American Hospital Association

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June 24, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1500-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1500-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of the American Hospital Association's (AHA) 4,800 member hospitals, health care systems and other health care organizations and 33,000 individual members, we appreciate the opportunity to submit comments on the fiscal year (FY) 2006 inpatient prospective payment system (PPS) proposed rule.

While the AHA supports many of the proposed rule's provisions, we are particularly concerned about the potential underestimation of the market basket, the proposed expansion of the post-acute care transfer policy, the increase in the outlier fixed-loss threshold and the potential restrictions on the relocation of critical access hospitals (CAHs) with necessary provider status.

Current law sets the FY 2006 inpatient PPS update for hospitals at the rate of increase in the market basket, now estimated at 3.2 percent. Legislative and proposed regulatory changes, however, along with technical adjustments to ensure budget neutrality would result in a proposed average per case payment increase of only 2.5 percent. At the same time, the current estimates of the actual market basket increase for FY 2005 is 4.1 percent. We are concerned that CMS is dramatically underestimating the market basket for FY 2006. **We request that CMS review and revise the methodology used to determine the projected FY 2006 market basket.**

In 2003, 54 percent of hospitals had negative Medicare inpatient margins and one out of every three hospitals was losing money overall. Hospitals cannot continue to receive actual updates that are less than the rate of hospital inflation. **We will continue to urge Congress to provide adequate Medicare reimbursement to hospitals. And in our comments on this proposed rule, we also encourage CMS to make changes that would prevent further decline in Medicare payments**.

We are tremendously disappointed that the rule contains a proposal to further expand the post-acute care transfer policy, which would reduce hospital payments by nearly $900 million in FY 2006 alone. This policy is not in the best interest of patients or caregivers. It undermines clinical decision-making and penalizes hospitals for providing the right care at the right time and in the right setting. **This policy must be withdrawn.**

We are concerned that CMS is proposing to increase the outlier fixed-loss threshold despite the fact that CMS did not fully spend the 5.1 percent of funds set aside for such payments in FY 2005. Using the proposed charge inflation methodology will only result in an inappropriately high threshold and a real payment cut to hospitals. **Instead, the AHA recommends a methodology that incorporates both cost inflation and charge inflation. The use of more than one indicator will make the threshold calculation more accurate and reliable.**

A state's authority to grant necessary provider status, and thus waive the distance requirement under the CAH program, expires January 1, 2006. However, the Medicare Modernization Act includes a provision allowing any CAH that is designated as a necessary provider in its state's rural health plan prior to January 1, 2006 to maintain its necessary provider designation. CMS' proposed rule would essentially bar necessary providers from ever rebuilding more than 250 yards from their current location. Appropriate and necessary relocations that will undoubtedly result in higher quality care, better patient outcomes and more efficient service should be allowed. **We urge CMS to rescind this overly restrictive policy and allow necessary provider critical access hospitals to relocate as needed to improve the care and meet the needs of their communities.**

We have enclosed detailed comments regarding CMS' proposed changes to the inpatient payment system. The AHA appreciates the opportunity to submit these comments on the proposed rule. If you have any questions about our remarks, please feel free to contact me or Danielle Lloyd, senior associate director for policy, at (202) 626-2340.

Sincerely,

Rick Pollack
Executive Vice President

American Hospital Association
Detailed Comments on the
Proposed Rule for FY 2006 Inpatient Prospective Payment System

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ATTACHMENT

Hospital Market Basket

Market Basket Projection. The hospital payment update is based on a market basket factor that is intended to reflect the average change in the price of goods and services hospitals purchase to furnish inpatient care. These price changes must be projected forward to estimate increases for the subsequent year so that an appropriate inflationary update can be determined in advance of payment. The payment system is prospective, and the update is not retroactively reconciled to reflect actual price increases for the year. Therefore, a reliable projection methodology is vital to ensure equitable payments.

For seven of the last eight years, the market basket projection has been lower than the actual increase (see attachment). While the market basket was overestimated for a number of years prior to that time, a methodology change was made in 1998 that appears to have overcorrected for the previous underestimations. For example, the actual increase in FY 2003 was 3.9 percent while the projected increase was 3.5 percent. In FY 2004 the actual increase was 3.8 percent compared to a 3.4 percent projection. CMS reports that, based on the most recent data, the FY 2005 market basket increase is now estimated to be 4.1 percent compared to the projected 3.3 percent increase that was used to determine the update factor. We are concerned that the methods used to project the market basket increase are flawed and fail to provide a reliable estimate of hospital cost increases. Given a 4.1 percent cost increase for FY 2005, a projected FY 2006 increase of 3.2 percent does not seem reasonable. **We request that CMS review the methodology that was used to determine the projected FY 2005 market basket and revise it for the FY 2006 projection. We also urge CMS to make the details of the calculation public.**

Blood and Blood Products Category. In the proposed rule, CMS proposes to remove the blood and blood products category from the market basket and instead include those costs in the miscellaneous products category. CMS believes that the Bureau of Labor Statistics (BLS) Producer Price Index (PPI) for blood and derivatives "may not be consistent with the trends in blood costs faced by hospitals," and that "the PPI for finished goods minus food and energy moves most like the recent blood cost and price trends." We urge CMS to publish the data upon which this judgment is based.

The AHA appreciates CMS' recognition that the current BLS PPI for blood and derivatives is not capturing the increasing price trends for the blood products most commonly used by hospitals. While we support CMS' proposal to include blood and blood product costs in the miscellaneous products category, we support it only as a temporary measure until a more appropriate blood and blood products PPI can be developed by BLS. We strongly encourage CMS to work with BLS as they proceed in their stated intention to add the Blood and Organ Banks, North American Industry Classification System industry code 621991 to the BLS PPI program. We further urge CMS to work with BLS to ensure that:

- the key, high volume blood products used in transfusion medicine be included in the PPI survey – especially red blood cells (with or without leukoreduction), single donor platelets, whole blood derived platelets (random donor, with or without leukoreduction), and fresh frozen plasma and plasma; and,

- the costs associated with ongoing blood testing and processing should be included as price changes in the new PPI, since these procedures are required either by federal regulation, voluntary accrediting agencies or as standard of care to protect the public's health and safety and to ensure that the all blood collected in the country meets the same safety standards.

The goal should be supporting the development of a PPI index that tracks the price of a safe unit of blood over time.

Hospital Quality Data

A hospital qualifies for its full Medicare market basket update if CMS determines the hospital has submitted data on the 10 specific measures of care for heart attack, heart failure and pneumonia that were the starter set for the Hospital Quality Alliance (HQA). The proposed rule includes several requirements for purposes of receiving the full market basket update. These requirements are: the hospital's continuous submission of quarterly data on the 10 measures, the submission of the data by May 15, 2005 for patients discharged through the fourth quarter of 2004; and the validation of the hospital's third quarter 2004 data.

To pass validation, the hospital must send copies of the relevant medical record information from five patient records chosen at random from among those on whom the hospital has submitted data to the Quality Improvement Organization (QIO) warehouse. CMS has contracted with an organization that will re-abstract all of the required data from the five records. If there is at least an 80 percent agreement between the information that the contractor has abstracted and the information the hospital abstracted for all of the measures that are applicable to those patients, then the hospital will have passed validation. If not, then the contractor will compare only those data elements that are required for the 10 measures included in the Medicare Modernization Act (MMA). If there is at least an 80 percent agreement on those required elements, then the hospital will have passed validation. If the hospital does not pass validation, it can appeal the results of the contractor's work to the contractor. The state's QIO will review and recommend to the contractor a disposition of the appeal. The contractor will reassess the hospital's submission in light of this additional information. Finally, if the hospital is unsuccessful in its appeal, it can ask that its fourth quarter data be used as well to determine validation. The hospital will have to submit the five randomly selected charts from its fourth quarter discharges by August 1, which is ahead of the normal schedule, and the contractor will use both the third and fourth quarter charts to determine if the data validate at least 80 percent of the time.

The AHA strongly supports the need for validation of the data that are submitted for the HQA. Validation is helpful in assuring that all information is being collected and processed similarly so that the publicly reported data create a reliable picture of the quality of care provided in each participating hospital. However, the law only calls for the submission of the data for hospitals to qualify to receive the full payment update. We believe that Congress recognized that taking submitted data and turning it into information that could be publicly reported is a process, and that there could be imperfections in that process. In linking payment to the submission of data, Congress suggested that hospital payments should not be held hostage to CMS or its contractors being able to correctly carry out the processing of the hospital data.

To date, there is enough evidence of flaws in the validation process to suggest that passing validation should not be a criterion for receiving the full Medicare market basket update. The validation process is sufficiently flawed that when it identifies a problem, one can only conclude that there is a difference between the information the hospital submitted and the data the contractor abstracted. No assumption can be made about which organization has correctly abstracted the data from the medical records. There have been numerous problems including logistical issues such as failure to get the request for the five files into the hands of a responsible authority at the hospital. In addition, data collection issues have arisen such as the misalignment of the data abstraction instructions hospitals were allowed to use and the instructions that the contractor had to adhere to in re-abstracting the data. Furthermore, processing issues have occurred such as the fact that hospitals have submitted appeals indicating why their data submissions were correct and the contractor's re-abstractions were incorrect, have had their QIOs verify to the contractor that the hospitals have correctly submitted the data, and had their appeals turned down without explanation. We have begun to collect information from hospitals about the problems with the validation process so that we can work with CMS to correct the validation process to ensure its accuracy and reliability.

However, until the validation process is reliable, the AHA opposes the proposed link between meeting the validation requirements and receiving the full market basket update. CMS' validation process is currently unreliable and needs improvement before it is used in determining which hospitals receive full updates.

Labor-Related Share

The MMA required CMS to update the inpatient PPS market basket at least once every five years. CMS proposes to update it every four years, beginning with rebasing and revising the market basket for FY 2006. For FY 2003, CMS rebased the market basket using 1997 data; however, CMS continued to calculate the labor-related share based on the 1992 data. The 1997 data would have raised the labor-related share to 72.5 percent from 71.1 percent, but there was concern at the time that the increase would hurt rural facilities that primarily have area wage indexes (AWIs) below 1.0. CMS cited the need to conduct additional analyses in deciding to leave the labor-related share at the 1992-based 71.1 percent. Shortly after, Congress included in the MMA a provision that held hospitals with a wage index below 1.0 at a 62 percent labor-related share.

For FY 2006, CMS is proposing to reduce the labor-related share from 71.1 percent to 69.7 percent due to the use of more recent data and the removal of postage from the labor-related share. This proposed change, if adopted, would adversely affect hospitals with an AWI greater than 1.0. The labor share for hospitals with AWIs less than 1.0 will remain at 62 percent as specified in the MMA. This change would be applied in a budget neutral manner by increasing the standardized amount for all hospitals.

We are concerned about CMS making any changes to the calculation of the labor-related share devoid of a broader plan to refine the methodology. Given that CMS was unable to discover an alternative methodology that is accurate, reliable and reasonably easy to apply, the AHA believes CMS should leave the labor-related share at 71.1 percent.

In particular, we are concerned about the large drop in the other labor-intensive services category (landscaping, protective services, laundry, etc.). We urge CMS to investigate this drop and whether it is a result of a flaw in the methodology. For instance, an inappropriately low-growth factor could cause an improper category weight and the underestimation of the market basket.

We also are concerned about the removal of postage from the labor-related categories. CMS' 2003 assertion that additional analyses are needed still stands today. The AHA believes that CMS should continue to consider this category labor-related until a broader look at the calculation of the labor-related share is taken. For example, another item that CMS should consider redesignating as a labor-related cost is professional liability insurance. These costs are wage-related - they are included in the wage index - and locally determined. However, because CMS has not recommended a full and thorough alternative approach to calculating the labor-related share, the agency should not alter the labor-related share.

CMS' proposed change will have a detrimental affect on all high-wage area hospitals while diverting funds back to low-wage hospitals that have already been protected through the MMA. **The AHA urges CMS to leave the labor-related share at 71.1 percent for FY 2006 and recommends that CMS continue investigating alternative methodologies for computing the labor-related share.**

Post-Acute Care Transfers

Medicare patients in certain diagnosis-related groups (DRGs) who are discharged to a post-acute care setting – such as rehabilitation hospitals and units, long-term care hospitals, or skilled nursing facilities – or are discharged within three days to home health services are considered a transfer case if their acute care length of stay is at least one day less than the national average. These cases are paid a per diem rate, rather than a fixed DRG amount.

The AHA is very disappointed with CMS' continued effort to expand the post-acute care transfer policy. In the proposed rule, CMS discusses the possibility of expanding the policy from 30 DRGs to either 223 DRGs (later revised to 231) or all DRGs. Specifically, CMS proposes to expand the application of the post-acute care transfer policy to any DRG that meets the following criteria:

- At least 2,000 discharges to post-acute care;
- At least 20 percent of its discharges are to post-acute care;
- At least 10 percent of its discharges to post-acute care occur before the geometric mean length of stay for the DRG;
- A geometric mean length of stay of at least three days; and
- If the DRG is one of a paired set of DRGs based on the presence or absence of a comorbidity or complication, both paired DRGs are included if either one meets the first three criteria above.

The AHA is frustrated with CMS' repeated attempts to find the right criteria to achieve the desired budget results, rather than the right policy regardless of its budget implications. The AHA conducted analyses to better understand the impact of the proposals in the rule as well as the revised list of DRGs potentially subject to the policy. This misguided approach to expand

the transfer policy to 231 DRGs will have a devastating impact on hospitals by reducing overall payments by an estimated $894 million in FY 2006 alone when the effects on disproportionate share hospital (DSH), indirect medical education (IME), capital and outliers payments are considered. This is particularly problematic given that more than 50 percent of hospitals are already losing money treating Medicare inpatients and overall Medicare margins have declined every year since 1997 to an estimated *negative* 1.9 percent.

The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare prospective payment system. The Medicare inpatient PPS is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs while cases with shorter than average stays tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals "lose" if a patient is discharged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay.

The post-acute transfer policy penalizes hospitals for efficient treatment, and for ensuring that patients receive the right care at the right time in the right place. The policy hurts hospitals that make sound clinical judgments about the best setting of care for patients – and this setting is often outside of the hospital's four walls. