American Hospital Association

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June 11, 2010

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-1498-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2011 Rates; Effective Date of Provider Agreements and Supplier Approvals; and Hospital Conditions of Participation for Rehabilitation and Respiratory Care Services Medicaid Program: Accreditation Requirements for Providers of Inpatient Psychiatric Services for Individuals Under Age 21; Proposed Rule (Vol. 75, No. 85), May 4, 2010

Dear Ms. Tavenner:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 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) 2011. We will submit comments separately on CMS' proposed changes to the long-term care hospital PPS.

While we support a number of the proposed rule's provisions, including those affecting Medicare-dependent hospitals and certified-registered nurse anesthetists, we have concerns about the documentation and coding adjustment, many of the new hospital quality measures, and the provider tax proposal affecting critical access and other hospitals.

MS-DRG DOCUMENTATION AND CODING ADJUSTMENT

The proposed rule includes a 2.9 percent cut – $3.7 billion – to recoup half of the payments made in FYs 2008 and 2009 that CMS claims were due to documentation and coding changes that did not reflect real changes in case mix. In combination with other policy changes, this cut results in hospitals actually being paid less in FY 2011 than in FY 2010. **However, AHA conducted multiple analyses that found only a 0.45 percent reduction is warranted to recoup half of the overpayments made in FYs 2008 and 2009. These analyses indicate that much of the change CMS found is actually the continuation of historical increases in the case mix index (CMI), not the effect of documentation and coding changes due to the implementation of the Medicare-Severity Diagnosis-Related Groups (MS-DRGs). Thus, CMS' proposed cut of 2.9 percent to recoup half the overpayments made in these years is excessive in light of these historical trends in CMI change and *should not* be implemented.**

The AHA believes there is a fundamental flaw in CMS' methodology for determining the effect of documentation and coding changes on the FY 2008 and FY 2009 CMIs. Specifically, in its analysis, CMS states that the increase in payments it found could not be due to "real" case mix change because its analysis looks at only one year of patient claims. However, we assert that the increase cannot be deemed documentation and coding change either, because, again, the analysis looks at only one year of patient claims.

Our analysis, which used multiple years of patient claims, clearly shows that a significant portion of the change CMS found is actually the continuation of historical trends, rather than the effect of documentation and coding changes due to implementation of MS-DRGs. This analysis found a documentation and coding effect of 0.9 percent for FYs 2008 and 2009. **Therefore, the AHA strongly urges CMS to implement a reduction of 0.45 percent to fulfill the agency's proposal to recoup half of the overpayments made in FYs 2008 and 2009.**

HOSPITAL QUALITY DATA

While the hospital field has long supported reporting quality measures for consumers' and payers' use, the proposed rule would dramatically increase the reporting burden on hospitals by requiring them to report a large number of new pieces of data. In addition, the AHA believes that the Secretary of the Department of Health and Human Services does not have the authority to include in the quality reporting program many of the measures that CMS has proposed. Our review of the *Deficit Reduction Act of 2005* indicates that the Secretary is authorized only to require hospitals to submit the necessary data to calculate "the set of measures that the Secretary determines to be appropriate for the measurement of quality of care furnished by hospitals in inpatient settings." It does not authorize the Secretary to use data submitted to CMS or its contractors for reasons other than the measurement of quality of care, nor does it authorize the Secretary to request additional data that are unrelated to the chosen quality measures.

COSTS OF PROVIDER TAXES AS ALLOWABLE COSTS FOR CRITICAL ACCESS HOSPITALS

CMS proposes to "clarify" its policy concerning when provider taxes are considered allowable costs under Medicare. **However, the AHA opposes this "clarification," which is actually a change in policy**. First, CMS does not actually state what its proposed revision is. It is neither appropriate nor reasonable for CMS to solicit comment on, and then perhaps finalize, an unspecified revision. Second, under the current regulations and guidance, these taxes are clearly allowable costs. Finally, although CMS states that the proposal on provider taxes is a "clarification in policy" and not a policy change, we strenuously disagree with that assertion and urge CMS to treat this revision as the policy change it actually is. **We strongly urge CMS not to implement this policy.**

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 jhiatt@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

American Hospital Association
Detailed Comments on the Inpatient Prospective Payment System
Proposed Rule for FY 2011

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CHANGES TO MS-DRG CLASSIFICATIONS AND RELATIVE WEIGHTS

The Centers for Medicare & Medicaid Services (CMS) recently 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 fiscal year (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 a documentation and coding adjustment 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.

The rule proposes a cut of 2.9 percent to eliminate what CMS claims is the effect of coding or classification changes the agency says do not reflect real changes in case mix. Previously, in FY 2008, CMS applied a negative 0.6 percent documentation and coding adjustment, and in FY 2009, applied a further negative 0.9 percent adjustment, for a total adjustment of negative 1.5 percent. However, the agency stated in the proposed rule 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 states it must cut payments by 1.9 percent to recoup overpayments made in FY 2008 and by 3.9 percent to recoup overpayments made in FY 2009. These two adjustments total 5.8 percent, and CMS proposes to apply half of this adjustment – or 2.9 percent – in FY 2011. Because it is a recoupment, this is a one-time cut that will be reversed for FY 2012.

CMS did not previously apply any documentation and coding adjustments to sole community hospitals (SCHs), Medicare-dependent hospitals (MDHs) or Puerto Rico hospitals. However, this rule proposes to do so. For SCHs and MDHs, CMS found that coding and classification changes that the agency says do not reflect real changes in case mix increased payments by 5.4 percent total in FYs 2008 and 2009, which is the same increase in payments as other hospitals. For these hospitals, CMS proposes to apply the same 2.9 percent adjustment, but on a prospective basis, which will permanently remove these increased 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 2.4 percent total in FY 2008 and 2009. CMS proposes to cut the Puerto Rico-specific rate, which accounts for 25 percent of payments to Puerto Rico hospitals, by the full 2.4 percent. They propose to do so on a prospective basis, which will permanently remove these increased payments from the system.

The remaining 75 percent of payments to Puerto Rico hospitals is based on the national standardized amount, to which CMS proposes to apply the 2.9 percent cut described above.

CMS' Methodology. In last year's inpatient PPS rule, CMS found that, in FY 2008, there was a documentation and coding-related increase in payments of 2.5 percent. To analyze changes due to documentation and coding in FY 2009, CMS used the same methodology as for FY 2008. Specifically, the agency divided the case mix index (CMI) obtained by running the FY 2009 claims data through the FY 2009 GROUPER by the CMI obtained by running these same FY 2009 claims data through the FY 2007 GROUPER, which yielded 1.056, or an increase of 5.6 percent. CMS states that this 5.6 percent is comprised of documentation and coding change, as well as a GROUPER change. CMS asserts that none of this 5.6 percent can be deemed "real" case mix because the analysis uses only one set of claims and, therefore, one set of patients.

To determine the effect of GROUPER changes, CMS divided the CMI obtained by running the FY 2007 claims data through the FY 2009 GROUPER by the CMI obtained by running these same FY 2007 claims data through the FY 2007 GROUPER, which yielded 1.0019, or an increase of 0.19 percent. CMS then divided 1.056 by 1.0019 to yield 1.054, or a documentation and coding-related increase of 5.4 percent in FY 2009.

Flaw in CMS' Methodology. **The AHA believes there is a fundamental flaw in CMS' methodology for determining the effect of documentation and coding change on the FY 2008 and 2009 CMIs. Specifically, CMS states that none of the 5.6 percent increase it found can be deemed "real" case mix change because the analysis looks at only one year of patient claims. However, we assert that, similarly, 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.**

The increase CMS found actually reflects differences in how the two DRG systems are designed to measure CMI. It should come as no surprise that analyzing the same set of claims yields different CMIs when they are grouped under the previous DRG system (the CMS-DRGs) compared to the MS-DRGs because, as CMS stated when it implemented the MS-DRGs, they were designed "to better recognize severity of illness among patients" (72 *Federal Register* 47130). In fact, it is possible that hospitals have maintained an absolutely consistent level of documentation and coding all along, but that the MS-DRGs simply recognize the consistent level of documentation and coding differently.

In addition, to support its assertion that real case mix is declining, CMS analyzed overall case mix changes for FYs 2000 through 2007 based on the GROUPER that was in effect in each year, along with cases and the relative weights applicable to that year. However, one should not use an analysis in which weights, and cases and the GROUPER all change each year to discuss trends in case-mix – some components must be held constant in order to properly isolate changes.

The Consumer Price Index (CPI) can serve as an example to illustrate this point. If one wants to measure the change in a specific component, for example, prices, then one would construct an index like the CPI that holds the quantities constant and allows the prices to vary. Using the same reasoning, if one wants to measure case mix change, one should construct a recalculated CMI that holds the weights and GROUPER constant, but allows the cases to vary. Similarly, CMS should not analyze changes in case mix based on the GROUPER that was in effect in each year, along with cases and the relative weights applicable to that year.

AHA's Analyses. The AHA conducted multiple analyses of the effect of documentation and coding after implementation of MS-DRGs. Specifically:

- We developed a more appropriate methodology to calculate the effect of documentation and coding on hospital payments. Under this methodology, **only a 0.45 percent reduction is warranted to recoup half of the overpayments made in FYs 2008 and 2009**.

- Next, we conducted several analyses that corroborated our assertion that much of the change CMS found is actually the continuation of historical increases in CMI. E**ach of these analyses found that patient severity is increasing.**

- We also conducted an analysis that, independent of our alternative methodology, found that **the CMI value CMS obtained when it ran the FY 2009 claims data through the FY 2007 CMS-DRG GROUPER is artificially low, meaning that CMS's estimate of documentation and coding is artificially high.**

- Finally, we also examined within- versus across-DRG changes because, in the proposed rule, CMS states that it found that within-base MS-DRG increases were almost entirely responsible for the CMI change, which it claimed supports its finding on documentation and coding. **However, we found that this is not a new trend that was a potential effect of MS-DRGs; rather, it is a continuation of a past trend.**

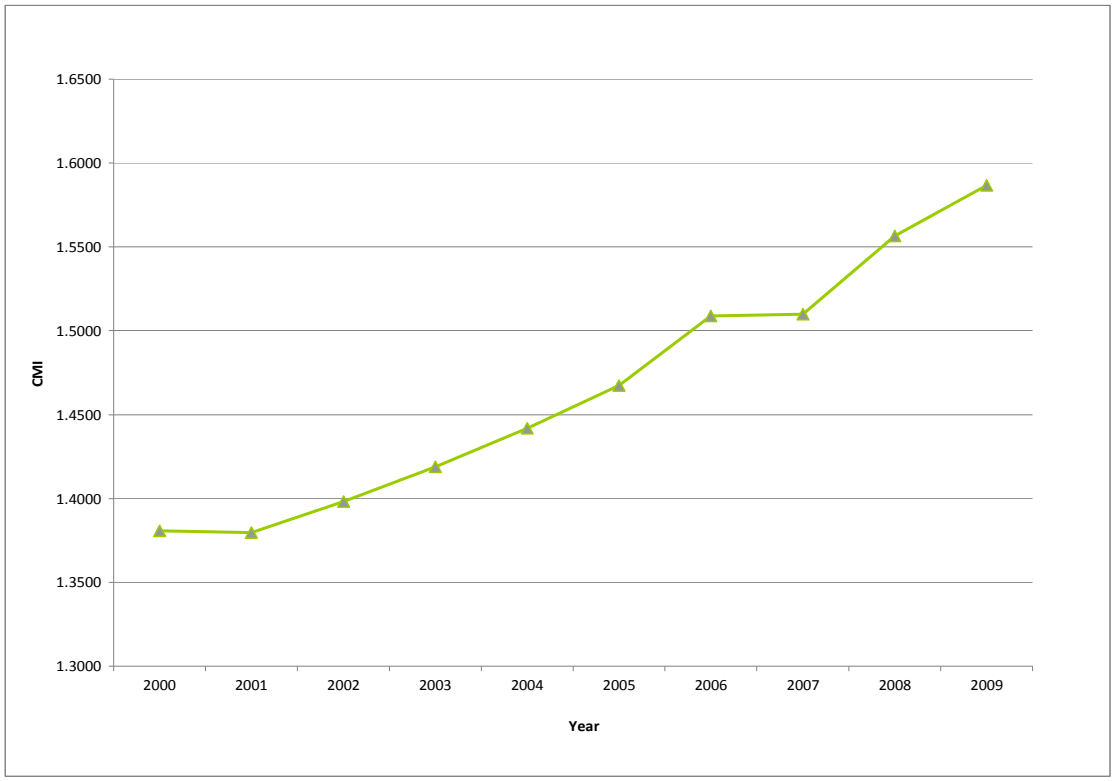
AHA's Alternative Approach to Calculating Documentation and Coding Effect. The AHA has identified an alternative methodology to calculate the effect of documentation and coding on hospital payments, which is more appropriate than CMS's methodology. Under this methodology, **the AHA believes that a reduction of 0.45 percent fulfills the agency's proposal to recoup half of the overpayments made in FYs 2008 and 2009. Thus, CMS' proposed cut of 2.9 percent to recoup half the overpayments made in these years *should not* be implemented.**

In order to evaluate the manner in which hospital documentation and coding practices changed upon MS-DRG implementation, the AHA analyzed inpatient PPS claims from FYs 2000 through 2009.[1] We grouped each year of claims using the FY 2009 MS-DRG GROUPER (Version 26) and calculated the associated CMI, holding the weights constant. Since CMS is attempting to

[1] We began our analysis with FY 2000 data because that was the earliest year of data available to us.

