American Hospital Association

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June 26, 2014

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

RE: CMS-1607-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 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record Incentive Program (Vol. 79, No. 94), May 15, 2014.

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) 2015. We will submit comments separately on CMS's proposed changes to the long-term care hospital (LTCH) PPS.

While we support a number of the inpatient PPS proposed rule's provisions, we have serious concerns about certain aspects of the Hospital-acquired Condition (HAC) Reduction Program proposals, the Inpatient Quality Reporting (IQR) program proposals and the proposed changes to the cost report requirements related to the jurisdiction of the Provider Reimbursement Review Board (PRRB). In addition, as CMS requested, we provide our views on the design of an alternate payment methodology for short inpatient hospital stays, which would supplement the existing "two-midnight" policy.

HAC REDUCTION PROGRAM

Beginning in FY 2015, the Affordable Care Act (ACA) requires CMS to impose a 1 percent reduction in Medicare payments for hospitals in the top quartile of risk-adjusted national HAC rates. America's hospitals are deeply committed to reducing preventable patient harm, and support quality measurement and pay-for-performance programs that effectively promote improvements in patient safety. Our longstanding principle is to support value-based approaches that promote attainment and improvement. **However, the AHA remains very concerned that the HAC policy is poorly designed.**

The overlap of measures between the HAC program and the hospital value-based purchasing (VBP) program creates the potential for unfair double payment penalties, and could send conflicting signals about the true state of hospital performance. For example, a hospital could incur a penalty under the HAC program, signaling poor performance on the HAC measures, but receive an incentive under the VBP program, signaling good performance on the VBP measures (including HACs). Moreover, the claims-based patient safety composite indicator (PSI 90) comprising 35 percent of a hospital's performance falls well short of the level of rigor needed for measures in accountability applications. We also are deeply concerned that the current measures in the program disproportionately penalize teaching and large hospitals (more than 400 beds). **Therefore, the AHA urges CMS to adopt several changes to the HAC program – such as eliminating the overlap of measures between the HAC and VBP programs, and developing a plan to identify and implement alternative measures to the PSI 90 – that would more effectively promote hospital improvements in patient safety, and improve the fairness of the program.**

IQR PROGRAM CHANGES

CMS proposes extensive changes to the IQR program, including an expansion of the voluntary electronic clinical quality measure reporting option, the removal of 15 chart-abstracted measures, and the addition of five new measures. The AHA strongly supports the long-term goal of using electronic health records (EHRs) to streamline and reduce the burden of quality reporting while increasing access to real-time information to improve care. **Nevertheless, we are concerned that some of the proposed methods to encourage participation in the voluntary electronic reporting option and to align clinical quality measure reporting in the IQR program and Medicare EHR Incentive Program undermine the goals of the IQR Program – namely, continuous hospital quality improvement.** The AHA also is concerned that CMS proposes several new measures for the IQR that lack the scientific rigor needed for public reporting.

COST REPORT REQUIREMENTS AND PRRB JURISDICTION

The AHA urges CMS to abandon its proposal to eliminate the current provision that gives the PRRB jurisdiction over specific items on a provider's cost report when the provider either claims reimbursement on its cost report for the item or self-disallows the item and files the cost report under protest. CMS also should withdraw its proposal that would require a provider to include on its cost report all items for which it is requesting payment as a condition for payment for those items. CMS's proposed change would inappropriately limit hospitals' ability to exercise their appeal rights based solely on the discretion of Medicare Administrative Contractors (MACs). CMS proposes to vest the MACs with overly broad

authority over hospitals' ability to correct items on the cost report, even in circumstances where hospitals did not and could not have accurate information. In light of these concerns, the AHA strongly urges CMS not to adopt these proposals.

ALTERNATIVE METHODOLOGY FOR SHORT INPATIENT HOSPITAL STAYS

CMS finalized its "two-midnight" policy in the FY 2014 inpatient PPS final rule. Under this policy, CMS will generally consider hospital admissions spanning two midnights as appropriate for payment under the inpatient PPS. We appreciate CMS's attempt to clarify what is required for payment of inpatient hospital services under Medicare Part A and support the agency's decision to pay for these cases under Part A. In contrast, hospital stays of less than two midnights will generally be considered outpatient cases, regardless of clinical severity.

The AHA strongly believes that CMS must appropriately and adequately reimburse hospitals for the care they provide. The existing two-midnight policy fails to meet this standard for medically necessary inpatient stays that span less than two midnights. However, we believe that a short-stay payment (SSP) policy, which would supplement the existing two-midnight policy, could reimburse hospitals more accurately for the resources they use to treat beneficiaries during these short stays. We offer a set of principles that CMS should consider in crafting an SSP policy.

At the highest level, we believe the decision about whether to admit a patient to the hospital for inpatient hospital services should be made by a physician, in accordance with the physician's medical judgment. CMS itself professes to hold physician judgment paramount, but the two-midnight policy is based on an arbitrary standard that clouds the role of physician judgment and seems to override the agency's longstanding policy. At least, the two-midnight and SSP policies would then govern how admissions are paid.

Our detailed comments on the proposed rule are attached. If you have any questions, please feel free to contact me or Priya Bathija, senior associate director, policy, at (202) 626-2678 or pbathija@aha.org.

Sincerely,

/s/

Linda E. Fishman
Senior Vice President
Public Policy Analysis & Development

American Hospital Association
Detailed Comments on the Inpatient Prospective Payment System Proposed Rule for FY 2015

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MEDICARE SEVERITY DIAGNOSIS-RELATED GROUP (MS-DRG) DOCUMENTATION AND CODING ADJUSTMENT

The Centers for Medicare & Medicaid Services (CMS) proposes a cut of 0.8 percentage point in fiscal year (FY) 2015 to 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. This is in addition to the cut of 0.8 percentage points that was finalized by CMS for FY 2014. **While we continue to believe these congressionally mandated adjustments are not warranted, we appreciate the agency's proposal to help mitigate extreme annual fluctuations in payment rates and provide hospitals with additional time to manage these sizeable cuts.**

In addition, although CMS proposes no additional documentation and coding cuts for FY 2015, it does indicate that its previously proposed *prospective* cut of 0.8 percentage points related to hospitals' documentation and coding in FY 2010 may be appropriate in future rulemaking. We continue to believe that this documentation and coding cut is overstated. In the FY 2014 inpatient prospective payment system (PPS) final rule, CMS agreed that the 0.8 percentage point figure was overstated and indicated that a cut of 0.55 percent would be more appropriate. Additionally, we note that our previous assertion that CMS's coding cuts are overstated is not limited to only the prospective 0.8 percentage point cut related to FY 2010 – it also applies to the recoupment cuts the agency made related to FYs 2008 and 2009. We remain 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 urge CMS not to propose any documentation and coding cuts, beyond those required by ATRA, in future rulemaking.**

DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENT CHANGES

FY 2015 DSH PAYMENT CALCULATION

The Affordable Care Act (ACA) requires that, beginning in FY 2014, hospitals initially receive 25 percent of the Medicare DSH funds they would have received under the DSH formula in place prior to FY 2014 – "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 distributed based on the proportion of total uncompensated care each Medicare DSH hospital provides relative to the national total.

Empirically Justified DSH Payments. CMS proposes to continue distributing empirically justified DSH payments in the exact manner in which DSH payments were distributed prior to FY 2014, but at 25 percent of the amount of what otherwise would have been paid. CMS estimates that the empirically justified Medicare DSH payments for FY 2015 will be $3.551 billion (25 percent of the total amount estimated). CMS also proposes, as it did in FY 2014, that

it will continue to cost-settle these payments at the appropriate level on the cost report. **The AHA continues to support these proposals.**

Uncompensated Care Payments. CMS proposes to calculate uncompensated care payments based on the three-factor formula the agency finalized in its FY 2014 inpatient PPS final rule.

- *Factor 1 – The Initial Size of the 75-percent Uncompensated Care 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 continue 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 continues to support these proposals.**

  For this proposed rule, CMS used the Office of the Actuary's (OACT) February 2014 estimate of Medicare DSH payments to determine the proposed size of the 75-percent pool. CMS estimates the total amount of Medicare DSH payments that otherwise would have been paid for FY 2015 to be $14.205 billion. Therefore, the initial size of the 75-percent pool would be $10.654 billion. **The AHA supports these proposals.**

- *Factor 2 – 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. Using the Congressional Budget Office's (CBO) February 2014 estimate of the effects of the ACA on health insurance coverage, CMS proposes to use a rate of uninsurance of 16 percent for calendar year (CY) 2014 and rate of uninsurance of 14 percent in CY 2015. CMS then weighted these figures appropriately to determine the rate of uninsurance for FY 2015. When the statutory formula for calculating the change in the uninsured is applied to these numbers, it results in 80.36 percent – or $8.56 billion – of the 75-percent pool being retained in FY 2015. This amounts to a reduction of about $132 million in Medicare DSH payments in FY 2015 compared to FY 2014. **The AHA supports these proposals.**

- *Factor 3 – Determining Hospitals' Additional DSH Payments*. CMS's proposed formula would continue to 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 reports; for FY 2015, this is hospitals' FY 2011 or 2012 cost reports (including the FY 2011 SSI ratios). The agency would calculate the percentage of total Medicaid and Medicare SSI days among DSH hospitals for which each DSH hospital accounts. Hospitals would then receive this same percentage of what remains of the 75-percent pool as their additional DSH payment. **The AHA supports these proposals. However, in the inpatient PPS final rule, we urge**

CMS to update the most recent dataset used to calculate the additional DSH payments using the latest available cost report information. We also 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. Finally, the agency should consider implementing a stop-loss and stop-gain policy to limit the amount by which a hospital's DSH payment could change in a single year.

HOSPITAL MERGERS

CMS proposes to address a discrepancy related to determining the uncompensated care payment, Factor 3, for merged hospitals. CMS proposes to define a merger as an acquisition where the Medicare provider agreement of one hospital is subsumed into the provider agreement of the surviving hospital. Accordingly, acquisitions where the new owner voluntarily terminates the Medicare provider agreement of the hospital it purchased by rejecting assignment of the previous owner's provider agreement would not be considered a merger. **The AHA supports this proposal.**

In the FY 2014 inpatient PPS final rule, CMS calculated Factor 3 for merged hospitals using only the surviving hospital's cost report data and Medicare SSI ratio data – which reflect the uncompensated care burden of only that hospital pre-merger and do not accurately reflect the uncompensated care burden for the newly merged hospital. At the request of the AHA and others, CMS now proposes to use the combined uncompensated care burden of the two hospitals that merged in calculating Factor 3. CMS also published a table containing a list of mergers that the agency is aware of, along with the computed uncompensated care payment for each merged hospital, and requested comment on the accuracy of this information. **The AHA supports this proposal and encourages CMS to carefully review comments received by hospitals to ensure that it has developed a complete and accurate list of all impacted mergers. In addition, the AHA requests that hospitals be given an additional 60 days following publication of the FY 2015 inpatient PPS final rule to comment on the accuracy of the updated merger information we presume the agency will publish in that rule.**

WORKSHEET S-10

In the FY 2014 inpatient PPS final rule, CMS discussed the alternative of using Worksheet S-10 of the Medicare cost report to determine the amount of uncompensated care each hospital provides. However, CMS did not propose to use these data to determine the uncompensated care costs at that time because of concerns regarding variations in the data reported on Worksheet S-10 and the completeness of these data. In this proposed rule, CMS indicates that it would be premature to propose to use the Worksheet S-10 for FY 2015. The agency invites public comment on this conclusion and states that it will work with the hospital field and others to develop appropriate clarifications and revisions to the Worksheet S-10 for reporting uncompensated care data – including what would be a reasonable timeline for adopting Worksheet S-10 as a data source for determining uncompensated care costs.

The AHA agrees that the S-10 uncompensated care data are not appropriate for use in FY 2015. 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 on previous occasions, including in a stakeholder discussion group lead by Dobson DaVanzo & Associates, LLC on Jan. 30, 2014. We are restating these concerns and suggestions in this comment letter as well. **We urge the agency to take action to revise and improve both the Worksheet S-10 and the instructions, as discussed below and, once stakeholders have had an opportunity to weigh in on the proposed changes, educate both the field and CMS's contractors about the Worksheet S-10 so that these data could potentially be used as soon as possible. CMS also should consider taking additional steps to verify the accuracy of these data given the concerns about their current validity and completeness.**

Definition of Uncompensated Care. **The AHA recommends that the definition of uncompensated care be broad-based and include all unreimbursed and uncompensated care costs calculated and reported on lines 19 and 30 and summed on line 31 of Worksheet S-10.** A broad definition of uncompensated care costs will be important in accurately measuring a hospital's unreimbursed costs, and it will ensure the most appropriate basis for distributing DSH payments based on uncompensated care payments in the future. Currently, Worksheet S-10 contains two major categories of cost. The first, summarized on line 19, is defined as the unreimbursed costs of Medicaid, State Children's Health Insurance Program, and other state and local government indigent care programs. The second, summarized on line 30, is defined as the uncompensated care costs of charity care and bad debt. Because these categories appear in separate sections of the S-10 Worksheet, it is imperative that CMS combine them when considering any policy on uncompensated care costs.

Inclusion of Direct Graduate Medical Education (GME) Costs in Cost-to-Charge Ratio. The ratio of cost to charges calculation on line 1 of Worksheet S-10 flows from Worksheet C, column 3 (costs) and column 8 (charges). Column 3 costs do not include the cost of direct GME; however, the column 8 charges do include overhead charges that account for direct GME. **To correct this inconsistency, the AHA recommends that the formula calculating the ratio of cost to charges for Worksheet S-10 be modified to include direct GME costs.** This could be accomplished easily by using costs from Worksheet B, column 24, line 118. Direct GME costs are allowable costs, but historically have been excluded on Worksheet C of the Medicare cost report since the Medicare program calculates separately an add-on payment for its share of those costs on Worksheet E-4. However, they are a significant part of the overhead of teaching hospitals; hospital charges by definition are established to help cover direct GME costs, and payment rates are negotiated to reflect the higher costs of teaching facilities. These costs are not related to the costs and charges for physician professional services to patients, which are appropriately removed from the costs and charges used to calculate the ratio of cost to charges. Further, we understand that many state Medicaid plans provide payment to hospitals for direct GME services, either explicitly or built into the state fee schedule. **Including direct GME costs on Worksheet S-10 would more accurately match charges with costs, resulting in a more accurate and appropriate calculation of non-Medicare uncompensated care costs.**

Clarification of Purpose of Lines 17 and 18. Lines 17 and 18 of Worksheet S-10 appear to be informational only since the data on these lines are not included in any of the totals elsewhere on this worksheet. The AHA has received numerous questions regarding both the data to be reported on these lines and the purpose of reporting them since they are not utilized. Line 18 also needs further clarification.

The AHA supports the concept of reporting all revenues, costs and payments related to uncompensated care on Worksheet S-10. However, data unnecessary for the calculations should not be included on this worksheet. **We ask CMS to clarify the purpose of these two lines, both in the near term and for the future. Pending further clarification of the purpose and possible future use of the data on lines 17 and 18, the AHA recommends that lines 17 and 18 be deleted from Worksheet S-10**.

Reporting of Charity Care. AHA members have expressed significant concerns regarding the reporting of charity care on line 20, primarily due to the requirement that the amounts claimed relate to services rendered in the cost-reporting year. In general, this reporting requirement will force hospitals to spend significant additional time documenting charity write-offs. The AHA believes that hospitals will not have identified and resolved all of the charity accounts related to services provided in the current cost-reporting year by the time the cost report is due five months after the close of the hospital's fiscal year. Charity write-offs in a hospital's accounting year include amounts related to services provided in both prior years and the current year. This is generally due to the realities and complexities of working with patients, including changes in specific patient circumstances and time involved in obtaining the necessary documentation from patients. Some hospitals even record a provision for charity care, consistent with the concept of the provision for bad debts. **The AHA recommends that CMS clarify the instructions for line 20 of Worksheet S-10 to allow hospitals to report the amounts written off and expected to be written off for services delivered in the cost reporting year, subject to final documentation at the time of audit.**

In addition, documentation requirements have not been defined. Medicare administrative contractors (MACs) and fiscal intermediaries (FIs) may evolve different processes and reporting requirements to audit and "allow" the charity amounts reported. The AHA requests that CMS provide guidance on the following:

- We request clarification on the plans for MACs/FIs relative to auditing the amounts reported on Worksheet S-10 and recommend that, to ensure consistency, CMS be responsible for developing documentation criteria and overseeing MACs/FIs as they audit compliance with those criteria. **The AHA believes that accepting the charity write-offs included in hospitals' audited financial statements as the amount to be reported on Worksheet S-10 minimizes the need for significant documentation effort by hospitals and audit work by CMS and its MACs/FIs.**

- Under the current S-10 structure, most hospitals will need to submit additional documentation of charity care write-offs after the cost report is submitted due to the

current requirement of reporting only amounts written off related to services during the cost-reporting period. As discussed above, charity write-offs related to the prior year will occur after the cost report has been submitted. This is similar to how final documentation for DSH and bad debt is done after cost report submittal and before finalization of the audit process. **The AHA recommends that CMS allow hospitals to estimate the amount to be written off and provide final documentation at the time of audit.**

TWO-MIDNIGHT POLICY – SHORT-STAY PAYMENT METHODOLOGY

TWO-MIDNIGHT POLICY

CMS finalized its "two-midnight" policy in the FY 2014 inpatient PPS final rule. Under this policy, CMS will generally consider hospital admissions spanning two midnights as appropriate for payment under the inpatient PPS. We support the decision to pay these cases under Part A. In contrast, hospital stays of less than two midnights will generally be considered outpatient cases, regardless of clinical severity. **Although we appreciate CMS's attempt to clarify what is required for payment of inpatient hospital services under Medicare Part A, the two-midnight policy is an arbitrary time-based benchmark that clouds the role of physician judgment. CMS itself professes to hold physician judgment paramount, but this arbitrary standard seems to override that longstanding policy.**

The two-midnight policy also fails to reflect the way hospitals function today. While it may address some problems, it has generated many others. For example, hospitals and CMS needed far more time to comply with the two-midnight policy than the two months CMS initially provided for implementation. Hospitals needed additional time to evaluate and change internal policies, update existing electronic medical record systems, alter work flow processes and provide extensive education to hospital staff and physicians to ensure compliance with the new policy. CMS needed additional time to issue clear, detailed and precisely written guidance to hospitals and Medicare review contractors. Fortunately, CMS and Congress agreed that more time was necessary and both have issued partial enforcement delays that now postpone enforcement of the two-midnight policy through March 31, 2015. **The AHA appreciates these partial enforcement delays, which have allowed hospitals, Medicare review contractors and CMS additional time to implement this complex policy. We recommend that CMS extend these partial enforcements delays until it implements an alternate payment methodology for short inpatient hospital stays, as discussed below.**

The two-midnight policy fails to provide adequate reimbursement for beneficiaries who require an inpatient level of care, but who do not meet the two-midnight benchmark for admission. Specifically, CMS reimburses for this care under the outpatient PPS, which does not cover the cost of the inpatient level of care that is provided and typically results in a higher cost-sharing burden for the beneficiary. The AHA has asked CMS to convene potential stakeholders to address this critical flaw and develop a payment methodology that would reimburse hospitals for short inpatient hospital stays (i.e., those stays spanning less than two-midnights).

CMS has requested comment on this issue in the past. For example, as part of the calendar year (CY) 2013 outpatient PPS proposed rule, CMS asked commenters to consider how aligning payment rates more closely with the resources expended by a hospital when providing outpatient care versus inpatient care of short duration might reduce payment disparities and influence financial incentives and disincentives to admit. As part of this proposed rule, CMS now solicits comments on an alternative payment methodology under the Medicare program for short inpatient stays, which would supplement the two-midnight policy. **The AHA appreciates the opportunity to offer its views on the design of such a methodology.**

SHORT-STAY PAYMENT POLICY

The AHA strongly believes that CMS must appropriately and adequately reimburse hospitals for the care they provide. As stated above, the two-midnight policy does not provide appropriate and adequate reimbursement for medically necessary inpatient stays that span less than two midnights. **However, we believe that a short-stay payment (SSP) policy, which would supplement the existing two-midnight policy, could reimburse hospitals more accurately for the resources used to treat beneficiaries during these short stays and would alleviate some problems regarding beneficiary cost-sharing.**

With both the two-midnight policy and the SSP policy in place, physicians would continue to determine whether patients should be admitted to the hospital as inpatients, in accordance with their clinical and medical judgment, as they would have prior to the two-midnight policy. **The two-midnight and SSP policies would govern how admissions are paid.** As a result, if the beneficiary meets the two-midnight threshold, the hospital will receive full Medicare Part A payment under the two-midnight policy. Alternatively, if the beneficiary does not meet the two-midnight threshold, the hospital will receive a reduced inpatient PPS rate under the SSP policy.

The AHA has sought feedback from our members and believes that any SSP policy should be designed based on the following guiding principles:

- The SSP policy should provide more appropriate and adequate reimbursement for medically necessary inpatient services that span less than two midnights – payment should be higher than the outpatient PPS rate for the service, but should not exceed the applicable full inpatient diagnosis-related group (DRG) payment;

- The SSP policy should not apply to those procedures on the "inpatient-only" list, regardless of the length of stay;

- The SSP policy should be budget neutral;

- The SSP policy could be designed similarly to CMS's longstanding transfer policy, which reimburses hospitals a graduated per-diem rate, instead of a full DRG payment rate, to approximate the reduced costs of transfer cases;

- Under the SSP policy, hospitals should be eligible for all add-on payments they would otherwise receive (e.g., DSH, IME) on a pro-rata basis;

- Beneficiaries requiring short inpatient hospital stays reimbursed under the SSP policy should be considered inpatients and cost-sharing obligations should be calculated under Medicare Part A;

- The SSP should be developed in a way that would not increase administrative burden for hospitals, physicians or other medical providers; and

- CMS would provide clear and consistent guidance and allow adequate time for hospitals to implement the SSP policy prior to its effective date.

The specific design of a SSP policy is something that must be addressed in detail and with additional input from potential stakeholders. These details include, but are not limited to, the definitions of a short inpatient hospital stay and an observation stay; the DRGs that may be included or excluded from the SSP policy; how such a policy would apply to non-IPPS hospitals that are subject to the two-midnight rule (e.g., critical access hospitals); and the tools a physician may use in determining whether a patient needs inpatient hospital services. The AHA intends to continue discussions with its members and will provide CMS with additional comments and suggestions on these extremely important details.

In addition to implementing an SSP policy, we encourage CMS to evaluate the adequacy of the outpatient PPS rates Medicare pays for observation care, which is the type of care hospitals often provide while making a determination of whether inpatient admission is appropriate. We do not believe the observation care rates cover hospitals' costs. Because outpatient PPS payment rates are based on the specific procedures a hospital provides to a patient, observation care payment rates historically have been quite low. Specifically, the CY 2014 payment rate for eight or more hours of observation services (furnished in conjunction with a hospital clinic visit and certain high-level emergency department visits) is $1,199. Further, this payment rate is the same whether a patient requires eight hours of observation care, or 48 hours of observation care. Therefore, hospitals receive the same reimbursement, regardless of the length, level or intensity of observation services (e.g., nursing and monitoring services) they actually provide to a patient and, in many cases, the payment rates are far less than the costs incurred by the hospital for providing these services. As a solution, CMS could, for example, consider allowing hospitals to record a room and board charge associated with these services, thereby more accurately reflecting their costs.

We look forward to continuing to work with CMS to further consider these issues of great importance to both hospitals and the Medicare program as well as other potential alternatives that do not compromise the integrity of the DRGs and the PPS.

RECOVERY AUDIT CONTRACTOR (RAC) PROGRAM REFORM

Finally, our members have made it patently clear that even upon implementation of an SSP policy, the two-midnight policy will continue to fail if it is not combined with comprehensive reform and management of the RAC program. Such reform must address the systemic issues that have led to avoidable claim denials and appeals. Without such reform, RACs will continue to second guess the medical judgment of the treating physicians, leading to inappropriate and excessive denials, and resulting in significant strain on hospitals and the appeals process.

For example, as we have previously communicated, we urge CMS to:

- Codify in regulation that the treating physician's judgment is paramount in making the admission decision;

- Impose a financial penalty on RACs when a denial is overturned on appeal – not just to recoup their contingency fee – to provide some check on the strong financial incentive RACs have to improperly deny claims;

- Eliminate application of the one-year timely filing limit to rebilled Part B claims;

- Codify in regulation its assertion in the preamble of the FY 2014 inpatient PPS final rule that RACs are limited to using the medical documentation available *at the time the admission decision was made* when determining whether an inpatient stay was medically necessary;[i] and

- Limit RAC approval for auditing approved issues (such as short inpatient stays) to a particular defined time period, instead of approving them indefinitely, as is now the practice.

In addition, the AHA has previously provided a number of additional actions CMS could take to mitigate the impact on hospitals of the lengthy delays in the Medicare appeals system. These have included, but are not limited to, the following:

- When a hospital appeals to the administrative law judge level (ALJ), CMS should not recoup the disputed funds until after the hospital has received an ALJ determination;

- CMS should enforce the statutory timeframes within which appeals determinations must be made by entering a default judgment in favor of the provider if an appeal has not been heard within the required time period; and

- CMS should provide a mechanism for erroneous denials to be reversed outside of the appeals process.

CMS also must improve oversight of the RAC program to ensure, among other things, that hospitals have an opportunity to avoid appeals by having an adequate and effective discussion period; problems with submitting documentation to RACs in response to additional documentation request are resolved; and claims for procedures on the "inpatient-only list" are no longer wrongly denied by RACs.

PAYMENT REDUCTION

In the FY 2014 inpatient PPS final rule, CMS finalized a *permanent* prospective 0.2 percent reduction to the operating PPS standardized amount as a result of the agency's belief that the two-midnight policy would increase inpatient PPS expenditures by $220 million. **The AHA continues to believe that this *permanent* prospective payment reduction is inappropriate, for reasons we have previously provided to CMS, and we strongly urge the agency to reverse these reductions.**

TWO-MIDNIGHT POLICY – CAH CONDITION OF PAYMENT

Pursuant to statute, for a critical access hospital (CAH) to receive payment for inpatient services, a physician must certify that the beneficiary may reasonably be expected to be discharged or transferred within 96 hours of admission to the CAH. Prior to FY 2014, CMS required that this physician certification be completed no later than one day before the date on which the claim for payment for the inpatient CAH service was submitted. CMS modified this timeframe in the FY 2014 inpatient PPS final rule, as well as in its guidance related to the two-midnight policy, requiring CAHs to complete, sign and document this certification prior to a beneficiary's discharge.

In order to provide CAHs with greater flexibility in meeting this certification requirement, CMS now proposes to revert back to the previous regulations governing the timing of the 96-hour certification: the physician certification would be required no later than one day before the date on which the claim for payment for the inpatient CAH service is submitted. We appreciate CMS's efforts to provide greater flexibility to CAHs, given its limited authority to change, modify or remove this statutory requirement. However, it is unclear whether CMS intends to allow the delayed time frame for *all* requirements of the physician certification or *only* the 96-hour piece of the physician certification requirement. **In order to provide CAHs with the full benefit of this flexibility and to avoid further confusion, the AHA requests that CMS clarify that CAHs have until no later than one day before the date on which the claim for payment for the inpatient CAH service is submitted to complete *all* requirements of the physician certification.**

AREA WAGE INDEX (AWI) – NEW LABOR MARKET DELINEATIONS

CORE-BASED STATISTICAL AREAS (CBSAS) FOR THE HOSPITAL WAGE INDEX

CMS proposes to apply the most recent labor market areas in the FY 2015 inpatient PPS wage index. The most recent delineations were issued by the Office of Management and Budget (OMB) on Feb. 28, 2013 in OMB Bulletin No. 13-01, and include an updated list of CBSAs that

reflect the OMB's new 2010 standards and 2010 Census data. In addition to using the new OMB labor market delineations, CMS proposes to continue to treat Micropolitan Areas as "rural" and to include the Micropolitan Areas in the calculation of each state's rural wage index. **The AHA supports these proposals.**

Because this update will result in a number of significant changes to the existing labor markets, CMS also proposes wage index transition periods applicable to all hospitals that experience negative impacts due to the proposed implementation of the new OMB labor market delineations. For urban counties that have become rural, the agency proposes to continue to apply the urban wage index value of the CBSA where the hospitals are physically located in FY 2014 for a period of three fiscal years. CMS also proposes to use a one-year blended wage index for all hospitals that would experience a decrease in their actual payment wage index *exclusively due* to proposed implementation of the new OMB labor market delineations. These proposed transitions are consistent with those made the last time the agency updated the CBSAs used in the wage index for FY 2005. **The AHA supports these proposals and appreciates CMS's attempts to mitigate the negative effects of the application of the new OMB labor market delineations on hospitals.**

CHANGES TO AWI TIMETABLE

CMS proposes changes to the wage index timetable – the process by which hospitals may review and request revisions to CMS's wage index data files – for FYs 2016 and 2017 to allow hospitals, MACs and CMS more time to review CMS's wage index data files and ensure a more accurate wage index. **The AHA appreciates that CMS is allowing hospitals, MACs and CMS more time to review CMS's wage index data files to ensure a more accurate wage index.**

However, we believe the changes to the FY 2017 wage index timetable would be more effective if hospitals were provided additional time to review the preliminary public use file (PUF) after CMS posts this file. Specifically, we recommend changing the FY 2017 deadline for hospitals to request revisions to the preliminary PUF to early September 2015, as opposed to early August 2015, as CMS proposes. In most cases, hospitals have limited cost-reporting personnel capabilities, which may be further limited by staff availability during the summer months. This short, one-month extension would ensure hospitals can devote sufficient cost-reporting capabilities and resources to reviewing wage index data, and as a result, will lead to more accurate wage index data. This change would apply to future years as well and CMS would need to adjust the remainder of the dates accordingly to allow sufficient time to complete the remaining steps in the AWI timetable.

HOSPITAL-ACQUIRED CONDITION (HAC) REDUCTION PROGRAM

As mandated by the ACA, for FY 2015, CMS will implement the HAC Reduction Program, which imposes a 1 percent reduction to Medicare payments for hospitals in the top quartile of risk-adjusted national HAC rates. The basic payment adjustment approach, measures and scoring methodology used in the program were finalized in the FY 2014 inpatient PPS final rule,

and the agency proposes largely non-substantive refinements for FY 2015. Hospital HAC rates are determined using three measures split into two measurement domains. One domain, which comprises 65 percent of a hospital's score, includes two healthcare-associated infection (HAI) measures – central line-associated blood stream infections (CLABSI) and catheter-associated urinary tract infections (CAUTI). The other domain includes a Patient Safety Indicator composite measure (PSI 90) that combines performance on several safety indicators, such as pressure ulcers, post-operative hip fractures, and post-operative blood clots. For FY 2016, the agency proposes to place a greater weight on the HAI measure domain in determining a hospital's Total HAC Score.

America's hospitals are deeply committed to reducing preventable patient harm, and support quality measurement and pay-for-performance programs that effectively promote improvements in patient safety. Our longstanding principle is to support value-based approaches that promote attainment and improvement. However, the AHA remains very concerned that the HAC policy is poorly designed. We acknowledge that the HAC Reduction Program's statutory requirements prevent CMS from addressing some of the program's most important shortcomings. For example, even though it is arbitrary to do so, CMS must assess HAC penalties on 25 percent of hospitals each year, regardless of any significant improvements in a hospital's performance, whether there is a significant difference between its performance and that of the rest of the field, or the overall progress the field has made in improving performance on measures. Although we strongly believe this requirement fails to promote patient safety improvements, CMS has implemented as reasonable a scoring methodology as permitted by the statute.

In light of these constraints, we have urged CMS to adopt measures that accurately and fairly assess hospital performance on critically important and potentially preventable patient safety issues. CMS has indicated that the measures in the program allow for hospitals to be assessed on a variety of patient safety issues. The three measures in the FY 2015 HAC program also are used in the hospital value-based purchasing (VBP) program, and CMS suggests that the commonality of measures with the VBP program promotes alignment of quality improvement efforts.

In practice, unfortunately, the overlap of measures between the HAC and the hospital VBP programs creates the potential for unfair double payment penalties, and could send conflicting signals about the true state of hospital performance. For example, a hospital could incur a penalty under the HAC program, signaling poor performance on the HAC measures, but receive an incentive under the VBP program, signaling good performance on the VBP measures (including HACs). Moreover, the PSI 90 measure does not have a level of reliability or validity acceptable for measures in accountability applications. We also are deeply concerned that the current measures in the program disproportionately penalize teaching and large hospitals (more than 400 beds). Therefore, we urge CMS to adopt several changes to the HAC program that would more effectively promote hospital improvements in patient safety and improve the fairness of the program. Specifically:

- CMS should eliminate the overlap in measures between the HAC Reduction Program and VBP program.

- CMS should identify and implement alternative measures to PSI 90 so that it can be phased out of the program as soon as possible. For example, the agency could explore the use of measures from the National Quality Forum (NQF) portfolio of safety measures.

- CMS should support innovative approaches to measuring patient safety events, including the work of organizations developing all-cause patient harm measures derived from electronic health records (EHRs). The agency should consider how to incorporate these innovations into the program in future years.

- CMS should adopt an exemption process for hospitals whose HAC Reduction Program performance may be affected by natural disasters or other extenuating circumstances beyond their control.

These recommendations are outlined in greater detail below.

ELIMINATING THE MEASURE OVERLAP WITH VBP

Many stakeholders, including CMS, have suggested 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 Reduction Program and VBP program because the programs use disparate ways to identify good versus bad performance. This could lead to inappropriate and unfair double payment penalties, or worse, 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 1 below, the measurement and performance periods of the HAI measures and PSI 90 differ significantly. This alone may cause differences in measure performance.

Table 1: Comparison of HAC Reduction and VBP Baseline and Performance Periods FY 2015

Measure	VBP Baseline Period	VBP Performance Period	HAC Measurement Period
HAI measures	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

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 they perform on certain quality measures or how much their performance improves from a baseline period. The HAC Reduction Program, by contrast, assesses penalties based on scoring in the top quartile of performance.

Based on an analysis of estimated HAC penalties and VBP payments from data in the proposed rule, the AHA has identified indirect, but troubling, evidence that hospitals will experience disparate signals from the VBP and HAC programs. Table 2 below categorizes hospitals by how they are projected to perform under both the HAC and VBP programs. Of the more than 3,300 hospitals potentially eligible for both programs, more than 1,100 hospitals, or 33 percent, will experience a loss under the VBP program, but not incur a HAC penalty. Moreover, 290 hospitals, or nearly 9 percent, will perform well on VBP by experiencing a gain, but also incur a HAC penalty. Thus, in FY 2015, nearly 42 percent of hospitals will have performance on the HAC and VBP program that is not directionally consistent.

Table 2: Projected FY 2015 Hospital Performance on VBP and HACs

Projected FY 2015 Hospital Performance	Number of Hospitals	Percent of Hospitals
VBP Loss, No HAC Penalty	1,113	33.05 %
VBP Gain, HAC Penalty	290	8.61 %
VBP Gain, No HAC Penalty	963	28.59 %
VBP Loss, HAC Penalty	361	10.72 %
No VBP Gain or Loss*, HAC Penalty	110	3.27 %
No VBP Gain or Loss*, No HAC Penalty	531	15.77 %
Total	3,368	100.00 %

*These hospitals are ineligible for the VBP program due to insufficient data.

The AHA is conducting further analysis to determine the extent to which performance on the three measures common to both programs is driving the inconsistency in performance. Given that the VBP's outcome measure domain – which includes both PSI 90 and the two HAI measures – comprises 40 percent of a hospital's total VBP score, we believe that the differences in scoring approaches and data timeframes between the HAC and VBP programs may be contributing at least in part to differences in hospital performance.

The 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, plain and simple. Penalizing organizations because they have not achieved some level of performance without being able to demonstrate clear and achievable strategies in which that level of performance could be reached is both arbitrary and unreasonable. As noted above, the legislative mandate of the HAC program restricts CMS's ability to implement a fairer approach to scoring hospital performance, such as recognizing both improvement and achievement. We would welcome the opportunity to work with CMS to replace the HAC program with a more effective approach to encouraging hospital improvements in patient safety.

Absent a legislative change to the HAC program, the AHA recommends that CMS consider all of its hospital pay-for-performance programs as being part of a comprehensive strategy in which measures are placed into programs using a staged approach. We believe the measures selected for all of the pay-for-performance programs should be valid, reliable and important. The measures chosen for the IQR program, should be the basis for selection into the pay-for-performance programs. Those used in VBP should show variation in performance and some evidence of potentially effective strategies for improving performance. The ones chosen for the HAC program should have generally good, but not "topped out," performance, with a limited performance gap to close and a set of highly effective proven strategies that will lead to improved performance. This 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 option rather than an occurrence of patient harm that may not have been preventable. However, we continue to believe that the legislative mandate to penalize a quarter of hospitals each year regardless of improvement is misguided.

For the reasons outlined above, we urge CMS to use measures in either the VBP or HAC program, not both. We again recommend that CMS retain CLABSI and CAUTI in the HAC 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. We also recommend that CMS use surgical site infection (SSI), *Methicilin-resistant Staphlococcus aureus* (MRSA) and *Clostridium Difficile (C. Difficile),* which will be added to the HAC program in FY 2016 (SSI) and FY 2017 *(*MRSA and *C. Difficile),* in the VBP program before putting them into the HAC program. The agency should monitor performance on these measures to determine when they should be transitioned to 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. Difficile* 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 public reporting of the measures began only in December 2013, meaning there has been limited experience with using the measure in a public reporting application.

PSI-90 MEASURE ISSUES

CMS proposes to change the weights assigned to the two domains of HAC measures. It would increase the weight of HAI measures from 65 percent to 75 percent, while lowering the weight of

the PSI-90 composite from 35 percent to 25 percent. CMS indicates that this change is appropriate because several stakeholders have indicated support for reducing the weight of PSI measures, and because the SSI measure will become part of the HAI measure domain.

The AHA appreciates CMS's responsiveness to stakeholder views about PSI 90 and we support this proposal. However, we continue to have significant concerns about the use of PSI 90 in the HAC Reduction Program because it fails to accurately and meaningfully reflect hospital performance. Therefore, we urge the agency to develop a plan to phase out the PSI measure from future years of the HAC program, and replace it with a more reliable and valid measure or small set of measures.

PSIs use hospital claims data to identify patients that have potentially experienced a safety event. However, claims data do not fully reflect the details of a patient's history, course of care and clinical risk factors. As a result, the rates derived from the measures are highly inexact. PSI data may assist hospitals in identifying patients whose particular cases merit deeper investigation with the benefit of the full medical record. But, the measures are poorly suited to drawing definitive conclusions about hospital performance. For example, a recent study that validated the results generated by PSI 3 (pressure ulcer rates) using direct patient surveillance found that PSI 3 frequently misclassified hospital performance.[ii] This finding is consistent with a CMS-commissioned study showing that many of the individual components of PSI-90 have low levels of reliability.[iii] Adequate measure reliability is critical to ensuring that differences in performance scores across hospitals are, in fact, due to underlying differences in quality and not just random variations in patient populations or in how hospitals capture clinical information and code it into claims.

A recent review of PSI 90 by the patient safety measure review committee of the NQF revealed additional concerns about the reliability and validity of the measure.[iv] In fact, the committee did not recommend the measure, as currently constructed, for continued NQF endorsement. PSI 90 is comprised of individual PSIs reflecting different patient safety issues, and each component PSI is assigned a weight towards calculating the total measure score. The committee noted that the weights assigned to each component may not reflect the relative importance or preventability of each component. For example, the committee expressed concern that PSI 15, which reflects the rates of accidental punctures or lacerations during surgery, has too high a weight. The committee also recommended that the weighting used more explicitly consider "the degree of preventability or actionability by a healthsystem [sic] to reduce it." [v] Lastly, the committee "expressed apprehension about the use of the measure in payment applications."[vi] In response, the measure developer has indicated that the measure will be revised and re-submitted to the committee for review.

The AHA strongly supports the use of NQF-endorsed measures in federal quality reporting and pay-for-performance programs, including the HAC Reduction Program. The NQF endorsement process is designed to bring together multiple stakeholders to assess whether measures are important, scientifically sound, useable and feasible to collect. The fact that the NQF Patient Safety Committee suggests that PSI 90 will require significant changes in order to

be suitable for continued endorsement is a strong indication that the measure is inappropriate for the HAC program.

The AHA also is concerned that PSI 90 focuses predominantly on surgical issues, which may contribute to the fact that large hospitals and teaching hospitals bear the brunt of penalties. 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 program, and some may have significantly higher surgical volumes than others. 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 toward surgical procedures, hospitals that have higher volumes of such procedures are more likely to receive penalties.

ALTERNATIVES TO PSI 90

For the reasons described above, we urge CMS to identify alternative measures that could be used in the HAC Reduction Program in place of PSI 90. In identifying alternative measures for the HAC program, we recommend that the agency use the following guiding principles:

- CMS should identify measures that address a variety of quality and safety issues relevant to a broadest possible range of hospitals. This will help ensure that hospitals do not experience HAC penalties simply because of the types of patients they treat.

- CMS should use only NQF-endorsed measures in the HAC Reduction Program.

- Before proposing measures for the HAC program, the agency should use the formal pre-rulemaking process of the Measure Applications Partnership (MAP). The ACA requires that measures for most CMS quality reporting and payment programs be reviewed by the multi-stakeholder MAP before they are proposed for programs. While the HAC program does not specifically require MAP review, we believe the MAP's perspective is critical to facilitating agreement among all stakeholders about which measures are the most important for national quality efforts.

- CMS should report measures publicly for at least one year before incorporating them into the HAC Reduction Program so that any unintended consequences of measurement and reporting can be addressed. Further, if the safety issue addressed by the measure is important, but it is unclear whether effective strategies exist through which a hospital could effectively reduce the incidence of harm, CMS should consider including the measure in the VBP program before moving it to the HAC program.

One potential source of stronger measures in the short term 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 provided another useful reference by assembling a patient safety "Family of Measures" that identifies suitable measures for possible use in federal programs.[vii] 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, which is a component measure of PSI 90. As noted above, CMS should seek formal MAP pre-rulemaking review of NQF #0201 and any other measure it identifies through this review process.

USE OF EHR-BASED ALL-CAUSE HARM MEASURES

The AHA also acknowledges that CMS may need to embark on longer-term efforts to either re-tool or develop new measures that better address important patient safety topics. In the proposed rule, CMS solicits comment on whether it should use a standardized, EHR-based composite measure of all-cause harm in future years of the HAC Reduction Program. The agency's interest in such a measure stems from the early work of some hospitals that are using EHRs to proactively identify potential and actual harm across their patient populations.

The AHA believes that EHR-enabled approaches to measuring preventable adverse events hold considerable promise for the future, and we strongly encourage CMS to support those hospitals that are engaging in innovation and experimentation in this area. If appropriately designed, EHR-derived measures of adverse events would result in significantly more reliable and valid data than the use of claims data. Such measures also could require significantly less effort to collect and report than measures manually abstracted from patient charts. Several AHA members are participating in efforts to use EHR-derived measures of all-cause adverse events and have reported considerable success in proactively identifying and reducing adverse events.

These exciting efforts are still under development, and not all hospitals have the capacity to deploy all-cause adverse event measures. For this reason, it would be premature to propose a "date certain" for using such a measure for all hospitals. However, we encourage CMS to use its Innovation Center to work with hospitals using such innovative approaches to gain an appreciation for what it would take to scale up such a measure more broadly. The agency also should consider using its authority to test innovative approaches to improving care and reducing cost by providing alternative mechanisms to participate in the HAC program for hospitals that use EHR-based all-cause adverse event measures.

DISASTER/EXTRAORDINARY CIRCUMSTANCES WAIVER

The AHA commends CMS for soliciting input on whether it should adopt a waiver process for hospitals that face natural disasters or other extraordinary circumstances. We are eager to work with the agency to develop fair, consistent waiver processes for all of its quality reporting and pay-for-performance programs. 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 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.

The AHA was pleased that the agency adopted a waiver process for the VBP program in the FY 2014 inpatient PPS final rule. The agency could consider adopting several aspects of that process for the HAC program. For example, hospitals could submit waiver requests to CMS describing how their performance on HAC measures was adversely affected within 60 days of the occurrence of the extraordinary circumstance. This would ensure that hospitals do not seek an advantage on their HAC scores long after a disaster period has ended. We also encourage the agency to develop a mechanism to waive program requirements for an area – such as federally declared disaster areas – when a natural disaster or other extraordinary circumstance affects a region or locale.

HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP)

The HRRP assesses penalties on hospitals for having "excess" readmission rates when compared to expected rates. For FY 2015, CMS proposes to increase the maximum payment penalty to 3 percent of Medicare base operating payments, as required by the ACA. CMS also proposes modifications to how it calculates its total hip and total knee arthroplasty (THA/TKA) measure, as well as how it excludes planned readmissions from the five 30-day readmissions measures used in the program – heart failure (HF), pneumonia (PN), acute myocardial infarction (AMI), chronic obstructive pulmonary disease (COPD), and total hip and THA/TKA. While no additional readmission measures are proposed for FY 2016, CMS proposes to add a readmission measure for patients receiving coronary artery bypass grafts (CABG) to the FY 2017 HRRP.

The AHA is disappointed that CMS has again failed to propose a process for excluding readmissions unrelated to the initial reason for admission in calculating the measures, as mandated by the ACA. We also are very concerned that the agency has again failed to propose to adjust the program's measures for sociodemographic factors. As demonstrated in numerous peer-reviewed publications and further highlighted by a recent draft report from an NQF-convened expert panel, outcomes such as readmissions can be influenced by community factors outside of the control of providers, such as poverty and access to support resources in the community.[viii] **We remain deeply concerned that, without sociodemographic adjustment, readmissions penalties will continue to disproportionately accrue to hospitals treating our nation's poorest and most vulnerable patients.**

MEASURE CALCULATION CHANGES

Planned Readmissions Algorithm. In the FY 2014 inpatient PPS final rule, CMS adopted a "Planned Readmissions Algorithm" intended to exclude planned readmissions from the calculation of readmission rates, as the agency is required to do by the ACA. CMS uses the Agency for Healthcare Research and Quality's (AHRQ) Clinical Classification Software (CCS)

to consolidate thousands of procedure and diagnosis codes into broad categories of procedures and diagnoses. CMS's algorithm then always excludes readmissions for obstetrical delivery, transplant surgery, maintenance chemotherapy and rehabilitation. Readmissions for procedures and surgeries that are considered "potentially planned" also are excluded, as long as the readmission does not have an acute primary discharge diagnosis. However, acute primary discharge diagnoses such as infections are always considered "unplanned" and, therefore, are included in the measure calculations.

With a stated purpose of improving the "accuracy" of the planned readmission algorithm, for FY 2015, CMS indicates that it undertook a "validation study" in which it classified readmissions as planned or unplanned based on chart review, and then compared those results to the claims-based planned readmission algorithm. CMS states that the study was conducted using 634 records from seven different hospitals. Based on that study's findings, CMS proposes to remove two categories of "potentially planned" procedures – therapeutic radiation (CCS 211) and cancer chemotherapy (CCS 224) – stating that its validation study showed that such readmissions for patients who do not have a principal discharge diagnosis of maintenance chemotherapy are generally unplanned. CMS also proposes to add hypertension with complications (CCS 99) to its list of acute principal discharge diagnoses that are always considered "unplanned" and, therefore, would be included in the readmissions rate.

The AHA again commends CMS for incorporating the planned readmission exclusion into the HRRP in the FY 2014 inpatient PPS final rule. We also agree that the algorithm should be periodically updated to ensure its lists of inclusions and exclusions are accurate. However, we believe the proposed changes to the algorithm are substantive enough that the agency should have them reviewed by NQF before finalizing them for the program. As demonstrated by data provided in the rule, CMS's proposed changes would increase the unplanned readmission rates for HF and PN by 0.1 percent, and the rate for THA/TKA by 0.4 percent. This is likely due to the increase in the number of unplanned readmissions included in the measures. While these shifts may appear to be minor, they matter greatly in the context of a payment penalty program in which up to 3 percent of a hospital's Medicare payment is at risk for performance.

Moreover, we are concerned that CMS's proposal to remove two cancer-related CCS groups from the list of "potentially planned" readmissions may have negative unintended consequences. Indeed, patients with cancer diagnoses often have complex clinical needs, and may require re-hospitalization as a part of sound medical care. While identifying strategies for reducing readmissions for cancer patients is important, we are concerned that classifying the readmissions of patients with cancer diagnoses as "unplanned" may provide a disincentive for those patients to receive needed in-hospital care.

We believe that both of the above concerns would qualify the algorithm for an *ad hoc* review under NQF's current measure maintenance policy.[ix] Indeed, the NQF policy includes two criteria directly relevant a review including:

- "There is evidence that implementation of the measure or practice may result in unintended consequences:
    - Use of the measure or practice may result in inappropriate or harmful care"
- "Material changes have been made to a currently endorsed measure." [x]

Given our concerns about the unintended consequences of the algorithm changes for cancer patients, and the marked changes in hospital performance on the measures, we urge CMS to immediately initiate an NQF *ad hoc* review of the algorithm.

Finally, we urge CMS to be more transparent about the changes to its planned readmission algorithm going forward. In the proposed rule, the agency indicates that it performed a validation study intended to improve the accuracy of the planned readmission algorithm. However, the proposed rule does not include any details on the study – it simply indicates how many charts were reviewed, and states CMS's conclusion based on the study. We believe the agency should make additional details on the study publicly available, such as descriptive statistics about the patient population in the sample, and the specific criteria used to judge "accuracy." These details would improve the ability of all interested parties to evaluate the appropriateness of the changes.

THA/TKA Readmission Measure Changes. The current THA/TKA readmission measure is intended to include only those patients undergoing *elective* THA or TKA. As a result, the measure excludes patients whose principal discharge diagnoses from their initial (or "index") hospital stay is femur, hip or knee fractures, since surgeries following such fractures are generally not elective procedures. However, CMS states it received feedback from several hospitals indicating that they code hip fractures occurring during the index hospitalization for THA as either a principal or secondary discharge diagnosis. As a result, the measure inadvertently includes a small number of patients with non-elective THA. Thus, for FY 2015, CMS proposes to exclude patients with hip fractures coded as *either* the principal or secondary diagnosis during the index hospitalization.

The AHA believes this proposed change to the THA/TKA measure likely is appropriate. However, before finalizing it, we recommend that CMS have the change examined by NQF as part of our recommended *ad hoc* review of the updates to the planned readmission algorithm. This will provide an opportunity for multiple stakeholders to understand the rationale behind the change, and reach agreement that it is appropriate.

Applying an Adjustment for Sociodemographic Factors. **The AHA remains gravely concerned about the lack of a sociodemographic adjustment in the HRRP, and we again strongly urge the agency to incorporate such an adjustment as soon as possible.** There is a growing consensus that sociodemographic adjustment for readmission and other outcome measures is urgently needed. As part of its March 2013 report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended that CMS incorporate an adjustment for socioeconomic factors. Most recently, an NQF-convened expert panel issued draft recommendations recognizing that outcomes, such as readmissions, can be influenced by community factors

outside of the control of providers, such as poverty and access to support resources in the community.[xi] The NQF expert panel supported sociodemographic adjustment for outcome measures when there is a conceptual relationship to what is being measured, and evidence that suggests an impact.

The AHA strongly supports the draft recommendations from the NQF expert panel on sociodemographic adjustment, and urges the agency to adopt them as soon as possible. As noted by the expert panel, it has long been known that patient outcomes, such as readmissions, are influenced by factors other than the quality of the care provided. In the context of quality measurement, risk adjustment is a widely accepted approach to account for some of the factors outside the control of providers when one is seeking to isolate and compare the quality of care provided by various entities. **Risk adjustment is meant to create a "level playing field" that allows fairer comparisons of whether providers are doing all they can to ensure the quality of care.** For this reason, NQF's current measure endorsement criteria require that when there is a conceptual relationship and evidence demonstrating a link between an outcome and *clinical* factors such as age, severity of illness and co-morbid conditions, those factors should be included in risk adjustment. Without risk adjustment, provider performance on most patient outcomes reflects differences in the patients being served, rather than true differences in the underlying quality of services provided.

Nevertheless, CMS and others have hesitated to adjust readmission measures for sociodemographic factors, citing concerns that such adjustment may "mask" information about health care disparities. **The AHA strongly agrees that identifying and reducing health care disparities is critically important. However, as the expert panel correctly identifies, the current approach of not adjusting measure scores in accountability programs for sociodemographic factors actually reveals little about health care disparities.** As noted in the draft report, "neither observed nor [sociodemographically] adjusted performance rates *alone* can provide any information on disparities." In order to determine whether disparities exist, one has to examine scores for *each* sociodemographic group. To understand the factors that contribute to disparities, it is necessary to conceptualize what factors might be associated with the outcomes of interest, and then to analyze the relative role of each of those factors in leading to the outcome. The current approach used to measure readmissions does not include this type of analysis, and effectively assumes that any disparities in outcomes are attributable only to either how sick the patient is or to the quality of care provided by the hospital. By contrast, the development of risk adjustment for sociodemographic factors would reveal more information about the potential underlying causes of disparities. Indeed, in order to apply sociodemographic adjustment, measure developers would need to proactively identify and analyze sociodemographic factors associated with patient outcomes, making them more visible and more likely to be addressed.

Some observers assert that socioeconomic adjustment creates a lower standard of care for providers treating disadvantaged patients. **This is not the case. Such adjustment would more accurately hold all of the providers being measured to the *same* standard of care. Adjusting for community factors that influence outcomes would enable more accurate**

comparisons of the quality of care provided by eliminating confounding factors beyond providers' control. The application of sociodemographic adjustment has the same intended purpose as risk adjustment for clinical factors – to create more accurate and fairer comparisons of the quality of care provided.

In the long run, the lack of sociodemographic adjustment could actually entrench health care disparities, to the detriment of both patients and providers. Early experience with the hospital readmissions program clearly demonstrates that hospitals caring for the poorest patients are disproportionately more likely to incur penalties under the program because the measures are not adjusted for sociodemographic factors. Data from the FY 2014 inpatient PPS final rule show that approximately 77 percent of hospitals in the top decile of DSH payments, which reflects how many impoverished patients hospitals treat, incur a readmissions penalty. By contrast, only 36 percent of hospitals in the lowest DSH decile will receive a penalty. If hospitals are to be expected to take on new roles and responsibilities to prevent readmissions, it is imperative that those serving the most economically challenged patients have resources to assist them, and this penalty program deprives them of those exact resources. The NQF expert panel report includes useful guidance on potential adjustment approaches, and we urge CMS to use it to improve the readmissions measures.

ADDITION OF CABG READMISSION MEASURE FOR FY 2017

Under the ACA, CMS may expand the HRRP to include additional disease conditions beginning in FY 2015. For FY 2017, CMS proposes to add a readmission measures for patients discharged after receiving a CABG surgery. The measure uses the same basic methodology as all other measures currently in the HRRP.

The AHA believes that before adding any additional measures to the HRRP, CMS must adjust them for sociodemographic factors and exclude readmissions unrelated to the initial reason for admission. Moreover, the measure is not yet endorsed by NQF, and we strongly urge the agency to use only NQF-endorsed measures in its programs. For these reasons, the AHA does not support the addition of the CABG readmission measure at this time. In general, the ACA requires that CMS use only NQF-endorsed measures in the HRRP. However, for measures added in FY 2015 and beyond, the Secretary may use non-NQF-endorsed endorsed measures. However, the Secretary is required to at least seek NQF-endorsement of the measures and give "due consideration" to "measures that have been endorsed or adopted by a consensus organization identified by the Secretary."

We appreciate that CMS recently submitted the CABG measure for NQF endorsement. However, we believe the agency should await the final outcome of the NQF review. Indeed, all of the other measures in the HRRP were NQF endorsed at the time CMS proposed them, and it would set an unfortunate precedent for CMS to add a non-endorsed measure to the program. NQF endorsement reviews are intended to ensure that measures are backed by evidence, accurate, reliable and feasible to collect. Without NQF-endorsement, hospitals and the public are provided little assurance that hospital performance is being accurately reported, and that payment

penalties are being fairly assessed. This is at least in part why the MAP supported the measure on the condition that it receives NQF endorsement before being placed into the program.

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 five readmissions measures. Any penalties would be applied to *each* Medicare discharge during the fiscal year.

For FY 2015, CMS proposes to again determine the hospital's aggregate payments for all discharges for applicable conditions using Medicare Provider Analysis and Review (MedPAR) claims data. It proposes to use claims with discharge dates on or after July 1, 2010, and no later than June 30, 2013. CMS proposes to again 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 to continue exempting Maryland hospitals, now being paid under the Maryland All-Payor Model, from the HRRP. **The AHA supports this proposal.**

HOSPITAL VBP PROGRAM

As required by the ACA, CMS proposes to fund the FY 2015 VBP program by reducing base operating MS-DRG payment amounts to participating hospitals by 1.5 percent in FY 2014. The VBP program is budget neutral; all funds withheld must be paid out to hospitals. CMS proposes a number of changes to the program beginning in FY 2017. CMS proposes to remove from the program six clinical process of care measures it believes are "topped out." CMS also proposes to add three new measures in FY 2017, and one new measure in FY 2019. In last year's rule, CMS finalized realigned measure domains for FY 2017 based on the National Quality Strategy (NQS). In this year's rule, CMS proposes to change the weighting assigned to the realigned measure domains, and proposes that clinical process measures will count only toward 5 percent of a hospital's VBP performance.

The AHA continues to support several aspects of the VBP program. In general, the AHA favors pay-for-performance programs, such as VBP, that assess multiple aspects of care, and that recognize providers for both achievement versus national benchmarks and improvement versus baseline performance. We believe this incentive structure can provide greater inducement for providers to improve performance.

However, as noted in our comments on the HAC Reduction Program, the AHA is concerned about the overlap of measures between the VBP and HAC programs given the different constructions and goals of each program. We urge CMS to ensure the programs do not provide hospitals with conflicting signals or double payment penalties by using measures in either the VBP or the HAC program, and not both. We refer the reader to the HAC program section of this letter for our specific suggestions for which measures are appropriate for each program.

Moreover, the AHA believes that CMS's proposed new measures for FY 2017 and FY 2019 are premature since the measures have not yet been publicly reported for a full year, as required by the ACA. Lastly, we urge CMS to address the shortcomings of the mortality measures in the Clinical Care-Outcome measure domain.

Our comments on CMS's specific proposals are outlined below.

FY 2017 PROPOSED REMOVAL OF TOPPED OUT MEASURES

The AHA supports CMS's proposals to remove six "topped out" measures from the VBP program. Specifically, CMS considers a VBP measure topped out if:

- The difference in performance between the 75th and 90th percentile is statistically insignificant; and

- The truncated coefficient of variation (TCV) is less than 0.10. TCV is a statistic with a score ranging from 0 to 1 reflecting the variation of scores across a sample. The larger the TCV, the greater the variation in performance.

We believe it is appropriate for CMS to employ specific criteria for determining whether measures have "topped out," and appreciate that the agency continually reviews the measures in the program to determine whether it is appropriate to remove them.

FY 2017 NEW MEASUREMENT PROPOSALS

CMS proposes three new NQF-endorsed measures for the FY 2017 VBP program:

- ***Methicillin-resistant Staphylococcus aureus* (MRSA) Bacteremia.** This HAI measure is collected and reported using the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) application. This measure would be added to the Safety domain of measures established in last year's inpatient PPS final rule.

- ***Clostridium difficile (C. Difficile)*.** This HAI measure also is collected and reported using the CDC's NHSN application, and would be added to the VBP Safety measure domain.

- **PC-01: Elective Delivery Prior to 39 Completed Weeks Gestation.** This chart-abstracted measure assesses the proportion of patients with elective vaginal deliveries or

elective Cesarean sections between 39 and 37 weeks of delivery. CMS proposes to add the measure to the Clinical Care – Process measure domain.

In general, the AHA believes that all three measures are promising additions to future VBP programs. However, we are concerned that proposing them now is premature, as they have yet to be publicly reported for a full year, as required by the ACA. Indeed, public reporting of all three measures on *Hospital Compare* began in December 2013. We recommend that CMS not finalize the measures in this year's rule, monitor the public reporting of these measures for the remainder of CY 2014, and re-propose them in the FY 2016 inpatient PPS rule.

When selecting measures for adoption in the VBP program, CMS is required by statute to use only those measures that are reported as part of the IQR program. **Moreover, those IQR measures must be publicly reported for at least one year before they become part of the VBP program.** CMS acknowledges this in the proposed rule when describing its intent to propose the three-item Care Transition Measure (CTM-3) in future rulemaking. CMS specifically states it will propose the CTM-3 measure "once [it] has been publicly reported on *Hospital Compare* for one year, *in accordance with the statutory requirements of the Hospital VBP program*" (emphasis added). Experience with public reporting measures is critical because it helps all stakeholders understand and identify any potential negative unintended consequences of measurement and public reporting. Indeed, the MAP agreed with this assessment when it conditionally supported the MRSA and *C. Difficile* measures, and urged that there be adequate experience with public reporting of the measure before adding them to the VBP. We believe that by deferring these measures for a year, CMS will not only comply with statutory requirements, but also ensure that the measures are appropriate for the program.

FY 2019 MEASURE PROPOSAL

CMS proposes one new measure for the FY 2019 VBP program – Hospital-Level Risk Standardized Complication Rate Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA). This measure was previously finalized for the FY 2015 IQR program and uses Medicare claims data to yield a hospital-level, risk-adjusted complication rate for elective primary total hip and total knee arthroplasty procedures. The measure includes a number of different complications that could range among several different post-discharge periods, including:

- seven days post-discharge: heart attack, pneumonia or sepsis/septicemia;
- 30 days post-discharge: surgical site bleeding, pulmonary embolism or death; and
- 90 days post-discharge: mechanical complications, periprosthetic joint infection or wound infection.

This measure is NQF-endorsed and was recommended by the MAP. CMS initiated public reporting of the measure on *Hospital Compare* in December 2013. **As with CMS's FY 2017 measure proposals, we believe this measure may be appropriate for a future VBP program, but are concerned that proposing it now is premature given that it has not yet been publicly**

reported for a full year. We recommend that the agency monitor the public reporting of the measure for the remainder of CY 2014, and re-propose it in the FY 2016 inpatient PPS rule.

FY 2017 VBP SCORING CHANGES

The VBP's measure domains remained unchanged until last year's inpatient PPS final rule in which CMS adopted, for FY 2017 and beyond, new measure domains aligned with the priority areas of the NQS. As a result of this realignment, CMS also established new domain weights. Specifically, the agency created 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).

In this year's rule, CMS proposes to increase the weight placed on the Safety domain from 15 to 25 percent, and decrease the weight of the Clinical Care – Process sub-domain from 10 to 5 percent. CMS suggests that these changes are warranted because it proposes the removal of six "topped out" measures from the Clinical Care–Process sub-domain and proposes two additional measures for the Safety domain. Moreover, the agency states its desire to provide hospitals with a "strong incentive" to improve patient safety.

The AHA agrees that patient safety measures should be a central component of programs such as VBP. Additionally, we agree that over time, the agency should reduce the weight placed on clinical process measures and focus on outcome measures. The AHA recently engaged hospital leaders in an exercise to identify quality measurement priorities. Of the six areas of the NQS, hospital leaders ranked patient safety issues as the highest priority for national programs. Similarly, there was agreement that rigorous outcome measures should make up most of the measures in programs. **Given that the patient safety domain is largely comprised of well-developed HAI outcome measures, the AHA supports increasing the weight of the safety domain**.

Using Outcome Measures Appropriately. **As CMS transitions to using mostly outcome measures, however, it should pay careful attention to whether those measures reliably assess hospital performance and, therefore, are appropriate for determining payment incentives.** Hospital leaders are eager to transition to a VBP program comprised of mostly outcome measures. However, they believe that such measures should be carefully crafted to ensure they accurately reflect hospital performance, and are appropriately risk-adjusted for issues outside of the control of the organization being measured (e.g., acuity of illness, sociodemographic factors). When measures do not meet these standards, using them to assess hospital performance can have negative unintended consequences, such as penalizing hospitals that care for more acutely ill patients populations.

The AHA continues to be concerned that the three mortality measures in the Clinical Care-Outcomes domain have substantial reliability issues. We urge CMS to develop a plan to improve or replace the mortality measures, and in the interim, to consider temporarily lowering the weight placed Clinical Care-Outcome domain. While it is

reasonable to include mortality measures in the VBP, the evidence to date suggests the measures in the program do not meaningfully reflect hospital performance. 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. We appreciate that in the past two inpatient PPS final rules, CMS has increased the amount of data it uses to calculate baseline and performance period performance. For example, beginning with the FY 2017 program, CMS will use 24 months of data, and with the FY 2018 program, 36 months of data. However, we note that even with 24 months, the CMS commissioned analysis showed that 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.

The AHA supports CMS's long-term vision of using mostly outcome measures. However, we also are concerned about the implications of having a significant portion of a hospital's VBP performance tied to measures with poor reliability. Thus, as transition strategy, we recommend that CMS develop a plan to improve or replace the mortality measures, and consider temporarily reducing the weight assigned to the domain. For example, it could increase the weight placed on the Clinical Care-Process domain. These temporary changes would ensure that hospitals are scored on measures that are an accurate reflection of their performance while CMS transitions to using more reliable outcome measures.

Lastly, we caution that hospitals are on a continuum of quality improvement. Depending on what is being measured, it may be appropriate to use a mix of both process and outcome measures. In the initial phases of improving an aspect of care, hospitals may need both process measures and outcomes measures so that process impediments to improving outcomes are identified. The concurrent use of an outcomes measure enables hospitals to assess the effectiveness of the interventions in improving care. As the performance of the field improves, and the interventions to improving outcomes are established, then a focus on outcome measures may be more appropriate. .

SCORING FOR HOSPITALS WITH DATA ON LESS THAN FOUR MEASURE DOMAINS

In previous rules, CMS finalized a policy that hospitals must have sufficient data to be scored on at least two measure domains in order for the agency to calculate a total performance score (TPS) and, consequently, for hospitals to be eligible for the VBP program. For hospitals with fewer

than four domains, the domains are re-weighted to ensure that the TPS is still a score out of 100 possible points, and so that the relative weights across domains are roughly equivalent to the weights of a hospital with sufficient data in all four measure domains.
However, beginning in FY 2017, CMS proposes to require that hospitals have sufficient data to be scored on at least three out of four measure domains in order to receive a TPS. CMS proposes to continue re-weighting measure domains for hospitals with less than four domains to ensure the TPS is still a score out of 100 possible points, and so that the relative weights across domains remain proportionate to hospitals scored on all domains. **The AHA supports this proposal.**

BASELINE AND PERFORMANCE PERIODS

The AHA supports CMS's proposed FY 2017 baseline and performance periods for FY 2017 for the Safety, Clinical Care-Process and Medicare Spending Per Beneficiary (MSPB) measures. CMS also proposes the FY 2019 and FY 2020 baseline and performance periods for its claims-based measures – PSI 90 (part of the Safety domain), the mortality measures in the Clinical Care-Outcome domain, and the newly proposed THA/TKA measure. CMS has expanded the baseline and performance periods for these measures to include three years of data in an effort to improve measure reliability. **While the AHA appreciates CMS's responsiveness to stakeholder concerns, we continue to be concerned that the mortality measures are not reliable enough for accountability applications.** Moreover, we urge CMS to re-propose the baseline and performance periods for the THA/TKA measures since we do not support finalizing the measure for the VBP program at this time.

FUTURE MEASURES – CARE TRANSITION MEASURE (CTM-3) ITEMS

The NQF-endorsed CTM-3 was incorporated in the HCAHPS survey for the FY 2015 IQR program, and is designed to solicit patient information on hospital care transition planning. CMS will publicly report the first year of CTM-3 data (Jan-Dec 2013) on *Hospital Compare* in October 2014. CMS indicates that it may propose the CTM-3 for the FY 2018 VBP program in future rulemaking.

The AHA supported the addition of the CTM-3 measure to the IQR program, and agrees that CMS should consider it for future years of the VBP program once it has been publicly reported for at least year. At the same time, we strongly encourage CMS to engage in efforts to update the HCAHPS tool as a whole. Hospitals have had nearly a decade of experience with using the HCAHPS in their facilities. While we continue to support the use of the HCAHPS survey, several important survey administration and performance reporting issues have begun to emerge. For example, while the CAHPS survey instruments are available free of charge, hospitals pay vendors to administer the surveys. Those vendors are permitted to use only two survey administration modes – mailed surveys and telephone surveys. Those vendors also provide hospitals with a performance report for internal use and facilitate data reporting to external agencies like CMS. Large hospitals and health systems often include an array of inpatient and outpatient services, each of which uses a different CAHPS survey tool. Typically, hospitals seek to obtain as much data as possible from these surveys. While these additional data add rigor to patient experience performance improvement efforts, hospitals must pay vendors higher fees to obtain a larger sample of responses. **Thus, we urge CMS to begin exploring**

how to employ less expensive survey administration modes, such as emailed or web-based surveys, as a means of alleviating burden. Electronic survey distribution modes, such as email and web-based portals, make survey data collection and aggregation less expensive, and may allow hospitals to increase sample size without greatly increasing costs

The AHA also continues to urge CMS to assess how it adjusts HCAHPS survey scores for the severity of patient illness. As we previously noted, emerging research suggests that patient characteristics may impact 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 believe this trend also may affect scores for other surveys in the CAHPS family. We encourage CMS to conduct an analysis that assesses the extent of the issue, and identifies potential mechanisms for enhancing how CAHPS scores are adjusted for patient factors.

ICD-9 TO ICD-10 TRANSITION

CMS had designated Oct. 1, 2014 as the date to transition to ICD-10. However, the Protecting Access to Medicare Act of 2014 (PAMA) prohibited CMS from implementing ICD-10 before Oct. 1, 2015. CMS subsequently announced that it intends to enforce the transition on Oct. 1, 2015.

In the proposed rule, CMS solicits comment on how the agency should adjust VBP performance scoring to accommodate quality data coded in ICD-10. CMS also indicates it intends to analyze the impact of ICD-10 on the VBP program in two ways. The agency will "assess measure specifications to qualitatively assess impact to measure denominators after CMS releases ICD-10-CM/PCS-based measures in the future." CMS also indicates it will "voluntarily solicit information from no more than nine hospitals before Oct. 1, 2015 to estimate the impact of ICD-10-CM/PCS on their Hospital VBP measure rates and counts" in order to inform future VBP policy decisions. Lastly, the agency indicates that it "might…consider scoring hospitals only on achievement if analysis indicates we are unable to reliably and validly calculate improvement scores when comparing ICD-9-CM based baseline period data to ICD-10-CM/PCS based performance period data."

The AHA agrees with CMS's planned analyses, and urges the agency to make the results of the analyses public when they are completed. However, we would object strongly to any proposal in which CMS chooses to score hospitals only on achievement. By statute, CMS must score hospitals on both improvement versus baseline performance, and achievement versus national benchmarks. Moreover, by design, the VBP program is budget neutral. Thus, if the agency finds that it cannot calculate both improvement scores and achievement scores, then it could "waive" hospital participation until it has adequate data without affecting total hospital reimbursements. The agency also could explore whether it could score hospitals only on those measures for which it has adequate data.

HOSPITAL IQR PROGRAM

CMS proposes substantial changes to the IQR program beginning in FY 2017. The agency proposes new criteria for determining which IQR measures have "topped out" and are, therefore, suitable for removal from the program. It then uses these criteria to propose the removal of 15 chart-abstracted measures for FY 2017. CMS also proposes to add 11 measures to the IQR program.

However, CMS's proposed measure additions and removals have taken on greater complexity because the agency also proposes to retain and expand the option for hospitals to report electronic versions of IQR measures, thereby receiving credit in both the IQR and Medicare EHR incentive programs. While CMS proposes to remove 15 chart-abstracted measures for the FY 2017 IQR program because their performance is topped out, it also proposes to retain the electronic versions of 10 of them to support the voluntary electronic reporting option. Moreover, six of the 11 proposed measures *only* would be part of the voluntary electronic reporting option. Of those six electronic measures, two are actually electronic versions of measures that were previously retired from the program because they were topped out. The agency also indicates its intention to propose mandatory reporting of certain electronic clinical quality measures for FY 2018 IQR payment determination.

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. Nevertheless, we are concerned that some of the proposed methods to encourage participation in the voluntary electronic reporting option and to align clinical quality measure reporting in the Hospital IQR Program and EHR Incentive Program undermine the goals of the IQR program – namely, continuous hospital quality improvement. The AHA also is concerned that CMS proposes several other measures for the IQR that are not NQF-endorsed, and that are not appropriate for public reporting.

Our comments on CMS's IQR proposals are outlined below.

PROPOSED CRITERIA FOR IDENTIFYING TOPPED OUT MEASURES

CMS states that, in previous years, it has used several general criteria to determine whether measures should be removed from the IQR program, including a consideration of whether "measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made." In the proposed rule, CMS proposes to adopt additional quantitative criteria for identifying topped out measures that are very similar to those used in the hospital VBP program. Specifically, the agency proposes to remove measures from the IQR if national measure data meet two specific criteria:

- The difference in performance between the 75^{th} and 90^{th} percentile is statistically insignificant; and

- The coefficient of variation (CV) is less or equal to 0.10.

The AHA supports CMS's proposed new criteria. In applying these criteria, however, we urge CMS to carefully assess the broader context and uses of topped out measures before removing them from programs. In limited cases, retaining measures that meet the quantitative criteria for being topped out may still provide value to patients and hospitals. We appreciate the intent behind CMS's proposal – that is, to provide more specific and, therefore, potentially more objective, criteria for determining topped out performance in the IQR. However, we believe the agency should publicly report measures used in pay-for-performance or payment penalty programs, such as the readmission or HAC program, so that the transparency of measure data are not compromised. Moreover, in some limited circumstances, retaining a topped out measure can help maintain focus on issues where hospitals have achieved high performance. For instance, it is likely that vaccinating health care personnel for the flu will remain important for hospitals in the foreseeable future, even after the measure is topped out. Finally, the agency may wish to retain very few topped out measures because of their basic value in informing a patient and family's decision in selecting a provider. For example, understanding the experience of care in hospitals may be of value to patients, even if HCAHPS scores are considered topped out. Thus, it would be reasonable for CMS to retain HCAHPS in the IQR program until the agency had other reliable, valid measures of patient experience to use in its place.

FY 2017 PROPOSED MEASURE REMOVAL

Using its criteria for topped out measures, CMS proposes to remove 15 chart-abstracted measures from the IQR program. However, it proposes to retain the eCQM versions of 10 of those measures for use in the voluntary electronic reporting option. CMS also proposes to remove a structural measure – Participation in a Systematic Database for Cardiac Surgery – from the program on the recommendation of the MAP. Finally, CMS proposes to remove four previously suspended measures from the program. CMS's proposed measure removals are summarized below.

Topped-Out Measures Proposed for Permanent Removal:

- Participation in a systematic database for cardiac surgery
- HF-2: Evaluation of left ventricular systolic function
- SCIP-Inf-3: Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)
- SCIP-Inf-4: Cardiac surgery patients with controlled postoperative blood glucose
- SCIP-Card-2: Surgery patients on beta blocker therapy prior to arrival who received a beta blocker during the perioperative period
- SCIP-VTE-2: Surgery patients who received appropriate venous thromboembolism (VTE) prophylaxis within 24 hours prior to surgery to 24 hours after surgery

Topped-Out Measures Proposed for Removal as Chart-Abstracted Measures and Retention for the Voluntary Electronic Reporting Option:

- AMI-8a: Primary Percutaneous Coronary Intervention (PCI) received within 90 minutes of hospital arrival

- PN-6: Initial antibiotic selection for community-acquired pneumonia (CAP) in immunocompetent patients
- SCIP-Inf-1: Prophylactic antibiotic received within one hour prior to surgical incision
- SCIP-Inf-2: Prophylactic antibiotic selection for surgical patients
- SCIP-Inf-9: Urinary catheter removed on postoperative day 1 (POD1) or postoperative day 2 (POD2) with day of surgery being day zero
- STK-2: Discharged on antithrombotic therapy
- STK-3: Anticoagulation therapy for atrial fibrillation/flutter
- STK-5: Antithrombotic therapy by the end of hospital day two
- STK-10: Assessed for rehabilitation
- VTE-4: Patients receiving un-fractionated Heparin with doses/labs monitored by protocol

Topped-Out, Previously Suspended Measures Proposed for Permanent Removal:

- AMI-1: Aspirin at arrival
- AMI-3: ACEI or ARB for left ventricular systolic dysfunction- AMI Patients
- AMI-5: Beta-blocker prescribed at discharge for AMI
- SCIP-Inf-6: Surgery patients with appropriate hair removal

The AHA supports CMS's proposed removal of the 15 chart-abstracted measures, the cardiac surgery participation measure, and the four previously suspended measures from the IQR. However, we do not support its proposal to retain the electronic versions of 10 of them to support the voluntary electronic reporting option. Our specific concerns about retaining electronic versions of IQR measures are detailed in the next section of this letter.

VOLUNTARY ELECTRONIC REPORTING OPTION FOR IQR MEASURES

The AHA appreciates CMS's recognition of the quality reporting burden placed on hospitals and the effort associated with developing a reporting option within the Hospital IQR Program that attempts to minimize duplicate submissions of clinical quality measure reports by hospitals. In the FY 2014 inpatient PPS final rule, with a stated purpose of fostering greater alignment between the Medicare EHR Incentive Program and the IQR, CMS created an option to voluntarily report electronic clinical quality measure (eCQM) versions of IQR measures, thereby receiving credit in both programs.

We acknowledge some proposed improvements in the voluntary electronic reporting option for FY 2015. Two proposals are positive: permitting participants to report on any 16 of the 28 eCQMs in the EHR Incentive Program that are electronic inpatient clinical quality measures and secondly, requiring a full year of reporting for each of the measures selected rather than permitting one quarter of data to be sufficient to assess a full year of performance.

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. Nevertheless, we are concerned that some of the proposed methods to encourage participation in the voluntary electronic reporting option and to align clinical quality

measure reporting in the Hospital IQR Program and EHR Incentive Program undermine the goals of the IQR program, namely continuous hospital quality improvement. Rather than consider exceptions to IQR program requirements, the AHA recommends that CMS leverage the data from the EHR Incentive Program for insight and development of a report on lessons learned to date from hospitals' experience with certified electronic health record technology (CEHRT), and their use for eCQMs. In addition, we urge CMS to make the report publicly available to foster shared learning and opportunities for improvement. Finally, CMS should implement the recommendation included in the March 2014 Government Accountability Office report on the EHR program that was specific to eCQMs:

> *Develop a comprehensive strategy for ensuring that CQM data collected and reported using certified EHR technology are reliable, including testing for and mitigation of reliability issues arising from variance in certified EHR systems tested to different CQM specifications.*

We offer comments on specific provisions in the FY 2015 IPPS proposed rule pertaining to eCQMs.

Reporting Topped Out Measures Solely for Electronic Reporting Experience is an Unnecessary Duplication of the Role of the EHR Incentive Program. The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted under the American Recovery and Reinvestment Act of 2009 (ARRA), (P.L. 111-5), specifies the reporting of clinical quality measures as one of three elements of meaningful use, specifically the use of CEHRT to submit information on clinical quality and other measures. In rulemaking for the EHR Incentive Program, CMS has shown a preference for quality measures that are endorsed by the NQF or that are used in the Hospital IQR Program. Yet, CMS proposes that the voluntary reporting option would include measures that are otherwise being removed from the IQR for being topped out. Moreover, several of these retained measures have been placed in "reserve status" by the NQF, a category of endorsement for measures whose level of national performance is already high and unlikely to further improve.

The proposal to retain topped out measures as eCQMs in the IQR and add four additional measures that are available only as eCQMs is a concerning development. The proposed modification in the voluntary electronic reporting program holds the form of the data collected for quality measurement to a higher scientific significance than the data collected as a metric to assess the delivery of care. The AHA disagrees with this proposal as it would neither lead to improved hospital quality nor offer CMS insight on how to improve eCQMs. We recommend that CMS work with Office of the National Coordinator for Health Information Technology and AHRQ to study the feasibility, reliability and validity of eCQMs to effectively calculate and report clinical quality measures that are at least as accurate as chart-abstracted measures.
Public Reporting of eCQMs Should Not Precede Validation of eCQMs for Clinical Fidelity. CMS is aware that the measure specifications used by CEHRT to support eCQMs do not result in accurate representations of quality measure performance. The Medicare EHR Incentive Program FAQ 3601 states that, for the purpose of reporting clinical quality measure data, CMS does not

require providers to record all clinical data in their certified CEHRTs at this time, and the agency acknowledges that the resulting values are not the same as values generated by chart-abstraction. The proposed rule also states that hospitals participating in the voluntary electronic reporting option will not have to validate the eCQMs by submitting chart-abstracted data for the same measures. The proposed rule adds that CMS will conduct a pilot test of validation activities in FY 2015 in which up to 100 hospitals would voluntarily allow a CMS Clinical Data Abstraction Contractor (CDAC) with limited remote access to abstract information from specific hospital data sources that also flow into EHRs and compare the abstracted data with the EHR-generated eCQM data file. The pilot test will not determine the reliability of the contractor abstracted data or the EHR-generated data in comparison with clinical quality measure data generated for the same measure from chart-abstraction.

As stated in our June 2013 comment letter on the FY 2014 inpatient PPS proposed rule, hospitals expect quality measures with identical measure titles to yield similar results regardless of the measure calculation method. To date, eCQMs 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 remains 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. Accepting data generated from CEHRT that have not been validated as comparable to chart-abstracted data to satisfy the IQR impairs the continued success of the IQR program and creates a significant impediment to moving any of measures deemed appropriate into the VBP program over the next few years. The proposal to simply not display data for eCQMs on *Hospital Compare* for any hospital that chooses to participate in the voluntary electronic reporting option also would fail to provide the public with reliable data for quality measures of importance such as stroke and VTE. The AHA recommends that CMS work with other federal agencies and private sector experts to develop the protocols and testing environments needed to begin validation of eCQMs.

CMS reiterates that it will publicly report eCQM data submitted for the voluntary electronic reporting option if deemed accurate enough to be publicly reported. The AHA recommends that CMS communicate the criteria that will be used to determine how and when eCQM data will meet this test of accuracy. Additionally, we urge CMS to clarify whether hospitals participating in the voluntary electronic reporting option in CY 2014 will have a preview period prior to public reporting of data submitted, comparable to the current process followed for data reported on Hospital Compare. The proposed rule outlines processes that will inform hospitals about the treatment of data subject to public reporting in CY 2015 but CMS has not offered a statement of the process that will be followed for public reporting in CY 2014.

<u>The Availability and Use of Certified EHRs Should Inform the Timeline for Requiring the Use of eCQMs in Other CMS Programs</u>. The proposed rule states that CMS intends to propose mandatory electronic reporting to meet IQR requirements beginning in CY 2016. **The AHA recommends that CMS not specify a date for mandatory electronic reporting until significant levels of CEHRT adoption are achieved, and a validation process for eCQMs is**

operational and yielding successful evidence of measure reliability. We believe that the delays in the delivery and use of 2014 Edition CEHRT, potential delays in the hospital experience with the eCQMs finalized in the meaningful use Stage 2 rule and ongoing challenges of generating accurate and reliable data from the eCQMs make any specified date for mandatory reporting speculative. The AHA recommends that CMS continue to support efforts to improve the validity and accuracy of eCQMs. Once it is clear that they generate reasonably accurate portrayals of performance, CMS can identify a timetable for mandatory electronic reporting.

FY 2017 PROPOSED MEASURE ADDITIONS

For FY 2017, CMS proposes five measures outside of its voluntary electronic reporting option. CMS indicates its desire to gradually transition the IQR away from chart-abstracted process of care measures, and to use a greater number of measures assessing outcomes and efficiency and cost.

As noted in our comments on the VBP program, we support CMS's long-term evolution of its measurement programs to emphasize outcomes. However, the AHA cautions that not every outcome measure is appropriate for use in programs, and that in some cases, process measures can add value. While we strongly agree that outcomes, efficiency and cost have significant value, hospital quality improvement efforts can benefit from a variety of measure types. Moreover, CMS must select outcome, cost and efficiency measures that accurately and reliably report on hospital performance, and that are appropriately risk-adjusted.

For this reason, we are very disappointed that four of the five measures proposed by CMS are not NQF-endorsed. The AHA has repeatedly and consistently urged CMS to use only NQF-endorsed measures in federal quality reporting programs, NQF endorsement provides assurance that the measure has been tested, can reliably and accurately collect data, is feasible to implement, and is usable. We also note that the MAP only conditionally supported these measures, and urged that they receive NQF endorsement before being placed into the IQR program. Our comments on each measure proposal are outlined below.

CABG Readmissions. CMS proposes to add a measure assessing the rate of hospital readmissions within 30 days for patients discharged following CABG surgery. It uses the same measure calculation methodology as the other readmission measures previously finalized for the IQR. CMS would calculate the measure using Medicare claims data. It is the same measure that CMS also proposes for the HRRP. **The AHA does not support this measure for either the HRRP or the IQR.** As noted in our comments on the HRRP, we urge CMS to incorporate an adjustment for sociodemographic factors and obtain NQF endorsement of the measure before finalizing it for the program.

CABG Mortality. CMS proposes to add a measure assessing risk-adjusted hospital mortality rates within 30 days for patients discharged following CABG surgery. The measure uses the same basic methodology as the other mortality measures previously finalized for the IQR, and is calculated using Medicare claims data. The measure is not yet NQF-endorsed, and the MAP only supported the measure only on the condition that it receives NQF endorsement before being

added to the program. **The AHA agrees with the MAP's assessment of the measure, and does not support its inclusion in the IQR until it has obtained NQF endorsement.** Given that the design of the measure is similar to that of other CMS mortality measures, we also urge CMS to improve the measure's reliability before implementing it in the IQR.

Heart Failure (HF) Payment per Episode of Care. This non-NQF-endorsed proposed measure calculates total payments for Medicare fee-for-service patients with a primary discharge diagnosis of HF 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, which influence resource use and, therefore, payment. CMS indicates that the measure, when paired with the HF mortality and readmission measures already in the IQR, can provide insight into the "value" of the care that hospitals deliver.

The AHA agrees that well-designed measures of cost that assist with assessing the value of care are urgently needed. However, we oppose the adoption of this particular measure for a number of reasons. The measure is being proposed for hospital-level quality measurement despite the fact that it reflects the actions of a multitude of health care entities, some of which are beyond hospitals' control. In general, a performance measure should assess processes and outcomes over which the measured entity (e.g., hospital, physician group) can exercise a reasonable level of control. Some hospitals are at the center of highly integrated delivery systems, or participating in bundled payment arrangements that include a range of services across the care continuum. In reality, however, there is considerable national variation in the mix of services and degree of integration in health care markets. Moreover, data clearly demonstrate that costs within 30-day episodes of 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 demonstrates that, on average, HF patients discharged alive have nearly three "sequence stops" in their care pathway during a 30-day episode of care.[xiii] These sequence stops ranged from inpatient care to inpatient rehabilitation facilities, to outpatient care provided by physicians, and are combined in many different permutations.

Additionally, the HF measure, along with the very similarly-constructed AMI measure finalized in last year's inpatient PPS proposed rule, is undergoing review by the NQF Cost and Resource Use Measure Committee.[xiv] The committee has yet to recommend the measures for endorsement, and its review uncovered substantial flaws with the measures, including their risk adjustment and attribution approaches. We believe CMS should immediately suspend the AMI measure from the IQR program, and not finalize the HF measure until the measure developer can addresses these issues.

Risk adjustment is critically important for cost measures. A variety of clinical and other factors beyond the control of providers can contribute to higher costs. Yet, the R-squared values for the

risk adjustment model – which reflect how much of the variation in performance is explained using the risk adjustment model – are very low for both measures (0.05 for AMI, 0.03 for HF). The developer suggests that lower R-squared values are to be expected with these measures because some variables that contribute to cost – e.g., complications of care – are under the control of providers and should not be included in risk adjustment. While this argument may be true for complications occurring *during* the episode, it is not enough to explain the low level of reliability demonstrated by the measures' risk adjustment model.

We believe that this low level of reliability illustrates another fundamental flaw of both measures – that is, they fail to adequately account for complicating conditions that patients have *prior* to an episode of care. These complicating conditions can markedly affect the costs of treatment, but the current risk adjustment model has limited ability to distinguish between conditions that a patient already has, and those that develop during the episode. Without risk adjustment or exclusions, a measured entity could appear to have higher costs than others simply because it cares for more complex patients. For example, HF patients that have had either heart transplant or VADs are likely to have significantly higher costs than other HF patients. However, the measures exclude heart transplant and VAD patients only if a heart transplant or VAD placement is performed **during the episode of care**. As recommended by the Technical Expert Panel (TEP) convened to review the measures when they were under development, we strongly urge the developers to embed a "look back" mechanism into the measures. For example, the HF measure should include a look back to determine whether a heart transplant or VAD placement occurred for a patient within at least the previous 12 months.

Finally, the AHA shares the concern of the committee about the attribution of transfer patients. Overall performance on the AMI and HF measures is attributed to the hospital that first admits a patient under the premise that the first admitting hospital "sets the course" for a patient's management during the 30-day episode. Thus, if a patient is transferred to another facility, the costs of care at that second facility are attributed to the first admitting hospital, not to the facility receiving the transfer. This attribution methodology is problematic for several reasons. As noted above, these measures should not be used only to assess the performance of acute-care hospitals. A wide variety of services and care settings are encompassed in 30-day episodes of HF or AMI care, making it essential to carefully select the measured entity. **Moreover, the organization that initially admits a patient may not have as much control over the patient's course of care as the measure implies.** The initial admitting hospital may or may not be part of an integrated delivery system in which it has a close working relationship with hospitals to which a patient would be transferred. **Finally, attributing payments in this way may incentivize suboptimal patient care.** Hospitals considering a medically needed patient transfer would have a stronger incentive to hold onto patients longer to avoid being held accountable for the costs of another facility. The objective of measuring hospitals on cost should not be to reduce needed care, but to encourage that care to be delivered in an efficient manner.

Pneumonia (PN) Payment per Episode of Care. This measure is constructed in a very similar manner to the proposed HF payment per episode of care measure, and the finalized AMI payment measure. **For the same reasons outlined above the HF measure, the AHA does not**

support CMS's proposal to add the PN payment per episode of care measure to the IQR program.

Severe Sepsis and Septic Shock Management Bundle (NQF #500). CMS proposes to add a chart-abstracted measure assessing whether hospitals implement certain care processes that may lead to decreased mortality for patients with severe sepsis and septic shock. For patients with severe sepsis or septic shock, timely intervention is critically important to reducing the risk of death from sepsis. CMS states that timely implementation of all of the interventions included in the sepsis bundle – i.e., measuring patient lactate levels, administration of antibiotics, adequate fluids, monitoring and management of blood pressure and oxygen levels – are associated with lower mortality rates for severe sepsis and septic shock.

The AHA commends CMS for proposing a measure that addresses a critically important patient safety topic. The AHA shares the agency's goal of implementing national standards for sepsis care that lead to the reduction in sepsis morbidity and mortality that we all want to see. However, in light of the recent NQF *ad hoc* review of the proposed sepsis bundle measure, we believe it is premature to finalize it for a national quality reporting program. Given the urgent importance of reducing preventable sepsis, we welcome the opportunity to work with CMS and all other relevant stakeholders to either update the proposed sepsis bundle measure to ensure it is appropriate for hospital measurement, or to identify other reliable, accurate and feasible measures of sepsis for implementation in the IQR.

The NQF's Patient Safety Measure Committee undertook an *ad hoc* review of the sepsis bundle in April 2014.[xv] While the measure has been endorsed since 2008, there has been considerable controversy over one aspect of it. Specifically, the measure specifications require that if patients do not respond to the administration of fluids or vasopressors to raise arterial blood pressure, then the physician should measure central venous pressure and oxygen levels. Performing this step requires the insertion of a central line. When the proposed sepsis bundle measure was designed, the available evidence suggested that the use of the entire bundle – including the measurement of central venous pressure and oxygen levels – led to lowered sepsis mortality.

However, the insertion of central lines carries a risk of infection. Therefore, some experts have expressed ongoing concerns about the sepsis bundle measure. Recent evidence suggests that the measurement of central venous pressure does not lead to improved outcomes. As noted in the NQF report, a recent, multi-center randomized trial compared the invasive approach in the proposed sepsis bundle measure and non-invasive monitoring of pressure and oxygen levels. The study found no difference in sepsis mortality when using the care protocol dictated by the proposed sepsis bundle measure and other non-invasive monitoring mechanisms. As a result, the NQF Patient Safety committee recommended that the sepsis bundle measure no longer require the invasive measurement of central venous monitoring. The committee solicited public comment on its decision in late May 2014.

The AHA applauds the exhaustive work of both the developer of the sepsis bundle and the NQF Patient Safety Steering Committee to weigh the pros and cons of the measure as

currently designed. We strongly urge CMS to take into account the committee's deliberations. We appreciate that the original design of the sepsis bundle has demonstrated promising results in hospitals. However, the results of the recent multi-center trial are compelling, especially since hospitals have been keenly focused on efforts to reduce CLABSIs. A measure that encourages the use of central lines, while well-intentioned, may jeopardize the important gains hospitals have made in reducing CLABSIs. Thus, we support the recommendation of the Patient Safety Committee. If the agency chooses to implement NQF #500, then at a minimum, it should remove the element of the bundle requiring the measurement of central venous pressure and oxygenation.

CMS also would need to address important data collection and reporting issues arising from a national implementation of NQF #500 before the measure would be appropriate to implement in the IQR. While we are aware of many hospitals that have used the sepsis bundle internally to varying extents for several years, its introduction in the IQR program would mark the first time that all hospitals would collect and report measure data. Supporting the national implementation of a publicly reported measure is usually more complex than the simpler use of a measure in hospitals for internal quality improvement. CMS left several important implementations unaddressed in the proposed rule. For example, in the proposed rule, CMS does not indicate whether sampling will be allowed for the measure, and it is not clear whether the measure developers have created a formal sampling methodology. We believe that sampling is an important part of implementing the measure on a national scale to ensure that collecting the measure is not unduly resource intensive. **Therefore, the AHA urges CMS to work with the measure developer to develop a sampling methodology. CMS also should define minimum case thresholds for publicly reporting the measure.** Adequate case volumes ensure that measure results reflect true performance, and not simply random variations.

REFINEMENTS TO EXISTING IQR MEASURES

Planned Readmission Algorithm Updates. CMS proposes the same updates to its planned readmission algorithm for the readmissions measures in the IQR that it proposes for the HRRP. **The AHA recommends that CMS have these changes reviewed by the NQF before finalizing them for the IQR.** Our specific comments on the changes are in the readmissions section of this letter.

Data Reporting Period for Condition-Specific Claims-Based Measures. Beginning with the FY 2017 IQR program, CMS proposes to use three years of Medicare claims data to calculate all of its condition-specific, claims-based measures "unless otherwise specified." This data reporting period would apply to all current and future condition-specific measures calculated using Medicare claims. This proposal does not apply to the hospital-wide all-cause readmission measure, or the episode-of-care payment measures finalized and proposed for the IQR.

As noted in our comments in the VBP section of this letter, we appreciate CMS's attempts to improve measure reliability by enlarging the data reporting periods for the claims measures. We also believe that using consistent data reporting periods makes measure results easier to interpret when the measures are publicly reported. **Thus, the AHA supports CMS's proposal.** At the

same time, we note our continued concern about the reliability of data reported from several IQR measures – the 30-day mortality measures – despite an expanded reporting timeframe.

NHSN Data Reporting. CMS proposes to expand the scope of required data reporting in the NHSN system to include patient-level data such as patient date of birth and gender. CMS also would require information on clinical details such as specific symptoms or test results. CMS also proposes to receive access to any data submitted voluntarily into NHSN, including patient name and race identifying information. CMS indicates that CDC would share these data with CMS for the purposes of monitoring and evaluation, measure validation, appeals review, program impact evaluation and future measure development activities.

The AHA is very concerned by this proposal, and urges CMS not to adopt it. The sharing of such sensitive personal information carries substantial security risks. Yet, CMS fails to describe the intended purposes of collecting these data beyond the vague terms provided in the proposed rule. CMS also does not indicate who in the agency would be authorized to access the data – is it CMS staff only, or also CMS contractors? Moreover, such sensitive information is not used by the CDC to calculate HAI measure performance. Lastly, we strongly disagree with CMS's claim that this information is necessary for measure validation. Indeed, CMS's validation process for HAI measures in the IQR pre-dates these proposed requirements.

VALIDATION PROCESS UPDATES

Number of Charts Required for Validation. CMS proposes that hospitals will need to submit 10 charts per quarter for HAI measures, and eight charts per quarter on clinical process of care measures. This lowers the number of charts required for a full year of data from 96 to 72 charts. CMS proposes this change because it is also proposing the removal of a significant number of clinical process of care measures from the IQR beginning with the FY 2017 IQR program. Moreover, CMS indicates that is can lower the number of charts it collects each year while still yielding an adequate sample size. **The AHA believes these changes are aligned with the changes in the program, and supports CMS's proposals.**

Selection of the Measures and Sampling of Charts in Validation. For FY 2017, CMS proposes to continue validating all of the HAI measures in the IQR, but would modify how it validates the process of care measures. Because the agency proposes the removal of chart-abstracted versions of the AMI, HF, PN and SCIP measures, CMS proposes to validate only the chart-abstracted versions of the stroke, VTE, ED, immunization (IMM) and proposed sepsis measures. Additionally, across all hospitals selected for validation, CMS proposes to select the process of care validation charts using a "systematic random sample" across all the topic areas except IMM. This means that each hospital could be validated on different topics. **The AHA supports this proposal.**

CMS proposes to use a separate process for the IMM measure. Instead of being made part of the systematic random sample, CMS would validate the IMM measure for three of the eight charts per quarter validated for clinical process of care. **The AHA supports this proposal.**

Validation Score Weighting. As a result of changes outlined above, CMS also proposes to increase the weight of HAI measures and decrease the weight of process measures in determining a hospital's overall validation score. The HAI score would count toward 66.7 percent of a hospital's validation score, while process measures would count towards 33.3 percent. However, within the process of care measure category, CMS would assign a greater weight to the IMM measure. **The AHA agrees with and supports this proposal.**

EHR INCENTIVE PROGRAM

ALIGNMENT OF HOSPITAL IQR PROGRAM REPORTING AND SUBMISSION TIMELINES WITH EHR INCENTIVE PROGRAM REPORTING AND SUBMISSION TIMELINES

The AHA supports the proposal to incrementally shift the Medicare EHR Incentive Program reporting and submission periods for eCQMs from fiscal year reporting to calendar year reporting and only for hospitals using an electronic submission option in CYs 2015 and 2016. As described, this proposed shift would allow CMS to align clinical quality measure data reporting and submission periods of the EHR Incentive Program with the IQR program while allowing the reporting period, incentive eligibility assessment and incentive payments in the overall EHR Incentive Program to remain on their current schedules.

The AHA believes that it is premature to require quarterly reporting of eCQMs for the Medicare EHR Incentive Program beginning in CY 2015. Given the implementation delays with 2014 CEHRT for meaningful use and the anticipated change in the attestation requirements for meaningful use in 2014, we recommend that CMS not propose quarterly reporting of eCQMs prior to the FY 2016 inpatient PPS rule.

QUALITY REPORTING DATA ARCHITECTURE CATEGORY III (QRDA-III) OPTION IN 2015

The AHA is disappointed to learn in the proposed inpatient PPS rule that CMS remains unable to accept electronic submission of QRDA-III aggregate-level data in 2015. CMS notes that the submission of aggregate CQM data via attestation will not satisfy the reporting requirements for the hospital IQR program and, therefore, the voluntary electronic reporting option requires submission of QRDA-I patient level data. We urge CMS to be transparent and explicit in its plans to improve its internal systems to be able to accept QRDA-III submitted data. Such a statement will help hospitals understand the timing of a transition from attestation to electronic submission of aggregate level data for clinical quality reporting in meaningful use. When available, the acceptance of QRDA-III submitted data will provide an option to sharing patient-level data for quality measure reporting. We also urge CMS to explain how the submitted QRDA-I patient-level data are maintained in a secure environment, as they are in the current IQR program. Given the intent expressed in this proposed rule to mandate electronic reporting of IQR measures in CY 2016, the AHA urges CMS to use this proposed rule to outline a transition and strategy for electronic quality measure data submission that will support requirements in meaningful use, IQR and other programs.

eCQM Reporting for 2015

CMS proposes to require that eligible hospitals and CAHs that seek to report eCQMs electronically under the Medicare EHR Incentive Program use the most recent version of the e-specifications for the eCQM and have a certified EHR that is tested and certified to the most recent version of the e-specifications for the CQMs. The AHA recommends that CMS clarify how eligible hospitals and CAHs will meet this requirement if CEHRT are not required to be re-certified for conformance to updated e-specifications in order to maintain their EHR certification status. In addition, we would appreciate clarification of how this proposal aligns with the rule's proposal to require quarterly reporting of electronically reported CQMs for the Medicare EHR Incentive Program to align with the currently established quarterly electronic CQM reporting periods for the Hospital IQR Program. Annual e-specification updates of hospital eCQMs are published at the beginning of April. The two proposals will require hospitals to use an EHR that is certified to one set of e-specifications and then re-certified to a different set of e-specifications within a given reporting year in order to satisfy the quarterly reporting requirement. Given the updates in logic, codes and corrections in the annual e-specification updates, it will be important for CMS to explain its understanding of how hospitals and CAHs would operationalize both proposals.

Clarification on Zero Denominators Reported in eCQMs for the EHR Incentive Program and the Hospital IQR Program

The AHA supports the clarification on zero denominators in a particular eCQM due to the absence of data. CMS proposes that if the certified EHR is certified to an eCQM, but the eligible hospital or CAH does not have patients that meet the denominator criteria of that eCQM, the eligible hospital or CAH can submit a zero in the denominator for that eCQM. Submitting a zero in the denominator will count as a successful submission for that eCQM for both the EHR Incentive Program and the IQR program. This flexibility will permit hospitals to report eCQM data that are relevant based on their patient population. The AHA requests CMS clarification on whether the clarification of this zero denominator policy is effective in CY 2015 or upon publication of the final rule.

Case Threshold Exemption Policy

The AHA supports the change in the case threshold exemption policy so that if an eligible hospital or CAH qualifies for an exemption from reporting on a particular eCQM, the exemption will count toward the 16 eCQMs required for reporting in the EHR Incentive Program. Eligible hospitals or CAHs with five or fewer discharges during the relevant EHR reporting period or 20 or fewer discharges during the year should have the opportunity to report data for the 15 eCQMs for which the case threshold exemption does not apply and invoke a case threshold exemption for the eCQM for which the exemption does apply. This flexibility recognizes that the hospital or CAH may not meet the case threshold of discharges for a particular eCQM.

CHANGES TO GRADUATE MEDICAL EDUCATION (GME) PROGRAMS

PROPOSED INDIRECT MEDICAL EDUCATION (IME) MEDICARE PART C PAYMENTS TO SOLE-COMMUNITY HOSPITALS (SCHS)

SCHs are paid their hospital-specific rate or the inpatient PPS federal rate, whichever is higher. Typically, hospitals providing services to Medicare Part C Medicare Advantage patients receive add-on IME payments to account for the additional costs incurred in treating these patients. As a result of the way payments to SCHs are structured, however, SCHs that are teaching hospitals and paid on their hospital-specific rate do not currently receive IME add-on payments for Medicare Part C patient discharges. CMS now proposes to provide all SCHs that are teaching hospitals with IME add-on payments for Medicare Part C patients, regardless of whether the SCH is paid on its hospital-specific rate or the federal rate. **The AHA supports these proposals.**

In addition, CMS proposes that these add-on payments would *not* be included in the comparison of whether the SCH should receive the hospital-specific or the federal rate, but would be added after the higher of those two rates is determined. SCHs are only eligible for DSH and uncompensated care payments if they are paid under the federal rate; therefore this proposal would have the unintended effect of disqualifying a subset of SCHs that otherwise would have qualified for DSH and uncompensated care payments. **Accordingly, the AHA does not support this proposal and recommends that CMS allow the Medicare Part C payments to be included in determining whether an SCH will receive the hospital-specific or the federal rate.**

PROPOSED CHANGES IN THE EFFECTIVE DATE OF THE FULL-TIME EQUIVALENT (FTE) RESIDENT CAP, THREE-YEAR ROLLING AVERAGE, AND INTERN- AND RESIDENT-TO-BED (IRB) RATIO CAP FOR NEW PROGRAMS IN TEACHING HOSPITALS

CMS permits hospitals that do not have direct graduate medical education (DGME) or IME FTE caps, because they were not training residents when the caps were established in 1997, to start new programs and establish Medicare DGME and IME FTE caps during a five-year cap-building window. Rural hospitals are also permitted to increase their existing DGME and IME FTE caps at any time by starting *new* programs (though not by expanding existing programs).

The resident FTE counts CMS uses to make DGME and IME payments to teaching hospitals are not based on current year counts but rather on the three-year rolling average of the DGME and IME FTE counts. Additionally, the IRB ratio used to determine IME payments is not paid based on the current year's ratio, but rather is capped at the lower of the current or the prior year's ratio. (This is the so-called "IRB ratio cap.") Until now, the three-year rolling average and the IRB ratio cap have not gone into effect for a new program until the number of years equal to the minimum accredited length of each new program has passed.

CMS currently calculates a new urban teaching hospital's DGME and IME FTE caps (or the cap increases of a rural teaching hospital building a new program) based on the number of residents

training in the fifth year of the cap-building window, and the caps take effect beginning the sixth year after the start of the first program at a new urban teaching hospital.

CMS proposes to begin "synchronizing" the effective date of the FTE resident caps with the effective dates and application of the three-year rolling average and the IRB ratio cap, such that all three would go into effect at the start of the hospital cost reporting period that *precedes* the start of the sixth program year after the start of the first program. This proposal would apply to any urban hospital that first began training residents in its first new residency training program on or after Oct. 1, 2012 and would apply to any new program at a rural hospital that was started on or after Oct. 1, 2012. **While the AHA acknowledges that this proposal would provide administrative simplicity, AHA recommends that CMS synchronize these three events effective at the start of the hospital cost-reporting period that *follows* the start of the sixth program year to enable hospitals to fully benefit from the five-year cap building window.**

Under current regulations governing new programs, CMS permits hospitals in their five-year cap building window to be reimbursed for "the actual number of residents participating in the new program" for each of the first five years, so long as that number does not exceed the number of accredited positions available to the hospital for that program year.[xvi] By setting the date the cap takes effect at the beginning of the cost reporting period that precedes the start of the sixth program year, CMS imposes the cap prior to the end of the cap-building window, effectively denying hospitals in certain circumstances the ability to be reimbursed for the actual number of residents participating in the new program in the fifth year.

Hospitals incur significant expense in establishing new training programs and should be permitted the benefit of the full five-year cap-building window to grow their caps and be paid for actual numbers of resident FTEs. Therefore, if CMS proceeds with its plan to synchronize the effective dates of the cap, three-year rolling average, and IRB ratio cap, the AHA urges CMS to set the effective date as the start of the hospital cost reporting period that *follows* the start of the sixth program year after the start of the first program so that new teaching hospitals may retain the payments they are entitled to under the current regulations.

