



American Hospital  
Association

Liberty Place, Suite 700  
325 Seventh Street, NW  
Washington, DC 20004-2802  
(202) 638-1100 Phone  
www.aha.org

June 19, 2012

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

*RE: CMS-1588-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; Proposed Rule (Vol. 77, No. 92), May 11, 2012*

Dear Ms. Tavenner:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our nearly 42,000 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) 2013. We will submit comments separately on CMS's proposed changes to the long-term care hospital PPS.

While we support a number of the proposed rule's provisions, including many of the value-based purchasing proposals, we have serious concerns about the documentation and coding adjustment, the readmissions proposal, and the sole community hospital (SCH) proposal.

#### **MS-DRG DOCUMENTATION AND CODING ADJUSTMENT**

The proposed rule includes a permanent documentation and coding cut of 1.9 percent to eliminate what CMS claims is the effect of documentation and coding changes that occurred from FYs 2007 to 2009 that the agency says do not reflect real changes in case-mix. It also contains a further cut of 0.8 percent to eliminate changes that occurred from FYs 2007 to 2010. As the AHA has repeatedly argued in the past with respect to the FY 2008 and 2009 adjustments, **there is a fundamental flaw in CMS's methodology for determining the effect of documentation and coding. Now, the agency proposes an additional cut of 0.8 percent with respect to FY 2010. The AHA is extremely troubled by this proposal and by the fact that CMS continues to compare hospitals' documentation and coding practices to their documentation and coding practices under an entirely different system in FY 2007; doing so is highly inappropriate.**



Ms. Marilyn Tavenner

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In contrast, our analyses have found that much of the change CMS cites is actually the continuation of historical increases in the case-mix index (CMI) rather than the effect of documentation and coding changes due to the implementation of the Medicare severity diagnosis-related groups (MS-DRGs). **Thus, CMS's proposed cuts are excessive in light of these historical trends and must not be implemented.**

**However, if CMS is unwilling to acknowledge that these cuts must not be implemented, at the very least, it should account for the fact that its methodology overestimates the effect of documentation and coding.** This overestimation has been raised in past comment letters by both the Medicare Payment Advisory Commission, as well as the AHA.

#### **HOSPITAL READMISSIONS REDUCTION PROGRAM**

*The Patient Protection and Affordable Care Act of 2010* mandates that CMS implement a program in which hospitals with higher-than-expected readmission rates will see reductions in their Medicare payments in FY 2013 and beyond. The statute mandates that CMS adjust the readmission measures to account for readmissions that are planned and related to the initial admission. For FY 2013, CMS previously finalized that it will use the three existing 30-day readmission measures for heart attack, heart failure and pneumonia patients. **However, CMS has not excluded all planned and unrelated readmissions from these measures, despite ongoing feedback from the AHA and others.** The AHA strongly disagrees with this decision and believes the agency has ignored Congress's intent that the measures be modified to explicitly exclude these readmissions. **In addition, we ask CMS to account for disparities in the readmission data by adjusting for patient characteristics that are beyond hospitals' control, such as dual-eligible status.**

#### **SOLE COMMUNITY HOSPITALS**

Currently, a hospital's SCH classification remains in effect without the need for re-approval unless there is a change in the circumstances under which the classification was approved. However, CMS proposes that an SCH be required to report to its fiscal intermediary any factor or information that could have affected its initial classification as an SCH; otherwise, CMS may cancel the hospital's SCH status retroactive to when it was granted. **The AHA strongly disagrees with this inappropriately punitive policy, which is inconsistent with similar existing regulations.**

**We urge the agency to modify its requirement to ensure consistency with other existing regulations.** First, CMS should require that an SCH report only if it becomes aware of one or more errors in its initial application that could have affected its initial classification. Second, we urge CMS to clarify that if a hospital is aware of, but does not report as required, the agency may cancel the hospital's classification effective on the date the hospital became aware of the factors or information, not retroactive to when its SCH status was first granted. Finally, we urge CMS to clarify that hospitals must make a report within 30 days of becoming aware of any factor or information that could have affected the initial classification.

Our detailed comments are attached. If you have any questions, please feel free to contact me or Joanna Hiatt Kim, senior associate director for policy, at (202) 626-2340 or [jkim@aha.org](mailto:jkim@aha.org).

Sincerely,

/s/

Rick Pollack  
Executive Vice President

**American Hospital Association  
Detailed Comments on the Inpatient Prospective Payment System  
Proposed Rule for FY 2013**

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## **CHANGES TO MS-DRG CLASSIFICATIONS AND RELATIVE WEIGHTS**

In fiscal year (FY) 2007, the Centers for Medicare & Medicaid Services (CMS) undertook significant efforts to reform the CMS diagnosis-related groups (CMS-DRGs) and the calculation of the corresponding relative weights. The agency began to transition to cost-based weights in FY 2007, and to Medicare-severity DRGs (MS-DRGs) in FY 2008, and to overhaul the complications and comorbidities (CC) list in FY 2008. In FY 2009, these changes were fully implemented.

### **MS-DRG DOCUMENTATION AND CODING ADJUSTMENT**

*The TMA, Abstinence Education and QI Programs Extension Act of 2007* required CMS to apply documentation and coding adjustments of negative 0.6 percent in FY 2008 and negative 0.9 percent in FY 2009. The law also specified that, to the extent that the required adjustments for FYs 2008 and 2009 resulted in overpayments or underpayments relative to the actual amount of documentation and coding-related change due to the introduction of the MS-DRGs, the Secretary of the Department of Health and Human Services (HHS) would correct the overpayments or underpayments going forward, as well as make additional adjustments during FYs 2010 through 2012 to offset the increase or decrease in aggregate payments that occurred during FYs 2008 and 2009.

CMS applied a negative 0.6 percent documentation and coding adjustment in FY 2008 and a further negative 0.9 percent adjustment, in FY 2009, for a total adjustment of negative 1.5 percent. However, the agency calculated that documentation and coding changes actually increased payments by 2.5 percent in FY 2008, and by an additional 2.9 percent in FY 2009 – a total increase of 5.4 percent. Therefore, CMS has stated that it must make one-time payment cuts of 1.9 percent to recoup overpayments made in FY 2008 and 3.9 percent to recoup overpayments made in FY 2009 – or 5.8 percent total. In FY 2011, the agency applied half of this adjustment; it applied the remainder in FY 2012. Because these were one-time cuts, CMS proposes to restore FY 2012's 2.9 percent cut in FY 2013.

CMS also proposes to make a permanent documentation and coding cut to remove increased FY 2008 and 2009 payments from the system. The agency asserts that a total prospective cut of 5.4 percent is necessary. However, CMS previously applied cuts of 3.5 percent; thus, a cut of 1.9 percent remains, which CMS proposes to apply in FY 2013.

In addition, CMS stated that it determined that implementation of the MS-DRGs continued to lead to documentation and coding changes in FY 2010 that it says do not reflect real changes in case-mix. Accordingly, it proposes a further permanent documentation and coding cut of negative 0.8 percent to remove increased FY 2010 payments from the system.

For sole community hospitals (SCHs) and Medicare-dependent hospitals (MDHs), CMS also found that coding and classification changes that the agency says do not reflect real changes in case mix increased payments by 5.4 percent in FYs 2008 and 2009. In FYs 2011 and 2012, CMS applied part of this cut – 2.9 percent and 2.0 percent, respectively. It proposes to apply the remainder of the cut – 0.5 percent – in FY 2013. In addition, CMS proposes to apply a new

permanent documentation and coding cut of 0.8 percent to the hospital-specific rates to remove increased FY 2010 payments from the system.

For Puerto Rico hospitals, CMS found that documentation and coding changes that the agency says do not reflect real changes in case mix increased payments by 2.6 percent total in FYs 2008 and 2009. In FY 2011, the agency applied the entire 2.6 percent cut. The agency states that it found no further documentation and coding change for Puerto Rico related to FY 2010.

**CMS's Methodology.** CMS used the same methodology to analyze changes due to documentation and coding in FYs 2008, 2009 and 2010. For example, for FY 2008, the agency divided the case-mix index (CMI) obtained by running the FY 2008 claims data through the FY 2008 GROUPEL by the CMI obtained by running these same FY 2008 claims data through the FY 2007 GROUPEL, which yielded 1.028, or an increase of 2.8 percent. CMS states that this 2.8 percent is comprised of documentation and coding change, as well as a GROUPEL change. CMS asserts that none of this 2.8 percent can be deemed "real" case mix change because the analysis uses only one set of claims and, therefore, one set of patients.

To determine the effect of GROUPEL changes, CMS divided the CMI obtained by running the FY 2007 claims data through the FY 2008 GROUPEL by the CMI obtained by running these same FY 2007 claims data through the FY 2007 GROUPEL, which yielded 1.003, or an increase of 0.3 percent. CMS then divided 1.028 by 1.003 to yield 1.025, or a documentation and coding-related increase of 2.5 percent in FY 2008. CMS used the same methodology to determine that there had been a cumulative documentation and coding-related increase of 5.4 percent in FY 2009, and cumulative documentation and coding-related increase of 6.2 percent in FY 2010.

**We are extremely troubled that CMS continues to believe that it should hold the CMI when using the FY 2010 MS-DRG GROUPEL equal to the CMI when using the FY 2007 CMS-DRG GROUPEL.** CMS adopted the MS-DRG GROUPEL because RAND and others found it to be a superior tool to measure CMI differences across hospitals. The same is true when looking at CMI differences over time. In fact, the MS-DRG GROUPEL was specifically developed to better measure within-DRG CMI change – something that the CMI-DRG GROUPEL did poorly. **It is time for CMS to discard this flawed methodology.**

In addition, the inpatient PPS has changed substantially since FY 2007. Specifically, the FY 2007 inpatient prospective payment system (PPS) utilized charge-based weights, CMS-DRGs, a pre-reform CC list and only nine diagnosis codes per claim. In contrast, the FY 2010 inpatient PPS utilized cost-based weights, MS-DRGs, and a reformed CC list, as well as, at the end of the year, up to 25 diagnosis codes per claim. **Yet, CMS continues to believe that the CMI in FY 2007 should be equal to the CMI in FY 2010. This is highly inappropriate. We applaud the many improvements the agency has made to the inpatient PPS; it is time to fully embrace this improved system and stop comparing it to the prior, obsolete system.**

**In addition, the AHA again asserts that there is a fundamental flaw in CMS's methodology for determining the effect of documentation and coding to begin with. Specifically, CMS states that none of the increase it found can be deemed "real" case-mix change because its**

**analysis looks at only one year of patient claims. However, we assert that this increase cannot be deemed documentation and coding change either, because the analysis looks at only one year of patient claims, which by definition are coded identically.** Analyzing a single year of claims is not the correct methodology for determining whether there is a change in documentation and coding practices relative to prior years. In contrast, CMS should use a more appropriate claims-based methodology to estimate documentation and coding change, one that takes real case-mix changes into account, as outlined below.

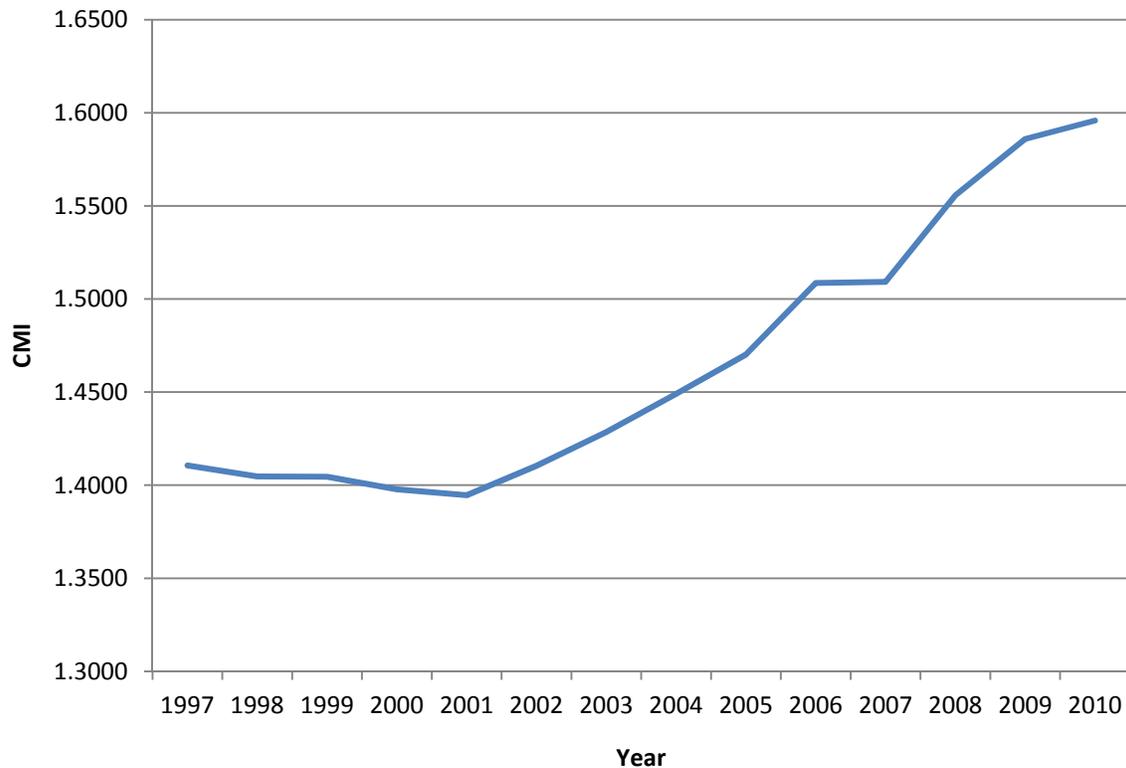
**If the agency is unwilling to do that, we ask that it take into account the effect of “negative documentation and coding.”** Specifically, while CMS asserts that changes in documentation and coding increased the CMI under the MS-DRGs, it does not consider that changes in documentation and coding also may have decreased the CMI under the CMS-DRGs. We term this effect negative documentation and coding and it has led CMS to overestimate the effect of documentation and coding. **To correct for this overestimation, the agency should lower its proposed documentation and coding cut, as well as correct its past documentation and coding cuts.** Specifically, CMS has proposed cuts of 1.9 and 0.8 percent – a total of 2.7 percent – in FY 2013. However, the Medicare Payment Advisory Commission (MedPAC) has estimated that CMS has overestimated the effect of documentation and coding by up to 0.25 percentage points. Thus, when taking into account this effect of negative documentation and coding, a cut of only 2.45 percent is justified – the 2.7 percent CMS has proposed, minus the 0.25 percentage point overestimation. In the past, the agency has implied that overstating its cut by 0.25 percentage points is a small amount. However, this overstatement would inappropriately cut inpatient payments by \$265 million in FY 2013 and \$2.9 billion over 10 years, which is no small amount to hospitals. Condoning such inaccuracy is a significant departure from the agency’s usual practices.

**AHA Analyses.** We once again urge the agency to use a trend-based analysis of claims data to determine the effect of documentation and coding. The AHA has conducted multiple analyses to this end. Specifically, in AHA’s comment letter on the FYs 2011 and 2012 inpatient PPS proposed rules, we presented our trend-based analysis that outlined a more appropriate methodology to calculate the effect of documentation and coding on hospital payments. This year we update that methodology to incorporate FY 2010. **Under this methodology, no further documentation and coding adjustments are necessary beyond what CMS already has implemented. Thus, CMS’s proposed cuts totaling 2.7 percent *must not* be implemented.**

To conduct our trends-based analysis, we included inpatient PPS claims from FYs 1997 through 2010, but excluded hospitals that converted to critical access hospital (CAH) status by the end of 2010 from all years of our analysis. We grouped each year of claims using the FY 2010 MS-DRG GROUPER (Version 27) and calculated the associated CMI, holding the weights constant. **Since CMS is attempting to assess the impact of documentation and coding changes relative to the new MS-DRG GROUPER, it is important that this one GROUPER be used to assess historical case mix change.** The FY 1997 through 2007 results reflect how claims would have been grouped under MS-DRGs had this system been in place at the time. In addition, these results reflect a combination of real case-mix growth and hospitals’ pre-MS-DRG documentation and coding practices. The FY 2008, 2009 and 2010 results reflect a combination of real case-

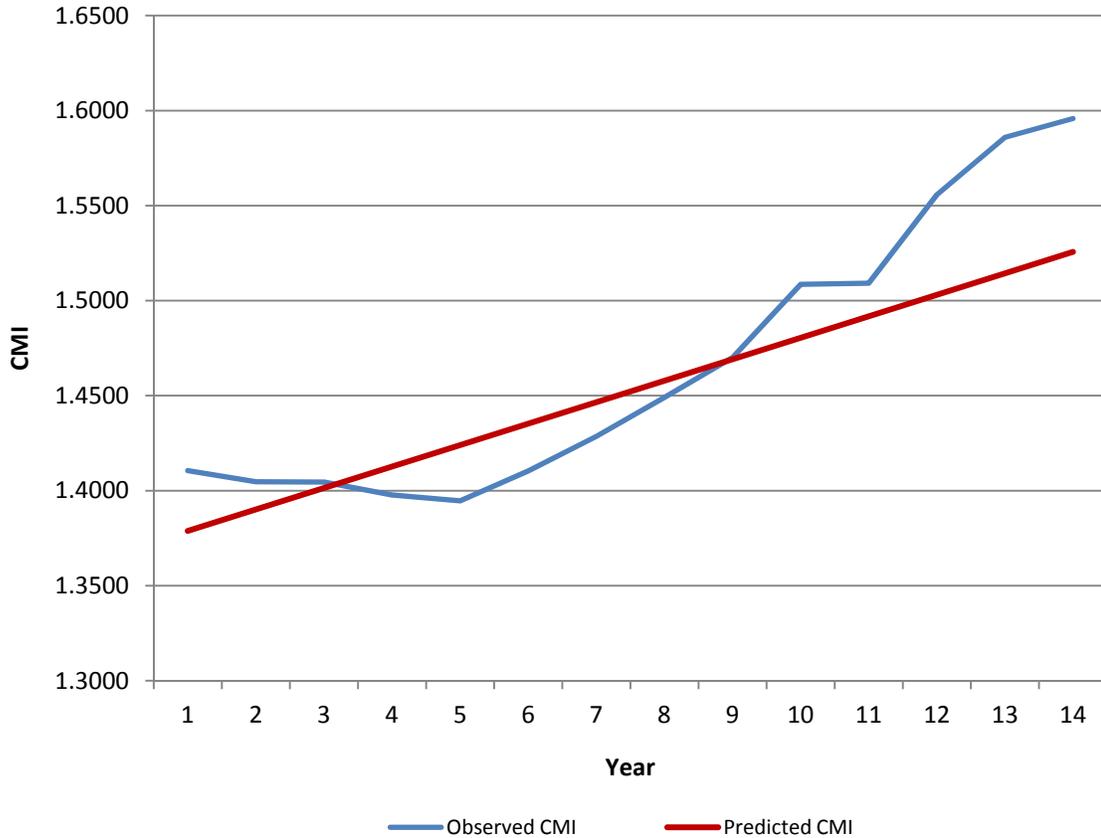
mix growth and hospitals' post-MS-DRG documentation and coding practices. See Figure 1 for a graphic depiction of these CMI values from FY 1997 through 2010.

**Figure 1 – CMI from FY 1997 through 2010 as Measured Using the Version 27 MS-DRG GROUPER**



Next, we used the FY 1997 through 2007 CMI values above to create “predicted” CMI values for all years, including FYs 2008, 2009 and 2010. These values represent what CMI would have been in FYs 2008, 2009 and 2010 had hospital case mix continued its historical trend. See Figure 2 for a graphic depiction of these predicted and observed CMI values from FY 1997 through 2010.

**Figure 2 – Predicted and Observed CMIs from FY 1997 through 2010 as Measured Using the Version 27 MS-DRG GROUPEr**



Finally, we compared the predicted growth rate to the observed growth rate in CMI from FYs 2007 to 2010. The predicted growth rate over these years was 2.27 percent, which represents what the growth in CMI would have been had real case mix continued its historical trend and had hospitals maintained consistent documentation and coding practices. The observed growth rate was 5.74 percent. Because the observed rate is higher than the predicted, it indicates that hospitals did change their documentation and coding practices when MS-DRGs were implemented. In order to determine the amount by which this change in documentation and coding affected CMI, we subtracted the predicted growth rate from the observed growth rate, which yielded 0.0347, or a cumulative documentation and coding-related increase of 3.5 percent for FY 2010.

Under this approach, there was a cumulative documentation and coding-related increase of 3.5 percent; however, CMS already has applied documentation and coding cuts of exactly 3.5 percent. **Thus, no additional cuts are necessary to permanently decrease the standardized amount to what it would have been absent documentation and coding changes. Accordingly, CMS's proposed cuts of 1.9 and 0.8 percent are excessive in light of historical**

**trends. The AHA urges the agency not to implement them; we also urge the agency to adjust its past recoupment cuts accordingly.**

In the analyses outlined above, we applied simple linear regressions to fit the trendline using the FY 1997 through 2007 CMIs to project values for FYs 2008, 2009 and 2010. We also tested using piecewise and quadratic regressions to fit the trendline. Although both the piecewise and quadratic regressions are a better fit, we presented the simple linear regression above because it was the most conservative approach in terms of the measured documentation and coding effect. However, because CMS has asserted, in the past that “changes in case-mix do not necessarily follow a consistent pattern over time,” we include the results of all the regression models below in Table 1. In fact, if one were to use these non-linear regressions, as CMS has implied is appropriate, the estimates of documentation and coding are lower than what we have presented above, and much lower than what CMS has proposed currently and in the past. We encourage the agency to test a range of regression models.

**Table 1 – Cumulative FY 2010 Documentation and Coding Estimates under Different Regression Models as Measured Using the Version 27 GROUPER**

<b>Regression Model</b>	<b>Adjusted R-squared</b>	<b>Percent change in observed CMI</b>	<b>Percent change in predicted CMI</b>	<b>Cumulative documentation and coding effect</b>
Simple linear	73%	5.74%	2.27%	3.47%
Piecewise	98%	5.74%	4.07%	1.67%
Quadratic	96%	5.74%	7.62%	-1.88%

Finally, CMS has applied documentation and coding cuts to SCHs, MDHs and Puerto Rico hospitals in the past; it also proposes further cuts to SCHs and MDHs for FY 2013. **However, we urge CMS to reconsider its past and proposed cuts to SCHs, MDHs and Puerto Rico hospitals. The agency should use the methodology outlined above to re-estimate documentation and coding increases related to SCHs and MDHs and Puerto Rico hospitals and to correct the cuts it has made already, as well as the cuts it proposes to make, accordingly.**

**Negative Documentation and Coding Effect on CMS-DRGs.** If CMS is unwilling to use a trend-based analysis of claims data to determine the effect of documentation and coding, we urge the agency to take into account the effect of “negative documentation and coding” with respect to the FY 2007 GROUPER. Specifically, in our comment letter on the FY 2011 inpatient PPS proposed rule, we brought to CMS’s attention that, while it asserts that changes in documentation and coding increased the CMI under the MS-DRGs, it does not consider that changes in documentation and coding also may have decreased the CMI under the CMS-DRGs. We refer to this effect as negative documentation and coding. Although the agency did not respond to our comments, whether or not documentation and coding decreased the CMI under the prior set of DRGs, the CMS-DRGs, is critical because CMS uses as a denominator in its analysis the CMI

value it obtained when running the FY 2010 claims data through the FY 2007 CMS-DRG GROUPEL. A decrease in this denominator yields an overestimation of documentation and coding. **When we took negative documentation and coding into effect and corrected for this overestimation, we found that smaller documentation and coding adjustments than what CMS has both implemented in the past and proposed for the future are warranted. Thus, CMS's cuts *must not* be implemented as proposed.**

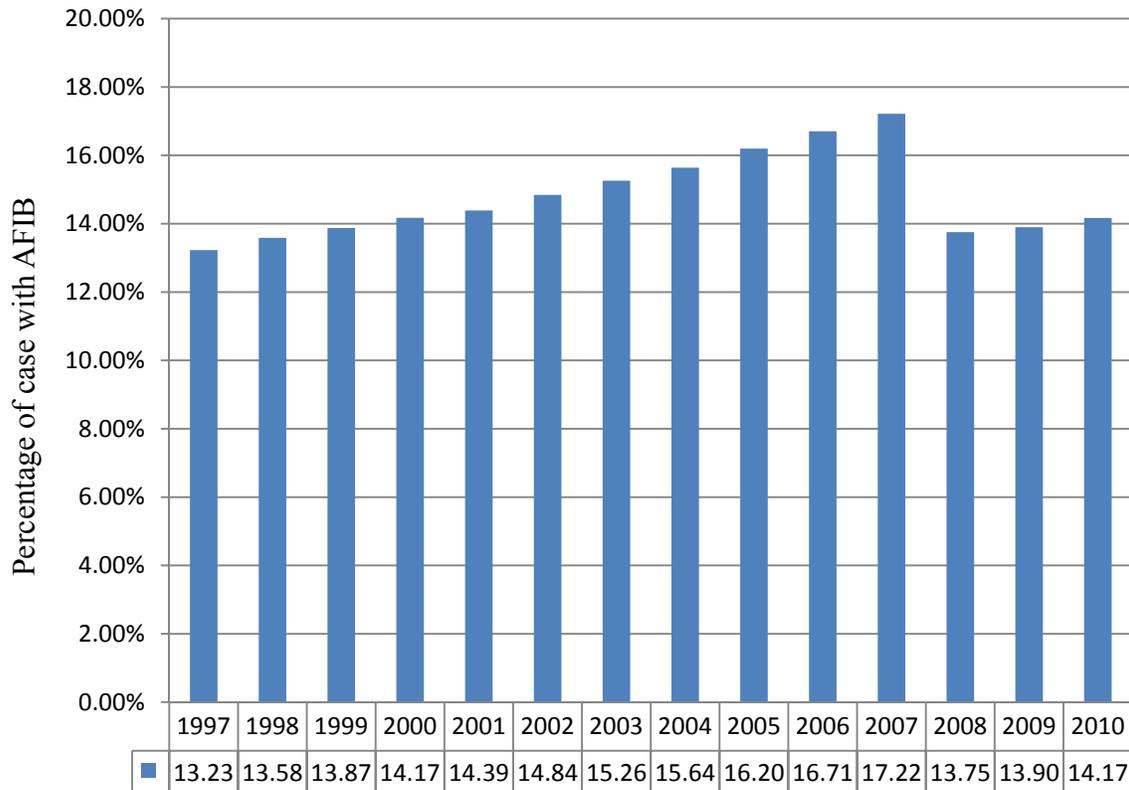
The fact that CMS should consider this possibility is not our view alone – it was corroborated by MedPAC in its comment letter on the FY 2012 inpatient PPS proposed rule. Specifically, MedPAC stated that it is possible that changes in documentation and coding may have decreased the CMI under the CMS-DRGs. It found that the magnitude of this effect cumulatively could have been as much as 0.36 percent in FY 2008, 0.36 in FY 2009 and 0.25 percent in FY 2010. CMS responded to MedPAC's comment by noting that MedPAC characterized the potential effect as "small" and did not provide any corroborating analysis or specific examples of when this scenario may have occurred. Further, the agency stated that it consulted with its medical coding experts and was unable to identify specific examples to support MedPAC's hypothesis.

**If CMS applies a documentation and coding cut in FY 2013 that is overstated by 0.25 percent, it will inappropriately cut hospital payments by \$265 million in FY 2013, and by \$2.9 billion over 10 years. While governmental agencies such as MedPAC and CMS may consider \$2.9 billion a "small" amount, America's hospitals do not. Considering the reality that hospitals care for Medicare beneficiaries with complicated medical needs, and that Medicare payments to hospitals for these services are already below the cost of providing the care, \$2.9 billion is an extremely substantial – and by no means "small" – amount.**

**We identified numerous examples of when changes in documentation and coding may have decreased the CMI under the CMS-DRGs, which CMS said it was lacking.** By comparing the 2007 CC list to the 2008 CC list, we were able to readily identify examples of chronic conditions that were CCs under the CMS-DRGs, but are no longer considered CCs or MCCs under the MS-DRGs, and that would also necessarily result in a lower MS-DRG assignment because more specific codes related to that condition were not developed. We are surprised that CMS's medical coding experts were unable to do the same.

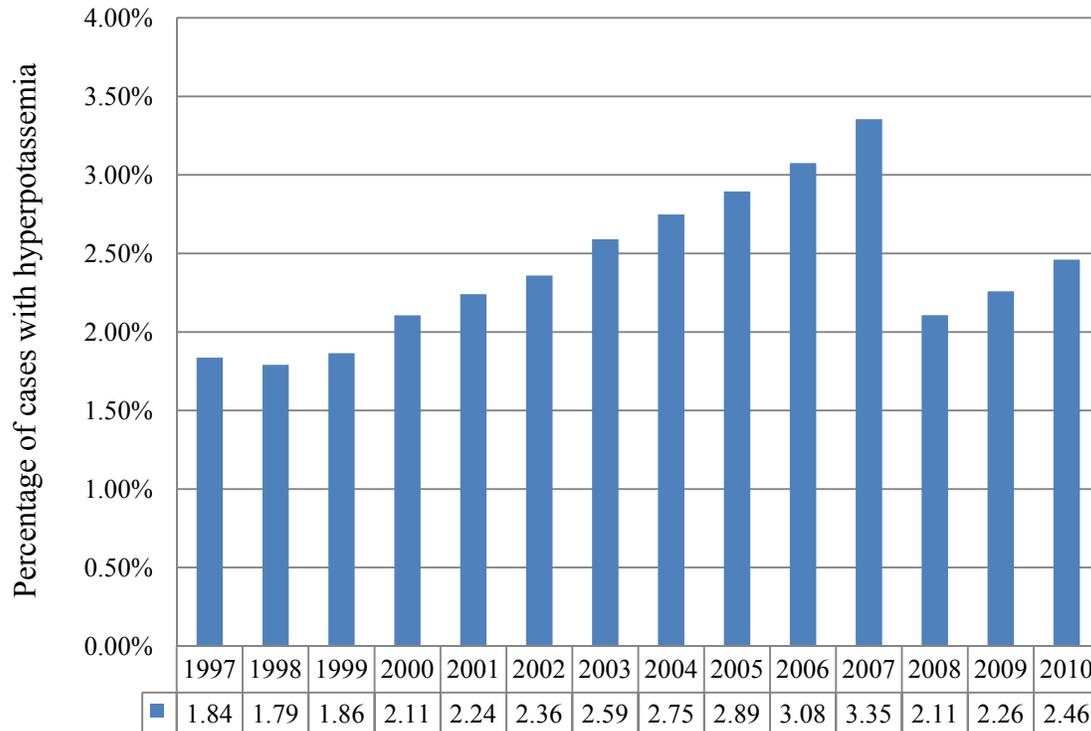
For example, atrial fibrillation was a CC under the CMS-DRGs, but is not a CC or MCC under the MS-DRGs. Because of this, as shown in Figure 3, there was a substantial decrease in the reporting of atrial fibrillation as a secondary diagnosis when the MS-DRGs were implemented in FY 2008. Specifically, after 10 years in which the proportion of inpatient PPS cases that included atrial fibrillation as a secondary diagnosis increased each year, the proportion decreased by 20 percent immediately upon implementation of the MS-DRGs in FY 2008. This decrease in coding of atrial fibrillation would cause the CMI as measured by the FY 2007 DRG GROUPEL to go down, while having no effect on the CMI as measured by the MS-DRG GROUPEL. If this negative documentation and coding effect is not taken into account in CMS's analysis, it will inappropriately increase CMS's estimate of documentation and coding change.

**Figure 3 – Proportion of Inpatient PPS Cases with Atrial Fibrillation, FY 1997 through 2010**



In addition, hyperpotassemia was a CC under the CMS-DRGs, but is not a CC or MCC under the MS-DRGs. Because of this, as shown in Figure 4, there was a substantial decrease in the reporting of hyperpotassemia as a secondary diagnosis when the MS-DRGs were implemented in FY 2008. Specifically, after nine consecutive years in which the proportion of inpatient PPS cases that included hyperpotassemia as a secondary diagnosis increased, the proportion decreased by 37 percent immediately upon implementation of the MS-DRGs in FY 2008.

**Figure 4 – Proportion of Inpatient PPS Cases with Hyperpotassemia, FY 1997 through 2010**



We also found that the secondary diagnoses of chronic blood loss anemia, mitral valve disorder and aortic valve disorder decreased in proportion immediately upon implementation of the MS-DRGs in FY 2008.

In responding to MedPAC’s analysis, CMS concluded that it did not think it would be appropriate to revise its estimates based solely on MedPAC’s analysis without knowing of any specific examples. Given that we are now providing such specific examples, **we urge the agency to revise its analysis to account for its overestimation of documentation and coding as identified by MedPAC and the AHA.** Specifically, CMS should subtract 0.25 percentage points from its estimate of a 6.2 percent cumulative documentation and coding effect; this yields a revised cumulative effect of 5.95 percent. **Under this methodology, because the agency has already implemented documentation and coding cuts of 3.5 percent, the cut remaining is actually only 2.45 percent, instead of the 2.7 percent the agency proposed.**

In addition, CMS already has made one-time payment cuts of 5.8 percent to recoup what it states were overpayments made in FYs 2008 and 2009 due to documentation and coding changes. However, MedPAC estimated that CMS overstated the effect of documentation and coding by 0.36 percent in each of FYs 2008 and 2009. Therefore, although CMS made recoupment cuts

totaling 5.8 percent, only 5.08 percent of this was justified. **We urge the agency to correct this over-recoupment by implementing a one-time increase of 0.72 percent to inpatient payment rates.**

#### **MS-DRG RECLASSIFICATIONS**

In general, the AHA has no objections to CMS's proposed changes to the MS-DRG classifications, which seem reasonable given the data and information provided.

**Medicare Code Editor (MCE) Changes.** CMS proposes to implement a new edit for procedure code 96.72 (continuous invasive mechanical ventilation for 96 consecutive hours or more) that would return claims with a length of stay less than four days to the provider for validation and resubmission. While such a circumstance may at first seem impossible, long-standing coding rules actually allow the counting of mechanical ventilation hours from the time the ventilation is initiated either in the emergency department or upon admission.

As CMS notes in the proposed rule, in particular circumstances, such as for patients who may require observation services, it is possible to have procedure code 96.72 reported on the claim with a length of stay of less than four days. Therefore, CMS's proposed edit would be an administrative burden to hospitals, the vast majority of which are legitimately and correctly reporting the code based on existing coding rules.

**The AHA urges CMS to reconsider its proposal to implement a new edit for procedure code 96.72 and consider using other elements on the claim to address any potential coding errors.** For example, CMS could implement a new revenue code for procedure code 96.72 in which with the units are reported as hours. Alternatively, it could create an edit that simultaneously evaluates the length of the inpatient stay, the reported units of revenue code 0762, which indicates the number of hours of observation, and the "from" and "to" dates on the statement period of the claim.

**Code Freeze. The AHA applauds CMS's recommendations to continue the limited code updates to both ICD-9-CM and ICD-10-CM/PCS to capture new technologies and diseases until a year before implementation of ICD-10. No updates should occur the year ICD-10 goes live. Regular updates to ICD-10-CM/PCS should resume a year after implementation.**

The 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, implementing the new system must be carefully orchestrated to minimize the administrative burden on providers. Continuing regular updates to ICD-9-CM and ICD-10-CM/PCS would make the implementation of these new code sets more costly and complex, requiring repeated changes to systems and educational training materials.

At a time when the health care field, payers and other stakeholders will be struggling to change and test their systems with their trading partners, making additional changes a few months prior to nationwide implementation of ICD-10 would create significant problems. Because of the granularity of ICD-10-PCS, even a "minor" change could potentially result in more than 100

new codes. For example, the proposal presented at the March 2010 Coordination and Maintenance meeting to add a single root operation (supplement) to a single body system (subcutaneous tissue and fascia body system) resulted in 132 new codes.

Virtually every information system where clinical codes are used will need to be modified, validated and tested internally before external testing can begin. Hospitals will need at least a year to test with health plans (and allow time for corrections/modifications based on the results of the testing). If new codes can still be introduced into ICD-10-CM/PCS on the go-live date, it will result in continuous changes and make the resolution of any testing failures all the more complex and costly.

#### **RECALIBRATION OF MS-DRG RELATIVE WEIGHTS**

**We are pleased that CMS has not proposed any major refinements to its methodology for calculating the MS-DRG relative weights for FY 2013.** The hospital field continues to support meaningful improvements to Medicare's hospital inpatient PPS. The AHA and CMS share the common goal of refining the system to improve accuracy and reimburse hospitals appropriately for the services they provide. The system also should be simple, transparent and predictable over time. One of the fundamental values of a PPS is the ability of providers to reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions.

#### **SOLE COMMUNITY AND MEDICARE-DEPENDENT HOSPITALS**

**Clarification of Regulations Regarding Duration of SCH Classification Period.** Currently, a hospital's SCH classification remains in effect without the need for re-approval unless there is a change in the circumstances under which the classification was approved. However, CMS states that these regulations do not explicitly address a situation where a hospital never met the requirements to be classified as an SCH to begin with, but was nonetheless granted such classification. CMS proposes to create a new requirement at §412.92 (b)(3)(iv) to state that an SCH must report to its fiscal intermediary (FI) or Medicare Administrative Contractor (MAC) any factor or information that could have affected its initial classification as an SCH. If it does not, CMS may cancel the hospital's classification retroactive to when it was first granted. This proposal would require SCHs to monitor and have knowledge of any and all factors and information that could have affected their initial classification – and then potentially allow the retroactive cancellation of their classification if they do not do an adequate monitoring job. **The AHA strongly disagrees with this inappropriately punitive policy, which is inconsistent with existing regulations.**

CMS cannot hold SCHs accountable for monitoring and having knowledge of any and all factors and information that could have affected their initial classification. Forcing them to do so would impose a tremendous administrative burden on these hospitals. We can envision many scenarios in which a hospital could have unintentionally obtained SCH status when it should not have, through absolutely no fault or knowledge of its own.

CMS's criteria for SCH classification are laid out in 42 C.F.R. §412.92(a), and the data that SCH applicants must provide for qualification under certain qualification pathways are laid out in 42 C.F.R. §412.92(b)(ii). Some of these data come from sources outside of the hospital. For example, §412.92(b)(ii)(B) states that "the hospital must provide patient origin data from all other hospitals located within a 35 miles radius of it or, if larger, within its service area..." It is possible that one of those "other hospitals" provided inaccurate patient origin data to the SCH. **However, CMS now seems to be proposing to require the SCH to continually monitor the accuracy of data provided by others, or risk the cancellation of its classification retroactive to when it was first granted. Such a proposal is unfair and inappropriate.**

SCHs may have also obtained SCH status when they should not have because of a misinterpretation of the regulations or a changed interpretation of the regulations due to, for example, an FI's staff turnover. The regulations are complex, to say the least, and thus, CMS does not simply rely on a hospital's interpretation of the regulations to grant SCH status. The application and approval processes are laid out in 42 C.F.R. §412.92 (b) and specify that:

- hospitals must make their SCH request to their FI;
- the FI must review the request and send it, along with its recommendation, to CMS; and
- CMS must review the request and the FI's recommendation and forward its approval or disapproval to the FI.

CMS does not simply take the hospital's word that it qualifies as an SCH. The agency's qualification criteria are complex; not only must the hospital demonstrate that it qualifies for SCH status, but both the FI, acting as CMS's representative, and CMS itself must review, agree as to the interpretation of the regulations, and approve the hospital's SCH status. **However, CMS now seems to be proposing to require the SCH to continually monitor and verify whether CMS itself correctly interpreted its own regulations. We also are concerned that this proposal puts SCHs at risk for a change in interpretation of the regulations, even after all parties involved have already agreed to the interpretation that led to the SCH's classification. Such a proposal is unfair and inappropriate.**

**Further, CMS's proposal is inconsistent with other existing regulations. We urge the agency to make three modifications to its proposal to rectify these inconsistencies and the inappropriately punitive nature of its proposal. First, we urge CMS to modify its proposed new requirement §412.92 (b)(3)(iv) so that it is consistent with its FY 2007 inpatient PPS final rule and the regulations at §412.92 (b)(3)(iii).** Specifically, the agency stated in its FY 2007 inpatient PPS final rule that "certain criteria may be excessively burdensome for a hospital to monitor" (71 *Federal Register* 48060). This recognition is why, in §412.92 (b)(3)(ii), a requirement similar to the one CMS proposes, the agency requires an SCH to monitor and report only certain changes in its circumstances, such as the opening of a new hospital in its service area. For other changes in circumstance, the agency requires the SCH to report only if it becomes aware of such a change. **Accordingly, we urge CMS to require that an SCH report to its FI or MAC if it becomes aware of one or more errors in its initial application that could have affected its initial classification.** Holding a hospital accountable for monitoring and having knowledge of any and all factors that could have affected its initial classification as an

SCH, especially considering that this initial classification was granted more than 20 years ago for many hospitals, is inappropriate.

**Second, we urge the agency to modify the effective date of any SCH-status cancellations.** Specifically, CMS proposes that if a hospital does not report factors or information that could have affected its initial classification, the agency may cancel the hospital's SCH classification effective the date the hospital failed to meet the criteria, which, by definition, is the date of the initial classification. However, §412.92 (b)(3)(iii), a regulation similar to the one CMS proposes, states that if CMS determines a hospital was aware of a change that affected its SCH status, but did not report it, CMS will cancel the classification effective on the date the hospital became aware of the change, consistent with the re-opening rules at §405.1885. **Thus, to be consistent with its own regulations, we urge CMS to clarify that if a hospital is aware of, but does not report, factors or information that could have affected its initial classification, the agency may cancel the hospital's classification effective on the date the hospital became aware of the factors or information.** A hospital should not be held accountable prior to the point at which it became aware of the problem.

However, to also be consistent with the interpretation of these regulations as laid out in its FY 2007 inpatient PPS final rule (71 *Federal Register* 48061), **CMS should clarify that if the hospital is aware of, and does report, factors or information that could have affected its initial classification, the SCH status will instead be terminated 30 days after the Regional Office's decision that the hospital no longer meets the SCH criteria.** We urge the agency to codify this effective date in the actual regulations at §412.92 (b)(3)(ii), §412.92 (b)(3)(iii) and §412.92 (b)(3)(iv), instead of simply in the rule's preamble, as has been done to date.

Lastly, as proposed, §412.92(b)(3)(iv) does not include a specific timeframe for the hospital to make a report. However, both §412.92(b)(3)(ii) and §412.92(b)(3)(iii) provide for reporting within a 30-day period. The proposed rule offers no explanation as to why the other provisions include a set timeframe for reporting, but §412.92(b)(3)(iv) does not. We believe that it is important for CMS to provide clarity on timeframes for reporting, and to give hospitals lead time between becoming aware of information that could trigger a requirement to report and when they must make a report. That lead time would allow hospitals time to assess whether the information warrants a report, for example. As such, **we urge CMS to modify the proposed text of §412.92(b)(3)(iv) to indicate that hospitals must make a report within 30 days of becoming aware or any factor or information that could have affected the initial classification.** Consistent with other aspects of the rulemaking, we believe that the new reporting requirement under §412.92(b)(3)(iv) should not take effect until 60 days after the issuance of the final rule, and that also should be clarified in the final rule.

**In summary, to be consistent with its own regulations and avoid being inappropriately punitive to SCHs, we urge CMS to modify its proposed regulation §412.92 (b)(3)(iv). The agency should require an SCH to report to its FI or MAC if it becomes aware of one or more errors in its initial application that could have affected its initial classification as an SCH. It should require that the SCH make this report within 30 days of becoming aware of the factor or information. The SCH's status would then be cancelled 30 days after the**

**Regional Office’s decision that the hospital no longer meets the criteria for such classification. If CMS determines that an SCH has failed to comply with this reporting requirement, CMS could cancel the hospital’s classification as an SCH effective with the date the hospital became aware of the factor or information that resulted in the SCH no longer meeting the criteria for such classification, consistent with the provisions of §405.1885.**

**Medicare-dependent Hospitals (MDHs) Applying for SCH Status.** CMS states that it has become aware of a number of MDHs that intend to apply for SCH classification upon the expiration of the MDH program. To facilitate a seamless transition for those MDH hospitals that will qualify as SCHs, CMS proposes to add an exception to its SCH effective-date policy. Specifically, it proposes that, for any MDH that applies for SCH status by August 31, 2012, and requests that its SCH status be effective with the expiration of the MDH program, the effective date of the hospital’s SCH classification would be October 1, 2012. **The AHA strongly supports this policy change and thanks CMS for its proposal, which will be very helpful to many MDHs.**

However, the possibility remains that Congress may extend the MDH program retroactively, after it expires on October 1, 2012. To account for this distinct possibility, **we ask that CMS provide hospitals with the ability to, in turn, rescind their new SCH status retroactively and reinstate their MDH status in a seamless manner, if a retroactive extension to the MDH program is made. Such an allowance would be extremely helpful for these hospitals, which are facing an unreasonably uncertain future of Medicare inpatient payments.**

## **OUTLIER PAYMENTS**

The rule states that CMS’s proposed outlier threshold for FY 2013 will yield outlier payments equal to 5.1 percent of operating DRG payments. We have been unable to successfully reproduce the cited operating outlier percentage of 5.1 percent. Instead, our analysis results in an operating outlier percentage of 4.8 percent. We believe this is because CMS is using the capital cost-to-charge ratio (CCR) adjustment factor when calculating the operating outlier percentage. **Therefore, we recommend that CMS re-evaluate its calculation to ensure that the operating outlier percentage is correct.**

**CCRs Used in Fixed-loss Threshold Calculation.** The rule states that CMS used hospital CCRs from the December 2011 update to the Provider-Specific File (PSF) – the most recent available data at the time of this proposed rule – to simulate FY 2013 outlier payments. However, it appears that CMS did not actually use the most recent CCRs available in the December 2011 PSF file. The current version of the PSF is the March 2012 update. We used the “effective date” of PSF records to reconstruct the December 2011 version, as generally PSF CCRs are not changed retrospectively. We deemed records with effective dates of January 15, 2012 (reflecting the mid-January release date) or earlier to have been present in the December 2011 PSF update. We then matched CCRs from the 2013 Proposed Rule Impact File (that was used by CMS to calculate the FY 2013 outlier threshold) against PSF records with effective dates

of January 15, 2012 to determine if CMS in fact used the most recent CCRs available in the December 2011 PSF file, as stated in the proposed rule. The matching process yielded the results displayed in the Table 2 below. As shown in the table, for only 200 hospitals were the CCRs CMS used actually equal to the most recent CCRs available in the December 2011 PSF file. To determine the impact of using these out-of-date CCRs, we compared the value of the impact file operating CCRs that CMS used to calculate the outlier threshold to the most recent CCRs available in the December 2011 PSF file. Higher operating CCRs yield a higher outlier threshold. We found that for about two-thirds of hospitals for which the CCRs did not match, the impact file CCRs were greater than the most recent CCRs. Thus, this finding confirms the reason that CMS's outlier threshold proposal is too high.

**Table 2 – Comparison of Proposed FY 2013 Impact File CCRs and Most Recent PSF CCRs**

	<b>Most Recent PSF CCRs as of Jan. 15 2012</b>
Hospitals with Impact File CCRs Matching Most Recent CCRs in the Dec. 2011 PSF	200
Hospitals with Impact File CCRs Matching Earlier Dec. 2011 PSF CCRs	3,097
Hospitals with Impact File Operating CCR Greater Than Most Recent Dec. 2011 PSF CCR	2,031
Hospitals with Impact File Operating CCR Equal To or Less than Most Recent Dec. 2011 PSF CCR	1,066

We simulated FY 2013 outlier payments with CMS's assumptions and methodology, but using the most recent PSF CCRs as of January 15, 2012. **We obtained an estimated fixed-loss amount of \$23,780, which is significantly lower than the fixed-loss threshold of \$27,425 that CMS estimated is necessary to accurately pay out the outlier pool of 5.1 percent. We are concerned that CMS's substantially overstated proposed fixed-loss threshold will lead to significant and unreasonable payment cuts to hospitals. Therefore, we urge the agency to review the CCRs it used to calculate its fixed-loss threshold and ensure it is using the most recent CCRs available.**

**Outlier Methodology.** The AHA appreciates that CMS has used a methodology that incorporates both cost inflation and charge inflation. **However, we continue to be concerned about the methodology CMS uses to calculate its outlier threshold.** CMS estimates that it spent only 4.7 percent, or about \$400 million, less than what it set aside in FY 2011, but 6.0 percent, or about \$900 million, more than what it set aside in FY 2012. **Using the proposed CCR adjustment methodology will continue to generate inaccurate outlier thresholds. The AHA urges CMS to address the flaws in the methodology for estimating the outlier threshold and recommends two improvements that will yield a more accurate threshold.**

First, in the proposed rule, CMS states that it is appropriate to apply a one-year adjustment factor to the CCRs. However, we believe that, for many hospitals, CCRs should be projected over periods of time other than one year to more accurately reflect the actual CCRs used in FY 2013. For example, as CMS states in the rule, we assumed that CCRs are updated nine months after the end of hospitals' fiscal periods. Therefore, the December 2011 Provider Specific File that CMS used for the outlier analysis contains the 2011 CCRs of hospitals with fiscal periods ending in January 2011. These hospitals will be paid using this 2011 CCR for the first month of FY 2013 (October 2012). In November 2012, however (nine months after the end of the hospitals' fiscal year), the hospitals' FY 2012 CCRs will become available and will be used for payment for the remaining 11 months of FY 2013. Therefore, the actual 2011 CCRs that CMS used in analyzing these hospitals should be used for one month of FY 2013. These 2011 CCRs should then be projected over one year to 2012 CCRs for the remaining 11 months of FY 2013. In contrast, when doing its analysis, CMS used the projected CCRs for all 12 months of FY 2013. See table 3 for our recommendation for projection periods for hospital fiscal periods ending in January through March.

**Table 3 – Recommended Projection Periods for 2011 CCRs for Hospital Fiscal Periods that End in January 2011 through March 2011**

<b>End of hospital fiscal period</b>	<b>Months of use for actual 2011 CCR</b>	<b>Months of use for 2011 CCRs projected to 2012 CCRs</b>
January	1	11
February	2	10
March	3	9

The situation is different for hospitals with fiscal periods ending in April through December. For example, the December 2011 Provider Specific File that CMS used for this analysis contains the 2010 CCRs of hospitals with fiscal periods ending in April 2011. However, in January 2012, these hospitals' 2011 CCRs will become available and used for payment for the first four months of FY 2013 (October 2012 through January 2013). Therefore, the actual 2010 CCRs that CMS used in analyzing these hospitals should be projected over one year to 2011 for four months of FY 2013. For the remaining eight months of FY 2013, these hospitals will be paid using their 2012 CCRs. Therefore, the 2010 CCRs that CMS used should be projected over two years to 2012 for the remaining eight months of FY 2013. In contrast, when doing its analysis, CMS used CCRs projected over one year for all 12 months of FY 2013. See Table 3 for our recommended projection periods for hospital fiscal periods ending in April through December.

**Table 4 – Recommended Projection Periods for 2010 CCRs for Hospital Fiscal Periods that End in April 2011 through December 2011**

<b>End of hospital fiscal period</b>	<b>Months of use for 2010 CCRs projected to 2011 CCRs</b>	<b>Months of use for 2010 CCRs projected to 2012 CCRs</b>
April	4	8
May	5	7
June	6	6
July	7	5
August	8	4
September	9	3
October	10	2
November	11	1
December	12	0

**If CMS were to use this approach for projecting CCRs, as well as to use the most recent PSF CCRs available as of January 15, 2012 (as we have urged it to do above), we estimate that the FY 2013 fixed-loss threshold would be \$23,190 (compared to CMS’s proposal of \$27,425).**

Second, CMS estimated the rate of change in CCRs by assuming the relationship between actual costs and the hospital market basket stays constant over time. An alternative approach to estimating the rate of change in CCRs is to use a recent historical industry-wide average rate of change as the projection factor, which is exactly how CMS projects charge inflation. In analyzing such an approach, we used the two most recent points in time separated by one year for which sufficient data were available: October 1, 2010 and October 1, 2011. Data were available for 3,390 out of the 3,405 hospitals used for outlier projections; these hospitals represent 99.9 percent of all Medicare Provider Analysis and Review (MedPAR) inpatient PPS cases. We found that for these hospitals, the average change in the operating CCRs from October 1, 2010 through October 1, 2011 (weighted by the number of inpatient PPS cases) was negative 2.73 percent. The average change in the capital CCRs was negative 2.25 percent.

In the past few years, the CCR rates of change calculated from historical data were consistently higher than the CMS projections. This is not the case for FY 2013. Nevertheless, we continue to believe that using historical data to project CCRs is more consistent with the CMS use of historical data to estimate charge inflation. If CMS adopts a policy of estimating charge inflation based on several years of data, that policy could be extended to the projection of CCRs rates of change.

In addition to examining CMS’s methodology for calculating its proposed FY 2013 fixed-loss threshold, we examined CMS’s estimate of outlier payments for FY 2012. Specifically, CMS estimated that actual outlier payments for FY 2012 will be approximately 6.0 percent of total payments, which is 0.9 percent higher than the 5.1 percent it intended. We projected FY 2011 charges forward by one year using the same charge inflation factor as CMS and used the most

recent CCRs from the March 2012 Provider Specific File. Since this file includes the CCRs in effect for the first three quarters of FY 2012, we applied them to the inflated charges for patients discharged during the same respective quarters of FY 2011. (The March PSF only shows the CCRs in effect at the beginning of the third quarter of FY 2012. Since, on the average, CCRs are on a downward trend, assuming CCRs at the beginning of the quarter will be effective the entire quarter is a conservative assumption). The fourth quarter FY 2012 ratios were obtained from the fourth quarter FY 2011 CCRs projected forward by one year using the CMS adjustment factors. Under this methodology, we estimate that the FY 2012 fixed-loss threshold of \$22,385 will actually result in outlier payments of 5.1 percent of total payments, as was intended.

We also examined the FY 2011 outlier amounts actually paid, which were significantly lower than CMS's intended level of 5.1 percent. We estimate that, to have hit the 5.1 percent target in FY 2011, CMS should have set the fixed-loss threshold at \$20,055 instead of \$23,075. We note that CMS set the FY 2011 fixed-loss threshold using projected 2010 to 2011 rates of change in operating and capital CCRs of negative 0.99 percent and positive 1.01 percent, respectively. These projections turned out to be substantially different from the now available actual values of negative 2.73 percent (operating) and negative 2.25 percent (capital). **Therefore, we believe our methodologies represent a substantial improvement. Given that the agency has significantly misestimated the outlier threshold, and thereby spent inaccurate amounts on outlier cases for many years, we urge CMS to adopt our suggested methodologies and more accurately estimate the outlier threshold.**

## **TREATMENT OF LABOR AND DELIVERY BEDS IN DISPROPORTIONATE SHARE HOSPITAL AND INDIRECT MEDICAL EDUCATION PAYMENTS**

**The AHA opposes CMS's proposal to include labor and delivery beds in the count of available beds used in the indirect medical education (IME) calculation.** Historically, labor and delivery beds and patient days have been excluded in the both the disproportionate share hospital (DSH) and IME calculations. In FY 2010, CMS finalized a change to count labor and delivery *patient days* in DSH calculations as long as the patient had been admitted as an inpatient (regardless of whether the patient occupied a routine bed prior to occupying an ancillary bed). However, CMS did not make a similar change to its policy for counting labor and delivery hospital beds for the Medicare IME adjustment.

While CMS tends to treat the counting of beds and patient days similarly for the purpose of the IME and DSH payment adjustment, labor and delivery services should remain an exception. CMS states that its policy is to include *patient days* available for inpatient PPS-level acute care hospital services in the DSH calculation, if the services furnished in the unit are generally payable under the inpatient PPS. And, similarly, to include *beds* available for inpatient PPS-level acute care hospital services in the IME calculation, if the services furnished in the unit are generally payable under the inpatient PPS. CMS indicates that its policies for counting beds and patient days for the IME and DSH programs are similar and, thus, they should generally be

interpreted in a consistent manner for both purposes. In the case of ancillary labor and delivery beds and patient days, however, we disagree; the counting of beds and patient days should be treated differently because Medicare does not generally pay for women undergoing labor and delivery services.

It is rational for Medicare to include labor and delivery *patient days* in the calculation of the Medicare DSH formula. The Medicare DSH adjustment is a complex statutory formula based on the level of the hospital's DSH Patient Percentage (DPP), which is equal to the sum of the percentage of Medicare inpatient days attributable to patients entitled to both Medicare Part A and Supplemental Security Income and the percentage of *total patient days attributable to patients eligible for Medicaid* but not eligible for Medicare Part A. It is reasonable that labor and delivery patient days be included in the calculation of a hospital's Medicare DSH adjustment given that the DPP relies heavily on Medicaid inpatient days and Medicaid covers a large portion of labor and delivery services. In its July 8, 2011 report, the National Bureau of Economic Research found that Medicaid covers 41 percent of all births in the United States, or about 1.68 million of the 4 million births each year. This percentage varies at the state level, with Medicaid covering 46 percent of all births in California, 56 percent of all births in Texas and 70 percent of all births in Louisiana. Given the large percentage of Medicaid births, and the fact that the DSH percentage is based on Medicaid patient days, it is sensible to include labor and delivery patient days in the DSH calculation.

However, it is not rational for Medicare to include labor and delivery beds in the calculation of the Medicare IME formula. The IME adjustment is based on a hospital's ratio of residents-to-beds. Including labor and delivery beds in this Medicare adjustment is unreasonable, because Medicare pays for less than 1 percent of all births. According to CMS's own data in the FY 2013 proposed rule, Medicare paid for roughly 14,000 births in FY 2011 (page 28046), or approximately 0.35 percent of all births in the United States each year. CMS's policy in the FY 2010 final rule to include labor and delivery patient days for the DSH calculation but to exclude labor and delivery beds for the IME calculation was accurate and does not require further revision.

**Now is not the time to reduce IME funding to teaching hospitals.** Including labor and delivery beds will decrease the resident-to-bed ratio and result in decreased IME payments to teaching hospitals. The agency estimates that its proposed change would decrease IME payments by \$170 million in FY 2013. Reductions to IME funding will jeopardize the ability of teaching hospitals to train the next generation of physicians. The nation already is facing a critical shortage of physicians, and *The Patient Protection and Affordable Care Act of 2010's* (ACA) expansion of health care coverage to 32 million uninsured in 2014 is projected to require an additional 31,000 physicians. Any reductions to IME funding would further exacerbate the physician shortage problem.

## **GRADUATE MEDICAL EDUCATION**

**New Teaching Hospitals.** The AHA strongly supports CMS's proposal to increase the cap-building period for new teaching hospitals from three years to five years. Under current regulations, a hospital with a new resident training program is given a three-year period (or a "three-year window") to grow its programs before CMS establishes the hospital's permanent full-time equivalent (FTE) resident cap. CMS proposes to extend this window to five years for new programs beginning on or after October 1, 2012. The agency would determine a new teaching hospital's resident cap at the end of the fifth program year of the first new program. Specifically, the FTE cap would be based on the product of: 1) the highest number of FTE residents training in any program year during the fifth year of the first program's existence for all new residency training programs; and 2) the number of years in which residents are expected to complete the program. This cap would be permanent and take effect with the sixth program year of the first new program.

Given current accreditation requirements, three years is not sufficient to establish a new residency program. It is particularly challenging if a new teaching hospital chooses to establish more than one new residency program. The Accreditation Council for Graduate Medical Education (ACGME), for example, may require new residency training programs to pass through a three-year "initial" accreditation period before they can be granted "continued" accreditation. During this initial accreditation period, a hospital is not allowed to add any additional positions to its new program. Thus, even if a hospital has plans to expand its new training program beyond the number of positions for which it is initially accredited, it may not be possible to do so until this initial period has expired. In addition, some hospitals prefer to stagger the start dates of their new residency training programs to gain experience before beginning all of their new programs. These hospitals need much longer than three years before CMS sets their permanent resident cap.

The AHA is pleased with CMS's proposal to increase the cap-building period. The longer five-year window should result in new teaching hospitals receiving a higher resident cap and one that is more reflective of the number of residents a hospital will actually train.