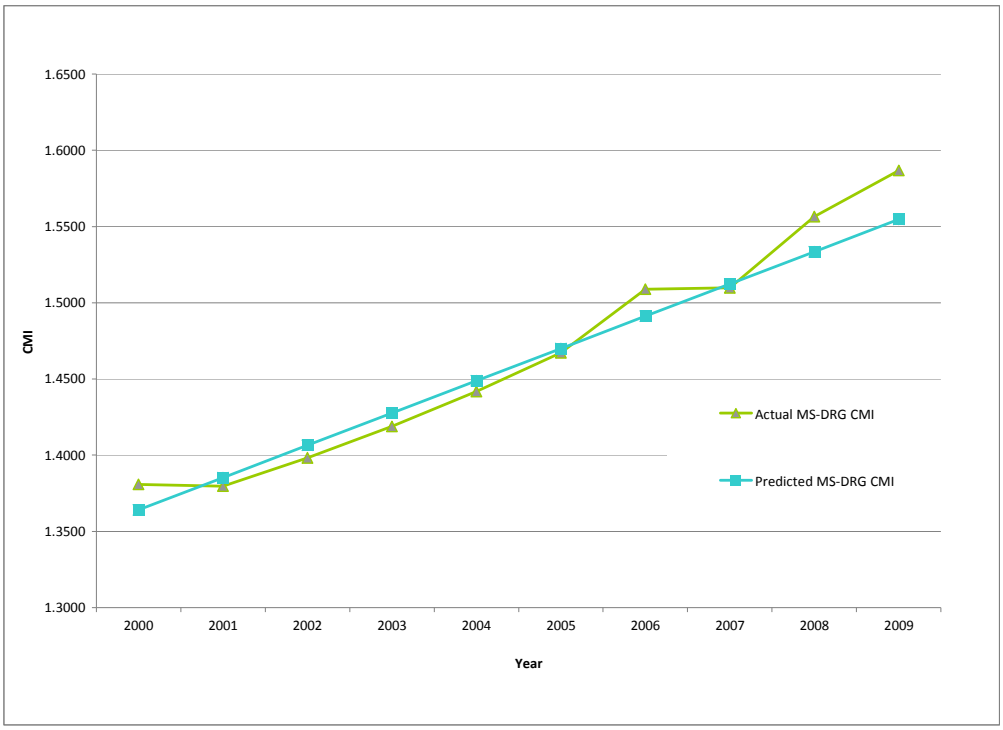
assess the impact of documentation and coding changes relative to the new MS-DRG GROUPER, it is important that this GROUPER be used to assess historical case mix change. The FY 2000 through 2007 results reflect how claims would have been grouped under MS-DRGs had this system been in place at the time. In addition, these results reflect real case mix growth and hospitals' pre-MS-DRG documentation and coding practices. The FY 2008 and 2009 results reflect 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 2000 through 2009.

Figure 1: CMI from FY 2000 through 2009 as Measured Using the Version 26 MS-DRG GROUPER



Next, we used the FY 2000 through 2007 CMI values above to create "predicted" CMI values for all years, including FYs 2008 and 2009.[2] These values represent what CMI would have been in FYs 2008 and 2009 had hospital case mix continued its historical trend. See Figure 2 for a graphic depiction of these predicted and actual CMI values from FY 2000 through 2009.

Figure 2: Predicted and Actual CMIs from FY 2000 through 2009 as Measured Using the Version 26 MS-DRG GROUPER

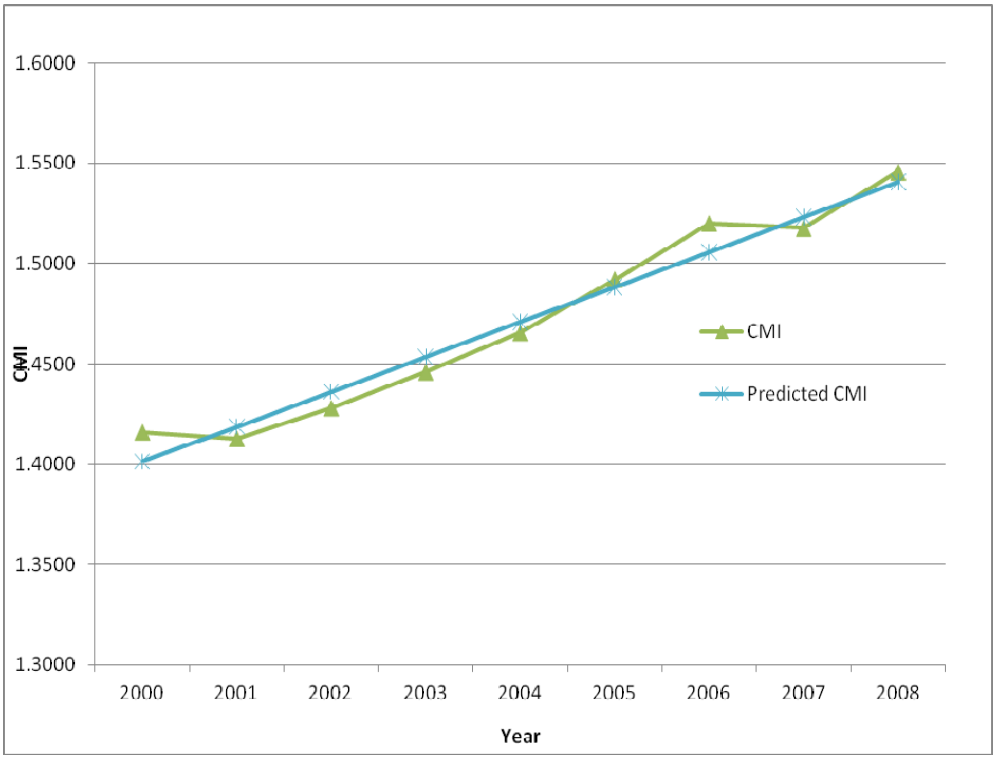


Finally, we compared the predicted growth rate to the actual growth rate in CMI from FYs 2007 to 2009. The predicted growth rate over these two years was 2.8 percent, which represents what the growth in CMI would have been had real case mix continued its historical trend and had hospitals maintained consistent documentation and coding practices. The actual growth rate was 5.1 percent. Because the actual 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 actual growth rate, which yielded 0.023, or a documentation and coding-related increase of 2.3 percent for FY 2009.

[2] We used a linear regression analysis to fit the trendline using the FY 2000 through FY 2007 CMIs to project values for FYs 2008 and 2009. We tested alternative methodologies for fitting the trendline (exponential and quadratic), but have presented the most conservative approach here. We encourage the agency to test these alternative methodologies.

To determine the documentation and coding-related increase in FY 2008, we conducted the same analysis as above, but using the FY 2008 GROUPER (Version 25), which is a 50/50 blend of the CMS-DRGs and MS-DRGs, and again holding the weights constant. As in FY 2009, the actual growth rate in FY 2008 was higher than the predicted. In order to determine the amount by which hospitals' change in documentation and coding affected CMI, we subtracted the predicted growth rate from the actual growth rate, which yielded 0.007, or a documentation and coding-related increase of 0.7 percent for FY 2008. See Figure 3 for a graphic depiction of these predicted and actual CMI changes from FY 2000 through 2008.

Figure 3: Predicted and Actual CMIs from FY 2000 through 2008 as Measured Using the Version 25 Blended GROUPER



Under this approach, in FY 2009, there was a cumulative documentation and coding-related increase of 2.3 percent. However, CMS already had cut hospital payments in FY 2009 by 1.5 percent, meaning an additional 0.8 percent cut is necessary to recoup overpayments made in FY 2009. In FY 2008, there was a documentation and coding-related increase of 0.7 percent. However, CMS already had cut hospital payments in FY 2008 by 0.6 percent, meaning an additional 0.1 percent cut is necessary to recoup overpayments made in FY 2008. Thus, a 0.9 percent cut is necessary to recoup overpayments made in FYs 2008 and 2009. **Therefore, the AHA believes a reduction of 0.45 percent would fulfill the agency's proposal to recoup half of the overpayments made in FYs 2008 and 2009. CMS' proposed cut of 2.9 percent to**

recoup half the overpayments made in these years is excessive in light of historical trends in CMI changes and *should not* be implemented. A significant portion of the change CMS found is actually the continuation of historical trends, rather than the effect of documentation and coding changes due to MS-DRG implementation.

In addition, for SCHs and MDHs as well as Puerto Rico hospitals, CMS proposes to apply documentation and coding adjustments of 2.9 and 2.4 percent, respectively. These adjustments would be applied on a prospective basis, which would permanently remove the increased payments from the system. CMS states it is proposing the same level of adjustment for these hospitals as for PPS hospitals in order to maintain, as much as possible, both consistency and equity among classes of hospitals. **However, we urge CMS to reconsider its proposed cuts to SCHs, MDHs and Puerto Rico hospitals.** While the level of the proposed cuts to these hospitals may be the same as the proposed cuts to PPS hospitals, the nature of the cuts is not. Specifically, although CMS has the authority to apply retrospective cuts to the standardized amount that is used to pay PPS hospitals, it does not have the authority to apply retrospective cuts to the hospital-specific and Puerto Rico-specific rates that are used to pay SCHs, MDHs and Puerto Rico hospitals. Therefore, it proposes permanent, prospective cuts to these hospital rates. However, permanent prospective cuts have a much greater effect on hospitals' long-term financial viability than one-time retrospective cuts do, and will hit SCHs, MDHs and Puerto Rico hospitals particularly hard. **Therefore, we ask CMS to postpone its proposed documentation and coding cuts to SCHs, MDHs and Puerto Rico hospitals. The agency would still be able to maintain, as much as possible, both consistency and equity among classes of hospitals if it delays these prospective cuts and instead applies them at the same time it applies prospective cuts to PPS hospitals.**

Additional Evidence of Increasing Patient Severity. We conducted several additional analyses that corroborated our assertion that much of the change CMS found is actually the continuation of historical increases in CMI. Specifically, we found that:

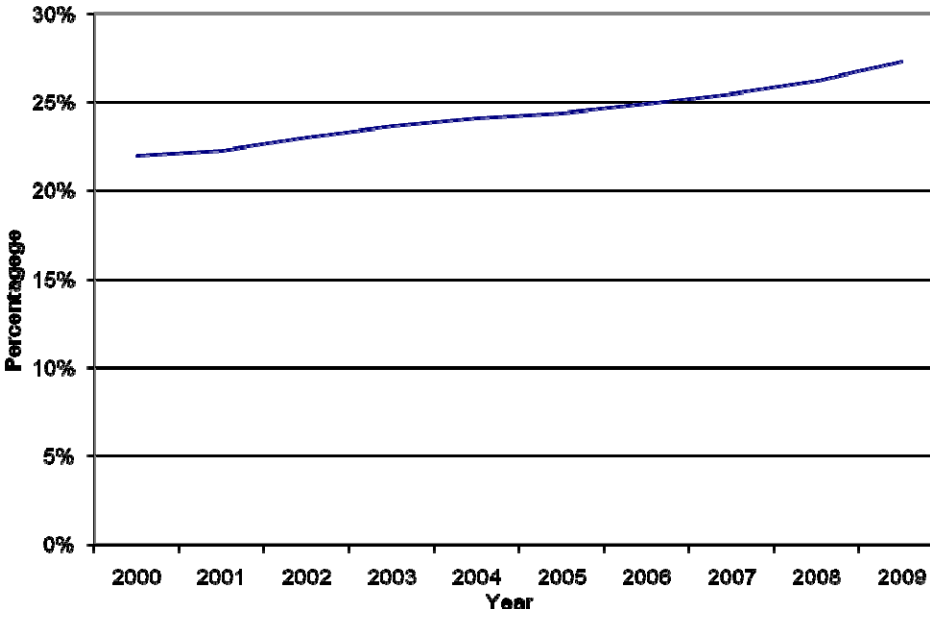
- Under the Medicare claims, the percentage of Medicare discharges involving the intensive care unit (ICU) increased steadily, which indicates that cases are becoming more severe (see Figure 4);

- Under the Medical Expenditure Panel Survey (MEPS) database, for which hospitals had no incentives to improve documentation and coding, the Medicare CMI, and thus, Medicare patient severity, is increasing (see Figure 5); and

- Under the Healthcare Cost and Utilization Project (HCUP) database, for which hospitals had no incentives to improve documentation and coding, the Medicare CMI, and thus, Medicare patient severity, is increasing (See Figure 6 and 7).

First, we examined the Medicare claims data to determine the proportion of discharges for which the patient stayed in the ICU. We found that, from FYs 2000 through 2009, the percentage of Medicare discharges involving the ICU increased steadily. See Figure 4 for a graphic depiction of these increases. Because a higher proportion of discharges involved the ICU, it supports our assertion that cases are becoming more severe – in other words, ICU stays are a proxy measure for real case mix change. We also found that ICU Medicare days as a percentage of total Medicare inpatient days increased steadily over this time period, as well as the mean number of ICU days per Medicare discharge.

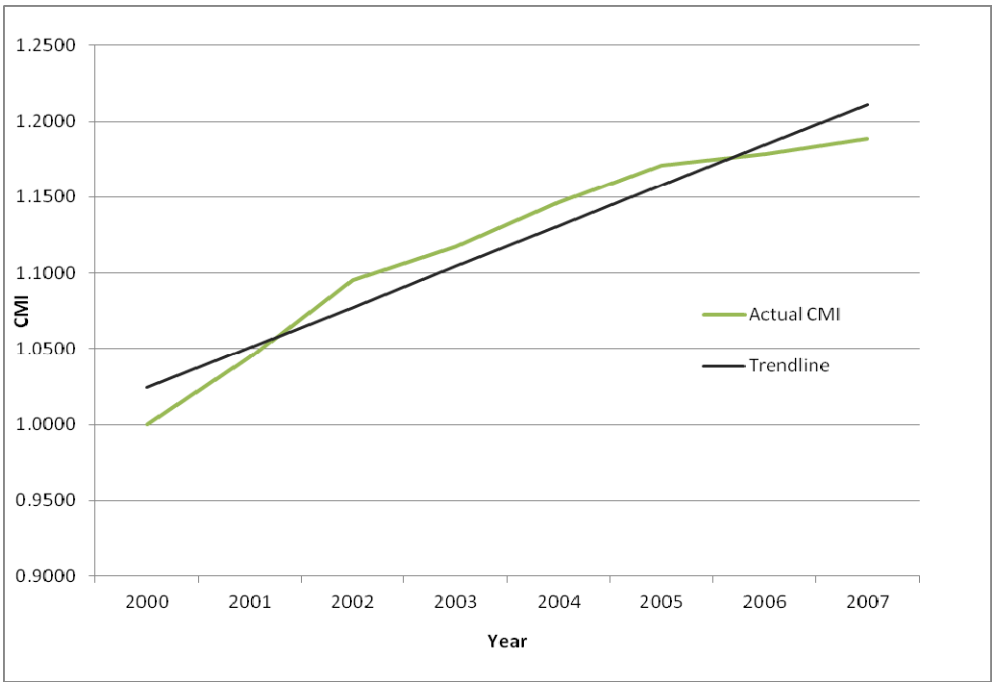
Figure 4: Percentage of Discharges Involving the ICU, FY 2000 through 2009



In addition, using several other data sets, we constructed CMIs under two other clinical classification systems designed to capture patient severity. As these systems were not used for reimbursement purposes, hospitals had no incentives specific to these systems to improve documentation and coding. Yet we still found that CMI is increasing, which again supports our assertion that patient severity is increasing. We analyzed the MEPS and HCUP databases, both of which were developed by the Agency for Healthcare Research and Quality (AHRQ), and examined calendar year (CY) 2000 through 2007 data (the latest years for which data were available at the time of the analysis).

First, we constructed CMIs under the Clinical Classification Software (CCS) developed by AHRQ. We used regression-based weights for each CCS category[3] and based these weights on health care spending across all types of services, not just inpatient. Consistent with our Medicare claims analyses, we used a constant set of weights (with CY 2007 as the base year) and looked at the Medicare population.[4] Again, consistent with our Medicare claims analyses, we performed a linear regression analysis to fit a trendline to the actual CMIs. Figure 5 shows that the CMI under the CCS system using MEPS data goes up continuously from CYs 2000 through 2007. This trend indicates that patient severity for the Medicare population is increasing.

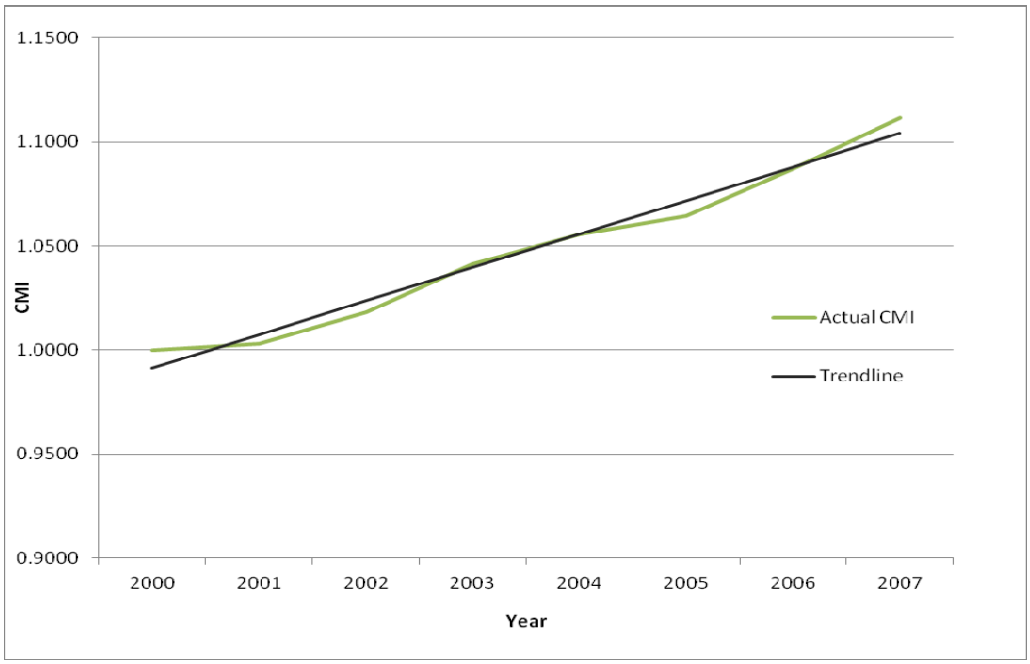
Figure 5: Actual and Predicted CCS-Based CMI of the Medicare Population Using Data from the Household Component of MEPS



[3] This software, which groups patients into clinically coherent categories based on their diagnoses and procedures, "makes it [easy] to quickly understand patterns of diagnoses and procedures…" according to AHRQ.
[4] We also examined the non-Medicare population, which showed similar trends to the Medicare population.

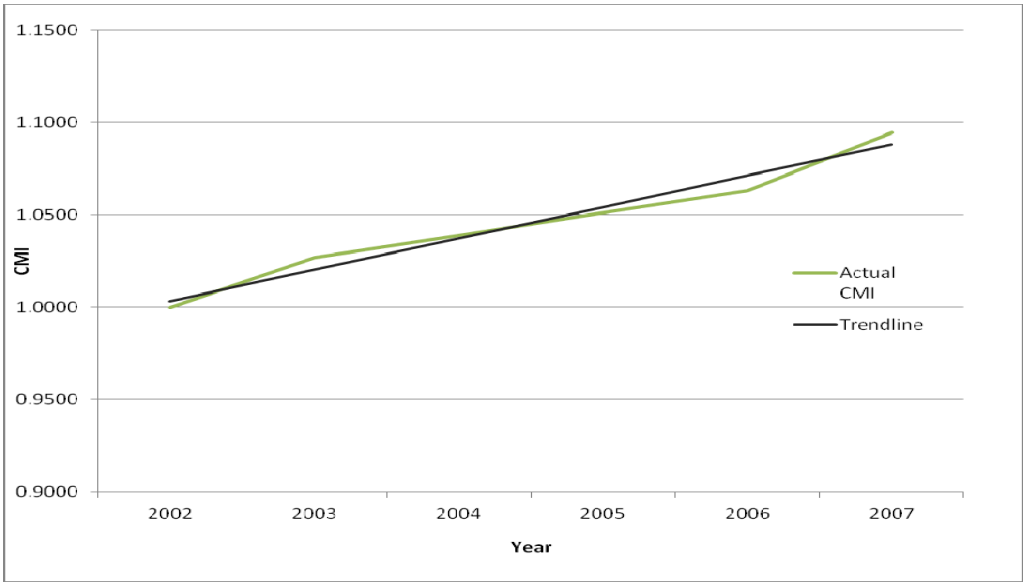
We also constructed regression-based weights under the CCS categories, based on charges, for the Medicare population in the nationwide inpatient sample (NIS) of HCUP for the Medicare population. The NIS contains data for approximately 8 million hospital stays per year. Again, we used CY 2007 as the base year. See Figure 6 for a graphic depiction of our results. Medicare HCUP data also indicates that patient severity is increasing.

Figure 6: Actual and Predicted CCS-Based CMIs of the Medicare Inpatient Population Using Data from HCUP



We also examined the trend in patient severity using MEDSTAT's Disease Staging Software (hereafter "DS-DRGs") applied to the Medicare population in the NIS. Data on DS-DRGs are available only from CY 2002. We constructed similar CMIs using the DS-DRGs as we did for the CCS categories and the trend in patient severity using these CMIs is consistent with the other trends discussed above. See Figure 7 for a graphic depiction of our results.

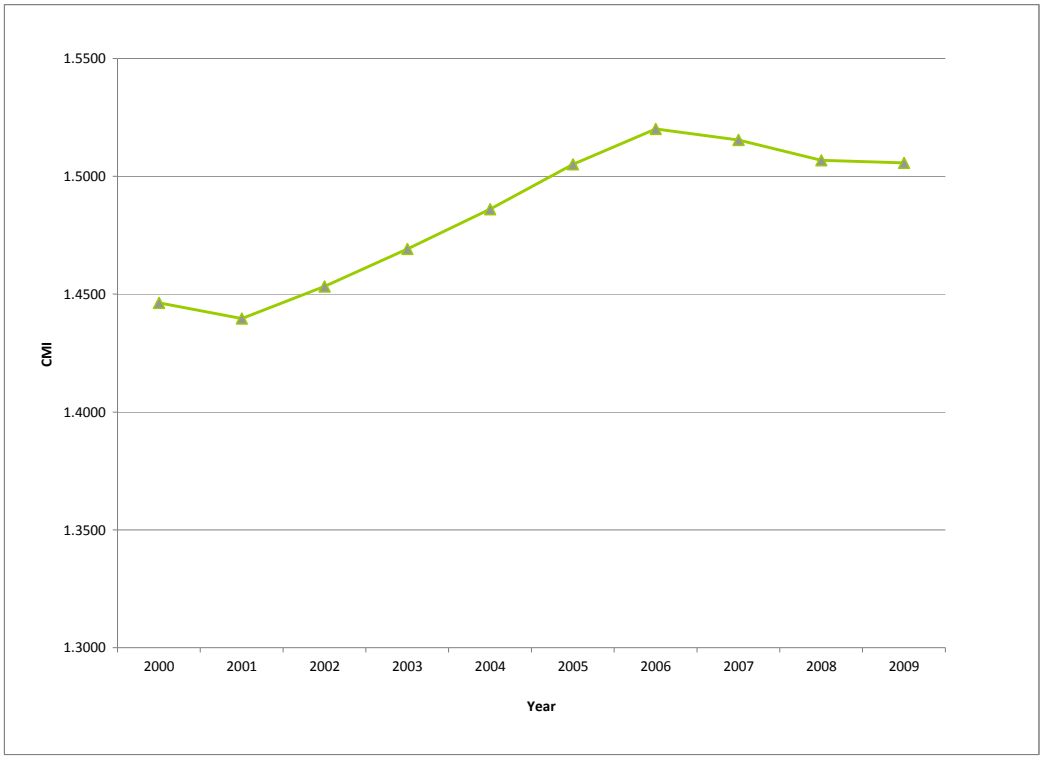
Figure 7: Actual and Predicted DS-DRG Based CMIs of the Medicare Inpatient Population Using Data from HCUP



Negative Documentation and Coding Effect on CMS DRGs. We also would like to offer several other specific criticisms of CMS' analysis. CMS asserts that changes in documentation and coding increased the CMI under the MS-DRGs, but it does not consider that changes in documentation and coding also may have decreased the CMI under the CMS-DRGs. 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 2009 claims data through the FY 2007 CMS-DRG GROUPER. **We found that this value is artificially low, meaning that CMS's estimate of documentation and coding adjustment is artificially high.**

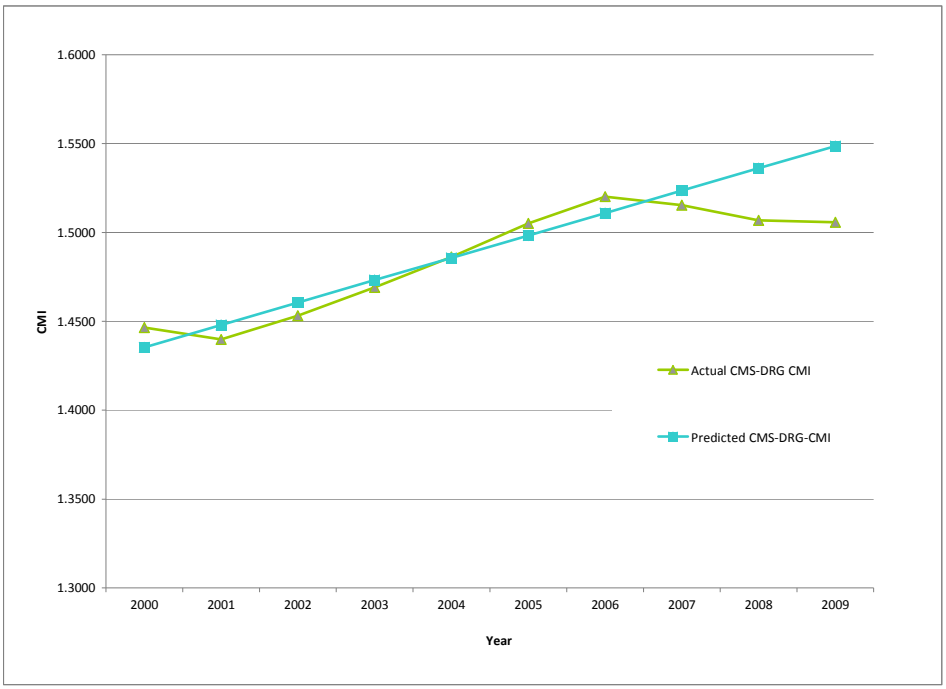
To examine this issue, we analyzed the historical trend in CMI under the CMS-DRGs. We grouped inpatient PPS claims from FYs 2000 through 2009 using the FY 2007 CMS-DRG GROUPER (Version 24) and calculated the associated CMI. The FYs 2000 through 2007 results reflect how claims were grouped under CMS-DRGs. The FYs 2008 and 2009 results reflect how claims would have been grouped under CMS-DRGs had they been in existence at the time. See Figure 8 for a graphic depiction of these CMI values from FYs 2000 through 2009.

Figure 8: Case Mix Index from FY 2000 through 2009 as Measured Using the Version 24 CMS-DRG GROUPER



Next, we used the FY 2000 through 2007 CMI values above to create "predicted" CMI values for all years, including FYs 2008 and 2009.[5] These values represent what CMI would have been in FYs 2008 and 2009 had real case mix change continued its historic trends and hospitals maintained consistent documentation and coding practices with respect to CMS-DRGs. In comparison, the actual values represent the CMI including any changed documentation and coding practices. See Figure 9 for a graphic depiction of these predicted and actual CMI values from FYs 2000 through 2009.

Figure 9: Predicted and Actual Case Mix Indices from FY 2000 through 2009 as Measured Using the Version 24 CMS-DRG GROUPER



Finally, we compared the predicted growth rate to the actual growth rate in CMI from FYs 2007 to 2009. The predicted growth rate over these two years was 1.6 percent, which represents what the growth in CMI would have been had real case mix change continued its historic trends and had hospitals maintained consistent documentation and coding practices. The actual growth rate was *negative* 0.2 percent. Because the actual rate is lower than the predicted, it indicates that hospitals changed their documentation and coding practices when MS-DRGs were implemented, in that they stopped coding for certain conditions that were "counted" as CCs under the CMS-

[5] We used a linear regression analysis to fit the trendline using the FYs 2000 through 2007 CMIs and projected values for FYs 2008 and 2009. We tested alternative methodologies for fitting the trendline (exponential and quadratic), but have presented the most conservative approach here. We encourage CMS to test these alternative methodologies.

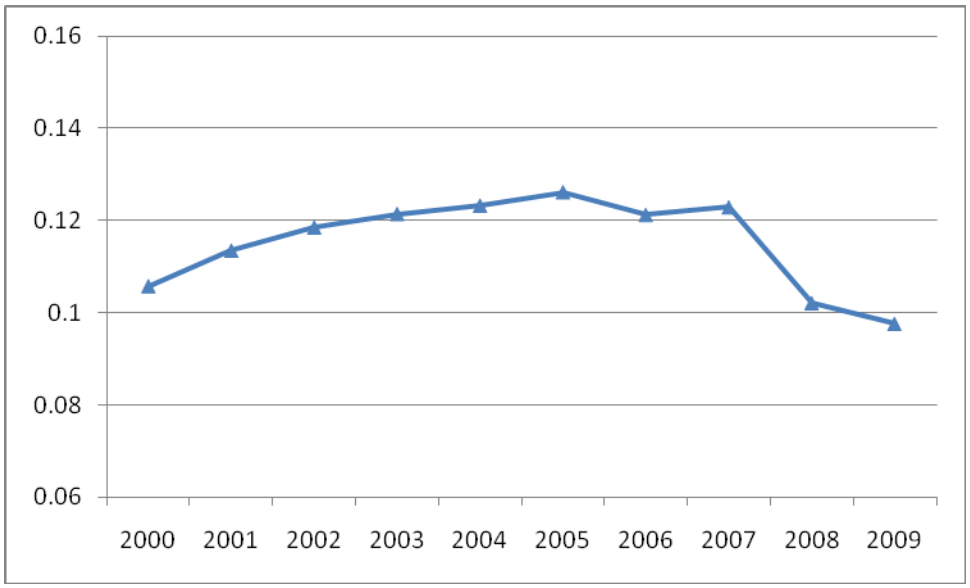
DRGs, but not counted as CCs or major complications and comorbidities (MCCs) under the MS-DRGs. Therefore, the CMI value CMS obtained when it ran the FY 2009 claims data through the FY 2007 GROUPER is understated by approximately 1.8 percentage points (1.6 percent minus *negative* 0.2 percent).

Although we assert that CMS' analysis is incorrect to begin with, if CMS were to continue with its existing analysis, it would have to adjust for this negative documentation and coding effect on the CMI as measured using the CMS-DRGs. To make this adjustment, it should use the predicted CMS-DRG CMI value, instead of the understated actual CMS-DRG CMI value. Doing so would result in a documentation and coding increase that is approximately 1.8 percentage points lower than what CMS estimated for FY 2009 and approximately 0.9 percentage points lower than what CMS estimated for FY 2008. **If the agency will not modify its analysis to be consistent with our analysis yielding a total recoupment of 0.9 percent, we urge it to, at a minimum, modify its existing analysis to use the predicted CMS-DRG CMI value instead of the understated actual CMS-DRG CMI value. Again, the proposed cut of 2.9 percent to recoup half the total overpayments made in these years is drastically overstated and *should not* be implemented.**

To corroborate our finding of negative documentation and coding change with respect to the CMS-DRG GROUPER in FYs 2008 and 2009, we examined more closely the coding of conditions that were "counted" as CCs under the CMS-DRGs, but not as CCs or MCCs under the MS-DRGs. Specifically, we examined claims for which all nine diagnosis code slots were filled and for which none of the CMS-DRG CCs on the claim "counted" under the MS-DRGs. We found that, from FYs 2000 through 2007, these claims represented a fairly constant percentage. However, in FYs 2008 and 2009, there is a relatively substantial decrease in the percentage of all claims that they represent. Specifically, there was a 2.1 percentage point decrease in FY 2008 and a further 0.5 percentage point decrease in FY 2009. **Thus, this analysis supports our finding that the CMS-DRG CMI value the agency is using in its analysis of FY 2008 and 2009 claims is understated, which artificially inflates its estimate of documentation and coding change.**

See Figure 10 for a graphic depiction of the proportion of discharges for which all nine diagnosis codes were filled in and none of the CMS-DRG CCs on the claim "counted" under the MS-DRGs from FYs 2000 through 2009.

Figure 10: Proportion of Discharges with Nine Diagnosis Codes and for which None of the CMS-DRG CCs "Counted" under MS-DRGs

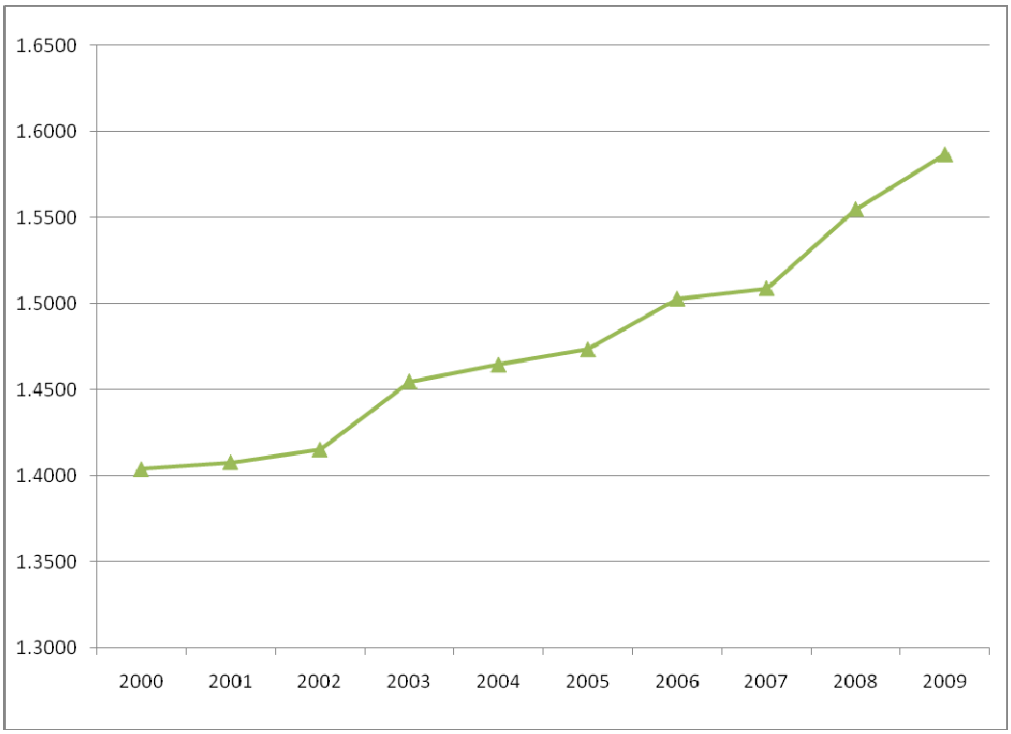


Historical Pattern of Increase in Within DRG CMI Change. Finally, to further corroborate our analysis, we also examined within- versus across-DRG changes because, in the proposed rule, CMS states that it found that within-base MS-DRG increases were almost entirely responsible for the CMI change, which it claims supports its finding on documentation and coding. **However, in this case as well, we found that this is not a new trend that was a potential effect of MS-DRGs. Instead, we found that it was a continuation of a past trend.**

We first analyzed within-base MS-DRG changes from FYs 2000 through 2009. To do so, we applied the FY 2009 GROUPER, weights and base-DRG distribution to all years of claims. We then allowed the within-base DRG distributions to change using the actual values from each respective year. We found that there had been steady increases in CMI due to within-base MS-DRG shifts from FYs 2000 through 2007. The increases then accelerated slightly in FYs 2008 and 2009. This finding is not surprising given that the purpose of moving to MS-DRGs was to better measure acuity differences between patients within DRGs. The results are consistent with our analysis indicating a steady increase in CMI before the implementation of MS-DRGs, which CMS needs to account for in estimating any documentation and coding effect due to MS-DRGs. **Our analysis clearly shows that a significant portion of the within-DRG change that CMS finds is the continuation of historical trend, rather than the effect of documentation and**

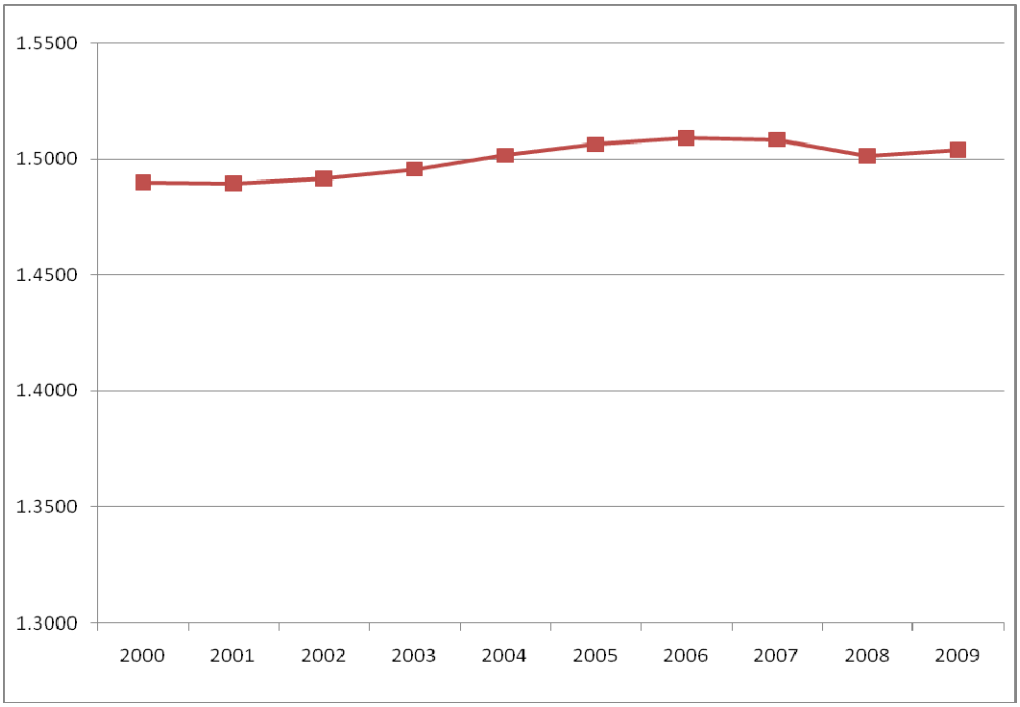
coding changes due to MS-DRG implementation. See Figure 11 for a graphic depiction of the within-base MS-DRG changes from FYs 2000 through 2009.

Figure 11: MS-DRG CMIs with Version 26 GROUPER, Weights and Base-DRG Distribution, but Within-Base DRG Distribution of Each Respective Year, FY 2000 through 2009



We also examined within-base CMS-DRG changes from FY 2000 through 2009. To do so, we applied the FY 2007 GROUPER (Version 24), weights and base-DRG distribution to all years of claims, but allowed the within-base DRG distributions to change using the actual values from each respective year. Similar to the MS-DRGs, we found that there had been steady increases in CMI due to within-base CMS-DRG shifts from FYs 2000 through 2007. However, in contrast to the MS-DRGs, these increases actually reversed themselves in FY 2008 so that the amount of within-base CMS-DRG change *decreased*. **This analysis also supports our finding that there is a negative documentation and coding effect on the CMI as measured by the CMS-DRG GROUPER. Therefore, the CMS-DRG GROUPER CMI value the agency is using in its analysis of FY 2008 and 2009 claims is understated, which artificially inflates its estimate of documentation and coding change.** See Figure 12 for a graphic depiction of the within-base CMS-DRG changes from FY 2000 through 2009.

Figure 12: CMS-DRG CMIs with Version 24 GROUPER, Weights and Base-DRG Distribution, but Within-Base DRG Distribution of Each Respective Year, FY 2000 through 2009



REFINEMENT OF THE MS-DRG RELATIVE WEIGHT CALCULATION

Regression-based Adjustments. The FY 2011 proposed rule discusses two CMS-commissioned studies that analyze the use of a regression-based approach for addressing charge compression. However, neither study provides evidence that this approach significantly improves payment accuracy. **The AHA continues to oppose a regression-based approach for reasons detailed in our comment letter on the FY 2009 inpatient PPS proposed rule. We hope that the results of these reports will encourage CMS to drop further consideration of the regression-based approach for addressing charge compression.** One study concluded that more refined and accurate accounting data are the preferred long-term solution to mitigate charge compression and related bias in the hospital cost-based weights. We agree that more accurate and uniform reporting within cost centers, combined with the cost report changes finalized in the FY 2009 inpatient PPS final rule, is the best method for calculating accurate payments.

RAND Evaluation of Alternative Relative Weight Methodologies. CMS asked the RAND Corporation to evaluate refinements to the methodology for calculating the inpatient PPS relative weights. RAND compared the current method to five other methods. RAND's analyses ultimately found that, while there were large redistributions in payment across DRGs and hospitals, "…none of the alternative weight methodologies represent a marked improvement over the current system" in terms of the ability to predict costs at the discharge or hospital level. **We hope that RAND's results encourage CMS to drop further consideration of the**

hospital-specific relative value (HSRV) methods for standardization. As stated in our earlier comments, the HSRV methods are inappropriate for use in a cost-based methodology and only applicable in charge-based systems to remove the effects of different mark-up practices. When applied in a cost-based system, other RAND research found evidence that the HSRV approaches inappropriately compress the weights.

Changes to the Medicare Cost Report. In July 2009, CMS issued a proposed rule containing changes to the Medicare hospital cost report. In this inpatient PPS proposed rule, CMS responds to certain comments from the cost report rule and proposes changes to the cost report itself – to create standard cost centers for computed tomography (CT) scanning, magnetic resonance imaging (MRI) and cardiac catheterization. CMS states that the creation of these cost centers would improve the accuracy of cost estimation for these services.

The AHA requests that CMS further consider the impact of adopting these cost centers before finalizing its decision. We have concerns that adopting these cost centers would implausibly reduce the cost-to-charge ratios for these services– so much so, that, in the outpatient setting, it may result in a CT of the chest being reimbursed at a similar level to a routine chest X-ray.

In addition, the AHA does not support the creation of a standard cost center for cardiac catheterization. CMS states that one-third of hospitals already report cardiac catheterization costs and charges separately through the available nonstandard cost center and subscripted lines, which suggests a modest hospital burden would be required to adopt these cost centers. However, we believe that the burden is actually much higher; the one-third of hospitals already reporting cardiac catheterization separately are likely larger hospitals or hospitals that have sophisticated accounting capabilities. We are concerned that smaller hospitals and hospitals with fewer resources may have a much more difficult time separating these costs and charges. For example, while revenue code 481, "Cardiology - Catheterization Lab," contains only cardiac catheterization charges, there are other revenue codes, such as 360 and 361, "Oper Room – General," and "Oper Room – Minor," that will contain *some* cardiac catheterization charges. Appropriately allocating costs and charges from these mixed revenue codes to cardiac catheterization would be very difficult for smaller hospitals and hospitals with fewer resources.

Further, it is unclear the extent to which reporting cardiac catheterization costs and charges separately will alleviate charge compression. **We urge CMS not to impose this significantly burdensome requirement when the impact on estimated costs, and therefore relative weights, may very well be negligible.**

In addition, we would like to take this opportunity to restate several previous requests. First, in our comment letter on the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program (see http://www.aha.org/aha/letter/2010/100308-cl-cms-0033-p.pdf), we requested that, for health information technology incentive payment purposes, CMS use a multi-pronged approach that allows a "hospital" to be defined in ways that acknowledge the varied organizational structures of multi-hospital systems, including by a distinct provider number, a distinct emergency department or a distinct state hospital license. We would like to reiterate that

CMS could use the hospital cost report, with certain modifications, to collect the hospital-specific data that will be necessary to determine the EHR incentive payment for each hospital. Specifically, hospitals with multiple sites that are under one Medicare provider number but in different core-based statistical areas must report separately wage data for each site on the cost report. CMS could create a similar worksheet on which hospitals with multiple sites that are under one Medicare provider number separately report EHR incentive payment data for each site.

In addition, because CMS references its efforts to comprehensively revise the hospital cost report, we would like to take this opportunity to express our concerns that the agency's proposed revisions are less than comprehensive in nature and require certain data that are virtually impossible for hospitals to provide. **The AHA continues to advocate that CMS perform a comprehensive review of its data collection practices and modify the cost report to allow hospitals to report information in a manner that is fully aligned with current hospital protocols and reimbursement methodologies.**

MS-DRG RECLASSIFICATIONS

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

However, we oppose CMS' proposal to reclassify diagnosis code 584.9 (Acute renal failure, unspecified) from an MCC to a CC. This change will have a substantial impact on hospital payments – CMS should not make such a dramatic change to case mix calculations without a compensating adjustment to rates. For example, one community hospital with 224 licensed beds analyzing data from the first six months of FY 2010 estimated that this change alone would reduce their net revenues by more than $1.5 million. Another hospital with 174 licensed beds analyzing data for the same period estimated the annual impact at $1.3 million. This is about a 2 percent reduction in total Medicare payments, on top of the other cuts proposed in this rule.

Acute renal failure is a complex disorder that occurs in a variety of settings with clinical manifestations ranging from a minimal elevation in serum creatinine to anuric renal failure. Emerging evidence suggests that even minor changes in serum creatinine are associated with increased inpatient mortality. Changing the status of code 584.9 from an MCC to a CC would unfairly penalize hospitals that are treating the more severe anuric patients who require more intensive resources.

While it may be true that there is no clear convention among clinicians for documenting acute renal insufficiency versus acute renal failure, several groups have recognized these limitations and have worked to correct these deficiencies. These efforts have included consensus conferences and publications from the Acute Dialysis Quality Initiative Group, the American Society of Nephrology Acute Renal Failure Advisory Group, the International Society of Nephrology and the National Kidney Foundation. CMS should continue to study the data on this diagnosis' impact on resource use until there is a more specific clinical definition of the stages of

acute renal failure and corresponding codes to recognize those differences (as has been done for chronic kidney disease).

Code Freeze in Anticipation of ICD-10.

Proposed last regular update of ICD-9-CM and ICD-10-CM/PCS on October 1, 2011. **We support CMS' recommendation that the last regular update to ICD-9-CM and ICD-10-CM/PCS be implemented on October 1, 2011.**

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 the development of educational training materials.

We recommend that after regular updates to ICD-9-CM and ICD-10-CM/PCS are frozen, proposals for new codes should flow through the coordination and maintenance process, but be approved for ICD-10-CM/PCS rather than ICD-9-CM. The Coordination and Maintenance Committee would continue to meet (and theoretically the National Center for Health Statistics and CMS could continue to approve and make draft changes available), but code changes would not be implemented until October 1, 2014.

Proposed limited code updates to both ICD-9-CM and ICD-10-CM/PCS on October 1, 2012. **We support CMS' recommendation for limited code updates to both ICD-9-CM and ICD-10-CM/PCS to capture new technologies and diseases.** Such updates should be limited to proposals for urgently needed codes. Such proposals should make a "clear and convincing" case to the Coordination and Maintenance Committee, including public comment, as to why the proposal cannot wait until the next regularly scheduled update, an example being the emergence of a new disease.

We urge the Department of Health and Human Services to commit to no new requirements for public health reporting that may necessitate new codes after ICD-9-CM codes are frozen and before ICD-10 is implemented.

Proposed limited code updates to ICD-10-CM/PCS on October 1, 2013. **We strongly recommend that there be no updates to ICD-10-CM/PCS on October 1, 2013 unless absolutely necessary, for example to meet the demands of a pandemic that cannot be otherwise reported with existing codes.**

While we understand the statutory requirements for add-on payments for new technology under the inpatient PPS, we strongly urge CMS to consider alternative solutions to recognize such new technologies. For example, consideration should be given to using other reporting mechanisms, such as special codes in the claims.

New technology add-on payments are strictly an inpatient PPS feature affecting only the providers capable of delivering that cutting-edge technology. However, creating new ICD-10-PCS codes to meet this requirement would adversely affect all providers, all payers, and all stakeholders without any benefits to them.

At a time when the health care field, all payers and other stakeholders will be struggling to make deadlines to change and test their systems with all their partners, it would be extremely difficult to have to make additional changes a few months prior to nationwide implementation of ICD-10. 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 Committee 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.

Other Recommendations. The AHA previously recommended that CMS direct its contractors to be ready at least six months prior to ICD-10-CM/PCS implementation for all policies and edits related to systems referencing diagnosis and procedure codes. Examples of such policies and edits include local coverage determination policies, national coverage determination policies, GROUPER applications, and the Medicare Code Editor. Ideally, edits should be revised and tested with the assistance of an expert provider panel to assist with validation. In order for Medicare contractors to meet this recommendation, the code sets need to be stable so that the changes to policies and edits can be made, analyzed and disseminated to providers.

Detailed information on how the reimbursement programs will be affected should be made available at least one year prior to ICD-10-CM/PCS implementation in order for providers to understand the impact of those changes. Providers need this information early in order to allow for hands-on training, financial analysis and financial modeling.

CMS has indicated in the past that the ICD-10-CM/PCS MS-DRG GROUPER will be available for review and public comment. **We strongly recommend that the GROUPER be made publicly available no later than the FY 2013 rulemaking period, with an extended public comment period in order to allow providers sufficient time to analyze and model the proposed DRG groupings. The final ICD-10-CM/PCS MS-DRG GROUPER should be made available to providers and vendors by no later than January 1, 2013 in order to allow providers and vendors to include the GROUPER in their testing activities prior to implementation.**

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 2011. 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 care 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.

HOSPITAL QUALITY DATA

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 the Secretary 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. In the proposed rule, CMS puts forward four new measures to be included for the FY 2011 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 pay-for-reporting annual payment update program and pass the established data validation tests.

Currently, the timeframe for which hospitals must collect measures in the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program covers different calendar quarters. Beginning in FY 2013, CMS proposes to change the current measurement collection timeframes so they are all the same. **We commend CMS for its proposal to move all measures to a consistent timeframe beginning with the FY 2013 program.** We agree that as CMS converts the RHQDAPU program into a Hospital Value-Based Purchasing (HVBP) program, all measures will need to be calculated across a consistent timeframe. Further, we are pleased that CMS has signaled its plans for the future of RHQDAPU by proposing measures for the next three FYs. **We support giving hospitals advanced planning notice on what CMS is considering for the future.**

However, although we do support the inclusion of certain measures, we do not believe that the Secretary has the authority to include in the RHQDAPU program many of the measures that CMS has proposed. Specifically, we do not believe the Secretary has the authority to:

- **Adopt the hospital-acquired conditions (HACs), AHRQ measures or indications of registry participation as measures, because they are defined by data submitted on claims, not for measures;**

- **Adopt all-patient volume data as measures, because they are defined by data submitted on claims, not for measures and because these data are not collected for the purpose of quality or reimbursement; and**

- **Adopt new measures beyond FY 2012 because *The Patient Protection and Affordable Care Act of 2010* (PPACA) revised the *Social Security Act* so that the Secretary has the authority to add measures to the RHQDAPU program only from FY 2008 through FY 2012.**

Thus, we request that CMS' Office of General Counsel review the statutory language and explicitly comment on CMS' authority to include the above measures in the RHQDAPU program.

A Vision for the RHQDAPU Program. The quality measures selected for public reporting purposes should be driven by a common set of national priorities for quality improvement and public reporting. These priorities exist in the work of the National Quality Forum's (NQF) National Priority Partners, in which CMS and other federal agencies participate. We are disappointed that CMS makes no mention of this group's work. **We encourage CMS to look to the Partners' goals as a framework for the types of measures that should be included in the pay-for-reporting program.** The goal of the partnership is to engage all stakeholders in a shared effort to make quality improvements in the most important areas of patient care. The Hospital Quality Alliance (HQA) agrees that the Partners' national goals should provide a foundation for its future work, and it would be beneficial for CMS to follow these national goals as well.

Through the NQF, interested health care stakeholders come together to choose measures that are useful for quality improvement and public reporting. Through the HQA, public and private partners come together to identify areas that are critical to hospitalized patients and warrant focus and, from among the NQF-endorsed measures, select those that best assess quality in those priority areas. These two organizations are the primary consensus groups for hospital quality reporting. However, in the proposed rule, CMS does not propose measures that are endorsed by the NQF and adopted by the HQA, thus failing to follow the statutory requirement that chosen measures represent a "consensus among affected stakeholders." **We believe that measures added to the pay-for-reporting program must first go through the rigorous, consensus-based assessment processes of both the NQF and HQA.**

Public reporting of a small and actionable set of measures on *Hospital Compare* leads to a significant investment of provider resources in collecting data and improving performance. Therefore, the measures chosen for public reporting should be important measures that accurately and reliably assess meaningful aspects of care. It is incumbent on CMS to choose the best possible measures for this purpose. To do this, CMS should follow a clear set of criteria to determine which measures are most scientifically sound. We suggest that CMS look to criteria recently developed by The Joint Commission. The Joint Commission has spent time examining what makes some measures better than others and concluded that: excellent measures are those for which there is a large volume of research linking the measure to improved outcomes; the measure accurately assesses the relevant clinical process; and implementation of the measure has minimal unintended adverse consequences. The AHA agrees with these criteria. One reason we urge CMS to adopt only measures that are NQF-endorsed and HQA-adopted is that the NQF process identifies those measures that accurately assess relevant clinical processes, and both the

HQA and the NQF processes help identify those measures that have an important linkage to improved clinical outcomes and have minimal unintended consequences.

We urge CMS to take steps toward developing a core measure set. The core measure set should be constructed to include enough cases to ensure a high level of reliability and validity. In this rule, CMS has proposed different measures using different reporting mechanisms, which will not lead to a core measure set. Rather, CMS should focus on core measures and, because hospitals are at various stages of information technology adoption, work with various stakeholders to ensure hospitals can submit those measures through their various different mechanisms. Hospitals should be able to choose between chart-abstraction, reporting into a registry, or reporting electronically, for reporting a core measure set.

Retirement. We do not support the retirement of individual measures. However, we do support, when evidence warrants such, the retirement of composites. **Therefore, we support CMS' proposal to retire the AHRQ composite for mortality for selected procedures.**

FY 2012 Proposals for RHQDAPU.

HACs. CMS proposes to include HACs, defined as selected ICD-9-CM codes that are coded as an "N" (not present on admission) or a "U" (medical record documentation is insufficient) for the present-on-admission (POA) indicator, in the RHQDAPU Program. However, ICD-9-CM codes do not constitute measures. **Therefore, because they are currently defined by ICD-9-CM codes, we do not support including HACs in the RHQDAPU program.**

Further, we note that the statutory authority for the RHQDAPU program allows the Secretary to include "data required to be submitted on measures." However, the HACs are defined from data submitted for claims, not for measures. Our review of the *Social Security Act* indicates that the Secretary is authorized only to require hospitals to submit the necessary data to calculate "the set of measures that the Secretary determines to be appropriate for the measurement of quality of care furnished by hospitals in inpatient settings." It does not authorize the Secretary to use data submitted to CMS or its contractors for reasons other than the measurement of quality of care.

If CMS will not abandon its proposal to include HACs in the RHQDAPU program, we urge it to further define HAC measure specifications. In the proposed rule, the agency does not provide any information on the availability of measure specifications as they pertain to HACs – therefore, we must assume that they do not exist. Yet, measure specifications are critical to defining a measure. CMS makes no reference to what population is applicable for measurement (denominator), nor any reference to what population is measured for a HAC (numerator). In addition, CMS fails to define whether certain populations should be excluded from HAC measurement. CMS references public reporting of "rates" of HACs, but without a defined numerator, denominator and exclusions, a rate cannot be calculated. Further, HACs are not NQF-endorsed measures. The NQF has included some of the selected HACs among its list of Serious Reportable Events (SREs), but SREs also are not measures and, therefore, are not

endorsed as measures by the NQF. Since the HACs are not endorsed measures by the NQF, they also are not HQA-adopted.

AHRQ Patient Safety Indicators (PSIs). **We do not support the two proposed AHRQ measures: (1) PSI 11: Post Operative Respiratory Failure; and (2) PSI 12: Post Operative PE or DVT. These measures are derived from claims data, which are not an accurate source of quality measures and are inferior to medically abstracted measures. Further, our review of the *Social Security Act* indicates that the Secretary is authorized only to require hospitals to submit the necessary data to calculate "the set of measures that the Secretary determines to be appropriate for the measurement of quality of care furnished by hospitals in inpatient settings."** It does not authorize the Secretary to use data submitted to CMS or its contractors for reasons other than the measurement of quality of care. We also do not support including these measures because we understand that CMS has had numerous difficulties validating these PSIs against external data sources. For this reason, these measures only have time-limited endorsement by the NQF – they are not fully endorsed.

All-patient Volume Data. CMS proposes that hospitals be required to submit all-patient volume data for the 55 MS-DRGs that relate to the RHQDAPU program. **We do not support including all-patient volume data in the RHQDAPU program**. In the FY 2011 inpatient PPS proposed rule, CMS states "we do not consider volume alone to be a quality measure…" Therefore, by CMS' own admission, this proposal does not constitute a quality measure. **Our review of the *Social Security Act* indicates that it does not authorize the Secretary to request additional data that are not related to quality, as CMS itself acknowledges in the proposed rule.** Further, the data requested represent identifiable patient information on patients who have no relationship to the Medicare program. **We are concerned that this requirement would have patient identifiable information transmitted to a federal agency that exceeds that which is required for payment or quality reporting, and, therefore, may not be in keeping with the tenets of the *Health Insurance Portability and Accountability Act of 2006*.**

In addition to the concerns raised above, we also note that this all-patient volume data proposal would place a significant burden on hospitals. CMS attempts to mitigate this burden by stating that "rather than require hospitals to group their all-patient claims data by MS-DRG category themselves, CMS would use the data to be submitted by hospitals to group the data." However, hospitals would still need to make determinations of whether a particular claim falls into one of the 55 MS-DRGs that relate to the RHQDAPU program. Given that CMS fails to propose a list of ICD-9-CM codes that group to the selected MS-DRGs, hospitals will not know which claims to submit unless they first group them. CMS also concludes that it believes "that the addition of this data will enable us and Medicare beneficiaries to better understand and evaluate the quality of care provided by hospitals with respect to both the chart-abstracted and claims-based measures." **We request that CMS provide additional information on how it plans to achieve this goal**. It is unclear whether the agency is planning to redesign *Hospital Compare* to display these data and how this display of information relates to CMS' new beta dashboard efforts.

Data Submission Requirements for Structural Measures. The three structural measures of clinical registry participation – participation in a systematic clinical database registry for stroke

care, nursing-sensitive care and cardiac care – collect data solely on whether or not a hospital participates in the registry. These measures should not be included in the pay-for-reporting program because they are neither tightly linked to improving quality and patient care, nor have they been endorsed by the NQF nor adopted by the HQA. For many of the pay-for-reporting measures, such as providing beta-blockers upon discharge to heart attack patients, there is a great deal of scientific evidence that providing that particular process of care can improve patient outcomes. The structural clinical registry participation measures fail to meet that standard. There is no established connection between whether a hospital answers "yes" or "no" to the registry participation measures and the quality of the care that hospital provides.

In addition, we are concerned that these measures contain an implicit encouragement by the Medicare program for hospitals to participate in clinical data registries designed and run by external organizations. Many clinical registries require hospitals to pay a costly fee to participate. **We urge CMS not to adopt the quality measures assessing participation in clinical data registries.**

FY 2013 Proposals for RHQDAPU.

AMI – Statin at Discharge. **We support the proposal to include the AMI – Statin at Discharge measure in the RHQDAPU program.** This measure is NQF-endorsed and HQA-adopted.

Infection Data Collected Through the National Healthcare Safety Network (NHSN). CMS proposes to require hospitals to report surgical site infection rates (SSI) and catheter-related blood stream infection rates (CRBSI) through the NHSN. CMS suggests that because the recently released National Healthcare Quality Report indicated no improvement in CRBSI, it is important that this information be publicly reported.

The AHA fully supports the reporting of CRBSI and SSI rates, and joined with the other members of the HQA in calling for the public reporting of these measures three years ago. However, we believe substantial changes must be made to the NHSN to enable efficient collection and entry of relevant information and appropriate validation of the data. NHSN is a system that was designed for epidemiologic surveillance, not for the efficient collection of the data elements needed to construct quality measures that will reveal opportunities for improvement and track progress in achieving it. It is a cumbersome and challenging data collection system to use, and our members who have had substantial experience with it have provided the Centers for Disease Control and Prevention (CDC) with substantial feedback about how to improve the data collection system. Thus far, CDC has not addressed these concerns. Member hospitals tell us that the system is so cumbersome to use that they believe it is causing them to expend more resources in collecting data than in improving performance.

CMS' proposal implies that because a number of states already are directing hospitals to collect and transmit such data to NHSN, the additional burden of data collection is lessened, but this ignores the fact that states do not have uniform requirements for hospitals in collecting the data. They use the same measures of CRBSI and SSI, but some require the CRBSI data be collected

only in ICUs; others include the entire hospital or specific units where patients are at greater risk of infection. Different states specify different surgical procedures for which the SSI data must be collected. Identical patient populations are needed if comparable data are to be collected, and that may lead to hospitals having to collect the data in one way for their state and differently for the national data collection.

Reliable portrayal of the data also requires that there be data checks on the information being entered and a process for validating the information once it has been received, but at this time, CDC has neither in place.

Further, CMS' proposal assumes that CDC can transmit the needed data to CMS in a timely fashion for use on *Hospital Compare*, but that assumption remains untested. It is our understanding that at the state level, transmission of the measurement results back to the state has not always gone as smoothly as had been hoped, and we believe it is imperative that CDC and CMS ensure that they have a working mechanism for sending and receiving the completed data prior to requiring hospitals to begin collecting and transmitting it.

Thus, we urge CMS to consider working with CDC to streamline the data collection mechanisms, synchronize them with existing measure collection activities to the greatest extent possible, and ensure they work for both collecting and transmitting the measure data before requiring all hospitals to participate.

Registry Measures. In the rule, CMS proposes to require hospitals to participate in at least one of four registry databases for FY 2013, and to contract with the registry of the hospital's choice to transmit the hospital's data to CMS for display on *Hospital Compare*. **However, we do not believe that the Secretary has the authority to include indications of registry participation in the RHQDAPU program. Our review of the *Social Security Act* indicates that the Secretary is authorized only to require hospitals to submit the necessary data to calculate "the set of measures that the Secretary determines to be appropriate for the measurement of quality of care furnished by hospitals in inpatient settings."**

The registries CMS is proposing will collect data on implantable cardiac defibrillator devices (ICD), cardiac surgery, stroke and nursing sensitive care. The principal reason CMS states for proposing this new strategy for collecting data is that it will reduce burden for hospitals. CMS believes this is true because it states that those hospitals that have already chosen to participate in these registries will simply have to allow their data to be sent to CMS.

T agency states it will allow organizations that are certified to collect these data to apply to become registries. However, it notes that it will certify only one ICD database and one database for cardiac surgery, and it proposes a set of criteria for identifying qualified registries that virtually assure that no organization other than the four that are currently collecting the data could successfully apply. For all intents and purposes, CMS' proposal creates a monopoly on the data collection for the four identified database registries, only one of which is a free, federally supported database. The others are private enterprises: two are run by physician

associations – the Society for Thoracic Surgery and the American College of Cardiology – one by the American Heart Association, and one by the American Nursing Association.

The AHA fully supports the intention of CMS' proposal to reduce reporting burden for hospitals. **Unfortunately, that is not what CMS' proposal would do**. The average hospital is struggling to keep up with the current burden of data collection and reporting to a wide variety of organizations, including payers, government agencies, oversight bodies and other organizations. Thoughtfully reducing this burden can be accomplished by focusing measurement activities on the truly important aspects of quality and reliably reporting on performance to the public.

To thoughtfully reduce burden, CMS needs to have a prioritized list of conditions on which it will focus its efforts. These priority areas should guide the selection of measures. PPACA directs the Secretary obtain advice on what those priorities should be by contracting with an entity, such as the NQF, that represents a diverse set of stakeholders, and to use that advice to craft a national set of priorities. CMS' proposal appears to ignore this mandate and proposes measures through FT 2014 when it does not yet know what the priorities will be or whether these measures will be consistent with those priorities.

CMS' proposed rule contends that the burden would be minimal because many hospitals are already reporting to one or more of these databases, but that assumption may not be right. The rule identifies the number of hospitals that currently report to three of the four proposed databases, but it fails to identify how many hospitals are actually reporting to more than one of the four databases. We suspect that there is substantial overlap among the hospitals reporting to the cardiac surgery database and those reporting to the implantable cardiac defibrillator database. The common characteristic is that they are hospitals that provide substantial amounts of cardiac care. Given that heart attack and stroke are both circulatory diseases, there also may be some significant overlap with those reporting into the stroke registry. Thus, we have no idea how many hospitals are currently reporting to one or more of these registries and for how many this proposed requirement to begin reporting to at least one registry would impose a new and substantial burden. While having nearly 1,200 hospitals reporting to the stroke registry is good, that is still less than a third of the hospitals involved in reporting quality data on *Hospital Compare*. **We request that CMS work with the identified registries to analyze how many hospitals already are reporting to one or more databases and for how many hospitals this new requirement would impose a new and significant data collection burden**.

Moreover, whether data are abstracted and reported to a registry and then on to CMS, or are abstracted and reported through a different organization into the CMS data warehouse, does not alter the data collection burden for a hospital. Having two uses for the data – one for public reporting and one for analysis and feedback – may increase the value of the effort to collect the data, but it does not reduce the burden. To be clear, any hospital that must begin data collection for one of these registries would need to incur the expense associated with abstracting the information from the medical record – either by hiring individuals to do it or working with their information technology vendor to add the capacity to accurately capture the data. They also would need to pay a fee to the registry to collect and process the data, provide staff to verify the data submission and check their accuracy for public display, and develop the

capacity to respond to any indications of the need for improved performance. Any hospital choosing to participate in the Nursing Sensitive Care registry will need to be prepared to abstract information from a broad array of sources.

What *is* likely to reduce data collection burden is the adoption of EHRs with the capacity to electronically abstract data and transmit information to CMS' data warehouse. **We ask CMS to explain why this expansion of data collection will be undertaken at a time when quality measurement and reporting might benefit more from an intense focus by hospitals and other providers on preparing for an era of electronic data transfer from EHRs to data repositories.** This electronic reporting can be done only when a sufficient number of hospitals have EHRs, and when quality measures have been re-specified to enable e-collection. This rule provides no clarity on e-collection of the registry measures other than the stroke measures, which have been re-specified and are being tested in their new form. When the measure specifications are available to be collected in electronic form and the majority of hospitals have EHRs in place, it is unclear what value there will be in having a registry receive data and retransmit it to CMS' data warehouse.

The AHA urges CMS to revamp the criteria to indicate that data collection through an approved ORYX vendor is an acceptable alternative for any and all of the proposed "registry" measures. Assuming CMS has a compelling reason for expanding the data collection now rather than working to facilitate collection from EHRs, it is imperative that CMS think critically about the rationale for creating a virtual monopoly for these registries when effective alternative mechanisms exist. For example, most of the measures that are derived from medical records and reported on *Hospital Compare* are collected by hospitals working through any one of approximately 50 vendors under contract with The Joint Commission. These vendors, as part of this contract, receive rigorous training in consistent data collection, have a resource to which they can turn with questions, have data edits and checks in place, and have the capacity to work with the hospitals to provide further analysis and help in addressing issues. Because these measures were developed by The Joint Commission, they are available for Joint Commission-accredited hospitals to use through their vendors. It is totally unclear what the additional benefit would be of creating a disparate relationship with another data collection organization – the stroke registry – solely for the purpose of collecting data that readily could be collected through the existing vendors. It is, however, unlikely that the vendors could meet all of the proposed criteria for becoming a "registry" under this rule. The value of these vendors to hospitals working on quality improvement activities is substantial, and since the fundamental purpose of data collection for *Hospital Compare* is to spur quality improvement through public reporting, the value of the vendors assisting hospitals with the collection and use of data on these measures should be recognized by CMS.

The AHA believes CMS' proposal to allow hospitals to choose to report data to any one of four disparate registries and to have that data publicly displayed is inconsistent with the underlying goals of *Hospital Compare* and, in the future, will not allow for any of these measures to be linked to HVBP. Thus, the AHA urges CMS to reconsider how to gather vital quality data from all hospitals with relevant patients. The work of the HQA, which led to the creation of *Hospital Compare,* began with the notion that a core set of important quality

measures should be identified, information should be collected from all hospitals that have relevant patients, and performance rates should be made publicly available. This was an effort to both identify what was important to measure and report to the public, and also to get all hospitals focused on improving critical aspects of care. Over the life of this public reporting initiative, measured performance has improved substantially – so substantially that CMS is now recommending that some of the measures be retired because they are "topped out." This kind of progress did not occur prior to the HQA's work when hospitals were allowed to choose different measure sets on which to be held accountable. Having data from all hospitals with relevant patients ensures that the public and clinicians are able to make comparisons among hospitals, increasing the usefulness and credibility of the data. In addition, without a common set of data on all eligible hospitals, CMS will not be able to incorporate these measures into the value-based payment system. Because CMS has not proposed these measures for FY 2012, there is additional time to receive the recommended national priorities and companion measures that will be identified. Then CMS can focus attention on identifying the most effective mechanisms for getting that data, which may include enabling registries to share data, pulling data from EHRs or pulling medically abstracted data from ORYX vendors or the CART tool.

FY 2014 Proposals for RHQDAPU.

ED Throughput – Admit Decision Time to Emergency Department (ED) Departure Time for Admitted Patients. **We support the proposal to include the ED Throughput – Admit Decision Time to ED Departure Time for Admitted Patients measure in the RHQDAPU program**. This measure is both NQF-endorsed and HQA-adopted.

ED Throughput – Median Time from ED Arrival to ED Departure Time for Admitted Patients. **We support the proposal to include the Median Time from ED Arrival to ED Departure Time for Admitted Patients measure in the RHQDAPU program.** This measure is both NQF-endorsed and HQA-adopted.

Global Flu Immunization. **We do not support including the Global Flu Immunization measure in the FY 2014 RHQDAPU program**. At this time, this measure is neither NQF-endorsed nor HQA-adopted. Further, we note that CMS does not reference specifications for this measure. We therefore have to assume that the measure specifications do not exist.

Global Pneumonia Immunization. **We do not support including the Global Pneumonia Immunization measure in the FY 2014 RHQDAPU program**. At this time, this measure is neither NQF-endorsed nor HQA-adopted. Further, we note that CMS does not reference specifications for this measure. We therefore have to assume that the measure specifications do not exist.

Overlapping Measures. We are concerned that there are several proposed measures that overlap with each other. In this respect, **CMS has not done the necessary due diligence to monitor overlapping measures**. We request that CMS provide a detailed table comparing ICD-9-CM codes and the time period of the inpatient stay for the following groups of measures:

1. Glycemic Control
    - Surgical Care Improvement Project (SCIP)-Infection-4: Cardiac surgery patients with controlled 6 AM postoperative serum glucose
    - HAC: Manifestations of poor glycemic control.
2. Mortality
    - AHRQ PSI: Death among surgical patients with serious treatable complications
    - ICD complications and mortality
    - Risk-adjusted operative mortality for Coronary Artery Bypass Graft (CABG)
    - Risk-adjusted operative mortality for aortic value replacement (AVR)/repair
    - Risk-adjusted operative mortality for mitral valve replacement (MVR)
    - Risk-adjusted operative mortality for MVR + CABG
    - Risk-adjusted operative mortality for AVR + CABG
3. Infection
    - NHSN: Central line-associated blood stream infection
    - Surgical site infection
    - Deep sternal wound infection
    - Vascular catheter-associated infection
4. Venous thromboembolism (VTE)
    - SCIP-VTE-1: VTE prophylaxis ordered for surgery patients
    - Stroke-1: VTE prophylaxis for patients with ischemic or hemorrhagic stroke
    - Stroke-4: Thrombolytic therapy for acute ischemic stroke patients
    - Stroke-5: Antithrombolytic therapy by the end of hospital day two
5. Patient Falls
    - Nursing sensitive: Patient falls
    - Nursing sensitive: Falls with injury
    - HAC: Falls and trauma
6. Pressure Ulcer
    - Nursing sensitive: Pressure ulcer prevalence
    - HAC: Pressure ulcers stages III & IV
7. Beta Blocker
    - Acute Myocardial Infarction (AMI)-5: Beta blocker described at discharge
    - SCIP-Cardiovascular-2: Surgery patients on a beta blocker prior to arrival who received a beta blocker during the perioperative period
    - Cardiac: Beta blockade at discharge
8. Prophylactic Antibiotic
    - SCIP-1: Prophylactic antibiotic received within 1 hour prior to surgical incision
    - SCIP-3: Prophylactic antibiotics discontinued within 24 hours after surgery end time
    - SCIP-Infection-2: Prophylactic antibiotic selection for surgical patients
    - Cardiac: Duration of prophylaxis for cardiac surgery patients

Not only is it unfair to hospitals to capture the same performance metrics through several different measures, but it will cause several problems for consumers when this information is displayed on *Hospital Compare*. **CMS must ensure that measures used in the RHQDAPU program are mutually exclusive and should not finalize any of the measures included in the eight overlapping sets included above.**

Possible New Quality Measures for Future Years. We note that many of the measures included in the proposed rule as a possibility for future years also overlap with the current RHQDAPU measures. We urge CMS to do the necessary due diligence to ensure that future measures are mutually exclusive from current measures.

Hospital Administrative Burden. CMS purports several times that many of the new reporting mechanisms being proposed will reduce hospital burden. Though adding chart-abstracted measures may be somewhat burdensome, hospitals are used to this reporting mechanism and have organized their internal quality teams to submit these measures. However, hospitals are not necessarily organized to submit measures through the new proposed reporting mechanisms including registry-based reporting, reporting into NHSN and reporting through a qualified EHR via the meaningful use requirements. **Contrary to CMS' assumption, rather than reducing burden, these reporting mechanisms increase burden to hospitals. Hospitals will need to train and recruit additional staff to take on these new requirements.**

Program Disaster Extensions and Waivers. We support CMS' proposal for hospitals to submit a form, which will be made available on QNet, to their Quality Improvement Organization to request an extension or waiver due to a natural disaster.

Hospital Value-based Purchasing (HVBP). In accordance with the DRA, CMS issued an HVBP Report to Congress in November 2007. We support the plan that was included in CMS' 2007 HVBP RTC. In addition, we support the transition of the RHQDAPU program into the HVBP program. Specifically, we support Year 1 of the HVBP program consisting of 100 percent pay-for-reporting, Year 2 of the program consisting of 50 percent pay-for-reporting and 50 percent pay-for-performance; and Year 3 of the program consisting of 100 percent pay-for-performance. This gradual transition will allow hospitals to be fully prepared for the rollout of this new program.

In addition, although CMS did not include any HVBP proposals in this rule, we note that §3001(a)(12)(2)(B) of the PPACA revises §1886(b)(3)(B)(viii)(V) of the *Social Security Act* to read: "effective for fiscal years 2008 through 2012, the Secretary shall add other measures that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities." **Therefore, we do not believe that the Secretary has the authority to propose new measures to the RHQDAPU program beyond FY 2012.**

Partnering with Stakeholders. During the development of the HVBP Report to Congress, CMS hosted two public listening sessions to inform policy development. In addition, CMS has also hosted public listening sessions for public input on both the HAC payment provision and the

development of the physician pay-for-reporting program. In contrast, however, we note that CMS has not conducted public listening sessions to obtain stakeholder input on the development of the RHQDAPU program. **We urge CMS to hold an annual listening session with the public as you refine the current RHQDAPU program and as you transition into the HVBP program.**

IPPS Market Basket Concerns. The newly legislated HVBP program implements a 1 percent withhold of a hospital's annual market basket update beginning in FY 2013. Currently, hospitals face a potential 2 percent market basket penalty under the RHQDAPU program, as well as many other potential market basket penalties, including those under the health information technology meaningful use program, and those mandated in the PPACA. **We are very concerned about these penalties and would like to work with CMS to ensure hospitals are not penalized multiple times for the same reason. This will require carefully considering each quality measure that is used across these various programs.**

DRGs: HOSPITAL-ACQUIRED CONDITIONS

The DRA required CMS to identify, by October 1, 2007, at least two preventable complications of care that could cause patients to be assigned to an MS-DRG with a CC or MCC. The conditions must be either high-cost or high-volume or both, result in the assignment of a case to an MS-DRG that has a higher payment when present as a secondary diagnosis, and be reasonably preventable through the application of evidence-based guidelines. The DRA mandated that for discharges occurring on or after October 1, 2008, the presence of one or more of these preventable conditions would not lead to the patient being assigned to a higher-paying DRG. In the FY 2008 inpatient PPS final rule, CMS adopted eight conditions for which it would no longer pay a higher MS-DRG rate if the conditions were not present on admission. In the FY 2009 rule, CMS selected two additional conditions and expanded one of the original categories.

This year, CMS does not propose to add or remove any HACs. Rather, the agency continues to focus on evaluating the impact of the HACs policy. We commend CMS for making the early findings of the evaluation publicly available and encourage the agency to continue to make additional findings available to the public.

HAC and POA Evaluation. We are interested in seeing additional data analyzing HACs that were not POA. The AHA and the Health Education Research Trust are working with several state hospital associations on quality improvement projects that are targeting implementation of comprehensive unit-based safety programs. These projects are leveraging the success of the Michigan Keystone project and are funded by AHRQ. For example, we encourage CMS to release a list of the top 25 CC/MCCs that are coded along with the selected HACs. In addition, we encourage CMS to begin a partnership with AHRQ and AHA to discuss this analysis and with others to enhance the comprehensive unit-based safety programs. This partnership can serve as a template for making critical data readily available to researchers.

POA Coding. The AHA is concerned regarding the accuracy of the POA indicator reporting for the HACs related to intracranial injury. It has come to the attention of the AHA's Central Office

on ICD-9-CM that there have been different interpretations of the POA coding guidelines for the reporting of the following ICD-9-CM code categories:

- 850, Concussions
- 851, Cerebral laceration and contusion
- 852, Subarachnoid, subdural, and extradural hemorrhage, following injury
- 853, Other and unspecified intracranial hemorrhage following injury
- 854, Intracranial injury of other and unspecified nature

The above ICD-9-CM code categories require a fifth digit to specify whether there was loss of consciousness, and the approximate length of time that the patient was unconscious. Currently, the POA guideline states to "assign 'N' if any part of the combination code was not present on admission." In some instances, coders have assigned "N" to these codes if the patient lost consciousness after admission, even though the intracranial injury occurred prior to admission. Loss of consciousness is a component of intracranial injuries rather than a separate condition. This has resulted in data implying that the intracranial injuries were a result of trauma sustained after admission to the hospital.

Questions regarding the interpretation of the POA guidelines and the correct POA reporting for patients with intracranial injuries that develop loss of consciousness after admission to the hospital were submitted for review by the *Coding Clinic for ICD-9-CM* Editorial Advisory Board (EAB). After review, the EAB has determined that the correct POA reporting for these clinical scenarios should be "Y" rather "N" because the intracranial injury was POA and the loss of consciousness is progression of the disease process.

Historically, CMS has collaborated with the AHA through the *Coding Clinic for ICD-9-CM* to provide coding advice. CMS has been collaborating with the AHA to promote the *Coding Clinic for ICD-9-CM* as the source for coding advice about the POA indicator. As such, a future issue of the *Coding Clinic* is slated to provide educational information on the proper POA reporting of intracranial injury with loss of consciousness.

RHQAPU Program. **We strongly disagree with the inclusion of HACs in the RHQDAPU program**. Information on the incidence rates of these conditions learned through POA coding should not be publicly reported. As stated earlier, the HACs are not measures, and they are neither endorsed by the NQF nor adopted by the HQA.

Changes to the Coding of the Blood Incompatibility HAC. We note that for October 2008 through June 2009, there were only 23 cases in which blood incompatibility was coded as a secondary diagnosis. Due to the low number of cases, we do not understand why CMS is introducing five new CC codes for blood incompatibility.

Payment Changes Based on POA Coding. The payment changes for HACs apply when the selected conditions are the only CCs or MCCs present on the claim that cause the patient to be assigned to a higher-paying MS-DRG. Under this policy, CMS does not make higher payments for the selected conditions if they are coded as not POA or if the medical record documentation

is insufficient to determine whether the condition was present on admission. In other words, CMS does not make a higher payment if the condition is coded on the claim with an "N" (not present on admission) or a "U" (medical record documentation is insufficient). CMS stated that it will not pay a higher payment amount when the medical record documentation is insufficient because it believes this will foster better medical record documentation. However, hospitals continue to learn how to apply POA indicators, as well as educate their physicians on the required documentation without which POA reporting is impossible. **We urge CMS to reverse its position and pay for HACs coded with the "U" indicator.**

Other Technical Clarifications. The AHA requests that CMS clarify how hospitals can appeal a decision under which a particular patient falls under the HAC policy and is ineligible for a higher DRG payment. A process for hospitals to appeal a decision about specific patient cases is essential to ensure accountability.

WAGE INDEX

Acumen's Recommendations on Wage Index Data. CMS hired Acumen LLC to review the Medicare Payment Advisory Commission's (MedPAC) recommendations for changing the area wage index and to analyze other options to revise the area wage index for hospitals and other Medicare providers. The first part of Acumen's final report, which analyzes the strengths and weaknesses of the data sources used to construct the CMS and MedPAC indices, was published immediately after the FY 2010 proposed rule. In the report, Acumen acknowledges that there are challenges and limitations involved with using BLS data as MedPAC recommended, but states that it still believes that these data should be used. **The AHA continues to have significant concerns about using BLS data**. Detailed comments about our key concerns can be found in our comment letter on the FY 2008 inpatient PPS proposed rule.

The second part of Acumen's final report, which analyzes the definitions of the wage areas used in the current Medicare wage index, was released in March. In the report, Acumen recommends further exploration of labor market definitions using a wage area framework based on hospital-specific characteristics, such as the commuting times from hospitals to population centers. Acumen also found that MedPAC's blending and smoothing method, whereby wage index values or wages of neighboring areas are artificially constrained to allow only a 10 percent difference in wage indices, is not well suited to the existing Medicare wage index. **The AHA shares this concern about MedPAC's blending and smoothing method.** More refined areas – as in MedPAC's proposal to vary wage indices by county – may be more realistic and less arbitrary. On the other hand, the "smoothing" approach may mask actual variation in wages between areas. For example, there may be real, greater differences between outlying counties and an urban core.

MEDICARE-DEPENDENT, SMALL RURAL HOSPITALS

Currently, for a hospital to qualify as a Medicare-dependent hospital (MDH), at least 60 percent of its inpatient days or discharges must be attributable to individuals "receiving" Medicare Part A benefits. However, the *Social Security Act* states that at least 60 percent of an MDH's inpatient days or discharges must be attributable to individuals "entitled to" Medicare Part A benefits. To conform to the *Social Security Act*, CMS is proposing to change the regulations to read "entitled to," instead of "receiving," which would allow hospitals to count Medicare beneficiaries who have exhausted their Medicare Part A inpatient benefits towards the 60 percent threshold.

The AHA supports this proposal, which CMS estimates could allow 48 more inpatient PPS hospitals to qualify as MDHs, thereby helping ensure access to essential hospital services for rural Americans.

CERTIFIED-REGISTERED NURSE ANESTHETIST SERVICES FURNISHED IN RURAL HOSPITALS AND CAHS

Certain hospitals located in rural areas are eligible for reasonable cost-based reimbursement for certified-registered nurse anesthetist (CRNA) services. Under the existing regulations, neither hospitals that have reclassified from urban to rural, nor hospitals that are located in "Lugar" counties, are eligible to receive this cost-based reimbursement. (Lugar counties are certain counties that are rural, but adjacent to one or more urban areas, and are treated as being located in the urban area.) However, CMS is proposing to make hospitals (including critical access hospitals (CAHs)) that have reclassified from urban to rural eligible for CRNA cost-based reimbursement. CMS does not propose to make hospitals (or CAHs) that are located in Lugar counties eligible for CRNA cost-based reimbursement.

We support CMS' decision to extend CRNA cost-based reimbursement to hospitals that have reclassified from urban to rural. However, we again urge CMS to extend CRNA cost-based reimbursement to CAHs located in Lugar counties. The regulations (42 CFR 412.113(c)(2)(i)(A)) state that a facility may not receive cost-based reimbursement for CRNAs if it is "deemed to be located in an urban county under the provisions of §412.64(b)(3) [the Lugar regulations]." However, in the August 12, 2005, inpatient PPS final rule, CMS states that the Lugar provision does not apply in determining eligibility for CAH status because it applies only for purposes of determining payment under the inpatient PPS, and CAHs are not paid under the inpatient PPS (70 *Federal Register* 47469). One consequence of this is that, unlike PPS facilities seeking to retain their special rural payment categories, CAHs in Lugar counties need not seek reclassification as "rural." **It is not appropriate for CMS to state that a statutory provision does not apply to CAHs in one context (eligibility for CAH status), but does apply to CAHs in another context (eligibility for CRNA pass-through payments). We urge the agency to revisit its prior ruling on CRNA cost-based reimbursement to CAHs that are located in Lugar counties.**

CRITICAL ACCESS HOSPITALS

CAH Optional Method Election for Payment of Outpatient Services. CMS proposes to modify how it handles CAH election of the "optional payment method" (also known as "Method 2"). Specifically, effective for cost-reporting periods beginning on or after October 1, 2010, once a CAH has elected to receive payments under the optional method, the election will remain in place until it is terminated. CAHs no longer will have to re-elect the optional method annually. CMS also proposes that, if a CAH is being paid under the optional method and wishes to terminate that election, it must submit a request in writing to its fiscal intermediary or Medicare Administrative Contractor at least 30 days prior to the start of the next cost-reporting period. **The AHA supports this proposal, which we believe will help ensure continued CAH access to these vital payments, as well as decrease their administrative burden.**

Costs of Provider Taxes as Allowable Costs for CAHs. CMS proposes to clarify its policy concerning when provider taxes are considered allowable costs under Medicare. The agency states that its proposed revision to the provider reimbursement manual (PRM) will clarify that the Medicare contractors will determine the allowability of provider taxes on a case-by-case basis, based on reasonable cost principles, and will determine if a reduction of the allowable tax expenses is necessary to account for payments providers receive that are associated with the assessed tax.

The AHA strongly opposes this proposed change for several reasons. First, CMS does not actually state what its proposed revision to the PRM is; instead, it vaguely states that the unspecified revision will reflect the agency's concerns regarding when certain provider taxes may be allowable. Unless CMS specifies the language of its revision, the public cannot properly comment on it. **It is not appropriate or reasonable for CMS to solicit comment on, and then perhaps finalize, an unspecified revision to the PRM.**

Second, under the current regulations and the PRM, these taxes are clearly allowable costs. Congress has authorized states to use provider taxes to fund Medicaid expenditures, and states have been imposing them for years, consistent with the authority found in § 433.68 of the regulations. These taxes are used by states to aid their funding of the delivery of health care services to their residents. The payments made by hospitals to the states are not voluntary donations; they are, instead, absolute requirements and constitute real costs to the hospitals. The taxes constitute a cost of doing business, and exemptions to the taxes are not legally available. Thus, under Medicare's general cost reimbursement principles as well as the provisions of PRM § 2122.1, these taxes qualify as reimbursable costs: they are "assessed against providers in accordance with the levying enactments" of the states and they constitute an expense for which exemptions are not available.

Moreover, the taxes are not among those that are expressly excepted from reimbursement in § 2122.2 of the PRM. All of the taxes listed in the PRM as not allowable relate to: (1) the cost of ownership (income related taxes and owners' self-employment taxes); (2) taxes that should be capitalized and amortized rather than recognized as a period expense (capital structure-related or

special land assessments); (3) taxes specifically related to non-covered services; (4) taxes that the provider was not required to pay; and (5) taxes the provider only collects and remits like sales tax. We would agree that these broad classifications of taxes are not allowable when incurred, and that the list seems quite complete. Provider taxes, as described above, however, do not fit into any of these broad categories of taxes that are not allowable. These taxes are a cost to hospitals of doing business, just like other administrative and general costs.

The fact that there may be payments made by the state to the provider – or the fact that Medicaid payments from the state may be funded by the provider taxes – does not change this result. Taxes, by their very nature, are imposed to generate income for states to allow them to furnish goods and services to the individuals and entities that pay the taxes, as well as to others. In other words, taxes are paid with the obvious expectation of someone receiving some benefit or service that is funded by the tax. The fact that there is something paid by the state to the providers, however, should be of no import as long as that tax is a CMS-approved tax that satisfies the provider tax limitations set forth in the Medicaid regulations. Those regulations, we note, include a requirement that the tax program not hold the providers harmless for their obligations. Therefore, as long as the tax is a Medicaid-approved provider tax, there should be no offset that Medicare seeks to impose.

Beyond this, to focus the proposed rule on CAHs is particularly problematic. CAHs are, as CMS is aware, reimbursed on a cost basis. These hospitals are, by statute, small and serve a particularly vulnerable population who may lack access to other hospitals. Moreover, CAHs typically have low operating margins. If Medicare does not reimburse the cost of these taxes, the CAHs will find themselves with even fewer resources to deliver the critically important care upon which their patients depend. Indeed, in some instances, it may force CAHs into severe financial difficulty.

Finally, CMS states that the proposal on provider taxes is a "clarification in policy" and not a policy change. We strongly disagree with that assertion and urge CMS to treat this revision as the policy change it actually is. The distinction between a clarification and a change is very important, because clarifications can, in theory, be applied retroactively, while changes can be applied only prospectively. Provider taxes have been in place since the early 1990s. Despite having opportunities to state as much in the past when addressing provider tax issues at the Provider Reimbursement Review Board and through Administrator review, CMS has never articulated a policy akin to what it describes in the proposed rule. It has never described provider taxes as non-allowable, or even as possibly non-allowable, nor has it stated that amounts received from the state may be applied as offsets to the taxes. Further, in 1995, CMS publicly announced that permissible provider taxes are an allowable Medicaid cost. This announcement, in combination with CMS' lack of statements to the contrary, has led hospitals to claim Medicare's share of the provider tax as an allowable cost on the Medicare cost report. Whether or not CMS believes that there has been "confusion" related to provider tax costs, the fact remains that it was CMS' own PRM and CMS' own actions that led to the current allowability of provider taxes. Calling these proposals "clarifications" is not accurate.

We also strongly disagree with CMS' statement that, because this is a "clarification" of its longstanding policy, it will have no financial impact on providers. Labeling this new policy a clarification would allow contractors to reopen past cost reports and possibly recover substantial amounts of payments. Thus, from the hospital perspective, revising the PRM will have a large financial impact, especially since those most affected are CAHs, which have limited cash flow, very modest margins, and are vital to providing critical care for a vulnerable population. CMS should not punish hospitals when it is the agency's own actions that led to the current widespread allowability of provider taxes. **We ask CMS to reconsider the financial impact this new policy will have on hospitals.**

For the reasons outlined above, we strongly urge CMS not to implement this policy. If the agency will not abandon its proposed change, we urge it to, at the very least, make the change effective for cost reporting periods beginning on or after October 1, 2012, or at least two years after the PRM provisions are revised. Providing a prospective implementation date would give CAHs time to adjust their financial footing to account for this significant loss of reimbursement. In contrast, if CMS implements this change retroactively, it will hold some of the smallest and most vulnerable hospitals accountable for CMS' failure to clearly state its policy – the effect will be devastating.

OUTLIER PAYMENTS

The rule states that CMS estimates the actual FY 2009 outlier payment level at 5.3 percent. However, our analysis results in an estimate of 4.9 percent. Through our conversations with CMS, we understand that this discrepancy is because CMS models FY 2009 payments, while we analyze actual FY 2009 payments from the Medicare Provider Analysis and Review (MEDPAR) file. We strongly believe that it is always preferable to use actual, rather than modeled, payments wherever possible. **Therefore, we recommend that CMS recalculate its estimate of the actual FY 2009 outlier payment level based on actual, rather than modeled, FY 2009 payments.**

When calculating the proposed FY 2011 fixed-loss amount, CMS excluded managed care claims specifically identified as such in the FY 2009 MEDPAR file. However, because of apparently incomplete coding of the "HMO Paid Indicator" field in the MEDPAR file, some managed care claims may continue to be included, albeit inadvertently. Specifically, we found 74,319 managed care claims that appear to have been inadvertently included. We identified these claims because although they were not identified as managed care claims in the "HMO Paid Indicator" field, the amount reimbursed is exactly equal to the amount of the indirect medical education (IME) payment. It is likely these are claims for managed care patients submitted by teaching hospitals in order to receive IME payments. **If so, we urge CMS to exclude these easily identifiable claims.**[6] Including them results in overestimating FY 2011 outlier payments by about $61 million.

[6] Of course, if the HMO indicator field is indeed not coded consistently, the possibility exists that other managed care claims that are not so easily identifiable are also inadvertently included.

In addition, we believe that a problem exists with the blood clotting drug charges used in the calculation of the proposed FY 2011 fixed-loss amount. Blood clotting drug costs are paid separately from the inpatient PPS, and therefore the associated charges should not be considered when estimating outlier payments. However, the proposed FY 2011 fixed-loss amount was calculated with blood clotting drug charges included. **We urge CMS to exclude these charges when calculating the fixed-loss amount for the final rule.**

While blood clotting drug charges cannot be determined from the MEDPAR file, the file contains a code indicating whether the patient received blood clotting drugs. This allows an approximate measurement of the impact of inappropriately including blood clotting drug charges in outlier calculations. We estimate that if the blood clotting drug charges are appropriately excluded from the calculations, FY 2011 estimated outlier payments decrease by approximately $24 million. However, a more accurate determination could be calculated if the MEDPAR file contained a field with the blood clotting drug charges – instead we used total pharmacy charges as a proxy for blood clotting drug charges. Such a simple change would not only allow a more accurate determination of outlier fixed-loss amounts but also benefit any research into Medicare expenditures for blood clotting drugs.

Combining the exclusion of claims that are apparently managed care claims and the removal of pharmacy charges for FY 2011 outlier patients receiving blood clotting drugs who were not outliers in FY 2009 results in an overall estimated FY 2011 outlier payment level of 5.01 percent (operating) and 5.75 percent (capital). Since our modeling of FY 2011 outlier payments without these two changes resulted in payment levels of 5.06 and 5.79 percent, respectively, in terms of absolute dollars, the proposed FY 2011 outlier payments were overestimated by approximately $85 million. In addition, making these two changes, but otherwise using the CMS assumptions detailed in the proposed rule resulted in an estimated FY 2011 fixed-loss amount of $23,945, as opposed to the amount of $24,165 that CMS has proposed.

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 continues to resist approval of new technologies and considers only a few technologies a year for add-on payments. Further, in FY 2010, the agency approved only one application. **The AHA also 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 previously requested.**

CONDITIONS OF PARTICIPATION AFFECTING HOSPITAL REHABILITATION SERVICES AND RESPIRATORY CARE SERVICES

CMS proposes to revise the Medicare hospital conditions of participation (CoPs) relating to the ordering of rehabilitation and respiratory care services. In doing so, the agency states it is responding to questions raised about apparent inconsistencies in its policies and between the CoPs and many state laws.

Regarding rehabilitation services, CMS proposes to "clarify" that only qualified, licensed practitioners can order rehabilitation services as long as such privileges are authorized by the medical staff and are in accordance with both hospital policies and procedures and state laws, and provided that the ordering practitioner is responsible for the care of the patient.

For respiratory services, CMS proposes to revise the existing CoPs to allow qualified, licensed practitioners (including nurse practitioners (NPs) and physician assistants (PAs)) to order respiratory care services as long as such privileges are authorized by the medical staff and are in accordance with both hospital policies and procedures and state laws, and provided that the ordering practitioner is responsible for the care of the patient. While prior policy allowed doctors of medicine and osteopathy to delegate the ordering of respiratory care services to NPs and PAs, it required such physicians to countersign the NP/PA orders.

We support both of these proposals. In addition, we encourage CMS to revise the CoPs and corresponding interpretive guidelines regarding the administration of propofol by an anesthesiologist or CRNA. CMS has taken a positive step forward in this proposed rule, recognizing the importance of state laws as they pertain to rehabilitation and respiratory services, and we encourage CMS to similarly recognize the importance of state law as it pertains to the administration of propofol.

ACCREDITATION REQUIREMENTS FOR MEDICAID PROVIDERS OF INPATIENT PSYCHIATRIC SERVICES FOR INDIVIDUALS UNDER AGE 21

The provision of inpatient psychiatric services to individuals under the age of 21 was authorized as part of the Medicaid program by the *Social Security Amendments of 1972*. At the time, these services were permitted to be provided only by psychiatric hospitals accredited by the Joint Commission on Accreditation of Hospitals (later renamed the Joint Commission on Accreditation of Healthcare Organizations and now named The Joint Commission). However, the Congress later authorized these services to be provided in inpatient psychiatric programs within hospitals and in psychiatric facilities other than hospitals, called psychiatric residential treatment facilities (PRTFs). While PRTFs were given the flexibility to seek accreditation from organizations other than The Joint Commission, The Joint Commission has remained a requirement for psychiatric hospitals and inpatient psychiatric programs within hospitals.

CMS proposes to provide psychiatric hospitals and hospitals with inpatient psychiatric programs the flexibility to choose among available accreditation options. Specifically, hospitals would be able to meet Medicare CoPs or obtain accreditation from a national accrediting organization whose psychiatric hospital accrediting program has been approved by CMS. **We support this proposal, which, as CMS notes, would facilitate the provision of medically necessary, Medicaid-reimbursable psychiatric services to vulnerable children, while maintaining the high quality of care demanded by the Medicaid program.**