CHANGES TO GME POLICIES AS A RESULT OF THE NEW OMB LABOR MARKET DELINEATIONS

Rural Teaching Hospitals. Under existing regulations, a new teaching hospital that starts training residents for the first time on or after Oct. 1, 2012 has five years from when it first begins training residents in its first new program to build its permanent FTE resident cap. If a teaching hospital is rural, it can continue to receive permanent cap increases for training residents in new programs after the initial five-year cap-building period ends. As a result of CMS's proposal to use the new OMB labor market delineations, some rural teaching hospitals may be redesignated from a rural area to an urban area, thereby losing their ability to increase FTE resident caps for new programs started after the initial five-year cap building period ends. CMS proposes to allow hospitals in this situation to continue to grow that program for the remainder of the period and receive a permanent cap adjustment for the new program. **The AHA supports these proposals.**

Participation of Redesignated Hospital in Rural Training Track. Urban hospitals that establish separately accredited approved medical residency training programs (or tracks) in a rural area or have an accredited training program with an integrated rural track, may count the FTE residents in the rural track in addition to those FTE residents allowed under the cap up to a "rural track FTE limitation." As a result of CMS's proposal to use the new OMB labor market delineations, some rural teaching hospitals may be redesignated from a rural area to an urban area, which would impact this policy that requires the participation of a rural teaching hospital. Therefore, CMS proposes that in this situation, where the rural hospital is redesignated as urban, the urban hospital would continue to receive the rural track FTE limitation for new programs that started while the redesignated hospital was still rural and for the duration of the three-year period in which the rural track FTE limitation is calculated. Additionally, CMS proposes a two-year transition period during which the either of the following conditions must be met in order for the urban hospital to be able to count the residents under its rural FTE limitation when the two-year transition period ends – (1) the redesignated newly urban hospital must reclassify back to rural; or (2) the original urban hospital must find a new geographically rural site to participate for purposes of the rural track. **The AHA supports these proposals.**

CHANGES TO THE REVIEW AND AWARDS PROCESS FOR RESIDENT SLOTS

Under Section 5506 of the ACA, the DGME and IME residency slots from any hospital that closed or closes on or after March 23, 2008, must be redistributed on a permanent basis to other hospitals. To date, CMS has announced seven rounds of slots available for redistribution and has made award announcements for five of these rounds. CMS now proposes to make several changes to the closed hospital redistribution program.

Under CMS's current application rules, teaching hospitals are permitted to apply for FTE slots for purposes of general cap relief. This option is the last ranking criterion, used only after all available positions have been distributed for other reasons. In this rule, CMS proposes to eliminate this option because there have been only a relatively small number of slots awarded specifically for cap relief and the application review process is administratively burdensome. **While the AHA appreciates the effort CMS has put into administering this program, we disagree with CMS's proposal to eliminate the cap-relief option from the Section 5506 application process.**

Since the Balanced Budget Act (BBA) imposed limits on Medicare-funded residency positions in 1997, teaching hospitals have been required to bear the entire cost of training any residents in excess of their DGME and IME caps. Hospitals around the country are growing residency positions, without any additional funding, in response to impending physician shortages. CMS should not remove over-the-cap hospitals' only opportunity to receive some funding for these positions. Though a small number, some positions have in fact been awarded for cap relief to date, and the agency cannot predict what hospital closures will take place in the future. **The AHA urges CMS not to preclude this option but instead to work collaboratively with the teaching hospital community to determine ways that applications might be reviewed in a more efficient and expeditious manner.**

CMS also proposes to change Ranking Criteria One and Three, which give preferences for Section 5506 slots to hospitals that assume an entire program or part of a program from the closed hospital. CMS currently requires hospitals applying under these ranking criteria to show that they are "seamlessly" replacing displaced FTE residents with new FTE residents once the displaced residents graduate. The agency now proposes to eliminate the "seamless" requirement, effective for application rounds announced after Oct. 1, 2014. CMS indicates that hospitals applying for Section 5506 slots under Ranking Criteria One and Three "would continue to be required to submit a supporting document when applying…that indicates that they have made a commitment to take over the closed hospital's program or that they have made the commitment to permanently expand their own residency training program resulting from taking over part of a closed hospital's program." **The AHA supports this proposal, but requests that CMS provide clear and consistent guidance explaining what type of supporting documentation would meet this new requirement.**

Finally, CMS proposes to permit hospitals that were members of an emergency Medicare GME affiliation agreement with the closed hospital prior to its closure to be considered under Ranking Criterion Two. The current application expressly permits only the application of Ranking Criterion Two to hospitals that received slots from the closed hospital through a Medicare GME affiliation agreement. **The AHA supports this proposal.**

OUTLIER PAYMENTS

In order to estimate the proposed FY 2015 outlier fixed loss threshold, CMS inflated the charges in MedPAR by two years, from FY 2013 through FY 2015. To estimate the one-year average annualized rate-of-change in charges per case for FY 2015, CMS proposes to compare charges from Jan. 1 – Dec. 31, 2012 to charges from Jan. 1 – Dec. 31, 2013. CMS finds a rate-of- change of 5.6 percent (1.055736) or 11.5 percent (1.114579) over two years. Since the publicly available FY 2013 MedPAR dataset contains claims only through Sept. 30, 2012, we do not have access to claims in the first quarter of FY 2014 (Oct. 1 – Dec. 31, 2013) and hence cannot replicate the rate-of-change computed by CMS.

The AHA urges CMS to add the claims data for the first quarter of FY 2014 (and any other quarters that it may use in the future for such calculations) to its list of limited data set (LDS) files that can be ordered through the usual LDS data request process. This will enable the field going forward to obtain the data necessary to replicate CMS' calculation of the charge inflation factor. Not having access to these data severely limits our ability to sufficiently comment on this issue.

PROPOSED MS-DRG RECALIBRATION BUDGET NEUTRALITY ADJUSTMENT FACTOR

The AHA believes CMS has miscalculated the MS-DRG recalibration BNA factor for FY 2015. Specifically, Section 1886(d)(4)(C)(iii) of the Social Security Act states that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner such that aggregate payments to hospitals are not affected. CMS normalizes the recalibrated MS-DRG relative weights by an adjustment factor so that the average case weight after recalibration is equal to the average case weight before recalibration. However, since payments to hospitals are affected by several factors other than just the average case weight, budget neutrality is not necessarily achieved by this normalization alone. To comply with the requirement that MS-DRG reclassification and recalibration of the relative weights be budget neutral for the Puerto Rico standardized amount and the hospital-specific rates, CMS used the FY 2013 MedPAR data to compare the following:

- Aggregate payments, net of the estimated FY 2015 hospital VBP and readmissions payment adjustments, using the new OMB labor market area delineations proposed for FY 2015 along with the FY 2014 pre-reclassified wage data and the *FY 2014* relative weights; and

- Aggregate payments, net of the estimated FY 2015 hospital VBP and readmissions payment adjustments, using the new OMB labor market area delineations proposed for FY 2015 along with the FY 2014 pre-reclassified wage data and the *FY 2015* relative weights.

Using the methodology above, CMS calculated a proposed MS-DRG recalibration budget neutrality adjustment factor of 0.992938, which is far lower than historical levels, which have ranged between 0.996731 (FY 2011) and 0.998431 (FY 2013) in the last five years, as shown in the table below.

Table 3: Historical Levels of the MS-DRG Recalibration Budget Neutrality Adjustment Factor

Year	Factor
FY 2015 - Proposed	0.992938
FY 2014	0.997989
FY 2013	0.998431
FY 2012	0.997903
FY 2011	0.996731
FY 2010	0.997941

The AHA, both internally and through its contractor, The Moran Company (TMC), tried to replicate this budget neutrality factor, using the FY 2013 MedPAR data but were unable to do so.

Specifically, we initially used the original MS-DRG weights that were published with the FY 2015 proposed rule and could not replicate the factor. CMS, in May 2014, published a revised set of MS-DRG weights since a number of post-acute care transfer adjusted cases for certain MS-DRGs in the FY 2015 proposed rule were "inadvertently miscalculated." Using the revised MS-DRG weights, we still could not replicate the budget-neutrality adjustment factor of 0.992938. The table below shows the AHA calculations and those of TMC and its subcontractor, Watson Policy Analysis Incorporated (WPA), which are very similar and were calculated independently of each other. Note that our calculations result in a factor that is in line with historical levels – in fact, when using the revised weights we even get a budget-neutrality adjustment factor that is greater than 1.

Table 4: MS-DRG Recalibration Budget Neutrality Adjustment Factor as Calculated by the AHA and TMC/WPA

MS-DRG Weights Used	CMS	AHA	TMC/WPA
Original	0.992938	0.998613	0.998587
Revised	N/A	1.000337	1.000301

The AHA strongly believes that, as a result of the post-acute care transfer calculation in the FY 2015 proposed rule, the MS-DRG recalibration budget-neutrality adjustment factor also has been miscalculated, and urges CMS to examine and correct the budget-neutrality adjustment factor in the FY 2015 final rule.

CHANGES TO MS-DRG CLASSIFICATIONS

In general, the AHA has no objections to CMS's proposed changes to the 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 2015. For FY 2015, there are no proposed new, revised or deleted ICD-9-CM diagnosis or procedure codes. **However, we recommend that no updates occur during the first year of ICD-10 implementation, FY 2016.** If new or revised codes can still be introduced into ICD-10-CM/PCS in FY 2016, 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 appreciate CMS making available the Version 31.0-R ICD-10 MS-DRG software and Definitions Manual. These tools will be useful as hospitals prepare for ICD-10 implementation.

The AHA supports implementation of ICD-10-CM and ICD-10-PCS on Oct. 1, 2015 without any further delays. Hospitals across the country have invested significant financial and human resources in preparing for the transition to ICD-10. Our members have told us that they are ready, or nearly ready, to start external testing with CMS and others. Therefore, we are concerned that CMS cancelled its plans for further testing during 2014. **We urge CMS to formalize its ICD-10 testing plans to ensure that end-to-end testing begins no later than January 2015 and be made available to all hospitals.** We appreciate the agency's efforts to offer extensive educational opportunities for providers. However **extensive end-to-end testing of both the electronic transaction and the adjudication of the claim by Medicare contractors and state Medicaid agencies will be needed to ensure a smooth transition from ICD-9 to ICD-10.**

PENALTY FOR FAILURE TO MEET MEANINGFUL USE

Under statute, both inpatient PPS hospitals and CAHs are subject to Medicare payment penalties in FY 2015 and later years if they fail to meet meaningful use, with the size of the penalty increasing over time. However, the two types of hospitals have different penalty structures based on different performance periods. All hospitals must meet either meaningful use or receive a hardship exception each and every year to avoid penalties.

The AHA is very concerned that CMS has not offered any policies on explanation in the proposed rule regarding how the agency will identify and notify the appropriate hospitals that they are subject to the significant payment penalties for failure to meet meaningful use. Given the magnitude of the penalties, and the newness of the program, the AHA believes it is crucial for the agency to be transparent and fair in its process for applying the penalties, as it has done for the quality reporting programs.

Based on CMS data on meaningful use attestations through December 2013, the AHA estimates that more than 500 hospitals could be subject to the penalty, leading to approximately $100 million in penalties. This is a substantial cut to hospitals that must be accompanied by a fair and transparent process for hospitals to be notified of penalties. PPS hospitals and CAHs must be provided the opportunity to ask for reconsideration and appeal a determination if the hospital disagrees.

We note that CMS has established a robust, timely process for hospitals to be notified of penalties under various quality programs, including the annual payment update (APU)

determination process used for the IQR program, and similar programs for inpatient psychiatric and rehabilitation facilities. All of these processes are in place to ensure fairness, and in recognition that unintentional errors may occur.

We urge CMS to clearly outline a process for both inpatient PPS hospitals and CAHs in subregulatory guidance as quickly as possible that:

- **Explains in detail the data and methods CMS will use to identify hospitals subject to the penalty;**
- **Describes how hospitals will be notified that CMS has identified them as subject to the penalty, including to whom the notification will be sent and how it will be sent;**
- **Provides specific and sufficient mechanisms for a hospital to ask for reconsideration of the penalty based on its own documentation (such as proof of attestation or hardship exception), and provides hospitals with at least 30 days, after receiving notification, to ask for such reconsideration;**
- **Provides specific and sufficient mechanisms for a hospital to appeal the agency's determination after reconsideration, with at least 30 days after receiving the determination, to appeal; and**
- **Ensures that these mechanisms are widely communicated to the hospital community and accompanied by adequate timelines for a hospital to use them.**

We believe that the first year of any payment program is most likely to have unintentional errors, and the meaningful use program is no exception. In fact, a number of aspects of the meaningful use program may increase the risk of unintentional errors, heightening the need for a reconsideration process. These include the various timelines for attestation (those in their first year of meaningful can attest up to July 1, 2014), the introduction of a hardship exception program, the use of both national provider identifiers (NPIs) and CMS certification numbers (CCNs) in the attestation process, and issues with the attestation system. In looking at the public attestation data, the AHA found a number of hospitals that attested using only a NPI, and not the CCN. Therefore, an identification system than used only the CCN would inadvertently tag those facilities as subject to the penalty, when they had, in fact attested. Further, we note that more than 50 hospitals that successfully attested in the fall of 2013 were later asked to re-attest because the system had inadvertently marked their attestation as incomplete.

CRITICAL ACCESS HOSPITALS (CAHs)

CMS proposes a two-year transition for facilities currently designated as CAHs that may be redesignated from rural to urban as a result of the new OMB labor market delineations. These CAHs will continue to be treated as rural through Sept. 30, 2016 (or when they reclassify, if sooner) and will be required to reclassify to a rural area during that same two-year time period. **The AHA supports these proposals.**

However, we believe that other hospitals in similar circumstances also should be afforded such a transition. Specifically, adopting the new OMB labor market delineations may impact 14 SCHs that qualify for that designation because they are located in a rural area under the current delineations but will not be under the new delineations. Although these hospitals have the opportunity to reclassify back to a rural area, that reclassification will not restore the hospital to its prior financial position because reclassifying hospitals are not eligible for wage index reclassifications or for an out-migration adjustment. The limited number of hospitals in this position need additional time to prepare for and adjust to this change in financial circumstances. **As a result, the AHA requests that CMS provide a two-year transition for these SCHs consistent with the transition discussed above for CAHs. In addition, this transition would further CMS's purposes of mitigating short-term instability and reducing "any disruption caused by new OMB delineations."**

In addition, adopting the new OMB labor market delineations may also impact 19 Medicare-dependent hospitals (MDHs) that qualify for that designation because they are located in a rural area under the current delineations but will not be under the new delineations. Most of these hospitals will not have the opportunity to reclassify from urban to rural because they do not meet the criteria set forth in 42 C.F.R. 412.103. For those that may reclassify, reclassification will not restore the hospital to its prior financial condition because reclassifying hospitals are not eligible for wage index reclassification or for the out-migration adjustment. The limited number of hospitals in this position need additional time to prepare for and adjust to this change in financial circumstances. **As a result, the AHA requests that CMS also provide a two-year transition for these MDHs consistent with the transition discussed above for CAHs and SCHs.**

REQUIREMENT FOR TRANSPARENCY OF HOSPITAL CHARGES UNDER THE ACA

The ACA requires each hospital to establish, update and make public a list of its standard *charges* for items and services it provides. In the proposed rule, CMS reminds hospitals of this obligation and indicates that it will provide hospitals with the flexibility to determine how they make their list of standard charges public. Specifically, CMS indicates that hospitals must either make public a list of their standard charges (whether that be the charge master itself or another form) or their policies for allowing the public to view a list of those charges in response to an inquiry. **The AHA supports this proposal and appreciates the additional flexibility CMS has granted to hospitals.**

While the ACA requires transparency of hospital charges, hospital charges do not provide the most meaningful picture of a patient's out-of pocket costs. In addition to encouraging our members to meet the ACA requirement, the AHA is developing tools and resources to assist our members in making reliable information on health care prices available to patients. We believe this will allow patients to make more informed health care decisions.

COST REPORT REQUIREMENTS AND PROVIDER REIMBURSEMENT REVIEW BOARD (PRRB) JURISDICTION

The AHA urges CMS to abandon its proposal to require a provider to include all items on its cost report for which it is requesting payment as a condition for payment for those items. We also urge it to withdraw its proposal to eliminate the current provision that permits a provider either to claim reimbursement on its cost report for a specific item or to self-disallow the item and file the cost report under protest in order for the PRRB to have jurisdiction over that item. Under CMS's proposal, the requirement to include all items on the cost report would apply even if the provider believes the payment requested may not comply with Medicare policy. However, if a provider does not include an appropriate claim for an item in its cost report, it would not receive payment for that item and also would lose the ability to appeal that item to the PRRB. CMS proposes to apply this requirement to cost reporting periods that begin on or after the effective date of the final inpatient PPS rule.

CMS's proposed change would inappropriately limit hospitals' ability to exercise their appeal rights based solely on the discretion of MACs. Specifically, under the proposed change, while a provider that fails to include an item on its cost report could file an amended cost report or request a reopening by its MAC to add the excluded item, whether to accept an amended cost report or issue a reopening is entirely at the MAC's discretion under current Medicare regulations. Further, the MAC's decision to not accept an amended report or to reopen a cost report is not subject to judicial review. Therefore, if a hospital does not correctly list an item on its cost report, its only avenue for correction would be to file an amended report or request reopening and hope that the MAC is amenable to the request. If the MAC is not, the hospital, under the changes proposed by CMS, would have no further administrative remedy.

The proposal unduly vests the MACs with overly broad authority over hospitals' right to appeal items on the cost report. In the preamble to the proposed rule, CMS states that it anticipates that providers and MACs will engage in a back-and-forth process to resolve issues that might currently end in appeal, and that this would help alleviate the workload of the PRRB. However, even assuming that reducing the PRRB's workload is an appropriate goal, it is wholly inappropriate to do so by limiting providers' appeals rights in such a manner. CMS presents no evidence that the MACs are equipped and prepared to engage in this type of back-and-forth process. Moreover, hospitals report that MACs routinely decline to accept an amended or reopen a cost report rather than making a considered decision after a thorough assessment of the facts.

In light of these concerns, the AHA strongly urges CMS not to adopt this proposal. However, in the event that CMS wants to require that all items for which payment is requested be included on the cost report, it should reissue for comment a revised proposal that addresses some additional issues to ensure that the requirement remains fair and is not unduly burdensome for providers' appeal rights. Such a revised proposal must at least:

- Include clear and uniform standards for MACs to apply when determining whether to accept an amended report or reopen a cost report;

- Address how CMS will monitor and enforce the MACs' exercise of their authority to make such decisions about amendments and reopening to ensure that they are fairly and consistently applying the standards for all providers; and

- Allow for exceptions in instances where a provider did not and – even exercising due diligence – could not have known information that it later discovers should have been listed on its cost report. Such situations appropriate for an exception might include cases where the hospital relies on information that it does not control to complete portions of the cost report, as well as situations where the hospital only discovers information after the fact has had a material impact on the cost report. For example, if a state that has expanded its Medicaid population has trouble identifying new enrollees, a hospital's Medicaid days may be impacted – a situation that is beyond the hospital's control. Similarly, as CMS is aware, appeals by a large number of hospitals related to the rural floor budget neutrality adjustment were based on the discovery, years after creation of the adjustment, that it was being erroneously implemented. In that case, hospitals pursued appeals in order to correct an error by the agency; the agency should not be able to avoid correcting its own errors by simply prohibiting hospitals from appealing on the basis that they did not discover the agency's error at the time their cost reports were initially filed. CMS should exempt such situations from any requirement to include items in the hospital's cost report when initially filed or forego any right to appeal to the PRRB.

ENFORCEMENT PROVISIONS FOR ORGAN TRANSPLANT CENTERS

To participate in Medicare, transplant centers must meet certain Conditions of Participation (CoPs) that set forth explicit expectations for outcomes, patient safety, informed choice and quality of transplantation services. Failure to meet transplant center requirements can lead CMS to deny approval or reapproval of a center's Medicare agreement. However, CMS can consider mitigating factors in determining approval or reapproval. These factors include (but are not limited to) the extent to which outcomes measures are met or exceeded, the availability of Medicare-approved transplant centers in the area, and extenuating circumstances that may have a temporary effect on the ability of the transplant center to meet the requirements.

In the proposed rule, CMS amends the current regulations to: (1) include additional examples of mitigating factors, (2) elaborate upon the content of requests for consideration based upon mitigating factors, and (3) outline the process and substance of Systems Improvement Agreements (SIAs). Our comments on those provisions follow.

EXPANSION OF ENUMERATED MITIGATING FACTORS

We support CMS's proposal to expand the enumerated list of mitigating factors the agency may consider for approval or reapproval. **However, the proposed language at § 488.61(f)(1) describing the proposed fifth and sixth factors is unclear. We suggest CMS clarify its intent with regard to these factors, and we offer the following language:**

(v) Data that is more recent than what is available from the Scientific Registry of Transplant Recipients that allows CMS to determine that the Center is in compliance with CMS requirements.

(vi) Evidence showing that the Center uses innovative practices to address the needs of complex patients, such as children who have undergone a Fontan procedure or individuals who are highly sensitized patients, where such practices are supported by

(1) evidence-based published research literature or nationally recognized standards, or
(2) Institutional Review Board approved innovative practices

and where the risk-adjustment methodology does not take the relevant key factors into consideration.

CONTENT OF REQUESTS

CMS proposes that requests for consideration of mitigating factors include "sufficient information to permit an adequate review and understanding of the transplant program, the factors that have contributed to outcomes, program improvements or innovations that have been implemented or planned, and, in the case of natural disasters, the recovery actions planned." CMS provides a list of the types of information to be submitted, and we believe the proposed examples represent strong criteria for evaluation, with one caveat. CMS states that the supporting evidence for CMS's review may include a root cause analysis (RCA) for patient deaths and graft failures. While the AHA believes transplant centers should be able to voluntarily provide RCAs, we do not believe that CMS has the authority to require a hospital or transplant center to disclose information provided to or by a Patient Safety Organization (PSO). To require the disclosure of patient safety work product potentially puts the hospital or center in a situation in which it must choose between forgoing a mitigating factors review, which could keep the center open, or facing civil monetary fines under the Patient Safety and Quality Improvement Act of 2005. Therefore, we caution that CMS must not ***require*** patient safety work product from providers who have submitted a RCA to a PSO. However, we believe a transplant center would be able to provide other data and make changes that would give CMS enough information to approve or reapprove a center based upon mitigating factors.

SYSTEMS IMPROVEMENT AGREEMENTS (SIAS)

Where a transplant center demonstrates that it is making significant progress toward correction and program improvement, but does not yet qualify for approval based on mitigating factors, CMS believes there may be merit in some cases to temporarily extend the effective date of termination from Medicare in exchange for an agreement to engage in a significant and directed regimen of improvement under an SIA. We believe the proposed regimen of specified activities to which a center must agree in exchange for an SIA is very robust, including the use of an external independent peer review team and an onsite consultant, the development of an action plan to address systemic quality improvements, the creation of a comparative effectiveness analysis, and analysis of the center's staffing, among other activities. In fact, this list could

conceivably constitute a "best practice" for transplant centers seeking improvement to acceptable or higher standards. We note that the regimen also includes "additional or alternative requirements specified by CMS, tailored to the transplant program type and circumstances." Given the high specificity of the required activities, the allowance for alternate requirements should provide CMS the flexibility it needs to successfully implement a SIA if a transplant center cannot meet all of the activities due to circumstances beyond its control.

REGULATIONS GOVERNING USE/RELEASE OF MEDICARE ADVANTAGE RISK ADJUSTMENT DATA

In Sec. 422.310, CMS proposes to expand the allowable uses and reasons for disclosure of risk adjustment data submitted to CMS by Medicare Advantage Organizations (MAOs), including clarification that disclosure would be permitted to contractors or other agents that conduct activities or analysis on behalf of CMS. The AHA is not fundamentally opposed to the additional purposes for disclosure of data used in determining Medicare Advantage risk adjustment as proposed. **We do, however, have significant concerns regarding the broad nature of these provisions, the potential risks associated with releasing sensitive and proprietary data, even when aggregated, and the potential expansion of disclosures for commercial purposes. Price and charge data should not be collected, released or used since they are not relevant to risk adjustment.**

The existing purposes for which CMS may use or disclose these data are to:

- determine risk adjustment factors used to adjust MA payments;
- update risk adjustment models;
- calculate Medicare DSH percentages;
- conduct quality review and improvement activities; and
- determine Medicare coverage.

CMS proposes to add the following purposes:

- conduct evaluation and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research;
- activities to support the administration of the Medicare program;
- activities to support program integrity; and
- purposes permitted by other laws.

The proposal also would allow other HHS agencies, other federal executive branch agencies, states and external entities to obtain and use these data from CMS, but only for one of the specified purposes. The notice states that CMS "anticipates that nongovernmental external entities would generally only gain access to risk adjustment data in connection with public health initiatives and health care related research…."

CMS also proposes conditions for the release of the risk adjustment data. The data could not include medical records and other data collected for purposes of risk adjustment data validation (RADV) audits. Rather, CMS proposes to authorize use or release of encounter data records, including contract, plan and provider identifiers, but not payment information, and seeks comment on approaches to aggregating payment data for release as well as whether releasing payment data at the level of an encounter record would reveal proprietary negotiated payment rates. However, we note that while the limitations on specifications of several of these conditions are codified in the current or proposed regulations, the restrictions on "commercially sensitive data" are listed only in the preamble.

CMS proposes to release the least amount of data required to accomplish the goal for a project. Additionally, data would be released subject to federal law and regulations, CMS data-sharing practices, aggregation of payment data (to protect commercially sensitive data) and protection of beneficiary identifier elements and confidentiality. While not proposing any revisions to the rules, CMS also asks for comments on whether the rules should address disclosure of these data for commercial purposes.

The AHA's specific concerns are outlined below.

PROPOSED RELEASE OF AGGREGATED PAYMENT DATA

The AHA recommends that Sec. 422.310 (f)(2)(iv) be revised to prohibit the disclosure of plan or provider identifiable payment data outside the federal government. Such releases could create distortions in competition or inflation and could trigger antitrust concerns within both the health plan and provider communities. We recognize that CMS is trying to moderate this potential by proposing that such data be released only in the aggregate, but there are many circumstances that would make aggregated information identifiable for a specific plan or provider.

Recently, the Healthcare Financial Management Association formed a Price Transparency Task Force with broad stakeholder participation that included consumer, provider (including AHA), health plan, watchdog and quality improvement representatives. In describing the policy considerations when forming the task force's recommendations, they noted:

> Among the unique features of the U.S. healthcare marketplace is the existence of a business-to-business marketplace between providers and private health plans... From a consumer perspective, as a general rule, the more transparency the better. But within a business-to-business marketplace, some healthcare economists and the federal antitrust enforcement agencies have noted that public transparency of negotiated rates could actually inflate prices by discouraging private negotiations that can result in lower prices for some buyers. Within the privately insured market, these considerations suggest than an approach to transparency that emphasizes out-of-pocket payments for insured patients instead of full transparency of negotiated rates may be preferable.

The AHA supports this approach.

Further, in its August 1996 "Statements of Antitrust Enforcement Policy" (http://www.ftc.gov/sites/default/files/documents/reports/revised-federal-trade-commission-justice-department-policy-statements-health-care-antritrust/hlth3s.pdf), the Federal Trade Commission and the Department of Justice laid out several conditions for an antitrust safety zone (pages 44-45) related to the collective release of negotiated provider payment rates, noting that there would be instances where negotiated rates possibly could be discerned, such as areas with a dominant private payer.

POTENTIAL USE OF DATA FOR COMMERCIAL PURPOSES

CMS has specifically asked whether Sec. 422.310(f)(1) should be further expanded to address the disclosure of data for commercial purposes. It is difficult to offer comment on this issue when there is no proposed definition or explanation of what CMS would consider commercially sensitive data, and no discussion of what CMS would consider an appropriate commercial purpose or even an example of what a commercial purpose might include. We assume that CMS will publish proposed regulatory language if this issue is further pursued. In general, the AHA cautions against release of data for commercial purposes, as those data are susceptible to misuse or mischaracterization and could have unnecessary and harmful ramifications for payers, providers, and patients.

NEEDED CLARIFICATIONS

The AHA recommends that CMS clarify Sec. 422.310(f)(1)(ix) regarding the allowable use and release of data for "purposes permitted by other laws." This provision is overly broad and must be further defined. For example, it does not distinguish federal from state or local laws, nor does it limit those laws to health care programs. We believe it is unwise to throw open the door this wide.

PPS-EXEMPT CANCER HOSPITAL QUALITY REPORTING PROGRAM (PCHQR)

The ACA mandated a quality reporting program for PPS-exempt cancer hospitals (PCHs), beginning in FY 2014. All PCHs are required to comply with all PCHQR program requirements. For FY 2016, the agency proposes one additional measure for the PCHQR program. CMS also proposes a number of updates to the program's data reporting requirements.

FY 2017 PROPOSED MEASURE

CMS proposes to add one chart-abstracted measure to the FY 2017 PCHQR program—External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822). The measure is NQF-endorsed, and was supported by the MAP for inclusion in the PCHQR. The measure assesses the percentage of patients with painful bone metastases with no previous radiation to the same site who receive EBRT using certain "fractionation," or dosing, schedules. CMS indicates its hope that reporting the measure will encourage PCHs to deliver no more radiation therapy to bone metastasis patients than is necessary.

The AHA believes the EBRT for bone metastases measure is a promising addition to the PCHQR program. However, before finalizing it, we urge CMS to conduct a formal analysis of the performance gap on the measure in PCHs to ensure that the measure will truly add value to the PCHQR program. The AHA has long urged CMS to promote parsimony and focus in its measurement programs by ensuring that the measures selected for them address high-priority areas for quality improvement. For this reason, we believe CMS should prioritize measures that have a performance gap so that patients and providers can identify opportunities to meaningfully improve care and be able to track improvements. Without this prioritization, finite resources to measure and improve care may be expended on areas where quality of care is generally high and unlikely to further improve. CMS suggests in the proposed rule that the measure would "address the performance gap in treatment variation," but does not include an analysis demonstrating a performance gap in PCHs. We believe such an analysis will provide all stakeholders with assurance that the measure addresses an area of importance for patients and PCHs.

We also ask CMS to clarify whether sampling will be permitted for collecting this measure, as it is not explicit in the proposed rule. We commend CMS for adopting the use of sampling for many of the measures in the PCHQR program in the FY 2014 inpatient PPS final rule. We believe the EBRT for bone metastases measure would be a substantial burden to collect and report without a sampling methodology.

SURGICAL CARE IMPROVEMENT PROJECT (SCIP) MEASURE CONCERNS

CMS proposes to remove nearly all of the SCIP measures from the hospital IQR program for being "topped out." **We also recommend that CMS consider removing the SCIP measures from the PCHQR.** We are concerned that the SCIP measures, when applied to the PCH patient population, apply to only a small number of patients, thereby limiting their relevance and usefulness.

Moreover, we are concerned that these measures have not been adequately tested for the cancer patient population, and as a result, may inadvertently encourage care that is not appropriate for the patient population. For example, SCIP-Inf-3 requires that prophylactic antibiotics be discontinued within 24 hours after surgery end time. However, our PCH members report that this approach is not well-suited for oncologic orthopedic patient populations who are undergoing total hip or knee replacement surgery for treatment of oncologic conditions. For such patients, the current practice is to use antibiotics until the drain has been removed since it is in direct communication with the metallic prosthesis. Antibiotics are administered anywhere from a few days to weeks, and the final determination to discontinue the drain should be patient- and surgeon-dependent. The AHA appreciates that the SCIP measures have been used in acute care hospitals for many years, and have been extensively validated for the general acute care population. However, the agency should carefully test measures before moving them into other care settings to ensure they are appropriate for the patient population being served.

DATA COLLECTION AND REPORTING

CMS proposes several changes to PCHQR program data collection and reporting requirements beginning in FY 2016:

All-payer Data Collection. For the five clinical process/oncology care specific treatment measures in the PCHQR, CMS proposes to require PCHs to report data on all patients, regardless of payer. CMS states that this requirement is consistent with the SCIP measures that also are part of the PCHQR. It also is consistent with the data reporting requirements for chart-abstracted measures in other CMS quality reporting programs (e.g., the IQR program). **The AHA supports this proposal.**

Alignment of Reporting Deadlines. With a stated purpose of reducing data reporting burden, CMS proposes to align the data collection and reporting periods for most of the PCHQR program's measures. Specifically, the three clinical process/cancer-specific treatment measures, the five clinical process/oncology care measures and the six SCIP measures would all share the same data collection periods and data submission deadlines. Currently, CMS requires that SCIP measures be submitted once per quarter, while the other measures are submitted once per year. Beginning in FY 2016, all of the measures in the above categories will be submitted once per year using the same submission deadline. **The AHA commends CMS for taking steps to simplify the PCHQR data reporting process, and supports this proposal.**

Data Format Requirements. Beginning in FY 2016, CMS proposes that PCHs will have two options for submitting the clinical process/cancer specific treatment, clinical process/oncology care measures and SCIP measures. These same options also would apply to the EBRT for Bone Metastases measure proposed for the FY 2017 PCHQR program. PCHs or their authorized vendors can either enter aggregate numerator and denominator data, or submit an aggregate data file via CMS's *QualityNet* website. **The AHA supports this proposal.**

Sampling. CMS last year finalized a policy allowing PCHs to submit data on a sample of patients for the clinical process/oncology care measures. CMS indicated the methodology would be the same specified in the Physician Quality Reporting System (PQRS) specification manual. However, given that the PQRS sampling methodology is intended for the physician office setting, for FY 2016, CMS proposes to replace it with the sampling methodology developed for SCIP measures since that methodology was developed for hospital-level reporting. CMS also proposes to require PCHs to report the initial population and sample size counts for Medicare and non-Medicare discharges. **The AHA agrees that a sampling methodology based on hospital-level reporting is much more appropriate than one based on physician-level reporting. Therefore, we support the agency's proposal.**

PUBLIC REPORTING

The ACA requires that measures from the PCHQR program be publicly reported. As finalized in the FY 2014 inpatient PPS proposed rule, CMS will report data on two PCHQR chemotherapy process measures during 2014. CMS proposes to expand public reporting of measures by reporting the adjuvent hormonal therapy measure in 2015, and displaying CAUTI and CLABSI data no later than 2017.

While the AHA supports these proposals, we urge CMS to carefully evaluate each PCHQR measure it plans to publicly report to ensure there is sufficient sample size to ensure accurate reporting. Facilities that do not meet the minimum sample size for measure reporting should not have data from the measure benchmarked against other PCHs or publicly reported unless the outcomes are statistically validated.

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[i] 78 Fed. Reg. 50495, 50952 (Aug. 19, 2013)

[ii] Meddings JA et al. Hospital Report Cards for Hospital-Acquired Pressure Ulcers: How Good are the Grades. Annals of Internal Medicine. 519(8):505-13. October 2013.

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

[iv] See National Quality Forum, *NQF-Endorsed Measures for Patient Safety: Draft Report for Comment*, May 28, 2014. Available at http://www.qualityforum.org

[v] See National Quality Forum, *NQF-Endorsed Measures for Patient Safety: Draft Report for Comment*, May 28, 2014. Available at http://www.qualityforum.org , page 55.

[vi] See National Quality Forum, *NQF-Endorsed Measures for Patient Safety: Draft Report for Comment*, May 28, 2014. Available at http://www.qualityforum.org , page 56.

[vii] 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

[viii] National Quality Forum, *Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors.* March 18, 2014. Available at http://www.qualityforum.org

[ix] See National Quality Forum, *Consensus Standards Maintenance and Endorsement Cycle Process*, available at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=73605

[x] See National Quality Forum, *Consensus Standards Maintenance and Endorsement Cycle Process*, available at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=73605, page 5.

[xi] National Quality Forum, *Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors.* March 18, 2014. Available at http://www.qualityforum.org

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

[xiii] 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.

[xiv] See National Quality Forum, *National Voluntary Consensus Standards for Cost and Resource Use Phase II*, April 21, 2014. Available at http://www.qualityforum.org.

[xv] See National Quality Forum. *NQF-Endorsed Measures for Patient Safety: Draft Report for Comment*, May 28, 2014. Available at: http://www.qualityforum.org.

[xvi] See 42 C.F.R. § 413.79(e)(1)(ii).