0383>

^{xvii} Emphasis added. The measure submission form can be found at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70617>

^{xviii} See the NQF Quality Positioning system at <http://www.qualityforum.org/QPS/0576>. The measure submission form can be found at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70617>