**We also support CMS's proposal to change how it calculates a new teaching hospital's cap if the residents in the new program are training at more than one hospital.** Specifically, the FTE cap would be based on the product of: 1) the highest total number of FTE residents training in any program year during the fifth academic year of the first new program's existence at *all* participating hospitals; and 2) the number of years in which residents are expected to complete the program. CMS proposes to distribute the aggregate cap based on the percentage of resident time spent at each hospital over the course of the entire five-year period (rather than solely during the fifth academic year). The AHA is pleased that CMS proposes to revise its methodology, which will allow new teaching hospitals to more appropriately count residents who spend a portion of their time training at another location.

**Redistribution of Residency Positions under the ACA.** The AHA opposes CMS's proposal to require hospitals to fill at least half of their new residency positions by the third year of

**the congressionally mandated five-year period.** The ACA mandated a redistribution of unused residency positions to encourage increased training of primary care physicians and general surgeons. In awarding the slots, hospitals had to “demonstrate the likelihood” that they would fill the new positions within the first three cost-reporting periods beginning on or after July 1, 2011. In the rule, CMS proposes that a hospital must fill at least half of the redistributed slots (for purposes of both IME and direct graduate medical education (GME) payments) in the first, second and/or third cost-report periods of the five-year period. The agency argues that it is reasonable to expect that hospitals would begin to use their slots by the third year of the five-year period, given that hospitals needed to demonstrate the likelihood that they would be able to do so.

CMS’s proposal over-reaches. Congress imposed two precise requirements that hospitals must meet to keep their redistributed slots. First, for the five-year period beginning on July 1, 2011 (the date of the increase), hospitals must maintain at least their current level of primary care residents averaged over the three most recent years (referred to as the primary care average). Second, hospital must ensure at least 75 percent of the increased positions are designated for primary care or general surgery (referred to as the 75-percent threshold). Congress did not require hospitals to fill half their slots by the third year. Hospitals should have the full five-year period, or until June 30, 2016, to fill their new slots.

As previously stated, hospitals often need more than three years to grow a residency program. Accreditation rules make it difficult for hospitals to ramp up to full capacity in just three years. Hospitals that applied for the redistributed slots needed to do so by January 21, 2011. CMS gave its Medicare contractors until May 16, 2011 to estimate the number of slots for redistribution. By law, the slots were to be redistributed by July 1, 2011. Given the compressed timing, many hospitals did not know until late summer 2011 whether they would receive additional slots and thus failed to meet the August 2011 Electronic Residency Application Service deadline for the resident match. In addition, accreditation rules make it difficult for hospitals to ramp up to full capacity in just three years, especially for those teaching hospitals that are starting a new primary care program. These hospitals would need to recruit a program director, recruit faculty, and create and file a Program Information Form (PIF) with the ACGME. The ACGME would then need to review the PIF, schedule a site visit and provide final ACGME approval. ACGME accreditation requirements are lengthy and complex. The site visit alone may take 12 to 18 months to complete. A three-year total timeframe is too short and will unjustly penalize hospitals that are building new primary care programs.

Additionally, the penalty is too harsh. Under CMS’s proposal, hospitals that did not fill at least half of their slots by the third year would lose all of their redistributed slots. For example, a hospital may fill a third of its slots by Year 3, two-thirds by Year 4, and all by Year 5. If this hospital received 30 total slots, 10 residents would be training in the facility. CMS’s proposal would result in eliminating these 10 occupied slots (as well as all 30 in the future). The hospital would either continue to train the resident without Medicare reimbursement, or terminate the residency position (and potentially the residency program altogether). This would result in significant disruption in training for these residents. Given the shortage of primary care physicians, and the fact that 75 percent of these new slots are for primary care physicians or

general surgeons, this could have devastating effects for the future supply of physicians. While the slot would be redistributed to another qualifying hospital, it could take that hospital a number of years to grow its residency program. The result is a delay in training physicians, which is in direct contrast to the goal of the ACA: to encourage increased training of primary care physicians and general surgeons.

## **WAGE INDEX**

**Reports on the Medicare Wage Index.** On April 11, the Secretary submitted to Congress a report to reform the Medicare wage index using the concept of a Commuting-based Wage Index (CBWI) to replace the current methodology. According to the report, a CBWI would yield wage index values that more closely correlate to actual labor costs because it accounts for specific differences in hospitals' geographic hiring patterns. The CBWI could be constructed using commuting data from the 2000 Census, but a more up-to-date reporting system for collecting commuting data from hospitals would likely need to be established so that the wage index calculations would reflect the current commuting patterns of hospital employees. In addition, the report states that, under the CBWI, existing statutory wage index reclassifications and exceptions may no longer be applicable and should be reviewed for their continued relevance. Implementation of the CBWI would require both legislative and regulatory changes.

This report is one of several on the wage index that have been issued in the past five years. In 2007, MedPAC developed an alternative wage index framework and made related recommendations to the Congress. In addition, in June 2011, the Institute of Medicine (IOM) issued a report containing recommendations.

In recognition of the substantial challenges entailed in revising the wage index, in July 2011, the AHA Board of Trustees created the AHA Area Wage Index Task Force to further examine the issue. Our Task Force is reviewing the CMS report, as well as those from MedPAC and IOM, and other design issues around the wage index. We anticipate issuing a report on the subject in late 2012 or early 2013.

**Imputed Rural Floor.** CMS proposes a change to its calculation of the imputed rural floor, a policy that is currently in place through FY 2013. Under the proposed new policy, the agency would continue to use its current methodology as its primary one. It would, however, apply a secondary, alternative methodology where an all-urban state has a range of wage indices assigned to its hospitals, but the state does not benefit from the primary methodology. CMS states that there are 29 hospitals in New Jersey that would benefit from the imputed rural floor policy under the primary methodology and an additional four hospitals in Rhode Island would benefit from the alternative proposed methodology.

As stated above, an AHA Task Force is currently examining the wage index. Among other issues, the Task Force is analyzing the existing system of reclassifications and exceptions, including the imputed rural floor. Because the Task Force's work is ongoing, it would be premature for the AHA to comment on the proposal at this time.

## **HOSPITAL SERVICES FURNISHED UNDER ARRANGEMENTS**

In the FY 2012 inpatient PPS final rule, CMS adopted a new policy, effective October 1, 2011, to preclude a hospital from providing certain services to its patients “under arrangements” with another hospital. The effective date of this policy was then delayed until October 1, 2012, to give hospitals additional time to make changes needed to comply with the new policy. In this rule, CMS proposes to delay the implementation date of the under arrangements policy again, to October 1, 2013, because hospitals need more time to comply.

**The AHA appreciates CMS’s recognition of the need to delay the effective date of the policy for another year. However, we believe that a delay in implementation is not sufficient.** Rather, CMS should rescind the revised policy or, at the very least, grandfather in hospitals that, prior to publication of the FY 2012 proposed rule, provided “routine services” under arrangements with other hospitals. CMS acknowledges that the new policy requires hospitals “to restructure existing arrangements and establish operational protocols.” However, CMS has implicitly and explicitly recognized that its revised policy is not required by statute or regulations. Further, CMS has not provided any policy rationale to support it. In fact, the policy is both inconsistent with the agency’s increasing emphasis on the efficient delivery of care and unnecessary as a mechanism to guard against potential abuse of “under arrangements” models. Therefore, in our view, there is neither a strong statutory nor policy basis for the revised under arrangements policy, making the costs that hospitals will incur to comply with the policy unnecessary and burdensome. Consequently, a further delay in the effective date of the policy simply is not sufficient.

## **NEW TECHNOLOGY**

Section 503 of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS to ensure that it would better account for expensive new drugs, devices and services. However, CMS receives only a limited number of applications and considers only a few technologies a year for add-on payments. **The AHA is disappointed that CMS did not propose to increase the marginal payment rate to 80 percent, rather than the current 50 percent, consistent with the outlier payment methodology, as we have repeatedly requested.**

## **HOSPITAL READMISSIONS REDUCTION PROGRAM**

The ACA mandates that CMS implement a program beginning in FY 2013 under which hospitals with higher-than-expected readmission rates would see reductions in their Medicare payments. It also mandates that reductions be based on the number of “excess” readmissions at the hospital, with a cap that would limit penalties in the first year of the program to 1 percent of the hospital's base operating Medicare payments.

CMS proposed very few changes to the readmission reduction program in this rule, as compared to last year's final rule. The agency still plans to begin the readmission reduction program on October 1, as required by law, and to use three 30-day readmission measures: acute myocardial infarction (AMI), heart failure (HF) and pneumonia (PN). The AHA has continually urged CMS to make changes to these readmission measures to: 1) properly adjust for patient characteristics (dual-eligible status and race/ethnicity); 2) differentiate between planned and unplanned readmissions; 3) differentiate between related and unrelated readmissions; and 4) exclude extreme circumstances (transplant, end-stage renal disease, burn, trauma, psychosis and substance abuse). Despite AHA's urging, CMS has failed to make any changes to account for these factors. **The AHA strongly disagrees with CMS's decision and believes that the agency has ignored Congress's intent that the measures be modified to address these factors.**

**Base Operating DRG Payment Amount.** CMS proposes to define the "base operating DRG payment amount" to which any readmission penalties would apply as the wage-adjusted DRG operating payment, plus any applicable new technology add-on payments. As required by statute, this definition does not include adjustments or add-on payments for IME, DSH, outliers or low-volume hospitals. It is our understanding that CMS is obtaining this amount from the "DRG Price" field in the Medicare Provider Analysis and Review (MedPAR) claims data.

For SCHs, CMS proposes to also exclude the difference between the hospital's applicable hospital-specific payment rate and the federal payment rate from its definition of "base operating DRG amount." CMS does not make the same proposal related to MDHs because, as it notes, the MDH program expires at the end of FY 2012, before the Hospital Readmissions Reduction Program begins in FY 2013.

**The AHA supports these proposals. We note, however, that the "DRG Price" field in the MedPAR file already excludes outlier payments; we urge CMS to ensure it is not then explicitly subtracting this amount from the base operating amount a second time. In addition, we urge the agency to also exclude the difference between an MDH's applicable hospital-specific payment rate and the federal payment rate from its definition of "base operating DRG amount" in the event that the MDH program is extended beyond FY 2012.**

**Payment Adjustment Factor.** Under the statute, the adjustment factor that will be used to penalize hospitals under the Hospital Readmissions Reduction Program is 1 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. CMS proposes to determine the hospital's aggregate payments for all discharges for applicable conditions based on its definition of the base operating DRG payment amount described above. The agency proposes to use MedPAR claims data to determine these amounts.

CMS proposes to determine the hospital's aggregate payments for excess readmissions by multiplying the hospital's aggregate payments for all discharges for an applicable condition by 1,

minus the hospital's excess readmissions ratio, the calculation of which the agency finalized in the FY 2012 inpatient PPS final rule.

CMS proposes to then calculate the ratio of the hospital's aggregate payments for excess readmissions to the hospital's aggregate payments for all discharges for an applicable condition and subtract this from 1 to determine the hospital's calculated payment adjustment factor. However, the hospital's actual payment adjustment factor will be the higher of its calculated factor or 0.99. This actual payment adjustment factor will be applied to each discharge in FY 2013, resulting in a maximum penalty of 1 percent in that year. **We support these proposals.**

**However, in general, we urge CMS to remove admissions and readmissions for beneficiaries who died in the hospital; were transferred to another hospital; were discharged against medical advice; and for percutaneous transluminal coronary angioplasty and coronary artery bypass graft procedures (AMI measure only) from the count of admissions for each condition.** By using its proposed rule impact file to calculate the penalty associated with a hospital and selecting discharges based on ICD-9\_CM codes, CMS is over counting admissions and therefore inflating the calculation of aggregate payments for excess readmissions.

For purposes of using these admission counts to calculate aggregate payments for excess readmissions, CMS has not proposed to exclude:

- index admissions for beneficiaries who die in the hospital;
- admissions for beneficiaries who were transferred to another acute care facility;
- admissions for beneficiaries who were discharged against medical advice;
- admissions for beneficiaries without at least 30 days post-discharge enrollment in fee-for-service Medicare; or
- admissions within 30 days of a prior index admission.

However, these admissions should be excluded as they are in CMS's contracted analysis presented in the "2012 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30 Day Risk Standardized Readmission Measure." These admissions account for a significant portion of all admissions; failing to exclude them from the aggregate payments for excess readmissions for each condition overestimates these payments. This, in turn, will result in higher-than-appropriate penalties being applied to inpatient PPS hospitals. Specifically, the AHA has estimated that failing to exclude these admissions will result in an overestimate of approximately \$31 million; though this may seem a relatively small amount, it represents over 10 percent of the estimated readmissions. In addition, there are individual hospitals whose penalties will be overstated by as much as 70 percent by failing to exclude these admissions. **Therefore, we urge CMS to exclude, for purposes of calculating aggregate payments for excess readmissions, index admissions for beneficiaries who die in the hospital; those that were transferred to another acute care facility; those that were discharged against medical advice; those without at least 30 days post-discharge enrollment in fee-for-service Medicare; or admissions within 30 days of a prior index admission.**

Most of these admissions can easily be identified in the claims data using the discharge destination. However, others are not easily identified in the Medicare claims data; for these, we urge CMS to estimate an “additional exclusions factor” (AEF) based on data available in the latest Measures Maintenance Technical Report and as described below. In addition, these exclusions should apply only to CMS’s calculation of aggregate payments for excess readmissions, not to its calculation of aggregate payments for all conditions for all discharges.

To calculate the AEF, we consulted the *2012 Measures Maintenance Technical Report*. It indicates how each of the above readmissions exclusions affects the readmissions count. Specifically, when in-hospital deaths, transfers, and beneficiaries discharged against medical advice were excluded from the AMI readmissions count, it decreased by 15.9 percent. However, once all AMI readmissions mentioned above were excluded, the readmissions count decreased by a further 2.8 percent. This 2.8 percent equals the AEF. Therefore, we urge CMS to apply not only the exclusions that can be identified in the claims data, but also to apply a condition-specific AEF to account for exclusions that cannot easily be identified in the claims data. This AEF should be calculated by multiplying the condition-specific aggregate payments for all admissions (excluding in-hospital deaths, transfers out, and discharged against medical advice) by the applicable AEF. The AEF should not be applied to aggregate payments for all discharges, which is the denominator of the ratio used to calculate the readmission adjustment factor.

**Applicable Hospitals.** Under the statute, subsection (d) hospitals (hospitals paid under the inpatient PPS) and hospitals paid under section 1814(b)(3) of the *Social Security Act* (Maryland hospitals) are subject to the Hospital Readmissions Reduction Program. The statute defines subsection (d) hospitals as hospitals located in the 50 states or the District of Columbia. Hospitals located in Puerto Rico and the Territories are not included in the definition of subsection (d) hospitals and therefore, are not included in the Hospital Readmissions Reduction Program. Excluded from the definition of a subsection (d) hospital are long-term care hospitals, cancer hospitals, children’s hospitals, and CAHs, as well as inpatient rehabilitation and inpatient psychiatric facilities. However, Indian Health Services hospitals, SCHs and current MDHs are considered subsection (d) hospitals. **The AHA supports this definition of “applicable hospitals.”**

The term “applicable hospital” is referenced in the statutory definition of readmission, defined as when an individual is discharged from an applicable hospital and then admitted to the same or another applicable hospital within a certain time period. In the context of CMS’s proposal to define an applicable hospital as subsection (d) and Maryland hospitals, the agency also proposes to refine its definition of readmission to include only admissions and readmissions occurring from an applicable hospital to the same or another applicable hospital. Accordingly, excess readmission ratios calculated for the purpose of the Hospital Readmissions Reduction Program would include only admissions and readmissions to “applicable hospitals.” **The AHA supports these proposals.**

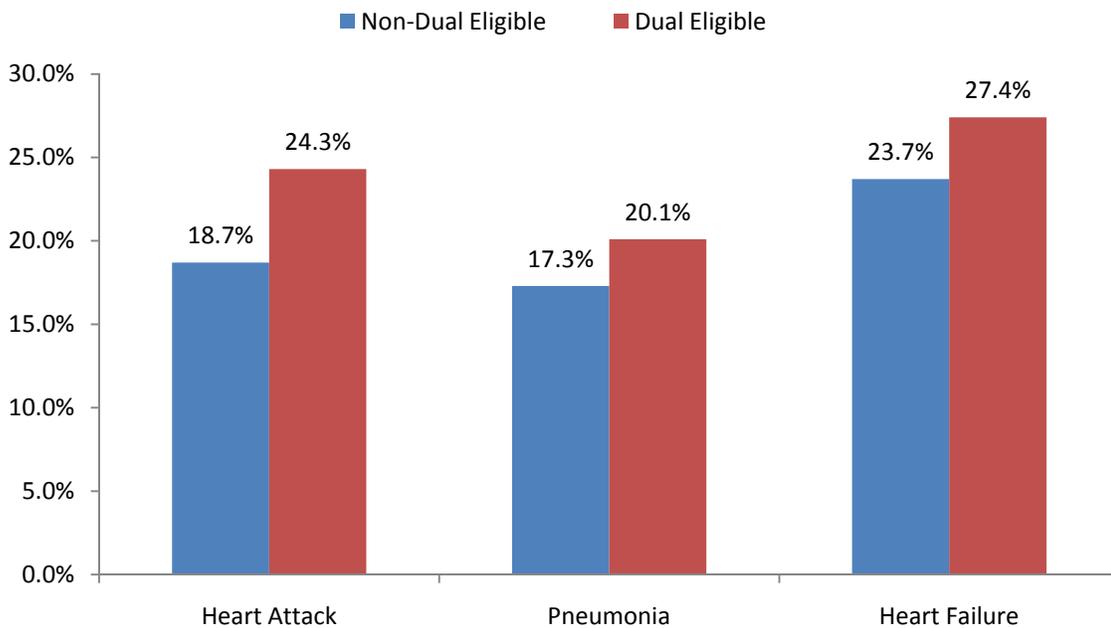
In addition, the proposed rule discusses the potential exemption of Maryland hospitals from the Hospital Readmissions Reduction Program. However, it is unclear whether CMS is proposing to exempt only certain hospitals or all hospitals regulated by the Health Services Cost Review

Commission. In addition, there is no reference to Maryland’s Total Patient Revenue (TPR) program, which is designed to reduce volumes and, thus, reduce readmissions in the state. **We urge CMS to make a statewide exemption for Maryland hospitals from the Hospital Readmissions Reduction Program.** Doing so will allow Maryland hospitals to continue focusing on their ongoing efforts to reduce readmissions across all payers and diagnoses.

**Adjusting for Patient Characteristics.** There are two ways to adjust for patient characteristics in the readmission measures. The preferred option is to apply a patient-level adjustment. The other option is to apply a hospital-level adjustment. We describe each option below.

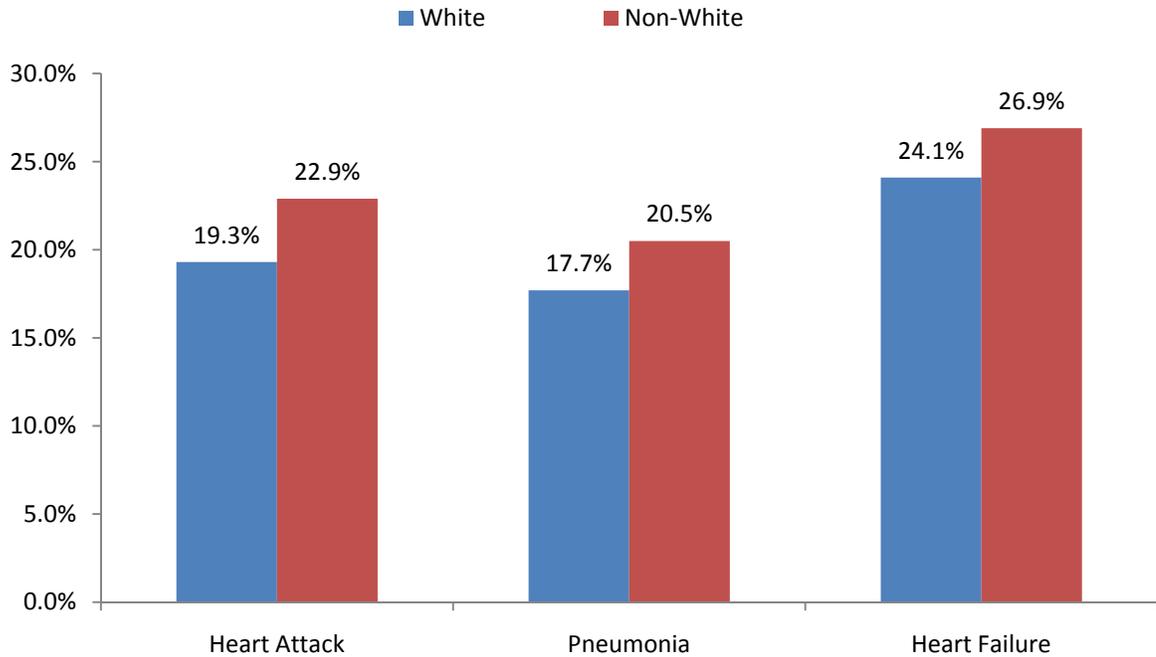
***Patient-level Adjustments.*** We urge CMS to direct its measure development contractor to adjust the AMI, HF and PN readmission measures for dually eligible beneficiaries and for race/ethnicity beginning with the FY 2014 readmission penalty program. There has been extensive research<sup>i,ii,iii</sup> illustrating that readmission rates are statistically higher among dually eligible versus non-dually eligible and non-white versus white beneficiaries. These factors are beyond the control of a hospital and must be adjusted for when calculating a hospital’s readmission rate. Figures 5 and 6 below illustrate the difference between dually eligible and non-dually eligible beneficiaries, and white and non-white beneficiaries with respect to readmission rates. These figures were derived from an analysis prepared for the AHA by KNG Health Consulting.<sup>iv</sup>

**Figure 5 – Readmission Rates Stratified by Dually Eligible and Non-dually Eligible Beneficiaries**



Source: KNG Analysis of 2009 100% Medicare inpatient file and FY 2011 Hospital IPSS final rule impact file

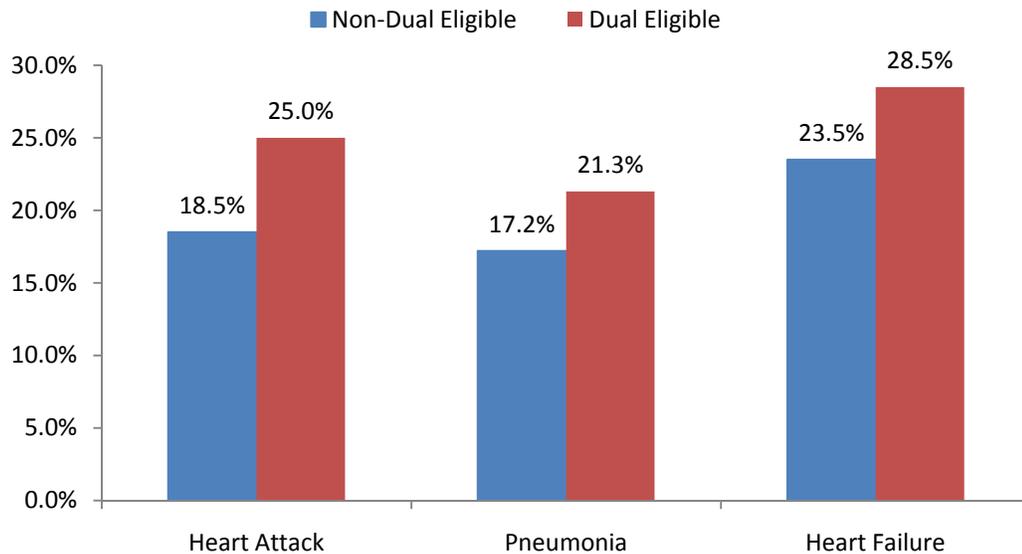
**Figure 6 – Readmission Rates Stratified by White and Non-white Beneficiaries**



Source: KNG Analysis of 2009 100% Medicare inpatient file and FY 2011 Hospital IPPS final rule impact file

Though Figures 5 and 6 demonstrate that the dually eligible and non-white beneficiary populations each have higher rates of readmission, beneficiaries with both of these characteristics have even higher rates of readmission. Figure 7<sup>v</sup> illustrates this effect.

**Figure 7 – Readmission Rates Stratified by Dually Eligible Non-white and Non-dually Eligible White Beneficiaries**



Source: KNG Analysis of 2009 100% inpatient claims file and denominator file

These three figures show that there is a statistically significant difference in readmission rates for these different types of beneficiaries, which is why we are urging CMS to direct its contractor to build a patient-level adjustment for both dually eligible and non-white beneficiaries into the readmission measures.

Though a patient-level adjustment for both dually eligible and non-white beneficiaries is the most appropriate adjustment, we recognize that CMS and the measure developer may not be able to make this change prior to the beginning of the readmission penalty program on October 1. Further, we are unsure whether CMS and the National Quality Forum (NQF) would view this change as a “material change” to the readmission measures and urge CMS to address this “material change” question in the final rule. Therefore, we urge CMS to pursue a patient-level adjustment for FY 2014. However, in the meantime, CMS does have time to make a hospital-level adjustment for FY 2013, as described below.

**Hospital-level Adjustments.** We urge CMS make a back-end (after the readmission measures already have been populated) hospital-level adjustment to the payment adjustment factors beginning with the FY 2013 readmission penalty program. As we stated above, the most appropriate adjustment for the readmission program would be a patient-level adjustment for dually eligible non-white beneficiaries. However, that adjustment cannot likely be put in place for the FY 2013 program; therefore, we identify a hospital-level adjustment as an

immediate next step. We are sure CMS is able to make this type of adjustment immediately because of the DPP analysis included in the proposed rule.

In the proposed rule, CMS included an analysis of readmission rates by hospital DPP because it “received public comments expressing concern that hospitals that treat a larger proportion of patients of lower socioeconomic circumstances may have higher readmission rates and could be unfairly penalized under the Hospital Readmissions Reduction Program.” We were unable to replicate CMS’s DPP table; Table 5 below shows the differences between the results CMS published and our results. In contrast to CMS’s results, our results show that a much larger number of hospitals in the highest four deciles of DPP receive the maximum negative 1 percent readmissions penalty. For example, while CMS’s data show that 61 of the 157 hospitals in the highest decile of DPP will receive the “-1 percent floor adjustment,” our data show that 83 of the 157 hospitals in the highest decile of DPP will receive the “-1 percent floor adjustment.” In conversations with CMS, we were unable to determine the reason for the difference.

**Therefore, we urge CMS to investigate this discrepancy and, if necessary, issue a correction notice as soon as possible.**

**Table 5 – DPP and Dually Eligible Analysis**

Decile	Number of Hospitals: CMS DPP Analysis		Number of Hospitals: AHA DPP Analysis		Number of Hospitals: KNG Analysis of Proportion of Hospital Patients with Dual-Eligible Status	
	-1 Percent Floor Adjustment	No Readmission Adjustment	-1 Percent Floor Adjustment	No Readmission Adjustment	-1 Percent Floor Adjustment	No Readmission Adjustment
Lowest	38	145	13	218	24	138
Second	57	118	39	126	26	141
Third	44	127	36	127	24	134
Fourth	48	121	37	120	28	122
Fifth	42	115	33	105	29	106
Sixth	43	125	38	112	32	110
Seventh	44	108	56	101	66	80
Eighth	43	114	66	84	72	72
Ninth	58	102	79	80	92	65
Highest	61	96	83	74	87	82
<b>Total</b>	<b>478</b>	<b>1,171</b>	<b>480</b>	<b>1,147</b>	<b>480</b>	<b>1050</b>

In addition, the AHA’s analysis of the number of hospitals subject to the “-1 percent floor adjustment” illustrates an important general trend – the greater a hospital’s DPP, the more likely it is that the hospital will receive the maximum readmission penalty in FY 2013. Further, the AHA’s “no readmission adjustment” data lends additional support to this fact – the lower a hospital’s DPP, the more likely it is that a hospital will have no readmission penalty in FY 2013.

The same trends occur when examining the proportion of a hospital's patients that are dually eligible. For example, 24 out of 162 hospitals in the lowest decile of dual-eligible patients will receive the "-1 percent floor adjustment." But 87 of 162 hospitals in the highest decile of dual-eligible patients will receive the "-1 percent floor adjustment."

***Adjusting for Dual-Eligible Status Is A Superior Adjustment When Compared to DPP.***

**Though we support the general concept of CMS's DPP analysis, our research indicates that a beneficiary's dual-eligible status is a much more powerful predictor of risk and, therefore, should be used as an adjustment factor in place of a DPP adjustment.** We agree with CMS and public commenters that hospitals that treat a larger proportion of patients of lower socioeconomic circumstances may have higher readmission rates and could be unfairly penalized. Rather than an analysis of a hospitals' dual-eligible population, CMS chose a DPP analysis because "the DPP is used as a proxy for low-income patients and is the sum of the hospital's Medicare fraction and Medicaid fraction. Thus, hospitals with higher percentages of Medicare patients entitled to [Supplemental Security Income] and higher percentages of Medicaid patients have higher DPPs." However, we purport that dual-eligible status is superior to DPP in predicting readmissions rates because it reflects the hospital's *Medicare* population, as opposed to its *overall* population. Since the readmission measures only include Medicare beneficiaries, an adjustment based on hospitals' proportion of dual-eligible beneficiaries is more appropriate.

***Applying a Dual-Eligible Adjustment to the Readmission Measures.*** We urge CMS to adjust readmission rates for the proportion of hospitals' beneficiaries that are dually eligible to ensure that hospitals that treat the most vulnerable populations are not unfairly penalized by the Hospital Readmissions Reduction Program. Beyond the basic descriptive data provided by the KNG analysis, KNG has modeled how such an adjustment could be applied to the readmission measures. KNG stratified the patient population for each hospital into a dual and non-dual cohort. KNG then weighted both populations based on the number of patients within each cohort. An example of this adjustment is below.

Hospital A unadjusted readmission rate = 15 percent

Hospital A dual readmission rate = 20 percent; dual-eligibles account for 25 percent of the total population

$(20 \text{ percent}) * (0.25) = 5 \text{ percent of readmission rate for dual patients}$

Hospital A non-dual readmission rate = 10 percent; non-dual-eligibles account for 75 percent of the total population

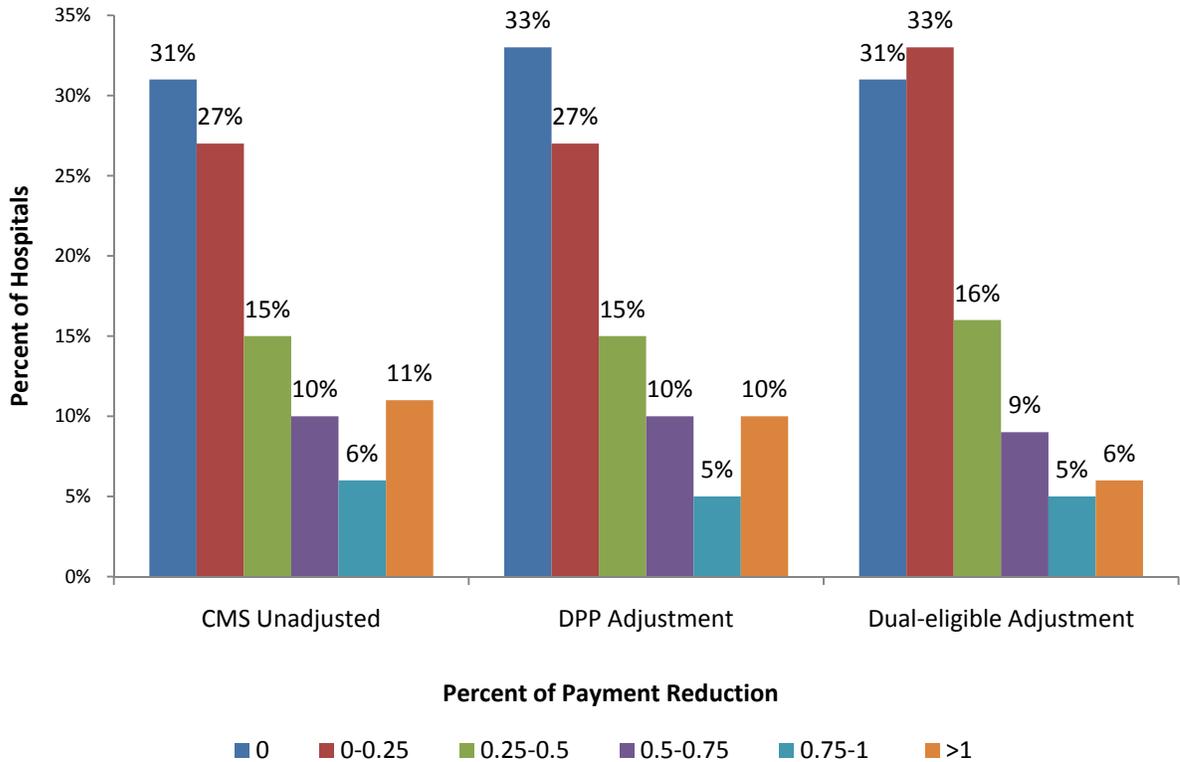
$(10 \text{ percent}) * (0.75) = 7.5 \text{ percent of readmission rate for non-dual patients}$

Hospital A adjusted readmission rate (dual + non-dual) = 5 percent + 7.5 percent = 12.5 percent

Figure 8 below illustrates the effect a dual-eligible adjustment would have on the penalties that hospitals are estimated to receive for the FY 2013. This analysis compares hospitals by their

payment reduction quintile for the CMS-unadjusted model, a DPP-adjusted model, and a dual-eligible-adjusted model that is consistent with CMS’s DPP analysis.

**Figure 8 – Comparison of Readmission Penalties both With and Without A Dual-eligible Adjustment**



The biggest impact of the dual-eligible adjustment is reducing the number of hospitals in the top quintile of penalties. As a result, when compared to both the CMS-unadjusted and the DPP-adjusted models, the dual-eligible adjusted model yields results that are fairer with respect to hospitals that treat a greater percentage of vulnerable patients.

**Planned Readmissions. We urge CMS to remove all planned readmissions from the AMI, HF and PN readmission measures, as required by the ACA. We have urged CMS to remove all planned readmissions from these measures for several years and we are disappointed that CMS has failed to make this change to comply with the law. CMS has stated that it cannot make changes to the readmission measures because they are NQF-endorsed, a criterion of the ACA statutory language. However, CMS has pursued removal of planned measures in its 30-day all-cause, all-condition readmission measure. This measure excludes patients undergoing medical treatment for cancer as their primary procedure and also includes 36 categories of procedures that are considered planned. CMS and the measure developer are using a methodology to define planned readmissions for the all-cause, all-condition**

**readmission measure; it also can and should use this methodology for all of the readmission measures. Using inconsistent methodologies across the readmission measures is inappropriate.**

***NQF Maintenance Review of AMI, HF and PN Readmission Measures.* We urge CMS to make changes to the AMI, HF and PN readmission measures when NQF is reviewing these measures under the maintenance process.** Of the three readmission measures that will be used for the FY 2013 readmissions penalty program, one (HF) already has completed a maintenance review. NQF aims to conduct a maintenance review of endorsed quality measures every three years. While the HF readmission measure was undergoing maintenance review, the AHA made several comments asking the measure developer to make changes to the measure to remove planned and unrelated readmissions, remove certain high-risk populations (described below) and adjust for dual-eligible status and race/ethnicity. We also urged the measure developer to harmonize its HF readmission methodology with the all-cause, all-condition methodology. **We are disappointed that CMS failed to work with the measure developer to make this change to the HF measure and urge CMS to do so immediately.**

The PN readmission measure is undergoing a maintenance review in NQF's pulmonary project. Again, we have urged the measure developer to remove planned and unrelated readmissions, certain high-risk populations (described below) and dual-eligible status and race/ethnicity. We urge CMS to work with the measure developer to ensure these changes are addressed during the NQF maintenance review. Further, we urge CMS to partner with NQF to make sure the AMI readmission measure undergoes maintenance review as soon as possible.

***Allowing Hospitals to Indicate When a Readmission is Planned.*** Though removing categories of planned procedures will address some of our concerns, it may not address all of our concerns. Hospitals are the most appropriate party to identify, from a frontline clinical perspective, what should be considered a planned readmission. The National Uniform Billing and Coding Committee (NUBC) is pursuing development of a claims data element that would allow hospitals to identify, upon discharge, whether a future readmission is planned. Specifically, the NUBC is currently considering adding new discharge status codes that would allow hospitals to indicate whether a future readmission is planned for beneficiaries with the following types of discharges:

- Discharged to home of self-care (routine discharge);
- Discharged/transferred to a short-term general hospital for inpatient care;
- Discharged/transferred to skilled nursing facility with Medicare certification;
- Discharged/transferred to a facility that provides custodial or supportive care;
- Discharged/transferred to a designated cancer center or children's hospital;
- Discharged/transferred to home under care of organized home health service organization;
- Discharged/transferred to a federal health care facility;
- Discharged/transferred to a hospital-based Medicare approved swing bed;
- Discharged/transferred to an inpatient rehabilitation facility including rehabilitation distinct part units of a hospital;

- Discharged/transferred to a Medicare certified long-term care hospital;
- Discharged/transferred to a nursing facility certified under Medicaid but not certified under Medicare;
- Discharged/transferred to a psychiatric hospital or psychiatric distinct part unit of a hospital;
- Discharged/transferred to a critical access hospital; and
- Discharged/transferred to another type of health care institution not defined elsewhere in this code list.

**The NUBC is expected to vote on these changes this summer; the AHA will be voting in favor of these changes; we urge CMS to also exercise its NUBC rights and also vote in favor of these changes.** In addition, although we are pleased to see this conversation occurring at the NUBC, more changes are needed in order to fully comply with all of the ACA requirements for the readmission program. Specifically, our understanding is that the “planned readmission” indication can only be made upon discharge for the initial admission; we would like to see it available also upon discharge for the readmission itself. This change is needed because hospitals may not be fully aware that a planned readmission will occur during the initial admission period. In addition, we urge CMS to work with the NUBC to expand the claims coding capacity to allow hospitals to indicate whether discharges are unrelated to the initial admission, as discussed below.

**Unrelated Readmissions. We urge CMS to remove unrelated readmissions from the AMI, HF and PN readmission measures, as required by the ACA. We have urged CMS to remove unrelated readmissions from these measures for several years and are disappointed the agency has failed to do so.** If CMS continues to refrain from developing a list of procedures/conditions that it would define as unrelated, we urge it to instead work with the NUBC to allow hospitals to make a judgment on whether a readmission is unrelated.

**Adding Exclusions for Certain Conditions to the Readmission Measures. We urge CMS to remove patients with extenuating circumstances from both the numerator and denominator of the AMI, HF and PN measures.** For several years, we have urged CMS to remove patients with the following conditions from the readmission measures: transplant; end-stage renal disease; burn; trauma; psychosis; and substance abuse. The current risk adjustment methodology does not adjust for these factors; however, patients with these characteristics are often readmitted because good, sound medical practice indicates that a readmission is the best course of action. Therefore, it is unfair to penalize hospitals treating these vulnerable patients by including these appropriate readmissions in their readmission rate.

**Measure Application Partnership (MAP). We urge CMS to include the Hospital Readmissions Reduction Program on the list of the programs for the MAP to review.** In the Inpatient Quality Reporting (IQR) section of this comment letter, we describe the MAP and its importance related to CMS’s quality measure programs. However, the Hospital Readmissions Reduction Program was not included in the list of the programs that the MAP reviewed in 2011. Since this program is dependent on quality measures, it is appropriate for the MAP to weigh-in on this program.

**Reliability of Readmission Measures.** We urge CMS to address the reliability problems with the current readmission measures. As referenced in our hospital value-based purchasing (VBP) comments, CMS recently released a study<sup>vi</sup> of reliability for several of the claims-based measures in the hospital VBP program. However, CMS has not performed the same analysis for the readmission measures.

In the absence of a CMS analysis, the AHA contracted with KNG to complete a reliability analysis of the readmission measures. We found that the median rate of the reliability for the AMI measure is 0.45; 0.53 for the PN measure; and 0.56 for the HF measure. In contrast, as we reference in the hospital VBP section of our comments, CMS sets the rate of reliability for chart-abstracted measures at 0.75 when determining whether a hospital will pass CMS's audit process. We do not see any reason why CMS would settle for a lower rate of reliability on claims-based measures than the chart-abstracted measures. Table 6 below includes the percentage of hospitals nationally that achieve an acceptable rate of reliability – between 0.7 and 0.8.

**Table 6 – Percentage of Hospitals Achieving Acceptable Rates of Reliability**

<b>Reliability Rate</b>	<b>AMI</b>	<b>PN</b>	<b>HF</b>
0.7	13%	16%	25%
0.8	4%	3%	9%

For a majority of hospitals, the readmission measures are not reliable. This is especially important to consider in light of the penalties that are at stake. In our analysis of the inpatient PPS impact file, some hospitals may be penalized by almost \$3 million in FY 2013. **Penalizing hospitals while failing to guarantee that these measures have even a moderate rate of reliability is completely inappropriate.**

One potential solution to ensuring adequate reliability in a measure is to include only hospitals that meet a minimum case threshold. Currently, a hospital must have a minimum of 25 cases on the readmission measures in order to qualify for the Hospital Readmissions Reduction Program. However, the KNG analysis indicates that in order to achieve a rate of reliability between 0.7 and 0.8, hospitals would need to have at least 370 cases for the AMI measure, 422 cases for the PN measure and 451 cases for the HF measure. **At a minimum, we urge CMS to significantly raise the minimum case threshold to qualify for the Hospital Readmissions Reduction Program.**

**Access to Readmission Data.** We urge CMS to provide each hospital a downloadable database containing all of the claims data used to calculate the hospital's readmission rates. In the proposed rule, CMS states that it intends to make confidential reports available to hospitals on June 20 with their readmission penalty for FY 2013. We have reviewed a sample report and commend CMS for the level of data it has included. However, although these reports are an important step forward, hospitals need access to the claims data so they can replicate the information in the reports and use the data within their collaborative networks. Further, we do not support CMS's proposal to give hospitals 30 days to review the reports and appeal the

calculations. **We urge CMS to give hospitals a minimum of 60 days to review the readmission feedback reports.**

***Data used to Calculate Readmission Measures.*** We do not support CMS's proposal to use data from the Common Working File (CWF) to calculate the readmission measures because this file does not contain final-action claims data – or data that have been through the claims editing process fully. It is essential that CMS use only final-action claims to which hospitals have made all final corrections; otherwise, CMS may be using data that are inaccurate for calculating a payment penalty.

**Savings from the Hospital Readmissions Reduction Program.** We urge CMS to correct the measure methodology to exclude planned and unrelated readmissions and adjust the criteria to exclude hospitals where case counts fail to meet reliability standards so that the overall national savings aligns with the Congressional Budget Office estimate of \$100 million for FY 2013. In contrast, in the proposed rule, CMS states that the program will yield three times this estimate – \$300 million. We believe if CMS were to make all of the exclusions and adjustments referenced in this section that this program would generate savings much more aligned with congressional intent.

## **HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM**

The ACA mandates that CMS implement a hospital VBP program beginning in FY 2013. Funding for the program will be generated by reducing base operating DRG payment amounts to participating hospitals by 1 percent in FY 2013. The VBP program is budget neutral; all funds withheld must be paid out to hospitals.

**Applicable Hospitals.** Maryland hospitals are exempt from the VBP program for FY 2013. However, CMS proposes that, beginning with the FY 2014 program, it plans to adopt “a new procedure for submission of the report in order for a hospital within the state to be exempt from the Hospital VBP Program” [emphasis added]. **In contrast, we believe that a Maryland exemption should apply to all HSCRC-regulated hospitals within the state, rather than to specific hospitals. We urge CMS to clarify this discrepancy in the final rule.**

**Base Operating DRG Payment Amount.** CMS proposes to define “base operating DRG payment amount” consistently with the Hospital Readmissions Reduction Program. That is, it would define it as the wage-adjusted DRG operating payment, plus any applicable new technology add-on payments, but not including adjustments or add-on payments for IME, DSH, outliers or low-volume hospitals. It also proposes to exclude the difference between an SCH's applicable hospital-specific payment rate and the federal payment rate from its definition. **The AHA supports these proposals. We urge CMS, however, to also exclude the difference between an MDH's applicable hospital-specific payment rate and the federal payment rate from its definition of “base operating DRG amount” in the event that the MDH program is extended beyond FY 2012.**

In addition, CMS proposes to define the base-operating DRG payment amount for Maryland hospitals as the case payment under the Maryland system. However, defining the base-operating amount in this manner is inconsistent with CMS's policy to utilize standardized payments across hospitals in the national program. Specifically, in Maryland, the case payment already includes DSH, IME, uncompensated care, labor-market adjustors, and assessments to fund other societal goods. **Therefore, while we are hopeful that all Maryland hospitals will be exempt from the VBP program, we request that CMS work with Maryland hospitals and the Maryland Health Services Cost Review Commission to develop an appropriate methodology for determining the base-operating amount for Maryland hospitals.**

**Calculation of VBP Funding Pool.** To fund the FY 2013 program, CMS proposes to reduce the base operating payment amount on each FY 2013 claim by 1 percent for hospitals eligible for the VBP program. CMS proposes to estimate the total amount of reductions across all eligible hospitals and the size of the funding pool prior to the start of each fiscal year; this is the only way it can then calculate each hospital's incentive amount ahead of time and ensure the program is budget neutral. CMS proposes to use MedPAR claims from two years prior to the payment year, with appropriate inflation factors applied, to estimate the size of the funding pool. For SCHs, which are paid the higher of their hospital-specific payment rate or the federal payment rate, CMS proposes to use MedPAR claims to model what the federal payment would have been and use that number in calculating the size of the VBP funding pool. **The AHA supports these proposals. We urge CMS, however, to use the same methodology for modeling the federal payment for MDHs as for SCHs in the event that the MDH program is extended beyond FY 2012.**

Based on this methodology, CMS states that it estimated that the FY 2013 pool will be \$956 million. However, we believe that CMS has included Maryland hospitals in this estimate, even though these hospitals are exempt from the VBP program in FY 2013. **The AHA urges CMS to review its estimate of the FY 2013 VBP pool and ensure that it is excluding Maryland hospitals.**

**Calculation of VBP Incentive Amounts.** CMS proposes to convert each hospital's VBP total performance score into a gross incentive amount by comparing each hospital's performance to the average hospital performance. The agency proposes to then subtract 1.0 percentage point from this gross incentive amount to arrive at a net incentive amount for each hospital for FY 2013. It then proposes to apply the net incentive amount on a per-claim basis to each of a hospital's discharges. **The AHA supports these proposals.**

However, we ask that the agency keep in mind that implementation of the VBP program represents a substantial change in how hospitals will be paid under the Medicare program. CMS's proposed policy will result in hospitals receiving a very small portion of their total VBP incentive amount with each Medicare claim and may not lead to hospitals identifying it as a performance incentive that could be used to further improve quality. **Thus, we urge CMS to provide hospitals with year-begin and year-end VBP "statements" or summaries to help them identify the payment as an incentive.** Similar to a financial statement, these documents would provide information on the hospital's total performance score, estimated/actual DRG

payments withheld, estimated/actual gross incentive payments made, and estimated/actual net VBP incentive payments made (or lost).

**Timing of VBP Payment Amounts.** CMS anticipates that the net VBP incentive amounts will not be added to its system until January 2013. Therefore, it proposes to reprocess claims from October 1, 2012 to January 2013 in order to accurately incorporate VBP payments for the first few months of the fiscal year into hospital payments. For FY 2014 and beyond, CMS anticipates it will be able to incorporate the net VBP incentive amounts into its system by the beginning of the applicable fiscal year. Thus, claims will need to be reprocessed only for FY 2013. **The AHA supports this FY 2013 proposal.** We ask, however, that CMS reprocess the VBP claims in its own, dedicated re-run of the claims. The VBP program is brand new to hospitals; it is very important that they be able to understand and analyze the impact of the program. Doing a dedicated reprocessing of VBP payments only and providing hospitals with the pertinent adjustments on a claim-by-claim basis will help facilitate that end.

**Addition of New Measures for FY 2015.** CMS proposes to add four new measures to the FY 2015 VBP program.

***Administration of Statin Upon Discharge for Heart Attack Patients.*** **The AHA supports adding this measure to the FY 2015 VBP program.** This measure evaluates whether the hospital provided heart attack patients with a statin at discharge, is closely tied to outcomes and has been validated by CMS. The validity testing of this measure indicates it is reliable and can therefore be used in a payment-based program. In addition, this measure is NQF-endorsed and was recommended by the MAP for use in VBP.

***CLABSI Measure.*** **Though CLABSI is an important quality measure, the AHA does not support its inclusion in the FY 2015 VBP program due to a lack of validity testing.** Specifically, CMS has yet to complete any CLABSI validation testing; rather, CMS will receive the first validation data in August. Although validity testing has occurred at the state level for several years, unfortunately, each state uses a slightly different validation methodology.

Prior to CMS's requirement, which began in January 2010, many states already had a CLABSI reporting requirement in place. A comparison of state CLABSI data compared to the federal CLABSI data shows that results vary for a given hospital's performance. Table 7 illustrates the differences in publicly reported CLABSI rates for a given hospital between the state and federal CLABSI reporting programs. When data are publicly reported on *Hospital Compare*, the hospital's performance is classified as "above national average," "national average" or "below national average." Individual states are also publicly reporting CLABSI rates, but use the state average for comparison purposes in place of the national average. For example, in New York, Hospital A is better than the national average, but no different than the New York average. This suggests that the difference in rates is due to factors other than hospitals' performance.

**Table 7 – Comparison of State and Federal CLABSI Data**

<b>Facility</b>	<b><i>Hospital Compare</i></b>	<b>State Department of Health</b>
<b>New York</b>		
Hospital A	Better	No Different
Hospital B	Better	No Different
Hospital C	Worse	Better
<b>Virginia</b>		
Hospital D	Better	Worse
Hospital E	Worse	Worse
Hospital F	No Infections	No Infections
<b>Pennsylvania</b>		
Hospital G	Better	Better
Hospital H	Better	Worse
Hospital I	Better	No Different
<b>Tennessee</b>		
Hospital J	Too Few Cases	Worse
Hospital K	Better	Better
Hospital L	Better	No Different

Source: State health department presentation at the May 30, 2012 HHS Healthcare-acquired Infection data conference.

Table 7 illustrates that we are far from standardizing measurement of CLABSI in hospitals. The differences in the overall rate between the state and federal (*Hospital Compare*) CLABSI rates may be due to several key factors. However, experts believe the biggest contributing factor to the differences is the robust validation efforts in place for these four states. Once federal validation of the CLABSI measure is more common, we expect to see similar results between the state and federal data. We urge CMS to make the results of the CLABSI validation publicly available, as required by law.

In addition, we are concerned with the level of CLABSI data that are currently being publicly reported. CLABSI data were posted for the first time on *Hospital Compare* on January 26. For the first quarter of CLABSI data, less than 25 percent of hospitals met the minimum case threshold to qualify for data display. Twenty-five percent of hospitals is not representative of the field; we are concerned that hospitals have not been properly informed of what the national CLABSI benchmark truly is. It is likely that once more CLABSI data are available, more hospitals will qualify for public reporting and the sample will be more representative. Since we will have more data by the end of this calendar year, we encourage CMS to propose the CLABSI measure for VBP for the FY 2016 program.

***Patient Safety Indicator (PSI) Composite.* The AHA does not support adding the PSI composite to VBP in FY 2015, due to poor results from reliability testing.** On February 13, CMS released a reliability study,<sup>vii</sup> required by the ACA, for claims-based measures. **The study shows that the majority of claims-based measures currently used in the VBP program are unreliable, including the proposed PSI composite.** The CMS study states that “reliability of

an outcome measure is the extent to which variation in the measure is due to variation in quality of care rather than random variation due to the sample of cases observed. 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. Reliability 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." Table 8 below includes the information from the study on the PSI composite.

**Table 8 – Validity of PSI Composite**

<b>Months of Data</b>	<b>Median Reliability</b>	<b>Percent of Inpatient PPS hospitals with a rate of reliability = 0.4</b>
6	0.67	73%
12	0.81	83%
18	0.86	88%
24	0.89	90%

CMS chose to test for a rate of reliability equal to 0.4 because Yale, a measure developer on contract to CMS for other quality measures (mortality and readmission measures) uses 0.4. However, the study also states that "R = 0.4 is considered to be the lower limit of 'moderate' reliability." **Achieving "the lower limit of moderate reliability" is not sufficient for a payment program.** A reliability rate of 0.4 may be good enough for public reporting, but it is not good enough for a program that is tied to as much as 2.0 percent (in FY 2017 and beyond) of a hospital's inpatient PPS payments. **At a minimum, CMS must be reviewing measure reliability at 0.9 or higher.** Hospitals must be assured that the incentives associated with the VBP program have high rates of reliability. We urge CMS to publish a study that repeats this analysis with the rate of reliability equal to 0.9.

CMS proposes a performance period just shy of nine months for the PSI composite, but Table 8 shows that even a 12-month performance period only yields a median reliability of 0.81. Thus, under the proposed nine-month period, the majority of hospitals would not achieve what we believe is acceptable reliability for this measure. We therefore cannot support including this measure in VBP.

**Medicare Spending per Beneficiary (MSPB) Measure.** The AHA recognizes that efficiency measures can be valuable and have a place in the VBP program. However, hospitals need more time to gain experience with the MSPB measure and learn about their potential for performance improvement. This measure was reported on *Hospital Compare* for the first time in April and is claims-based; therefore, hospitals do not have the same level of familiarity with it as they do other VBP measures. Further, CMS has only provided hospitals with data indicating whether the average spending for patients treated by their hospitals is above or below the national average; CMS has not provided hospitals with access to the raw data that would allow them to independently replicate and verify the agency's calculation of this measure. **Therefore, we urge**

**CMS to delay its decision to finalize the MSPB measure until the FY 2014 rulemaking cycle.** Doing so would still allow CMS to include the measure in the VBP program for FY 2015.

In addition, we urge CMS to be more transparent with respect to the data underlying this measure. CMS provides very little data on *Hospital Compare* regarding this measure – it only indicates whether the average spending for patients treated by the hospital is above or below the national average. Because the measure includes a 30-day post-discharge period, it is likely that many other costs beyond inpatient care contribute to the overall metric. Yet, CMS makes this information available only to each hospital in a confidential report, meaning the hospital cannot learn by comparing its performance to other hospitals. For example, each hospital has access to a report that provides a percentage breakdown of the dollars spent in each service category – *i.e.*, 20 percent of spending for patients treated in Hospital X comes from a skilled nursing facility. For many hospitals, this information is new; yet, CMS does not include it on *Hospital Compare*. Hospitals need to see this level of transparency so they can properly benchmark their performance against other similar hospitals. We urge CMS to make these data publicly available.

In addition, hospitals have had only a short period of time during which to understand this measure. Hospitals received their first feedback on this measure during an initial “dry-run” confidential feedback period in February. Following that, the measure was posted on *Hospital Compare* in April. Given these milestones, hospitals have had less than a full calendar quarter to understand this new measure. Understanding where each hospital stands on this measure in comparison to other hospitals has not been helped by CMS’s treatment of the MSPB performance standards in this proposed rule. Specifically, CMS proposes the methodology for determining the MSPB benchmark and attainment threshold; however, it does not provide the numerical thresholds that this proposed methodology would lead to, despite doing so for all other VBP measures, including mortality measure thresholds that will be in effect in FY 2016. This is inadequate notice on what the performance standards will be for this measure. **Because CMS does not provide the numerical standards, we do not support the methodology it proposes for determining the standards.**

We also are concerned about the lack of reliability testing on this measure. In the February reliability study referenced above, CMS failed to include testing of this measure. It is likely to yield similar reliability results as the other claims-based measures. For example, the 30-day MSPB measure is constructed in a similar manner as the 30-day mortality measures (discussed below). Given the unreliable nature of the mortality measures, in the absence of further data, we must assume a similar level of unreliability for the MSPB measure. We urge CMS to pursue a reliability analysis of the MSPB measure and publicly release the analysis prior to finalizing the measure in hospital VBP.

Finally, **the MSPB measure must go through the NQF endorsement process.** In the proposed rule, CMS states that it will put the MSPB measure through the NQF process but does not indicate when. We urge CMS to be more transparent regarding its intentions for NQF endorsement of this measure. In addition, the MAP did not recommend this measure for use in hospital VBP, in part due its lack of NQF-endorsement.

**Removal of Measures.** CMS makes a proposal to remove one measure (described below) from hospital VBP, beginning in FY 2015. In addition, we urge CMS to remove the 30-day mortality measures from the VBP program.

**Ordering Venous Thromboembolism Prophylaxis for Surgery Patients.** We support removal of the Surgical Care Improvement Project (SCIP) measure regarding the ordering of venous thromboembolism (VTE) prophylaxis for surgery patients from the hospital VBP program. Specifically, CMS proposes to remove SCIP-VTE-1 (ordering of prophylaxis) beginning with the FY 2015 VBP program. CMS states its reason for removal is that SCIP-VTE-2 (receipt of prophylaxis) is more closely linked to outcomes than SCIP-VTE-1 because it monitors for receipt of prophylaxis, rather than simply ordering prophylaxis. We agree with CMS's reason to remove SCIP-VTE-1 from the program and urge CMS to remove it before FY 2015. If CMS is unable to finalize removal of the SCIP-VTE-1 measure in FY 2013 and 2014 because it was not proposed, we urge CMS to use the CY 2013 outpatient PPS proposed rule to remove the measure.

**Mortality Measures.** On April 29, 2011, CMS issued a final rule on the hospital VBP program. In that rule, CMS finalized three 30-day mortality measures (heart attack, heart failure and pneumonia) for the FY 2014 hospital VBP program. **However, on February 13, 2012, well after the mortality measures were finalized, CMS released a reliability report (described above) indicating that all of the mortality measures are unreliable.** Table 9 includes the data on the mortality measures from the study.

**Table 9 – Mortality Measure Reliability Data**

Measure	6 Months		12 Months		18 Months		24 Months	
	Median* Reliability	% of Hospitals R ≥ 0.4**	Median* Reliability	% of Hospitals R ≥ 0.4**	Median* Reliability	% of Hospitals R ≥ 0.4**	Median* Reliability	% of Hospitals R ≥ 0.4**
AMI Mortality (R = 0.4 with 107 cases)	0.09	2	0.17	12	0.23	24	0.29	33
HF Mortality (R = 0.4 with 196 cases)	0.11	2	0.20	14	0.27	28	0.33	40
PN Mortality (R = 0.4 with 211 cases)	0.11	1	0.19	8	0.27	22	0.32	35
* Reliability of measure of hospital of median case size								
**Proportion of hospitals with case size large enough that R ≥ 0.4								

Table 9 illustrates that none of the three mortality measures, regardless of the time period used, have even what CMS considers to be the “lower limit of ‘moderate’ reliability,” equal to an R of 0.4. For example, a median reliability of only 0.29 would be achieved with a 24-month performance period for the AMI mortality measure, of only 0.33 for the HF mortality measure and of only 0.32 for the PN mortality measure. In addition, 40 percent or less of hospitals would have the “lower limit of ‘moderate’ reliability of 0.4 for this time period. This is especially troubling considering CMS intends to use only a nine-month performance period for the mortality measures in FY 2014. **We do not support CMS’s proposal to codify the mortality measures for FY 2014. Further, we do not support CMS’s proposal to include the mortality measures in the FY 2015 program. We urge CMS to permanently remove the mortality measures from the VBP program due to their lack of reliability.**

Beyond the reliability study that CMS released, a validity study must be pursued. To date, the mortality measures have never been validated against medical records. The ACA requires a validation process for all VBP measures. Specifically, the ACA statute requires that “the Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital.” **We urge CMS to pursue a validation study of the mortality measures immediately and make the results of the study publicly available.**

**Process for Retention of VBP Measures.** The AHA does not support CMS’s proposal to automatically adopt previously finalized measures for all subsequent VBP program years. Quality measurement is an evolving process and measures can and do change from year-to-year. What may be the standard of care in one year may not be the standard in subsequent years. The results of CMS’s reliability study for the mortality measures, described above, are a clear example of why CMS should not automatically retain VBP measures from year to year. We urge CMS to re-propose all VBP measures each year to allow for new research to be considered in a continual evaluation of the VBP program.

**Changing Measures.** The AHA urges CMS to establish a transparent process to indicate when a VBP measure is altered and how the agency will ensure that the alteration does not arbitrarily affect hospitals’ total performance scores. For example, CMS has made extensive alterations to the previously finalized “SCIP – beta blocker for surgery patients” measure. Specifically, in the baseline period, the numerator was defined as all surgery patients who received a beta blocker between the period of 24 hours before surgical incision and through discharge to the post-anesthesia period. However, in the performance period, the numerator was defined as all surgery patients who received a beta blocker between the period of 24 hours before surgical incision through post-operative day two. By extending the numerator and keeping the denominator constant, more patients will qualify for the numerator as an artifact of the measure change, rather than an actual shift in the patient population. This change to the numerator may benefit some hospitals and may penalize others.

CMS must understand that a small “tweak” to a measure from the baseline period to the performance period can have a large effect on the hospital’s overall level of performance on a measure. We have long supported CMS’s position to make sub-regulatory changes to quality measures. **However, if CMS does not implement a process to monitor and account for how those changes affect a hospital’s VBP score when comparing the baseline to performance periods, we will no longer be able to support sub-regulatory measurement changes.**

**Establishing Future Performance Periods and Standards through a Sub-regulatory Process.** The AHA does not support CMS’s proposal to establish future performance periods and performance standards through a sub-regulatory process. Further, the annual inpatient PPS rulemaking process, which has a predictable timeframe, is the avenue which all hospitals follow for changes to quality reporting and payment programs. In addition, official Federal Register notices are established processes to which everyone has equal access. In contrast, issuing sub-regulatory guidance is not guaranteed to reach all relevant interested parties. Any quality measurement changes that affect hospitals’ payments should go through a formal, “notice and comment” rulemaking process.

**Measurement Domains.** CMS makes domain weighting proposals for the FY 2015 VBP program and seeks public comment on a framework for the FY 2016 VBP program. We also provide feedback on the previously finalized domain weighting for the FY 2014 VBP program.

***Concerns with FY 2015 Measurement Domain Weighting.*** The AHA does not support CMS’s proposed measurement domain weighting for the FY 2015 VBP Program. We believe that a decision on whether to include the MSPB measure should be delayed until the FY 2014 inpatient PPS rule making cycle. We have urged CMS to remove the mortality measures because they are unreliable, and we have urged CMS to delay implementation of the CLABSI measure.

***Framework for FY 2016 Measurement Domains.*** We urge CMS to consider the measurement priorities identified by the National Quality Strategy (NQS) as guiding principles, rather than as measurement domains. CMS seeks comment on making the six measurement priority areas of the NQS the measurement domains for the FY 2016 VBP program. The six domains would be: patient and family engagement; care coordination; clinical processes; patient safety; efficiency; and population/public health. Though we agree that population/public health and care coordination are important goals of the NQS, we do not feel they are necessarily appropriate goals for a hospital VBP program at this time. However, these would be important goals for a program in which participants agree to take on full responsibility of patients, such as Accountable Care Organizations.

We also are concerned about into which priority areas each measure would be placed. In the proposed rule, CMS provides a crosswalk of all finalized and proposed measures to each of the six priority areas. However, CMS states that many of the measures could potentially fit into multiple priority areas. We agree that measures may align with multiple priorities and it would be somewhat arbitrary to assign measures to only one.

***Hospital View of Quality Domains.*** Hospitals relate to condition-specific domains of quality measures, rather than generic domains such as “process” and “outcomes.” It is promising to see CMS’s recognition that we may not have the current domains of quality measurement right, which is evident in CMS’s attempt to change the measurement domains and weighting for each of the first four years of the VBP program. However, it will be difficult for hospitals to keep track of their performance in the VBP program when the domains and weighting are constantly changing. Rather than making continual changes, we urge CMS to move toward a more clinically-based domain framework. For example, most hospitals think about the VBP measures in terms of domains for heart failure, heart attack, pneumonia and surgery and rather than a process domain that lumps those measures together. When CMS considers how to change domains and weighting in the future, we urge the agency to also consider our proposed organizational framework. Further, we urge CMS to use the experience and data from the first few years of the VBP program to drive future changes in domains and weighting. It seems premature to consider domains and weighting for FY 2016 when the VBP program has not yet begun.

***Concerns with Previously Finalized Domains.*** As previously stated, the mortality measures are unreliable and must be removed from the VBP program. However, CMS has finalized an outcomes domain, which contains only the mortality measures, for the FY 2014 VBP program. **Thus, we urge CMS to use a 0 percent weighting for the outcomes domain until appropriate, valid and reliable measures are available for inclusion in it.** For example, while we do not support the inclusion of CLABSI in the VBP program at this time due to a lack of validity testing, it is a type of quality measure that would be appropriate for inclusion in an outcomes domain in the future.

In addition, we also have had a long-standing concern with placing so much emphasis on the patient experiences of care domain. While much work has gone into developing the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measures, new research is emerging that shows that HCAHPS scores may be impacted by patient characteristics more than previously thought. For example, research conducted 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 the HCAHPS questions; as symptoms of depression worsened, HCAHPS scores declined. These findings indicate that hospitals that treat the most severely ill patients may have systematically lower HCAHPS scores. Yet, these patient characteristic variables are not adjusted for in the HCAHPS methodology. This unfairly disadvantages hospitals that care for the sickest patients in the VBP program. We urge CMS to reduce the weighting of the HCAHPS domain. We believe that a weighting of 15 percent strikes a balance between the importance of including a measure of patient experience in the VBP program with the concerns about potential biases present in the survey.

**Performance Periods.** The AHA is concerned about the performance periods proposed for the FY 2015 and 2016 VBP program. CMS makes performance period proposals for all of the new proposed measures, as well as a different performance period for the mortality measures.

***Administration of Statin upon Discharge for Heart Attack Patients.*** The AHA supports CMS's proposed performance period for the statin upon discharge measure for heart attack patients for the FY 2015 program. CMS proposes to use a nine-month performance period for this measure. Though we prefer a full calendar year of performance for this measure, we understand that CMS is limited to a nine-month period for FY 2015 due to the initial posting date of this measure on *Hospital Compare*. We urge CMS to use a 12-month period for this measure in the future.

***CLABSI, PSI, MSPB, and Mortality Measures.*** The AHA does not support CMS's proposed performance period for the CLABSI, PSI, MSPB or mortality measures for the FY 2015 program. These measures have either been shown to be unreliable or have not undergone validity testing.

**Benchmarks.** The AHA supports all of CMS's proposed benchmarks for FY 2015, with the exception of the MSPB benchmarks because insufficient information is provided, as noted above.

**In addition, we do not support CMS's proposed benchmarks for FY 2016 for the mortality measures and the PSI composite measure** because we do not support including either the mortality measures or the PSI composite in the VBP program.

**Minimum Cases.** We do not support CMS's proposals for the minimum number of cases for the mortality or MSPB measures. CMS proposes to increase the minimum case threshold for the mortality measures from 10 cases to 25. This does not increase the reliability of the measures sufficiently. As the CMS reliability study clearly illustrates, even if the minimum case count was 100 cases, the measures still would not achieve even the lower end of a moderate rate of reliability for the majority of hospitals. However, because CMS already has finalized the mortality measures for FY 2014, if the agency chooses to act against our recommendation and keep the mortality measures in the FY 2014 program, we urge CMS to increase the minimum case threshold to 25 cases.

CMS also proposes a minimum case count of 25 for the MSPB measure and seeks public comment on whether 50 cases are a more appropriate minimum for the MSPB measure. As stated above, we do not have sufficient information to make a meaningful comment on this proposal. CMS's reliability for the mortality measures indicate that even a minimum of 100 cases does not produce reliable results for those measures. Since the MSPB measure is also a claims-based measure, it is highly probable that the same conclusion holds true. **To better understand how many cases are needed to generate reliable results for the MSPB, we urge CMS to include this measure in its reliability study and make the results publicly available.**

***Lack of Implementation of Key ACA Demonstrations.*** We urge CMS to begin the ACA-mandated small numbers and CAH VBP demonstrations. To help address the issue of minimum case counts, the ACA-mandated VBP demonstrations for both hospitals with small numbers of patients and cases and CAHs. These demonstrations were mandated to begin no later than March 23, 2012; to date, CMS has not released any information on these demonstrations.

**Review and Correction Process.** The AHA urges CMS to give hospitals a minimum of 60 days, rather than the 30 days proposed, to review the claims-based measure and total performance feedback reports. Hospitals will receive discharge-level information on the claims-based measures for the first time. This is an important step forward, and we applaud CMS for making these data available. However, hospitals will need to verify the discharge-level information for patients outside of their facilities. Since the majority of the claims-based measures utilize a 30-day post-discharge period that includes data from all Medicare providers that furnish services to a beneficiary, hospitals will need additional time to work with multiple providers to identify any errors.

**Appeals.** The AHA supports CMS's proposals for appeals in the VBP program. CMS proposes that if a hospital's request for correction under the "review and correction process" described above is rejected, the hospital can pursue an appeal. CMS proposes that hospitals be able to appeal the following aspects of the program:

- Whether the achievement and improvement points were calculated correctly;
- Whether CMS properly used the higher of the hospital's achievement or improvement points in calculating the hospital's measure/dimension score;
- Whether CMS correctly calculated the domain scores, including the normalization calculation;
- Whether CMS used the hospital's HCAHPS lowest dimension score in calculating the hospital's HCAHPS consistency points;
- Whether CMS calculated the HCAHPS consistency points correctly;
- Whether the correct domain scores were used to calculate the total performance score;
- Whether each domain was weighted properly;
- Whether the weighted domain scores were properly summed to arrive at the total performance score; and
- Whether the hospital's open/closed status (including mergers and acquisitions) is properly specified in CMS's systems.

**Immediate Jeopardy.** We support CMS's proposals for handling immediate jeopardies that are issued during a VBP performance period. The ACA excludes from the VBP program hospitals that have been cited for deficiencies that pose immediate jeopardy to the health or safety of patients during the course of a survey for compliance with the conditions of participation for the Medicare and Medicaid programs. At the AHA's urging, CMS proposes to exclude a hospital from the VBP program if the hospital was cited for an immediate jeopardy on *at least two* surveys during the VBP performance period. CMS states that the ACA clearly states that hospitals should be excluded from the VBP program if the Secretary has cited multiple "deficiencies" that pose immediate jeopardy – not a singular "deficiency" that poses immediate jeopardy.

**Comparing a Hospital's Performance When Moving from ICD-9-CM to ICD-10-CM/PCS Coding.** The AHA is extremely concerned about how CMS's measurement of hospital performance may change when ICD-10-CM/PCS codes begin to be used for claims-based

**measures.** We urge CMS to compare baseline data to performance data using the same classification system. It would be unfair, and potentially impractical, to compare a hospital's measurement results using ICD-9-CM in the baseline period and ICD-10-CM/PCS in the performance period. For calculation of the claims-based measures, we urge CMS to either re-run the baseline data using ICD-10-CM/PCS or re-run the performance data using ICD-9-CM. We cannot make a judgment in favor of either method without seeing the data. We urge CMS to test this concept both ways on a subset of hospitals and make the data publicly available.

**Estimated Impact of VBP program.** We note that the impact section of the proposed rule (77 FR 28124) references the proposal of two process measures for FY 2015 – statin at discharge for heart attack patients, and perioperative temperature management for surgery patients. However, the preamble language notes that CMS is *not* proposing the perioperative temperature management measure for FY 2015 because it is “topped out.” We assume that the preamble language is correct and an error was made in the impact section, especially since CMS did not propose a performance period for the perioperative measure. **We urge CMS to confirm that there is an error regarding the perioperative measure in the VBP impact section in the final rule.**

## **HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM**

*The Deficit Reduction Act of 2005 (DRA)* expanded quality reporting requirements for hospitals to be eligible to receive a full market-basket update; it also provided HHS with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures on the basis that they are no longer appropriate. CMS proposes five new measures and the removal of 17 measures for the FY 2015 annual payment determination, as well as one measure for the FY 2016 annual payment determination. To receive a full market-basket update, hospitals would have to pledge to report data on these and all measures currently included in the hospital IQR annual payment update program and pass the established data validation tests.

**Removal of Quality Measures.** The AHA supports CMS's proposal to remove 17 measures from the IQR program. Of the measures proposed for removal, 16 are claims-based measures and one is a medical record-abstracted measure. For all 17 measures, CMS proposes removal beginning with the FY 2015 IQR program. **We urge CMS to remove these measures for the FY 2013 and FY 2014 IQR program as well.** Since CMS has concluded that these measures are unfit for the program, they should be removed as soon as possible. If CMS is unable to remove these measures before FY 2015 because it was not proposed, we urge CMS to use the CY 2013 outpatient PPS proposed rule to remove these measures for the FY 2013 and 2014 IQR program. Further, we urge CMS to remove these measures from *Hospital Compare* as soon as possible.

***Removal of Claims-based Measures.*** CMS proposes to remove eight hospital-acquired conditions (HACs), five PSIs and three inpatient quality indicators (IQIs) from the IQR program. **The AHA supports removal of the HAC, PSI and IQI measures from the IQR program.** These measures have never been validated against medical records and the HACs are not

endorsed by the NQF. The MAP also has recommended that the HACs be removed from the IQR program.

***Removal of Chart-abstracted Measure.*** CMS proposes to remove the Surgical Care Improvement Program (SCIP) measure for ordering recommended venous thromboembolism prophylaxis for surgical patients from the IQR program. **The AHA supports removal of this SCIP measure from the IQR program.** However, in the proposed rule, CMS failed to propose a date for when hospitals can cease submission of data for this measure. **We urge CMS to finalize an end date for data submission of this measure that is effective immediately, or is effective on the date of publication of the FY 2013 inpatient PPS final rule.** If CMS is unable to finalize an end date for data submission because it was not proposed, we urge CMS to use the CY 2013 outpatient PPS proposed rule to propose a date by which hospitals can cease data submission for this SCIP measure.

**FY 2015 Proposed Addition of New Quality Measures.** **The AHA supports the new HCAHPS, hip and knee complication and readmission measures. However, we do not support the all-cause, all-condition readmission and 39-week elective delivery measures.**

***HCAHPS Changes.*** CMS proposes to add one new measure and two new items to the HCAHPS patient experience of care survey instrument. The new measure, a three-item Care Transition Measure (CTM-3), includes the following statements:

- During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left the hospital;
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health; and
- When I left the hospital, I clearly understood the purpose for taking each of my medications.

**The CTM-3 measure is an important measure of a patient's experience of care, and we support its inclusion in the HCAHPS survey that is required in the IQR program.** CTM-3 is NQF-endorsed and was recommended by the MAP.

CMS also proposes two new questions to be added to the HCAHPS survey in the "About You" section. The first question would require a beneficiary to declare whether he/she entered the hospital through the emergency department (ED). The beneficiary would choose either "yes" or "no" in response to this question. CMS is proposing to add this question because these data were previously obtained through another mechanism that is no longer available. **We agree with CMS that adding this question would enhance the HCAHPS survey and support the agency's proposal.** However, we suggest that CMS modify the question by clarifying whether the beneficiary entered "this" hospital through the ED. This minor modification would allow for differentiation between transfer and non-transfer cases.

The second question CMS proposes to add would ask a beneficiary to rate his/her overall mental or emotional health on scale ranging from excellent to poor. CMS offers neither a rationale as to

why it wants to add this question, nor a statement of what it will do with the data. In addition, CMS does not state whether it has pilot-tested this question with beneficiaries. We have several concerns about this question. First, we are concerned that patient characteristics, which are not adjusted for, may unduly influence how beneficiaries respond to this question. This could result in the potential unintended consequence of hospitals treating the most severely ill patients having systematically lower scores on this question, thereby unfairly disadvantaging these hospitals. In addition, we are concerned that beneficiaries may not feel comfortable answering this question and may perceive it as an invasion of privacy. Finally, we also are concerned that this type of self-diagnosing of psychiatric conditions may have potential unintended consequences for hospitals, such as increased liability risk. **Because there are many unanswered questions and we are unsure of the state of pilot testing, we cannot support this proposal at this time.** We are willing to work with CMS to examine viable alternatives for assessing this type of information.

***Hip and Knee Arthroplasty Complications.*** CMS proposes to add a measure to the IQR program that captures a composite of complications occurring after hip or knee arthroplasty procedures. We believe this is an important measure that captures patient outcomes during the post-discharge period and provides hospitals access to data to which they may not have access otherwise, including a limited set of complications that occur after the patient has left the hospital. Further, this measure is NQF-endorsed and was recommended by the MAP. **We support including this measure in the IQR program.**

***Hip and Knee Arthroplasty 30-day Readmissions.*** CMS proposes to add a claims-based measure to capture all-cause readmissions within 30 days of discharge following hip or knee arthroplasty procedures to the IQR program. This hip and knee readmission measure is specified in a similar way to existing AMI, HF and PN readmissions measures. We do not support the addition of these readmission measures because they fail to:

- differentiate between planned and unplanned readmissions;
- differentiate between related and unrelated readmissions;
- exclude extreme circumstances (transplant, end-stage renal disease, burn, trauma, psychosis and substance abuse); and
- properly adjust for patient characteristics (dual eligible status and race/ethnicity).

We urge CMS to make these changes to the hip and knee arthroplasty readmission measure, as well as to the AMI, HF and PN measures.

**Despite this lack of necessary adjustments, we still believe that hip and knee arthroplasty readmissions are an important measure of patient outcomes.** In addition, this measure is NQF-endorsed and was recommended by the MAP. **The AHA supports its inclusion in the IQR program.** We feel that focusing on this measure, as well as public reporting, will have a positive impact on reducing readmissions. **We note that this measure is not properly specified for use in the Hospital Readmissions Reduction Program and would need extensive revision in order to qualify for inclusion in that program.**

***Hospital-wide, All-cause, All-condition 30-day Readmissions.*** CMS proposes to add a claims-based measure to the IQR program that captures all-cause readmissions across all diagnoses within 30 days of discharge. However, all readmissions are not equal. Decreasing readmissions involves a very careful and deliberate partnership among several stakeholders that is tailored to a specific condition. The hospital field has five years of experience working to reduce AMI, HF and PN readmissions and has found that there is not a universal strategy that reduces readmissions across all three conditions. Rather, different interventions are needed to reduce readmissions associated with each of these conditions. Hospitals have been successful in reducing AMI, HF and PN readmissions because the condition-specific nature of these measures allows hospitals to target their efforts on specific causes of readmissions for each condition. In contrast, the proposed hospital-wide, all-cause, all-condition readmission measure does not allow for any focus and, therefore, will only serve to detract away from successful condition-specific strategies. **The AHA does not support the hospital-wide, all-cause, all-condition readmission measure.**

Although we provided extensive comments to CMS and the measure developer throughout the development of this measure, both in its early stages and during the NQF endorsement process, the agency has failed to make proper adjustments to this measure. Specifically, CMS has failed to:

- differentiate between related and unrelated readmissions;
- exclude extreme circumstances (transplant, end-stage renal disease, burn, trauma, psychosis and substance abuse); and
- properly adjust for patient characteristics (dual-eligible status and race/ethnicity).

An all-condition readmission measure greatly exacerbates the unintended consequences of failing to make these necessary measure adjustments.

CMS and the measure developer have, however, attempted to remove some planned readmissions from this measure. Specifically, this measure excludes patients undergoing medical treatment for cancer as their primary procedure but then includes 36 categories of procedures that are considered planned. Further, the rule includes a table of 27 categories of procedures that are considered unplanned. **The AHA appreciates CMS's efforts to exclude certain planned readmissions from this measure. We urge the agency and the measure developer to use this methodology to exclude planned readmissions from all readmission measures and thereby harmonize methodologies.**

***Elective Delivery Prior to 39 Completed Weeks of Gestation.*** **The AHA supports this measure for inclusion in the IQR program, as proposed, but does not believe it is appropriate for the hospital VBP program.** The AHA recently adopted a formal board position supporting policies to eliminate early-term, non-medically necessary deliveries, meaning inductions or cesarean sections performed at 37 and 38 weeks gestation without a medical indication. The AHA, the Health Research and Educational Trust through its Hospital Engagement Network contract, the March of Dimes, many state hospital associations and several other groups are all working with hospitals and hospital associations to reduce or eliminate early-

term, non-medically necessary deliveries, and many hospitals across the U.S. have implemented procedures to eliminate these deliveries based on evidence that babies born at 37 and 38 weeks gestation have higher risks of morbidities. HHS also has launched a campaign through its “Strong Start Initiative” to raise awareness of the risks of these deliveries.

CMS proposes to include a NQF-endorsed measure (#0469) requiring hospitals to report, in aggregate form (numerator, denominator and exclusions), the hospital’s rate of early-term elective deliveries. However, the preamble to the proposed rule does not specify whether a hospital is expected to report the early-term elective delivery rate for all obstetric patients or only for the tiny fraction of Medicare patients with deliveries. Approximately 4 million babies are born in the U.S. each year, while Medicare paid for only about 14,000 deliveries in 2011. We assume that CMS proposes this measure for all patients given that individual hospitals would likely lack enough data for Medicare-only deliveries to produce meaningful rates of early-term elective deliveries. We believe these data should be collected and publicly reported. However, we do not believe this measure will be appropriate for inclusion in the hospital VBP program in future years. A measure focusing on obstetrical delivery of babies seems more appropriate for potential inclusion in a Medicaid VBP program or for use by other purchasers for whom this constitutes a substantial proportion of hospitalized patients.

**FY 2016 Addition of New Quality Measures.** **The AHA does not support the safe surgery checklist measure CMS proposes for the FY 2016 IQR program.** Though the use of a safe surgery checklist may lead to reduced surgical errors, the proposal is merely a concept that is not a fully developed measure. Therefore, it is not endorsed by the NQF, nor recommended by the MAP (although the MAP did support the general concept of the measure).

Further, there are many requirements already in place to address safe surgeries. CMS previously issued National Coverage Determinations (NCDs) to measure the outcome of adverse surgery events. In addition to not receiving any reimbursement for any aspect of a surgery that results in an adverse event, the NCDs also require all provider types to notify CMS of adverse surgical events. In addition, The Joint Commission surveys all accredited institutions for surgery checklists as part of its patient safety requirements. A recent study<sup>viii</sup> focused on the most common barriers associated with the use of a surgical checklist and identified the top barrier as “duplication with existing processes that already covered several of the items in the surgical checklist.” With these more comprehensive safeguards already in place, **adding this concept to the IQR program would be redundant.**

**Data Submission.** CMS makes two proposals concerning data submission changes. The first proposal addresses data submission for the 39-week elective delivery measure and the other proposal addresses reporting to the National Healthcare Safety Network (NHSN).

***39-week Early-term Elective Delivery Data Reporting.*** **The AHA supports CMS’s proposal to require aggregate data (numerator, denominator and exclusions) for the 39-week elective delivery measure.** The AHA supported aggregate data across all payers in response to CMS’s proposals for Stage 2 of “meaningful use” of electronic health records (EHRs). Though we support aggregate data reporting, we want to be clear that it does not alleviate hospitals of

any burden. Hospitals must still collect data on every applicable patient in order to generate the aggregate data.

***Exemptions for Reporting NHSN Data.*** The AHA supports CMS's proposed exemption process for reporting of CLABSI, Catheter-Associated Urinary Tract Infections (CAUTI) and Surgical Site Infection (SSI) measures. Specifically, CMS proposes to exempt hospitals without an intensive care unit (ICU) from reporting of CLABSI and CAUTI. CMS also proposes to exempt hospitals with fewer than 10 combined cases of colon/abdominal hysterectomy procedures from reporting the SSI measure. Hospitals that do not have a relevant population for measure reporting should be exempt from applicable quality measure reporting.

**Validation.** The AHA does not support CMS's proposal to combine validation of the Centers for Disease Control and Prevention (CDC) infection measures with the current validation used for the chart-abstracted quality measures for all hospitals. Many states already validate the CDC infection measures. For those states, adding a separate federal validation process doubles the burden on hospitals. Rather than combine the validation process for the chart-abstracted measures with the infection measures, it is better to keep them separate for those hospitals in states that already validate the infection measures. However, in those states that do not validate the infection measures, it is important to have a federal validation process that is combined with the chart-abstracted validation process. This federal validation process should be centrally managed by CDC, as it is the measure developer and, therefore, the most qualified entity to validate results.

***Existing Burdensome Validation Process for Infection Measures.*** In the FY 2012 inpatient PPS final rule, CMS finalized a federal process for validating the CLABSI measure that applies to the FY 2014 program. That validation process is described on the QNet website at: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FOneTier2&cid=1228760487021>. This federal validation process is very burdensome and requires submission of data, beyond what is already submitted to CDC, on every patient with a positive blood culture.

***Concerns Regarding FY 2015 Validation Requirements.*** In this rule, CMS proposes to validate the CAUTI measure by focusing on those cases with a positive urine culture. However, the proposed rule does not link to any other detailed documentation on the role hospitals are required to fulfill if selected for validation. It is unclear if CMS intends to use the same validation process that is currently included for CLABSI on the QNet website for the FY 2015 validation for all of the infection measures. We seek further clarification, including a link to subsequent documentation, on what information hospitals would need to submit for the FY 2015 validation of the infection measures. **In the absence of this information, we cannot support the FY 2015 validation proposals.** Further, if CMS intends to require the same process for FY 2015 CLABSI validation, as required in FY 2014, we do not support the proposal. Likewise, if CMS intends to require the same process for FY 2015 CAUTI and SSI validation, as required for CLABSI in FY 2014, we do not support the proposal.

***Reducing the Total Number of Hospitals Selected for Validation.*** In the proposed rule, CMS states that “a very high percentage (99 percent) of hospitals pass validation.” Since the vast majority of hospitals pass validation, **we support CMS’s proposal to reduce the total number of hospitals from 800 to 400 selected for annual random validation.**

**Process for Retention of IQR Measures.** We do not support CMS’s proposal to automatically adopt measures for all subsequent payment determinations unless the measures are proposed for removal, suspension or replacement. Quality measurement is an evolving process and measures can and do change from year to year. What may be the standard of care in one year may not be the standard in subsequent years. A recent study<sup>ix</sup> released by CMS itself highlights why all measures must be proposed each year in regulation.

***Reliability Testing Indicating Measures Are Unreliable.*** On February 13, CMS released a validation study required by the ACA for claims-based measures. The study shows that the majority of claims-based measures used in the IQR program are unreliable and has led to CMS’s proposal to remove 16 claims-based measures from the program. However, CMS did not propose to remove PSI-4: death among surgical inpatients with serious, treatable complications from the IQR program. Currently PSI-4 is reported on *Hospital Compare* using 18-months of claims data; according to CMS’s study, the average rate of reliability for PSI-4 using 18-months of data is 0.24. In contrast, CMS has defined an acceptable rate of reliability as 0.4; and only 34 percent of hospitals achieve this rate for this measure. **Since this measure is unreliable for the majority of hospitals in the country, we urge CMS to remove this measure from the program.** If CMS is unable remove PSI-4 because it was not proposed, we urge CMS to use the CY 2013 outpatient PPS proposed rule to cease data submission for this measure.

Further, this example highlights why it is important to propose measures for each year of the program because evidence may emerge that suggests a measure should be removed.

**Expansion of Infection Measures beyond the ICU.** CMS seeks comment on whether the CLABSI and CAUTI measures should be expanded to all areas of the hospital, instead of applying only to the ICU. The AHA supports moving toward this goal in the long-term; however, expansion of these measures is currently inappropriate. A few more years of data collection and validation are needed to ensure hospitals are properly and accurately capturing this infection data – display of CLABSI data on *Hospital Compare* only began in January 2012 and CAUTI reporting will begin in January 2013. We urge CMS to monitor reporting and validation progress on these measures and make a proposal for expansion only after hospitals have had a few years of data reporting experience.

**Use of EHRs for IQR Measure Reporting.** CMS seeks comment regarding the best options for transitioning data collection to automated reporting from EHRs. CMS discusses two options: 1) to select a date after which chart-abstracted data would no longer be used in the hospital IQR program where it is possible to report the data via certified EHR technology; or 2) allow hospitals to submit the same measure for the hospital IQR program based on either chart-abstracted or, when available, EHR-based reporting. In the proposed rule, CMS states that “we recognize that considerable work needs to be done by measure owners and developers to make

this [automated quality measure reporting] possible. This includes completing electronic specifications for measures, pilot testing, reliability and validity testing, inclusion of such specifications into EHR technology to capture and calculate the results, and implementing systems.”

We agree with CMS’s assessment of the current state. In our comment letter in response to the Stage 2 meaningful use proposals, we stated all of the concerns that CMS references. We urge CMS to review this comment letter and take it into consideration. Because both we and CMS feel that much more work needs to be done, we have no other choice but to support the agency’s second option – to allow hospitals to submit the same measure for the hospital IQR program based on either chart abstraction or, when available, EHR-based reporting. We urge CMS to allow this option of reporting through the IQR immediately. **With both the IQR and meaningful use requirements, hospitals are collecting data through two mechanisms for the same measure. These duplicative processes are overly burdensome and a waste of resources.** Hospitals should be able to choose the method of reporting IQR measures that they determine is best.

**Consideration of Recommendations from the MAP.** We applaud CMS for its recognition of recommendations from the MAP in this proposed rule. The MAP is a multi-stakeholder board charged with making annual recommendations to the Secretary regarding which measures should be included in national quality reporting programs. The MAP was mandated by the ACA and functions under appropriated dollars from HHS. It conducted a review of measures from CMS in early 2012, including 14 IQR measure proposals that overlap with MAP recommendations. Of those 14 proposals, only one did not perfectly align with the MAP recommendation – safe surgery checklist. The MAP “supported the direction” of this measure, but did not recommend it for inclusion in the IQR program.

Despite the overall positive response to the MAP’s IQR recommendations, there were a few areas that can be targeted for future improvement. For example, CMS proposed to remove nine measures that the MAP did not address. In addition, upon CMS’s request, the MAP reviewed and recommended four measures that CMS did not propose. For the 2012 MAP process, we urge CMS to aim for a higher level of alignment between MAP recommendations and IQR proposals. In addition, CMS should aim to provide the list of measures for MAP review in advance of the statutory deadline. Further, CMS should aim to provide the list of measures for the MAP sooner than the statutory deadline. During this past review cycle the MAP had only two months to review a list of more than 300 measures. This was not a sufficient amount of time.

**NQF Maintenance Review of Measures.** The NQF has a policy that each measure under endorsement must complete a mandatory maintenance review every three years to receive continued endorsement. In the past, we have commented that CMS must be more transparent about this maintenance review process in the annual proposed rule. This year, CMS referenced the maintenance review process for only the CLABSI and CAUTI measures, which is a positive step forward, but more transparency is needed.

**We urge CMS to release the NQF status, including maintenance review, of every proposed and previously finalized measure in the proposed rule each year.** In addition to the CLABSI and CAUTI measures, many of the previously finalized IQR measures are undergoing maintenance review. For example, both the pneumonia 30-day mortality and 30-day readmission measures are undergoing maintenance review at NQF. Failure to reference the NQF status of all IQR measures puts the public at a disadvantage and may result in inadequate public comment.

## **PPS-EXEMPT CANCER HOSPITAL QUALITY REPORTING PROGRAM**

The ACA mandated that PPS-exempt cancer hospitals must begin reporting quality measures no later than FY 2014. Failure to report these quality measures will subject cancer hospitals to a 2 percentage point reduction to their annual rate-of-increase limit. Data reporting for the program is proposed to begin with discharges beginning on October 1, 2012. CMS proposes five measures to begin the Cancer Quality Reporting (CQR) program.

**Proposed Infection Measures. We support the proposed infection measures for the FY 2014 CQR program.** CMS proposes two infection measures – CLABSI and CAUTI. Both of these measures have been developed by the CDC for reporting through the NHSN. Inpatient PPS hospitals have been reporting the CLABSI measure since January 2011 and the CAUTI measure since this January. Reporting on both of these measures has gone smoothly for inpatient PPS hospitals. These measures also have been finalized for reporting in the long-term care hospital and inpatient rehabilitation facility quality reporting programs.

**Proposed Cancer-specific Measures. The AHA supports the proposed cancer-specific measures for the FY 2014 CQR program and applauds CMS for its recognition of the MAP recommendations in this proposed rule.** CMS proposes three cancer-specific measures: adjuvant chemotherapy within four months for colon cancer patients; combination chemotherapy within four months of breast cancer diagnosis; and adjuvant hormonal therapy for breast cancer patients. Currently, these measures are being reported by 1,500 cancer programs to the American College of Surgeons (ACS) as part of the ACS's cancer program accreditation process. Ten of the 11 PPS-exempt hospitals are among those programs already reporting these measures to ACS.

**Data Reporting. We support CMS's proposal to report the infection measures to NHSN.** Though reporting infection measures into NHSN is a moderately burdensome process, we feel that it is the appropriate mechanism for reporting infection data. Cancer hospitals will have more than six months to become familiar with NHSN prior to the first data submission date. While this should be an adequate amount of time, we urge CMS to monitor data submission closely in case cancer hospitals need an extension of the initial May 15, 2013 data deadline.

**We need more information in order to support CMS's data reporting requirements for the cancer-specific measures.** We believe that cancer hospitals will be able to leverage their existing ACS data reporting requirements to also fulfill the CMS reporting requirements; however, CMS did not explicitly state that this will be the case. Until we understand how the

data will flow, we cannot fully support the data collection proposals for the cancer-specific measures. Therefore, we urge CMS to provide more detail on how it envisions receiving data to populate the cancer-specific measures.

**Registration in the COR Program.** We support CMS's proposals for requiring cancer hospitals to obtain *QualityNet* accounts and become NHSN users. Cancer hospitals will need to register, designate an administrator, complete a notice of participation, upload data and correct data within the *QualityNet* ([www.qualitynet.org](http://www.qualitynet.org)) system. Cancer hospitals also will need to complete all of the same steps for the NHSN system. However, at this time, it is unclear whether cancer hospitals will need to register for yet a third system to report the cancer-specific measures or whether the cancer-specific measures will be reported into *QualityNet*. We urge CMS to provide more information in the final rule about where it intends to receive the cancer-specific measures.

**Public Reporting.** We support CMS's proposals for public reporting of the CQR measures. Specifically, CMS proposes to publicly report all of the CQR measures on *Hospital Compare*. It also proposes to allow cancer hospitals the opportunity to review their data at least 30 days prior to public reporting of the information.

**Data Accuracy.** We support CMS's proposals regarding ensuring data accuracy. CMS proposes to require cancer hospitals to electronically acknowledge their data accuracy and completeness annually. The data accuracy process would begin with the FY 2015 program and must be submitted by August 31, 2014.

## **DRGs: HOSPITAL-ACQUIRED CONDITIONS (HACs)**

Since October 1, 2008, an inpatient hospital discharge is not assigned to a higher paying MS-DRG if a selected HAC was not present-on-admission (POA). That is, the case is paid as though the secondary diagnosis were not present. The selected HACs are among those that CMS determines: (1) are high-cost, high-volume or both; (2) would result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines. There are currently 10 HACs, and CMS proposes to add two more to the list. In addition, CMS proposes to modify the codes associated with the vascular catheter-associated infection HAC.

**Addition of SSIs following Cardiac Implantable Electronic Device (CIED).** The AHA does not support including SSIs following CIED in the HAC penalty program because these infections do not fulfill the statutory criteria of being a high-volume condition. CMS states that "more than 500,000 CIEDs are implanted each year in the United States and 70 percent of CIED recipients [350,000] are age 65 or older." However, CMS also states that there were only 859 cases of SSIs following CIEDs in FY 2011. This constitutes only 0.25 percent of all CIED cases, which is not a "high volume." Hospitals take HACs very seriously; in fact, hospitals often reconstitute care delivery to avoid HACs. However, building processes and procedures to avoid an outcome that occurs only 0.25 percent of the time is not an effective use of resources. We are

concerned that CMS's selection of SSIs following CIEDs will result in hospitals dedicating time and effort to avoiding this extremely low-incidence adverse event (when resources could have been devoted to more highly prevalent safety concerns).

**Addition of Iatrogenic Pneumothorax (IP) with Venous Catheterization.** The AHA does not support including IP with venous catheterization in the HAC penalty program because it puts hospitals at risk of being penalized twice for the same event. Specifically, CMS proposes to add a patient safety composite measure to hospital VBP that will also capture IP with venous catheterization. According to our analysis of the proposed rule impact file, approximately 41 percent of hospitals will experience a net penalty in FY 2013 for hospital VBP. If these same hospitals also were to be reimbursed a lower-paying MS-DRG due to the selection of IP with venous catheterization as a HAC, those hospitals could be penalized twice for the same adverse event. While we support targeting IPs as a patient safety goal and support CMS incentivizing their reduction, the agency must select only one program in which to measure hospitals' performance on IPs with venous catheterization.

**Changes to the Vascular Catheter-Associated Infection HAC.** The AHA does not support the addition of ICD-9 codes 999.32 and 999.33 to define the vascular catheter-associated HAC; CMS should remove this HAC from the penalty program. In addition, we urge CMS to also remove ICD-9 code 999.31, which currently defines the vascular catheter-associated HAC, from the HAC penalty program, as this will serve to remove the entire HAC. Similar to the situation articulated above for IP, CMS is proposing to add a CLABSI measure to hospital VBP that also will capture vascular catheter-associated infections. This could penalize hospitals twice for the same event. Thus, while we do not object to the proposed ICD-9 codes themselves, we cannot support the expansion of this HAC in the penalty program. Therefore, while we support targeting CLABSIs as a patient safety goal and support CMS incentivizing reduction of CLABSIs, the agency must select only one program in which to measure hospital performance for vascular catheter-associated infections.

**Crosswalk of ICD-10 Codes that Define HACs.** We thank CMS for making this cross-walk publicly available. Upon initial review, we do not have any major concerns. However, we will continue to review the list and intend to provide additional comment if it is warranted.

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<sup>1</sup> Jha, A. *et.al.* (2011) "Low-Quality, High-Cost Hospitals, Mainly in South, Care for Sharply Higher Shares of Elderly Black, Hispanic and Medicaid Patients. *Health Affairs.* 30:10. 1904-1911.

<sup>2</sup> Bhalla *et.al.* (2009) "Could Medicare Readmission Policy Exacerbate Health Care System Inequity?" *Annals of Internal Medicine.* 152. 114-117.

<sup>3</sup> Kociol, R. *et.al.* (2012) "International Variation in and Factors Associated with Hospital Readmission After Myocardial Infarction." *Journal of the American Medical Association.* 307:1. 66-74.

<sup>iv</sup> KNG used 2009 100% Medicare inpatient claims data to identify Medicare beneficiaries admitted to short-term acute care hospitals with a principal diagnosis of one of the 3 initial conditions that will be included in the program (acute myocardial infarction, pneumonia and heart failure). To develop the analytic sample, we applied inclusion and exclusion criteria consistent with the Medicare readmission measures endorsed by the National Quality Forum and used by CMS. Demographic and other characteristics of Medicare beneficiaries, such as age, sex, race, and dual eligible status were obtained from the 2009 Medicare denominator file. We were unable to use CMS's risk-

adjustment methodology because 100% Medicare physician claims were not available to us. Instead, we used the Elixhauser comorbidity index for risk adjustment. The Elixhauser comorbidity measure is widely used in the literature as a risk-adjustment method for its proven predictive power of inpatient mortality. Following the approach used by CMS, we computed risk-standardized readmission rates (RSRRs) for each hospital and condition using a hierarchical regression model (HRM), which included hospital-level random effects. Using the regression results, we calculated the predicted probability of a readmission for each case using a patient's characteristics and the hospital's estimated quality effect. We also computed the expected probability of a readmission for each case using a patient's characteristics and an overall average quality effect. We summed the predicted and expected probabilities of readmission across patients for each hospital to estimate predicted and expected numbers of readmissions for each hospital, respectively.

<sup>v</sup> Ibid.

<sup>vi</sup> <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing>

<sup>vii</sup> Ibid.

<sup>viii</sup> Fourcade, A., Blache, J., Grenier, C., Bourgain, J., and Minvielle, E (2011). "Barriers to staff adoption of a surgical safety checklist." *British Medical Journal of Quality and Safety*. 21: 191-197.

<sup>ix</sup> <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing>