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June 15, 2009

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

RE: CMS-1406-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System for Acute Care Hospitals and Fiscal Year 2010 Rates and to the Long-Term Care Hospital Prospective Payment System and Rate Year 2010 Rates; Proposed Rule (Vol. 74, No. 98), May 22, 2009

Dear Ms. Frizzera:

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) 2010. 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 on hospital-acquired conditions and diagnosis-related group reclassifications, we have concerns about the documentation and coding adjustment and market basket revision, as well as payment cuts related to the wage index rural floor, capital payments, Medicare-dependent hospitals and critical access hospitals.

MS-DRG DOCUMENTATION AND CODING ADJUSTMENT

The proposed rule includes a 1.9 percent cut to both operating and capital payments in FY 2010 and beyond – \$23 billion over 10 years – to correct the base rate for payments made in FY 2008 that CMS claims are the effect of documentation and coding changes that do not reflect real changes in case mix. In combination with other policy changes, this cut results in hospitals being paid \$1 billion less in FY 2010 than in FY 2009. **In its analysis of documentation and coding changes, CMS concludes that from FY 2007 to FY 2008, there was a decline in real case mix; in contrast, our analysis found that there is a historical pattern of steady annual increases of 1.2 to 1.3 percent in real case mix and we are concerned that CMS' conclusion is incorrect.** Further, because CMS' conclusion that real case mix declined is an inference based on its analysis of documentation and coding-related increases, we are concerned that the 1.9 percent proposed cut also is inaccurate and overstated. We recognize that CMS could have taken action to reduce payments more than proposed in this rule. **We appreciate that CMS did not propose cuts for documentation and coding changes in FY 2009 or cuts to recoup the estimated documentation and coding**



overpayments in FY 2008. However, given the severity of the 1.9 percent proposed cut, and in light of the fact that our analysis shows real increases in patient severity, we ask that the agency significantly mitigate its proposed documentation and coding cut.

HOSPITAL MARKET BASKET

As required by law, CMS proposes to rebase the market basket from FY 2002 to FY 2006 and revise certain categories and price proxies. However, the projected increase in the market basket could be extremely volatile this year. While the country has recently experienced a period of very low inflation, funds from the *American Recovery and Reinvestment Act of 2009* are beginning to work their way into the economy and we are beginning to see signs of a recovery. We do not know the effect this will have, but a period of inflation could substantially affect the market basket estimate. In addition, the predictability of hospitals' payments has been, and will continue to be, extremely volatile. CMS is required to revise the weights used in the hospital market basket every four years to reflect the most current data available, but the agency is not required to modify the price proxies used in the market basket calculation. Accordingly, **we urge CMS only to rebase the data and weights used in the market basket calculation, and not to revise the price proxies used in the calculation.** Doing so will result in a more stable estimate of the increase in the market basket and demonstrate forbearance given the economic volatility that has occurred and may be yet to come.

OTHER PROPOSALS

We also strongly oppose the following direct payment cuts:

- Applying budget neutrality for the rural floor and imputed rural floor on a statewide basis;
- Not making a positive budget-neutrality adjustment to reverse the FYs 1999 through 2006 standardized amount budget-neutrality adjustments for the rural floor, which have cost hospitals \$2.6 billion through FY 2009;
- Eliminating the indirect medical education adjustment to capital payments, which cuts payments to teaching hospitals by \$350 million in FY 2010 and \$1.8 billion over five years;
- Applying a cumulative retroactive budget-neutrality adjustment to the FY 2002-based Medicare-dependent hospital and the FY 2006-based sole community hospital hospital-specific rates, which will reduce payments by \$90 million in FY 2010; and
- Reducing payments for outpatient services to certain critical access hospitals from 101 percent of costs to 100 percent of costs, which will cut payments to these hospitals by \$22 million in FY 2010.

Our detailed comments are attached. If you have any questions, please contact me or Joanna Hiatt, 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 2010**

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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 diagnosis-related groups (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. This law also specified that, to the extent that the required adjustments for FY 2008 and FY 2009 resulted in overpayments or underpayments relative to the actual amount of documentation and coding-related increases, the Secretary would correct the overpayments or underpayments going forward, as well as make additional adjustments during FY 2010 through FY 2012 to offset the increase or decrease in aggregate payments that occurred during FYs 2008 and 2009.

In the proposed rule, CMS states that documentation and coding-related increases in FY 2008 were 2.5 percent. For hospitals paid using the standardized amount, the agency already has applied a negative 0.6 percent adjustment in FY 2008, and therefore proposes to apply a further adjustment of negative 1.9 percent in FY 2010 and beyond to reflect a base rate that has been corrected for the FY 2008 overpayments. CMS did not propose to correct the base rate for the FY 2009 overpayments or underpayments, nor did it propose to offset the increase or decrease in aggregate payments that occurred during FYs 2008 and 2009. **The AHA thanks CMS for demonstrating prudence in choosing not to propose additional cuts at this time, especially given the current economic climate and lower-than-usual market basket update.**

For sole community and Medicare-dependent hospitals paid using a hospital-specific rate, CMS previously has not applied a negative adjustment, and therefore proposes to apply the full adjustment of negative 2.5 percent in FY 2010 and beyond. For Puerto Rico hospitals, CMS states that documentation and coding-related increases were 1.1 percent in FY 2008. CMS has not previously applied a negative adjustment to these hospitals, and therefore proposes to apply the full adjustment of negative 1.1 percent to the Puerto Rico-specific rate, which accounts for 25 percent of payments to Puerto Rico hospitals. The remaining 75 percent of payments to Puerto Rico hospitals is based on the national standardized amount, to which CMS proposes to apply the 1.9 percent cut described above.

To analyze documentation and coding-related increases in FY 2008, CMS divided the case-mix index (CMI) obtained by running the FY 2008 claims data through the FY 2008 GROUPER by the CMI obtained by running these same FY 2008 claims data through the FY 2007 GROUPER, which yielded 1.028, or an increase of 2.8 percent. CMS states that this 2.8 percent is comprised of documentation and coding changes, as well as GROUPER changes. CMS asserts that none of

this 2.8 percent is due to “real” case mix because the analysis only uses 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 2008 GROUPER by the CMI obtained by running these same FY 2007 claims data through the FY 2007 GROUPER, which yielded 1.003, or an increase of 0.3 percent. CMS then divided 1.028 by 1.003 to yield 1.025, or a documentation and coding-related increase of 2.5 percent in FY 2008.

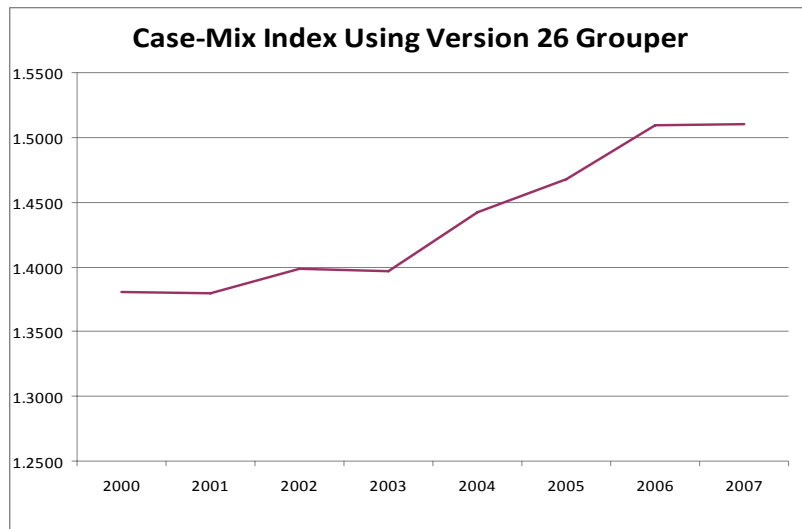
CMS then sought to corroborate this 2.5 percent estimate using several methods. Under one of these methods, CMS looked at overall CMI increases by dividing the CMI obtained by running the FY 2008 claims data through the FY 2008 GROUPER by the CMI obtained by running the FY 2007 claims data through the FY 2007 GROUPER, which yielded 1.019, or an increase of 1.9 percent. CMS states that this 1.9 percent is comprised of documentation and coding changes, GROUPER changes and real case-mix changes. The agency attempted to use Clinical Data Abstraction Center (CDAC) medical records data to distinguish documentation and coding changes from real case-mix changes, but found aberrations and significant variation in the data. Therefore, because CMS previously determined that documentation and coding and GROUPER changes resulted in an increase of 2.8 percent, the agency inferred that real case mix was negative 0.9 percent, because 1.9 percent minus 2.8 percent equals negative 0.9 percent. CMS further stated that a decline in real case mix is corroborated by the fact that there was an above-average relative decline in short-stay surgical cases that can be performed on an outpatient basis, such as certain high-volume pacemaker procedures.

The AHA is disappointed that CMS is unable to use the CDAC data to quantify real case-mix changes, and we are very concerned about CMS’ conclusion that there was a decline in real case mix from FY 2007 to FY 2008. Therefore, the AHA undertook further analysis of this issue, which is an integral part of CMS’ proposed negative adjustment. Specifically, we ran the FY 2000 through FY 2007 claims data through the FY 2009 GROUPER, which reflects the fully implemented MS-DRGs. This analysis provides a historical trendline for CMI. Because there were limited incentives for documentation and coding changes prior to the implementation of MS-DRGs in FY 2008 and because we used a constant grouper, the observed CMI change should reflect real case mix only.

Our analysis found that from FY 2000 through FY 2007, CMI increased by about 9.3 percent, or about 1.3 percent annually. During this period there was only one notable change that might have provided hospitals with an incentive to improve documentation and coding. Specifically, in FY 2006, CMS replaced nine existing cardiac DRGs with 12 new cardiac DRGs that were based on the presence or absence of major cardiovascular conditions for cardiac patients undergoing certain procedures. It is possible that this change could have provided an incentive to improve documentation and coding. In order to account for the possibility that this change encouraged coding and documentation improvements, we also looked at CMI increases from FY 2000 through FY 2005 – before both the new cardiac DRGs and the new MS-DRGs were implemented – and found that CMI increased by about 6.3 percent, or about 1.2 percent

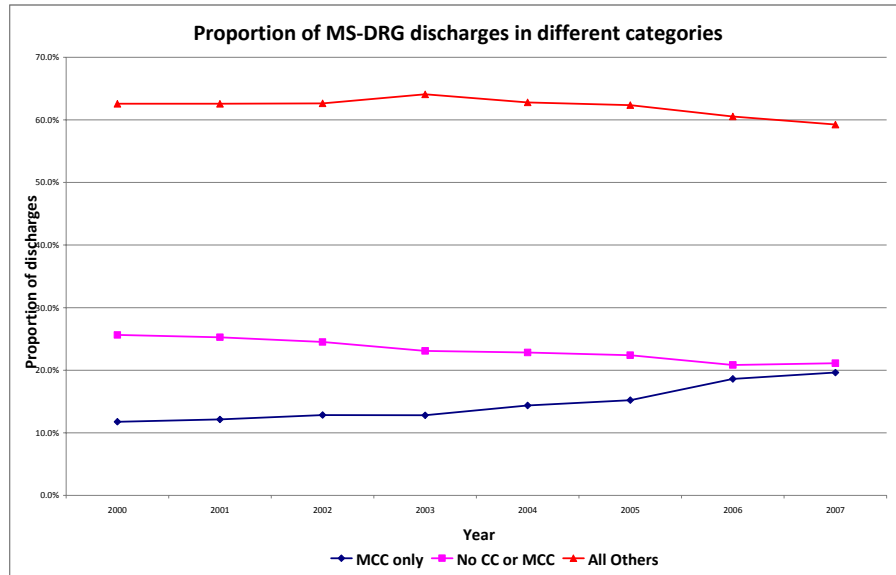
annually. These changes occurred steadily over the time period – there were not jumps in any one or two years that entirely accounted for the changes. See Figure 1 for a graphic depiction of the CMI changes from FY 2000 through FY 2007.

Figure 1: Case-Mix Index from FY 2000 through FY 2007 as Measured Using the Version 26 MS-DRG Grouper



We also looked at changes in the mix of patients with and without major complications or comorbidities (MCCs) to analyze severity changes over this time period. We found that the percentage of discharges for patients with MCCs increased from about 12 percent to about 20 percent from FY 2000 through FY 2007, while the percentage for patients without a CC or MCC decreased from about 26 percent to about 22 percent. These trends occurred steadily over the time period. Again, the results were similar for FY 2000 through FY 2005 – the percentage of discharges for patients with an MCC increased from about 12 percent to 15 percent and the percentage of discharges for patients without a CC or MCC decreased from about 26 percent to about 22 percent. See Figure 2 for a graphic depiction of these changes in the percentage of discharges for patients with different severity levels from FY 2000 through FY 2007.

Figure 2: Percentage of Discharges by MS-DRG Severity Level from FY 2000 through FY 2007



In order to understand the potential impact of the change in the cardiac DRGs in FY 2006 noted above, we also identified the 10 MS-DRGs with MCCs that had the largest increase in the percentage of discharges from FY 2000 through FY 2007. As noted above, in FY 2006, CMS replaced nine existing cardiac DRGs with 12 new cardiac DRGs that were based on the presence or absence of major cardiovascular conditions for cardiac patients undergoing certain procedures. It is possible that this change could have provided an incentive to improve documentation and coding. However, none of the 10 MS-DRGs referenced above were also one of the 12 new cardiac DRGs. See Table 1 for a list of the 10 MS-DRGs with MCCs that had the largest increases in the percentage of discharges from FY 2000 through FY 2007.

Table 1: MS-DRGs with MCCs with the Largest Increases in the Percentage of Discharges from FY 2000 through FY 2007

MS-DRG	MS-DRG Title
871	Septicemia or severe sepsis w/o MV 96+ hours w MCC
291	Heart failure and shock w MCC
682	Renal failure w MCC
314	Other circulatory system diagnoses w MCC
252	Other vascular procedures w MCC
391	Esophagitis, gastroent, and misc digest disorders w MCC
377	G.I. hemorrhage w MCC
853	Infectious & parasitic diseases w O.R. procedure w MCC
193	Simple pneumonia & pleurisy w MCC
371	Major gastrointestinal disorders & peritoneal infections w MCC

Taken together, these findings indicate that patient severity levels – indicative of real case-mix change – have steadily increased from FY 2000 through FY 2007, and that these increases are

generally due to real case-mix change. CMS' conclusion that there was a decline in real case mix is sharply at odds with historical trends suggesting real case-mix growth of 1.2 to 1.3 percent per year. **In fact, CMS did not attempt to measure real case-mix change but instead derived it by comparing overall case-mix growth to its finding that documentation and coding-related increases were 2.5 percent. An alternative approach of comparing the overall CMI growth of 1.9 percent with the historical average for real case-mix change of 1.2 – 1.3 percent would yield a much different documentation and coding effect.**

While CMS states that its observed decline in real case mix from FY 2007 to FY 2008 is due to a relative decline in above-average short-stay surgical cases that can be performed on an outpatient basis, such as certain high-volume pacemaker procedures, analysis shows that this change could not have decreased CMI by as much as CMS indicates. We analyzed the FY 2007 and FY 2008 volume of discharges for above-average short-stay surgical cases that can be performed on an outpatient basis, such as certain high-volume pacemaker procedures. While we found that the volume decreased substantially for some cases, at most, these decreases would have caused a 0.1 percent reduction in CMI, which does not account for the 0.9 percent decrease in CMI that CMS found.

Further, there are other policy changes that could have caused increases in real case mix, and should have mitigated any decrease due to the short-stay surgical cases. For example:

- The implementation of present-on-admission coding is leading hospitals to assess patients for a broader array of conditions. This is likely to result in additional secondary diagnoses being identified, treated and coded, which involves a real increase in resource use and, therefore, real case-mix change.
- The Recovery Audit Contractor program is encouraging hospitals to more carefully scrutinize low-acuity patients and shift care to the outpatient setting to avoid retrospective denial of short-stay admissions. This change in practice will increase the average acuity within each base DRG of patients that remain in the inpatient setting.
- *The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)* changes accelerated beneficiaries moving to Medicare Advantage. Overall, Medicare Advantage has been shown to enroll the healthier segment of the Medicare population, thereby increasing the average acuity level of the population that remains in fee-for-service Medicare.¹
- Effective in calendar year 2008, CMS made dramatic changes in the criteria for procedures that can be done in an ambulatory surgery center, thereby adding hundreds of additional procedure types. We believe that these changes are accelerating the move of lower-acuity patients to the outpatient setting, again resulting in increased acuity in the

¹ See Medicare Payment Advisory Commission, *The Medicare Advantage Program and MedPAC Recommendations*, Testimony before the Committee on the Budget, U.S. House of Representatives, June 28, 2007.

inpatient setting. The majority of ambulatory surgery centers involve physician ownership and self referral, creating a strong incentive for shifts in site of service that did not exist when physicians were deciding between the inpatient and outpatient hospital setting.

As stated above, our analysis found a historical pattern of steady annual increases of 1.2 to 1.3 percent in real case mix, which directly conflicts with CMS' conclusion that there was a decline in real case mix from FY 2007 to FY 2008. Because CMS' conclusion that real case mix declined is an inference based on its analysis of documentation and coding-related increases, we believe that the agency's finding that there were documentation and coding-related increases of 2.5 percent in FY 2008 is incorrect. Further, the reason that CMS has set forth to explain this decline in case mix (that there was a relative decline in above-average short-stay surgical cases that can be performed on an outpatient basis) is not compelling. **We appreciate that CMS neither proposed cuts for documentation and coding changes in FY 2009, nor cuts to recoup the estimated documentation and coding overpayments made in FY 2008. However, the documentation and coding adjustment CMS does propose will have a detrimental effect on hospitals – it will cut \$2 billion for FY 2010 and \$23 billion over 10 years from inpatient prospective payment system (PPS) payments.** This decrease in payment, coming on top of a Medicare payment system that is already severely underfunded, a weak economy, state budget cuts and more, simply cannot be sustained. Given the severity of these cuts, and in light of the fact that our analysis shows real increases in patient severity, **we urge CMS to significantly mitigate its proposed documentation and coding cuts to reflect our findings of real increases in case mix.**

REFINEMENT OF THE MS-DRG RELATIVE WEIGHT CALCULATION

Regression-based Adjustments. The FY 2010 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 last year's inpatient PPS final rule, is the best method of 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 will encourage CMS to drop further consideration of the**

hospital-specific relative value (HSRV) methods of 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.

While RAND found no clear advantage to the HSRV methods of standardization, it stated that its analysis revealed significant limitations in CMS' current standardization method. Specifically, RAND found that the current method "over standardizes" by removing more variability for hospitals receiving certain payment factors than can be empirically supported as being cost-related. CMS stated that, for purposes of standardization only, one option may be to use the empirically justified levels of the payment factors, such that only the cost-related component is removed from the billed charges prior to calculating the relative weights. However, the effect of doing so cannot be predicted without further analysis.

The changes CMS implemented from FY 2007 through FY 2009 represent the most significant changes to the PPS since it was implemented in 1983. In addition to weathering these fluctuations, hospitals have seen the predictability of their payments decline due to the current economic climate and the proposals in this rule. While we appreciate CMS' desire to improve the standardization process and thereby improve the accuracy of the relative weights, FY 2010 will be the first year since FY 2006 that does not include significant change in the payment methodology compared to the prior year. **Therefore, further modifications to the inpatient PPS payment methodology should not be considered at this time.** Rather, hospitals should have several years of stability to allow them to regain their footing and reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions.

Timeline for Revising the Medicare Cost Report. CMS stated that it is comprehensively reviewing the Medicare hospital cost report and plans to issue proposed changes in the future. We agree that a re-examination is warranted. In our FY 2009 inpatient PPS proposed rule comment letter, we stated that comprehensive cost report reform must be conducted in collaboration with the hospital field, but were unaware of CMS soliciting participation from either the AHA or other hospital field representatives. In response to this comment, in this FY 2010 proposed rule, CMS stated that the public will have an opportunity to suggest comprehensive reforms and will be able to make suggestions for ensuring that these reforms are made in a manner that is not disruptive to hospital billing and accounting systems. We are pleased that CMS plans to propose its changes; however, **we continue to be disappointed in the agency's failure to work with the hospital field from the outset on such an important endeavor. In the past, we have suggested that efforts to comprehensively revise or replace the cost report should be mutual and are concerned that such efforts seem to have occurred unilaterally.**

Although the AHA cannot comment on potential revisions to the Medicare cost report, we urge CMS to avoid making piecemeal changes that do not fully align with the current hospital

protocols and reimbursement methodology. Doing so would not help accomplish our mutual goal of improving the accuracy of the cost-based MS-DRG weights.

MS-DRG RECLASSIFICATIONS

Given the recent major changes to the MS-DRGs, it is appropriate for CMS to propose a limited number of MS-DRG classification changes for FY 2010. **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.**

RECALIBRATION OF MS-DRG RELATIVE WEIGHTS

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. **We are pleased that CMS has not proposed any major refinements to its methodology for calculating the MS-DRG relative weights for FY 2010.**

In its description of the methodology used to calculate the MS-DRG relative weights for FY 2010, CMS states that, as in years past, it excluded discharges for Medicare beneficiaries enrolled in Medicare Advantage managed care plans. However, we believe that these discharges were inadvertently included when both calculating the relative weights and analyzing the impact of the rule's proposed changes. **Therefore, we recommend that CMS re-evaluate its calculation to ensure that Medicare Advantage claims are excluded. However, we encourage CMS to continue to include these claims in the MedPAR data set for analysis purposes.**

REBASING AND REVISION OF THE HOSPITAL MARKET BASKET

Since the inpatient PPS was implemented, the projected change in the hospital market basket has been the integral factor by which operating payment rates are updated each year. The projected change in the capital input price index (CIPI) is the integral factor by which capital payment rates are updated each year.

Rebasing and Revising the Inpatient PPS Market Basket. Section 404 of MMA requires CMS to revise the weights used in the hospital market basket every four years to reflect the most current data available. Accordingly, in this rule, CMS proposes to rebase the market basket from FY 2002 to FY 2006, and to revise certain categories and price proxies.

The proposed methodology and data sources yield a projected 2.1 percent increase in the hospital market basket rate, while the historical methodology and data sources yield a projected 2.3

percent increase in the hospital market basket rate. CMS states that this difference is primarily a result of its proposed revision of the proxy used for the chemicals cost category.

We believe that the projected increase in the market basket could be extremely volatile this year. While the country has recently experienced a period of very low inflation, funds from the *American Recovery and Reinvestment Act of 2009* (ARRA) are beginning to work their way into the economy, and we are beginning to see signs of a recovery. We do not know the effect this will have, but a period of inflation could substantially affect the market basket estimate. In addition, the predictability of hospitals' payments has been, and will continue to be, extremely volatile due to CMS' recent reform of the inpatient PPS, the current economic climate and the proposals in this rule. While the MMA requires CMS to revise the weights used in the hospital market basket every four years to reflect the most current data available, it does not require CMS to modify the price proxies used in the market basket calculation. Given that the revision of the proxy used for the chemicals cost category causes the most difference in the market basket compared to the current market basket, **we urge CMS only to rebase the data and weights used in the market basket calculation, and not to revise the price proxies used in the calculation. Doing so will result in a more stable estimate of the increase in the market basket, and will demonstrate forbearance given the economic volatility that has occurred and may be yet to come.**

Labor-related Share. The MMA also requires CMS to revise the labor-related share every four years. For FY 2010, CMS proposes to reduce the labor-related share from 69.7 percent to 67.1 percent due to the use of more recent data, as well as removing a portion of professional fees from the labor-related share. This proposed change, if adopted, would adversely affect hospitals with a wage index greater than 1.0. The labor share for hospitals with wage indices less than 1.0 will remain at 62 percent, as specified in the MMA.

We are concerned about the methodology CMS used to remove a portion of professional fees from the labor-related share. To estimate the proportion of professional fees that are labor-related, CMS surveyed hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market (and are therefore, not labor-related). However, CMS received only 108 responses to its survey. It is statistically impossible for these 108 hospitals, which represent just 3 percent of PPS hospitals, to constitute a representative sample. Further, the agency fails to share data on the characteristics of the hospitals that responded, possible selection bias or survey methodology.

The AHA urges CMS not to use the statistically dubious results of this survey to estimate the proportion of professional fees that are labor-related. Rather, CMS should continue to consider these fees as it has done historically and continue to investigate alternative methodologies for determining the proportion that is labor-related.

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 and 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. The proposed measures include two surgical care measures and two structural measures of participation in clinical database registries.

We appreciate that CMS recognizes the need to minimize the data collection burden for hospitals by limiting the number of new measures that would require chart abstraction to collect the quality measures data. However, we are concerned that CMS appears to select quality measures based on the criteria of what hospitals can feasibly collect and what the agency is capable of accepting. 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 national priorities 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) has agreed 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.

Proposed Quality Measures. Two of the measures put forward by CMS have not been endorsed by the NQF and none has been adopted by the HQA. 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 to focus on that are critical to hospitalized patients 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. In the proposed rule, CMS fails to follow the DRA requirement that chosen measures represent a "consensus among affected stakeholders," as the agency did not propose measures that are endorsed by the NQF and adopted by the HQA. **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 that were recently developed by The Joint Commission. The Joint Commission has spent time examining what makes some measures better than others. It 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.

Although they have been endorsed by the NQF, because they have not been adopted by the HQA, **we do not support the inclusion of the two proposed surgical care measures – postoperative urinary catheter removal on postoperative day 1 or 2 and perioperative temperature management – into the pay-for-reporting program.** With regard to the two structural measures of clinical registry participation – participation in a systematic clinical database registry for stroke care and participation in a systematic clinical database registry for nursing sensitive care – these measures should not be included in the pay-for-reporting program because they are not tightly linked to improving quality and patient care, nor have they been endorsed by the NQF or 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.**

In order to maintain consistency with national consensus standards, for FY 2011, CMS proposes to harmonize the specifications for two measures adopted for the FY 2010 payment determination: PSI 4 – Death among surgical patients with treatable serious complications, and Nursing Sensitive – Failure to rescue. However, CMS states it may continue to report the measures in two different topic areas on the *Hospital Compare* Web site, with both the nursing sensitive measures and Agency for Healthcare Research and Quality patient safety indicators. The proposal to report the same measures on two different sections of *Hospital Compare* highlights a shortcoming of the Web site. Currently, the *Hospital Compare* site is cumbersome to navigate, and the data are displayed in a rigid fashion. Consumers searching for information for use in health care decision-making and hospitals using the site for quality improvement purposes can view the data only in static, pre-designed screenshots.

The *Hospital Compare* site lacks flexibility to create customized reports or to tailor the data display to the end user's needs. CMS notes that the harmonized measure is relevant to both patient safety measures and nursing sensitive measures; however, other measures on *Hospital Compare* also are relevant to multiple health conditions or departments within a hospital. For example, hospitals may wish to examine how well they are performing on delivering care at discharge and, thus, they would want to develop a *Hospital Compare* report that shows their performance on each of the care processes that take place during discharge. We urge CMS to examine how to improve the functionality of the *Hospital Compare* Web site and build more user-friendly capabilities into the site.

The NQF endorsed and the HQA adopted several other measures that CMS did not propose to include for FY 2011. In particular, the NQF endorsed and the HQA adopted two measures of infection rates: surgical site infection and central line catheter-associated blood stream infection. The HQA believes that these measures are ready for public reporting. They have been thoroughly specified, are currently used in other reporting initiatives, are salient to consumers and hold important information that hospitals can use for their quality improvement programs. CMS lists the central line catheter-associated blood stream infection rate measure as a possible measure for FY 2012 or beyond; the surgical site infection rate measure is not listed in the proposed rule. **We urge CMS to reconsider implementing these measures of infection rates as soon as possible.**

Maintenance of Technical Specifications for Quality Measures. We appreciate that CMS asked for comments on how the agency could better inform the public about the periodic changes to quality measures' technical specifications. We believe the QualityNet Web site is a useful tool. One aspect of posting updated technical specifications that can be problematic is that revisions are often made to the specifications right before data collection begins. These last-minute changes cause problems as hospitals finalize their data collection efforts. We suggest CMS share the draft technical specifications with hospitals and data vendors 30 days prior to their release so that any errors or omissions can be identified and corrected before the final version of the specifications is released. This method would reduce the necessity of publishing numerous rounds of revisions.

Program Procedures. Although not proposing major procedural changes to the pay-for-reporting program, the proposed rule specifies many of the program's processes in detail for the first time. The AHA appreciates this specificity. It is helpful for hospitals to have clear direction on both the requirements and the process of the pay-for-reporting program. With the exception of the attestation requirement, the AHA supports the program procedures as outlined in the proposed rule. However, we take issue with the proposed requirement for electronic attestation of the accuracy of the data. This requirement is unnecessary because the accuracy of the data already is assessed through the data validation process, and it adds another layer of administrative burden that could cause confusion among hospitals. Requiring hospitals to attest to the accuracy of their data will not increase the reliability of the data collected for the pay-for-reporting program. Historically, almost all hospitals have passed the data validation requirements, meaning that their

data are found to be accurate and complete. **We suggest that CMS strike the proposed data attestation requirement.**

Program Disaster Extensions and Waivers. The AHA appreciates CMS' recognition that hospitals facing certain disasters, such as a hurricane, should be granted an extension or waiver of the pay-for-reporting program requirements. Although the decision to grant an extension or waiver is best made on a case-by-case basis depending on each hospital's unique situation, we suggest that CMS develop some general criteria for when such extensions or waivers would be granted. We also remind CMS that when a hospital is damaged or destroyed, the agency's usual means of communicating to the hospital, such as over the QualityNet Exchange or by mail, may be impossible. We urge the agency to develop a creative and flexible approach to communicating with hospitals in these situations to ensure that such hospitals are aware of their waivers during difficult times.

Data Resubmission, Validation and Appeals. The proposed rule does not address the issue of data resubmission when a hospital or its vendor becomes aware of an error in the data that was sent for posting on *Hospital Compare*. **The AHA urges immediate adoption of an effective mechanism that allows hospitals and their vendors to resubmit quality measure data if they discover an error.** The point of public reporting is to put accurate and useful information into the hands of the public, and this is facilitated by allowing known mistakes to be corrected.

In the rule, CMS proposes a new process for validating hospitals' quality data beginning in FY 2012. Unlike the current process, which involves the review of a small number of medical charts from all hospitals, the proposed process would audit a larger number of charts from a randomly selected sample of hospitals. For the FY 2012 payment determination, CMS proposes to review 12 medical charts each quarter from 800 hospitals randomly selected each year from among all hospitals with at least 100 eligible patient cases. The review would assess the accuracy of the hospital's measure rate, as opposed to the accuracy of the individual data elements. **CMS' proposed process holds promise as a reasonable approach to ensure the accuracy of the quality data and improve upon the deficiencies in the current validation process.**

It is appropriate to focus on the hospital's measure rate, as opposed to individual data elements, because the measure rate captures the information that is truly important to patient care. For data validation in the current program, there have been several instances in which a mismatch between single data elements unrelated to the quality of care provided by a hospital, such as the patient's birth date, have caused hospitals to fail validation. Validating the hospital's measure rate should eliminate these unfortunate incidents.

The burden to hospitals will be reduced if they do not have to submit records for validation every year. However, because hospitals will be selected at random each year, there is no guarantee that a hospital selected in one year will not be selected in the following year as well. We urge CMS to refine the validation selection process so that hospitals selected for validation in one year are not eligible for selection again until two years later. Alternatively, CMS could ensure that no hospital is selected more than two times within a five-year period. This will help guarantee that

a particular hospital is not disproportionately burdened by the selection process. In addition, CMS should consider allowing hospitals that pass validation with a very high score to receive a “pass” from the validation process for several years. Such a policy would encourage hospitals to ensure their data are as accurate as possible and reward those hospitals with high accuracy rates.

We appreciate that CMS plans to send two certified letter requests for medical records for data validation in case the hospital does not receive the first letter. We suggest that CMS contractors also place phone calls to hospitals that do not respond to the first letter to ensure that every effort is made to communicate the request to the appropriate staff in the hospital.

To pass validation, CMS proposes that hospitals meet a minimum of 75 percent reliability from the chart validation instead of the 80 percent match rate currently used. We support setting a slightly lower validation threshold for the beginning years of the new validation process as hospitals and CMS gain experience with the new system. Again, we are generally pleased with CMS’ proposal for the changes to the data validation process, and we urge the agency to continue to refine the plan put forward in the proposed rule.

With regard to the appeals process, we support CMS’ proposal allowing hospitals to submit their paper medical records for re-abstractation when they submit an appeal involving data validation. This process will give hospitals that believe the results of their data validation testing were inaccurate an opportunity to have their data re-abstracted.

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 a 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 PPS final rule, CMS adopted eight conditions for which it would no longer pay a higher 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 hospital-acquired conditions. Rather, the agency focuses on evaluating the impact to date of the hospital-acquired conditions policy. We support CMS’ evaluation of the policy and believe that a robust program evaluation should be conducted before CMS considers adding any more hospital-acquired conditions. In its evaluation, we encourage CMS to explore how information learned from present-on-admission coding could be used to better understand and prevent certain hospital-acquired conditions. Improving care for patients should be the end goal of this policy. We urge CMS to use any information learned from the evaluation to examine ways that care can be improved.

Payment Changes Based on Present-on-Admission Coding. The payment changes for hospital-acquired conditions apply only when the selected conditions are the only CCs or MCCs present on the claim that cause the patient to be assigned to a higher MS-DRG. Under this policy, CMS does not make higher payments for the selected conditions if they are coded as not present on admission 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, the reporting of present-on-admission indicators is still new, and hospitals continue to learn how to apply them, as well as educate their physicians on the required documentation without which present-on-admission reporting is impossible. **We urge CMS to reverse its position and pay for hospital-acquired conditions coded with the “U” indicator.**

Other Technical Clarifications. The AHA requests that CMS clarify how hospitals may appeal a decision under which a particular patient falls under the hospital-acquired conditions 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 indexes, was published immediately after the FY 2010 proposed rule. Thus, we would like to take this opportunity to describe some of the hospital field’s fundamental concerns with Acumen’s recommendation.

Acumen stated that the methods recommended by MedPAC for changing the wage index represent an improvement over existing methods, and recommended using wage data from the Bureau of Labor Statistics (BLS) so that the MedPAC approach can be implemented. While Acumen acknowledges that there are challenges and limitations involved with using BLS data, it still believes that these data should be used. **However, the hospital field continues to have significant concerns about using BLS data and urges CMS to move forward cautiously.** Detailed comments on our key concerns about the BLS data can be found in our comment letter on the FY 2008 inpatient PPS proposed rule. In brief, these serious shortcomings include:

- The BLS data have wage data for a particular occupation from *all employers*, not just short-term, acute-care hospitals participating in Medicare. Wage rates, however, vary depending on the type of employer and the mix of employers by market.

- Wages paid by companies that offer temporary employees to health care providers are included in the BLS sample. However, their wages reflect the lower rate that the employees are paid *by* the agency as opposed to what hospitals pay *to* the agency for the contract workers. In addition, there are employee wages included in the current CMS data that are not included in the BLS data, such as Part A physicians' time unrelated to medical education.
- Unlike CMS' public process for review and correction of wage data at the hospital level, BLS has a strict confidentiality policy – hospitals would be unable to verify the accuracy of the data.
- Every six months, BLS surveys 200,000 establishments (“a panel”), building the full sample of 1.2 million unique establishments over a three-year period. These data are inflated to a certain month and year using a “single national estimate” of wage growth for broad occupational divisions. This approach fails to account for any differences in wage growth between markets over the three-year period.
- While CMS collects wage data for a 12-month period, the BLS survey captures only two payroll periods per year, each capturing data from one-sixth of the total number of sampled establishments.
- Because BLS data do not contain information on employee benefits, MedPAC used benefit data from hospital, home health agency and skilled-nursing facility cost reports, which negates the potential benefit of eliminating the collection of hospital-specific wage data.
- BLS excludes shift differentials, overtime pay and jury duty – all of which CMS includes.
- Full- and part-time employees are equally weighted in BLS' data.
- Estimates using a sampling methodology like the BLS approach are subject to sampling error and will be less reliable than using the entire universe of PPS hospitals, as CMS does.

Reclassification Average Hourly Wage Comparison Criteria. Each year, many hospitals apply for reclassification to another geographic area to receive a higher wage index. In its FY 2009 final rule, CMS re-evaluated the average hourly wage (AHW) criteria for reclassification for the first time since they were established in FY 1993. Based on this analysis, CMS changed the AHW criteria. For FY 2009 reclassifications, an urban hospital needed an AHW that was 84 percent of the area to which it wants to reclassify. For FY 2010 reclassifications, this percentage increased to 86 percent and for FY 2011 and beyond, it will be 88 percent. For FY 2009 reclassifications, a rural hospital needed an AHW that was 82 percent of the area to which it

wants to reclassify. For FY 2010 reclassifications, this percentage increased to 84 percent and for FY 2011 and beyond, it will reach 86 percent.

We oppose this policy, as outlined in our comment letter on the FY 2009 inpatient PPS proposed rule. Although CMS went forward with its proposal, **the AHA continues to oppose recalibration of the AHW criteria, which raises the threshold for reclassification, thereby making it more difficult for hospitals to qualify. Making these revisions without including additional funding simply moves the system's deficiencies around, rather than eliminating them. Instead, we urge the agency to continue its study of the wage index in favor of future changes that create a more equitable system and adequately reimburse hospitals for providing quality care to beneficiaries.**

Budget-Neutrality Adjustment for the Rural and Imputed Floors. By law, the wage index for a hospital in an urban area of a state cannot be less than the wage index for a hospital in the rural area of a state. In addition, in 2006 CMS temporarily adopted an "imputed" rural floor measure by establishing a wage index floor for those states that did not have rural hospitals. For FY 2009, CMS finalized a policy to apply a statewide (rather than a nationwide) rural floor and imputed rural floor budget-neutrality adjustment to the wage index, with a three-year transition. For FY 2010, CMS proposes to continue with the second year of this transition and use a wage index that will reflect 50 percent statewide budget neutrality and 50 percent nationwide budget neutrality.

In our comment letter on the FY 2009 inpatient PPS proposed rule, we outlined our opposition to this policy. Although CMS went forward with its proposal, **the AHA continues to oppose applying budget neutrality on a statewide basis.** CMS stated that the intent of the rural floor is to afford some measure of protection to urban-rural states; it created the imputed rural floor to do the same for all-urban states. However, despite the fact that these floors affect only certain states, they are nationwide policies that exist in a nationwide payment system. Applying budget neutrality on a nationwide basis minimizes the policy's impact on payments and results in all hospitals in the nation funding a national policy. In contrast, applying budget neutrality on a statewide basis maximizes the policy's impact on the payments of a few hospitals, and results in several states funding a national policy. **Accordingly, we urge CMS to withdraw this policy and again apply rural floor budget-neutrality adjustments on a nationwide basis.**

In addition, CMS states that when it calculates the wage index that reflects 50 percent statewide budget neutrality and 50 percent nationwide budget neutrality, it does not necessarily result in overall budget neutrality to the system. Therefore, on page 24243 of the rule, CMS states that it applies an additional budget-neutrality factor of 1.00016. However, on page 24663 of the rule, CMS states that this same additional budget-neutrality factor is 1.000017. We request that CMS clarify what the additional budget-neutrality factor related to the rural floor is.

Further, in FY 2008 CMS began applying the rural floor budget-neutrality adjustment to the wage index, rather than the standardized amount. When CMS began applying the rural floor budget-neutrality adjustment to the wage index, it made a positive budget-neutrality adjustment

to the standardized amount that was intended to reverse the FY 2007 standardized amount budget-neutrality adjustment.

We are very concerned that, despite repeated requests, CMS has not also made a positive budget-neutrality adjustment to reverse the FY 1999 through FY 2006 standardized amount budget-neutrality adjustments for the rural floor. Not doing so cost hospitals about \$2.6 billion from FY 1999 through FY 2009. We are particularly concerned about this error given the level of payment CMS proposes for FY 2010. Specifically, not only will there not be an increase in Medicare's payments to hospitals for FY 2010, but these payments are projected to *decrease* by almost \$1 billion in FY 2010 compared to FY 2009. If CMS would fix this past \$2.6 billion error and restore these funds for FY 2010, hospitals would at least see a small increase in overall payments. Given these tough economic times, as well as the fact that MedPAC projects that overall Medicare hospital margins will reach *negative* 6.9 percent in FY 2009, such a small increase would provide some relief and allow hospitals to better serve their communities. **Accordingly, the AHA urges CMS to remove the compounding effect of applying the rural floor and budget-neutrality adjustment to the standardized amount annually in years past and restore these \$2.6 billion in funds to hospitals. If CMS will not restore these funds, we urge the agency to, at the very least, remove the FY 1999 through FY 2006 rural floor budget-neutrality adjustments from the standardized amount for FY 2010 and beyond.** This will ensure the base rate is accurate on a prospective basis.

Core-based Statistical Areas for the Hospital Wage Index. In the proposed rule, CMS states that the Office of Management and Budget has announced that three Micropolitan Statistical Areas now qualify as Metropolitan Statistical Areas (MSAs). Consequently, as of FY 2010, the hospitals in these areas will be designated as urban instead of rural. According to our data, this will cause three critical access hospitals (CAHs) to lose their CAH status and be forced to convert to PPS hospitals. We believe it is *essential* that these facilities maintain their CAH status. Even though they may no longer be located in "rural" counties, their physical location has not changed and these areas still have health care access concerns that can be adequately addressed only by protecting the local hospital's CAH status. Further, in this proposed rule, CMS does not appear to recognize the impact of the new MSA designations on these CAHs. Specifically, we do not believe that CMS is forecasting that these hospitals will become part of the PPS on October 1, as they are not included in the FY 2010 PPS impact file.

This same problem presented itself in FY 2005 when revisions to the MSAs were made. In response to comments, CMS provided special treatment for these facilities by modifying section 412.103 and section 485.610 of the regulations. Specifically, the agency allowed CAHs that were located in counties that were considered rural in FY 2004, but urban in FY 2005, to maintain their CAH status through either FY 2006 or when the CAH obtained a rural designation under section 412.103. These facilities were allowed to continue participating as CAHs and were not required to convert to PPS hospitals unless they were unable to obtain a rural designation under section 412.103 by the end of FY 2006 (see 69 *Federal Register* 49221).

The AHA urges CMS to exercise executive discretion again to allow continued CAH status for facilities that have CAH status in one year, but are located in counties that will be considered urban in the next year due to MSA revisions. We ask that CMS take the same approach that it did for FY 2005, but make the provisions permanent so that the agency does not have to address this issue each time MSA revisions affect CAHs. To do so, CMS would need to revise section 485.610(b)(3) to delete references to specific dates and instead incorporate general language to allow CAHs that have CAH status in one year, but are located in counties that will be considered urban in the next year, to retain their status for two fiscal years. CMS also would need to revise section 412.103(a)(4) to delete references to specific dates and instead incorporate general language to allow CAHs that have CAH status in one year, but are located in counties that will be considered urban in the next year, to have two years to be reclassified as rural.

CAPITAL INPATIENT PPS

Medicare is required to pay for the capital-related costs of inpatient hospital services. These costs include depreciation, interest, taxes, insurance and similar expenses for new facilities, renovations, expensive clinical information systems and high-tech equipment (e.g., MRIs and CAT scanners). This is done through a separate capital PPS. Under the capital inpatient PPS, capital payments are adjusted by the same MS-DRGs for each case, as are used in the operating PPS. Capital PPS payments also are adjusted for indirect medical education (IME), disproportionate share hospital and outlier payments.

In the FY 2008 final rule, CMS made two changes to the structure of payments under the capital PPS. First, the agency eliminated the 3.0 percent additional payment provided to hospitals located in large urban areas. Second, the agency adopted a policy to eliminate the IME adjustment to teaching hospitals. In FY 2009, teaching hospitals were to receive half their capital IME adjustment, and in FY 2010 and beyond, the adjustment was to be eliminated. Subsequently, the ARRA prevented the FY 2009 cut; however, in this rule, CMS announced that it will continue with its plans to eliminate the adjustment in FY 2010.

CMS' elimination of the add-on payment for hospitals in large urban areas reduced payments to hospitals by \$600 million from FY 2008 through FY 2012. **Elimination of the IME adjustment will reduce payments to teaching hospitals by an additional \$350 million in FY 2010 and \$1.8 billion over five years. These cuts are based solely on the discretion of the administration with no congressional direction and are unprecedented.** We are particularly concerned about these cuts given the level of payment CMS has proposed for FY 2010. Specifically, not only will there not be an increase in Medicare's capital payments to hospitals for FY 2010, but these payments are projected to *decrease* by 4.8 percent – or almost \$400 million – in FY 2010 compared to FY 2009. However, if CMS would reverse this cut to the capital IME adjustment, this decrease in payment would be substantially mitigated. According to MedPAC, overall Medicare margins for teaching hospitals were 1.1 percent in FY 2007, and the commission projects that overall Medicare hospital margins will continue to decline in FYs 2008 and 2009. Teaching hospital margins will likely be negative or barely positive in FY 2009.

Given these margin projections, as well as these challenging economic times, mitigating these cuts would provide much needed relief and allow hospitals to better serve their communities. **Accordingly, the AHA urges CMS to reverse its elimination of the capital IME adjustment and restore these payments that are vital to hospital investments in the latest medical technology, ongoing maintenance and improvement of hospitals' facilities and medical education.**

GRADUATE MEDICAL EDUCATION PAYMENTS

The rule proposes to “clarify” the definition of new medical residency training programs for the purposes of determining Medicare payments. With limited exceptions, the *Balanced Budget Act of 1997* capped the number of residents that Medicare will recognize for direct graduate medical education (DGME) and IME at a teaching hospital’s 1996 level. An adjustment to this cap is allowed for hospitals that establish new medical residency training programs.

Current regulations define a new program as “a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.” In this proposed rule, however, CMS states that even though an accrediting body (such as the Accreditation Council on Graduate Medical Education) grants an “initial” accreditation, or reaccredits a program as “new,” it is not necessarily sufficient for CMS to consider the program new and thus increase the hospital’s resident cap. CMS states that the residency program must be accredited “for the first time,” and not be a program that existed previously at the same or another hospital. The agency indicates that a hospital must now itself evaluate whether its program is “new” for Medicare purposes, and not rely on a determination made by an accrediting body. Further, CMS now will evaluate whether a program is truly new by looking beyond an accreditation decision to other “supporting factors,” which include, but are not limited to, whether the new program has a new program director, new teaching staff and new residents.

CMS’ proposed change is not a “clarification,” but a major change to long-standing agency policy. The agency is specifying new criteria that hospitals will need to meet in order for a residency program to qualify as “new.” While CMS is not changing the regulatory language, the agency is changing the meaning of that language. Medical residency training programs will no longer be able to qualify as new by meeting the literal wording of the regulation (initial accreditation by the appropriate accrediting body); instead, they will have to meet new and ambiguous criteria in the form of “supporting factors.”

The new policy will result in less clarity, given that determination of a new program will be based on a variety of characteristics rather than a clear and concise determination by an accrediting body. What if a new program has new teaching staff and new residents but the same program director? Will CMS consider the program to be new or existing? These “supporting factors” will lead to subjective determinations, making it difficult for hospitals to know up front whether their programs will be eligible for Medicare funding. This approach offers hospitals

little reassurance that a program established and approved by CMS one year will continue to qualify as a new program by CMS in future years.

This policy change may be applied retroactively. By indicating that this is a “clarification” in policy, we are concerned that CMS is retroactively imposing its new interpretation of “supporting factors” to deny current hospitals – who in good faith complied with the existing regulations and who have been appropriately receiving Medicare DGME and IME payments – from establishing a residency cap by initiating programs that meet the definition of “new.”

The AHA recommends that CMS establish a definitive, prospective process whereby hospitals will know up front whether a new residency program qualifies as “new” and, thus, is eligible for Medicare DGME and IME funding. Congress established the inpatient *prospective* payment system so that hospitals would be paid a predetermined, specific rate, and so that hospitals could determine up front what payments they would receive for Medicare patients. **We strongly urge CMS to withdraw this confusing, arbitrary, retrospective “clarification” as to what constitutes a new medical residency program.**

MEDICARE-DEPENDENT AND SOLE COMMUNITY HOSPITALS

Under the inpatient PPS, certain payment protections are provided to Medicare-dependent hospitals (MDHs) and sole community hospitals (SCHs). MDHs are paid the highest of their PPS payments plus 75 percent of the difference between their PPS payments and their hospital-specific rate from 1982, 1987 or 2002, adjusted for inflation, for their inpatient operating costs. SCHs are paid the highest of their PPS payments or their hospital-specific rate from 1982, 1987, 1996 or 2006, adjusted for inflation, for their inpatient operating costs.

When calculating the hospital-specific rates and determining the associated payment, CMS takes several steps:

1. CMS determines a hospital’s cost per discharge by dividing its total costs for the base year by its total discharges for the base year.
2. CMS adjusts this cost per discharge for case mix by dividing it by the hospital’s average DRG relative weight for the base year. This yields a base-year hospital-specific rate.
3. CMS updates this base-year hospital-specific rate to the current year by applying the inpatient PPS market basket updates and budget-neutrality factors for each year from the base year through the current year. In the inpatient PPS, CMS applies these budget-neutrality factors, which ensure that DRG reclassifications and recalibration of the relative weights are budget neutral, to the standardized amount. However, the standardized amount is not used when determining payments based on hospital-specific rates. Therefore, it is necessary to separately apply these factors to the hospital-specific rates to ensure budget neutrality for reclassifications and recalibration.

4. Finally, once CMS has calculated the current-year hospital-specific rate, it determines the payment for each discharge by multiplying that rate by the relative weight of the discharge.

In this rule, CMS states that it will apply a cumulative, retroactive budget-neutrality adjustment to FY 2002-based MDH hospital-specific rates. Specifically, it will apply budget-neutrality factors from FYs 1993 through 2002, which had not previously been built into these rates. The agency will not retroactively adjust MDH payments, but will apply this new adjustment for discharges occurring on or after October 1, 2009. As a result, FY 2002-based MDH hospital-specific rates are lowered by 1.7 percent, affecting 50 MDHs and cutting their payments by approximately \$6 million in FY 2010.

Further, in instructions to its fiscal intermediaries (FIs), CMS applies retroactive budget-neutrality factors from FYs 1993 through 2006 to the FY 2006-based SCH hospital-specific rates. This policy lowers FY 2006-based SCH hospital-specific rates by 2.3 percent, affecting all 228 SCHs and cutting their payments by approximately \$81 million in FY 2010.

While CMS states that application of these retroactive budget-neutrality factors is necessary to meet the statutory requirement that DRG reclassification changes and recalibration of relative weights are budget neutral, we believe this is incorrect.

- In calculating the 2002 MDH hospital-specific rates, the cost per discharge is divided by the hospital's 2002 average DRG relative weight (see step 2 above).
- This average weight has not been adjusted for budget neutrality because budget-neutrality factors are applied to the standardized amount, not to the weights (see step 3 above).
- CMS states that, in total, the budget-neutrality factors from 1993 through 2002 reduced payments by 1.7 percent; therefore, since the 2002 weights have not been adjusted for these factors, they are 1.7 percent higher than they would have been. In calculating 2003 payments (for example), the hospital-specific rate is multiplied by the 2003 relative weights (see step 4 above), which have not been adjusted for budget neutrality either.
- In total, the retroactive budget-neutrality factors from 1993 through 2003 reduced payments by about 2.5 percent; therefore, since the 2003 weights have not been adjusted for these factors, they are 2.5 percent higher than they would have been.

Since CMS divides by the 2002 average DRG relative weight, which is 1.7 percent higher than it would have been, and then multiplies by the 2003 average DRG relative weight, which is 2.5 percent higher than it would have been, the 1.7 percent mathematically cancels out. An additional 0.8 percent does not mathematically cancel out, but CMS considers this when it applies the inpatient PPS market basket updates and budget-neutrality factors for each year from the base year through the current year (see step 3 above). Since the 1.7 percent cancels out, if

CMS separately applies another 1.7 percent reduction, as it states it will, it doubles the impact of the budget-neutrality adjustments and unduly penalizes these hospitals.

In addition, eventually over time, the retroactive budget-neutrality factors will total 100 percent. When this occurs, their application to the hospital-specific rates will yield rates of \$0. This again demonstrates that applying a cumulative retroactive budget-neutrality adjustment is not correct and, further, cannot be consistent with what the Congress intended when rebasing the hospital-specific rates.

Applying cumulative retroactive budget-neutrality adjustments to the hospital-specific rates is not necessary to ensure that MS-DRG reclassification changes and recalibration of the relative weights are budget neutral. **We request that CMS reverse its decision to apply a cumulative, retroactive budget-neutrality adjustment to FY 2002-based MDH hospital-specific rates. We also request that CMS revise its instructions to the FIs on calculating the FY 2006-based SCH hospital-specific rates so that these rates do not include a cumulative, retroactive budget-neutrality adjustment. Application of these adjustments is mathematically incorrect and improperly cuts operating payments to almost 300 MDHs and SCHs by about \$90 million in FY 2010.**

We are particularly concerned about these substantial cuts given the level of payment CMS proposes for FY 2010. Specifically, not only will there not be an increase in Medicare's operating payments to MDHs and SCHs for FY 2010, but these payments are projected to *decrease* by 0.1 percent for MDHs and 2.3 percent for SCHs – or about \$75 million total – in FY 2010 compared to FY 2009. However, if CMS were to reverse the incorrect application of these retroactive budget-neutrality adjustments, these hospitals would at least see a small increase in overall payments in FY 2010. Given these difficult economic times, as well as the fact that MedPAC has projected that overall Medicare hospital margins will reach *negative* 6.9 percent in FY 2009, doing so would provide some much needed relief and allow MDHs and SCHs to better serve their communities.

HOSPITALS EXCLUDED FROM THE PPS

Payment for Clinical Diagnostic Laboratory Tests Furnished by CAHs. *The Medicare Improvements for Patients and Providers Act of 2008* provided that clinical laboratory services furnished by a CAH would be reimbursed 101 percent of costs, regardless of whether the patient is physically present in the CAH at the time the specimen is collected. To implement this provision, CMS proposes that CAHs receive 101 percent of costs for clinical laboratory services, as long as the patient is receiving services directly from the CAH. For these purposes, the patient is considered to be receiving services directly from the CAH if the patient received outpatient services in the CAH on the same day the specimen was collected or if the specimen was collected by an employee of the CAH. In either case, the individual would not need to be physically present in the CAH at the time the specimen was collected. If the patient is physically

present in the CAH or a facility that is provider based to the CAH at the time the specimen is collected, neither of the above two conditions needs to be met.

We support CMS' proposed implementation of this provision, but ask that the agency clarify two aspects of its proposal. First, we ask CMS to explicitly state that if the patient for which the laboratory services are performed is in a facility that is *not* provider based to the CAH, the CAH will still receive 101 percent of costs for these services, as long as the patient received outpatient services in the CAH on the same day the specimen was collected or an employee of the CAH collected the specimen. Second, we request CMS state explicitly that employees of CAHs' provider-based facilities are considered employees for purposes of this policy. That is, we would like clarification that CAHs will still receive 101 percent of costs for clinical laboratory services if the specimen was collected by an employee of a CAH's provider-based facility. We believe there is potential for confusion on these aspects of the policy.

CAH Optional Method of Payment for Outpatient Services. CMS proposes to change the manner in which "Optional Method" or "Method 2" payments to CAHs are made. Currently, under Method 2, CAHs are reimbursed 101 percent of their costs for outpatient CAH services and 115 percent of the allowable amount under the Medicare Physician Fee Schedule for professional services. However, CMS indicates that the statute calling for these payments does not specify that CAHs be reimbursed *101 percent* of their reasonable costs for outpatient services. Therefore, the rule proposes to reimburse CAHs electing Method 2 at 100 percent of their reasonable costs for outpatient CAH services instead of at 101 percent of their reasonable costs for outpatient services.

This proposed change to Method 2 payments goes directly against the intent of Congress. Section 405(a) of MMA increased CAH reimbursement for outpatient services from 100 percent to 101 percent of reasonable costs. While the statutory language of the MMA erroneously did not specify that CAHs electing Method 2 also should be reimbursed 101 percent of reasonable costs, the accompanying conference report makes it abundantly clear that it was Congress' intent to do so. Specifically, in summarizing the present law, the conference report references both types of payment methods, stating that CAHs may elect either "cost-based hospital outpatient service reimbursement or an all-inclusive rate, which is equal to a reasonable cost reimbursement for facility services plus 115 percent of the fee schedule payment for professional services." In summarizing the conference agreement, the report more generally refers to CAH payments, stating that "outpatient...services provided by a CAH will be reimbursed at 101 percent of reasonable cost." The summary of present law draws a distinction between the traditional method of payment and Method 2, but the summary of the conference agreement does not – making it clear that the conference agreement applies to both methods of payment.

In addition, we are disappointed that CMS did not conduct a financial impact analysis of this proposed change. When CAHs elect Method 2, they must notify their FIs or Medicare administrative contractors (MACs) of their decision. Given that the FIs and MACs are CMS contractors, the agency could have obtained this information in a timely manner and performed a thorough impact analysis. On behalf of the AHA, the state hospital associations contacted the

FIs and MACs after the release of the proposed rule and asked them for a list of the Method 2 CAHs in each state. We received timely and detailed responses, which indicate that the vast majority of CAHs elect Method 2 payment. For example, 88 percent of the CAHs in Iowa, 71 percent of the CAHs in Kansas, and 86 percent of the CAHs in North Dakota have elected to be paid under Method 2.

Based on this information, the AHA estimates that CMS' proposal will cut payments to CAHs by \$22 million in FY 2010 – an enormous impact for these small hospitals. **Given that the impact of this proposal is so large for these small hospitals, we urge CMS to withdraw its proposed change to CAH Method 2 payments. If the agency wants to move forward with this proposal, we urge it to both set forth its own detailed and thorough impact analysis and re-issue its proposed change in the inpatient PPS final rule to again solicit comments that will be informed by the results of CMS' impact analysis. Unless this occurs, the public will be lacking information that is critical for them to adequately comment on this proposal.**

Further, if CMS is unwilling to withdraw its proposed change to CAH Method 2 payments, it must specify the effective date of its proposed change. To allow CAHs adequate time to evaluate their circumstances and make an informed decision as to whether or not to elect Method 2 payments, the effective date should be no earlier than cost reporting periods beginning on or after January 1, 2010.

Provider-based Status for CAH-based Clinical Diagnostic Laboratory Facilities. In the rule, CMS proposes to require facilities furnishing only clinical diagnostic laboratory tests that operate as part of a CAH to meet applicable provider-based criteria in order for the CAH to be paid for the services furnished at those facilities at 101 percent of reasonable costs. If these facilities were subject to provider-based rules, they would have to meet the distance requirement that is applicable to CAHs – that is, they would have to be located more than 35 miles from a hospital or another CAH (or more than 15 miles in areas with mountainous terrain or only secondary roads).

This distance requirement is problematic. Specifically, hospitals that are deemed as CAHs using the “necessary provider” provision are not required to meet CAH distance requirements and are therefore less than 35 (or 15, if applicable) miles from another hospital. However, for a laboratory facility to obtain provider-based status, it must be 35 (or 15) miles from another hospital. Therefore, a facility that is on the campus of a “necessary provider” CAH would be unable to meet this distance requirement and unable to obtain provider-based status and receive cost-based reimbursement. As a result, these facilities may close, decreasing beneficiary access to these essential services.

In addition, any CAH provider-based department that was established after January 1, 2008 must be 35 (or 15) miles from another hospital. However, because laboratory facilities were not previously subject to provider-based rules, CAHs may have established facilities after January 1, 2008 that do not meet this distance requirement, and thus would be unable to receive cost-based reimbursement.

Therefore, we oppose requiring laboratory facilities that operate as part of a CAH to meet applicable provider-based criteria in order for the CAH to be paid for the services furnished at those facilities at 101 percent of reasonable costs and urge CMS to drop any further consideration of this requirement. If the agency does choose to move forward with its consideration of this requirement, we urge CMS to recognize the conflicts this change would create and allow CAH laboratory facilities that otherwise meet the provider-based rules and were operating in their current location prior to FY 2010, or were under development at that time, to be granted provider-based status without regard to the 35 (or 15) mile requirement.

CMS also must specify an effective date of the proposal. To allow CAHs adequate time to obtain provider-based status without receiving payment cuts in the form of lab fee schedule payments, the effective date should be no earlier than cost reporting periods beginning on or after October 1, 2010.

Provider-based Status for CAH-based Ambulance Services. In the proposed rule, CMS solicits comments on whether an ambulance service that is owned and operated by a CAH and is eligible to receive reasonable cost-based reimbursement should be required to meet provider-based status rules. CMS states that CAH-owned and -operated ambulance services already must meet distance requirements in order to receive reasonable cost-based payment but, under provider-based status rules, also would have to demonstrate that the ambulance services are integrated with the CAH.

The Social Security Act states that cost-based reimbursement is provided for “...ambulance services if such services are furnished (A) by a critical access hospital (as defined in section 1861(mm)(1)), or (B) by an entity that is owned and operated by a critical access hospital, but only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such critical access hospital.” Current CMS regulations follow these provisions exactly in that the law does not require provider-based status for cost-based reimbursement. In fact, by allowing cost-based reimbursement for ambulance services furnished by an entity that is owned and operated by a CAH, Congress is specifically allowing cost reimbursement in a situation that very likely *would not meet provider-based rules*. For CMS to require provider-based status for ambulance services that are owned and operated by a CAH and are eligible to receive reasonable cost-based reimbursement is contrary to the clear wording of the law and congressional intent.

In addition, we note that while CAH-owned and -operated ambulance services do have an existing distance requirement as CMS states, these providers would have to meet an additional distance requirement if they were subject to provider-based rules. Specifically, to receive reasonable cost-based reimbursement, an ambulance service must currently be the only provider of ambulance services within a 35-mile drive of the CAH. However, if an ambulance service is subject to provider-based rules, it also would have to meet the distance requirements of the CAH. That is, it would have to be located more than 35 miles from a hospital or another CAH (or more than 15 miles in areas with mountainous terrain or only secondary roads).

This additional distance requirement is problematic. For example, hospitals that are deemed as CAHs using the “necessary provider” provision do not have to meet CAH distance requirements and are therefore less than 35 (or 15, if applicable) miles from another hospital. However, if an ambulance service is subject to the provider-based rules, it would have to be 35 (or 15) miles from another hospital. An ambulance service that is on the campus of a “necessary provider” CAH would not be able to meet this distance requirement and therefore would not be able to receive cost-based reimbursement. Due to the extremely high capital costs of ambulance services and the extremely low volume that is commensurate with these small hospitals, ambulance fee schedule payments are generally inadequate for CAH-owned and -operated ambulance services. These services are typically not viable unless they receive cost-based reimbursement. Therefore, many ambulance services that are owned and operated by “necessary provider” CAHs will likely close, decreasing beneficiary access to these vital services.

Such a provision also is problematic for CAHs that own ambulance services that are off-campus and are the only service within 35 miles of the CAH, but for which the service is less than 35 (or 15) miles from another hospital. If ambulance services are subject to provider-based rules, the CAH would receive the ambulance fee schedule amount for these ambulance services. Again, because CAH-owned and -operated ambulance services are typically not viable unless they receive cost-based reimbursement, CAHs in this situation will likely close such a service, again decreasing access to this vital service. The same result will occur if a CAH is looking to acquire a struggling ambulance service – if the service is less than 35 (or 15) miles from another hospital, the CAH likely will be unable to acquire it and it will close, decreasing access to this important service.

Even if CMS were to grandfather existing CAH-owned and -operated ambulance services into the new policy, this would still create potential access problems over time. Our members and state hospital associations report that many ambulance services operated by CAHs are located in buildings that are aging and in need of repair or replacement. However, if ambulance services are subject to provider-based rules, a CAH ambulance service that moves into a new building after January 1, 2008, will have to be 35 (or 15) miles from another hospital, even if that other hospital did not operate an ambulance service.

For these reasons, requiring ambulance services that are owned and operated by a CAH and are eligible to receive reasonable cost-based payment to meet provider-based status is not appropriate. The existing 35-mile ambulance-related distance requirement meets the requirements of the law and is more than adequate to ensure that only appropriate ambulance services receive cost-based reimbursement. Therefore, we urge CMS to drop any further consideration of this requirement.

NEW TECHNOLOGY

Section 503 of the MMA 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 2009, the agency only approved 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.**

CHANGES TO THE EMTALA WAIVER AUTHORITY IN PUBLIC HEALTH EMERGENCIES

CMS proposes to refine current regulations allowing waivers in a public health emergency of certain sections of the *Emergency Medical Treatment and Labor Act* (EMTALA). Specifically, CMS proposes that waivers of EMTALA sanctions may be limited in their application to one or more hospitals in a portion of an emergency area or a portion of an emergency period. In addition, CMS sanctions would be waived only if the hospital did not discriminate based on the source of an individual's payment or ability to pay. Finally, the proposed rule provides that waiver of EMTALA sanctions for inappropriate transfers would apply only if the transfer arises out of the circumstances of the emergency.

The AHA supports CMS' intent to ensure that the regulations more accurately reflect the language of the *Social Security Act*. We agree that waiver of EMTALA sanctions would only apply if the transfer did not discriminate based upon insurance status. We further agree that it would be useful to make explicit that CMS has the authority to target EMTALA waivers to only those hospitals that need this flexibility due to the circumstances of the emergency and its impact on individual hospitals or groups of hospitals. We believe that such authority should enable the Secretary to make the decision to waive EMTALA sanctions in a more expeditious manner when a public health emergency is declared. The AHA, along with state, regional and metropolitan hospital associations, works closely with local public health authorities and is able to rapidly assess which facilities would need such flexibility.

Waiver of Sanctions for Inappropriate Transfers. The AHA is concerned that the new regulatory language waiving EMTALA sanctions for inappropriate transfers is inconsistent with congressional intent and will be interpreted too narrowly to be useful for hospital emergency response in a public health emergency. To address this, **we recommend that the regulatory language more closely mirror the language in the *Social Security Act*.**

CMS proposes that EMTALA sanctions would not apply "if relating to an inappropriate transfer, the transfer arises out of the circumstances of the emergency." This could be interpreted to mean

that the waiver would apply only to the transfer of a patient whose emergency medical condition is the direct result of the public health emergency.

CMS' proposed language reflects a much narrower and distinctly different emphasis than the *Social Security Act* provision that generated the change. Section 1135(b)(3) of the act states that the Secretary may temporarily waive sanctions under EMTALA for "a transfer of an individual who has not been stabilized in violation of subsection (c) of such section if the transfer is necessitated by the circumstances of the declared emergency ..."

Clearly, Congress' intent in giving the Secretary this flexibility does not hinge on whether the patient's emergency medical condition is tied to the declared emergency, just that the hospital's need to transfer patients to another facility in a way that may be inconsistent with an "appropriate" transfer under EMTALA is a result of the circumstances of the emergency. For instance, the hospital may be operationally disabled and unable to perform its mission due to an overwhelming number of patients, structural damage, utility failure or staffing shortage. In such circumstances, the hospital should not have to consider the source of a patient's illness or injury in order to carry out a transfer that is in the best interest of the patient and hospital emergency response.

To meet congressional intent and to ensure that this provision assists in hospital emergency response, **we recommend that CMS revise the proposed regulatory language as follows to better reflect the language in the *Social Security Act*: "(A) If relating to an inappropriate transfer, the transfer is necessitated by the circumstances of the declared emergency."**

Consideration of Other Flexibilities in Disasters. The AHA is pleased that CMS puts into place a process, consistent with its current statutory authority, which allows the Secretary to waive certain regulations, such as EMTALA, in public health emergencies. However, the lessons learned from recent disasters make it clear that changes to the law are needed in order to provide additional flexibility in regulatory enforcement and payment policy so that hospitals can maximize their ability to quickly and safely respond to the needs of their communities and patients in disasters. The AHA, together with its members and state, regional and metropolitan hospital association partners, has compiled examples of areas in which changes and additional flexibility are needed and would be happy to work with CMS and the Secretary on legislative proposals to affect these changes.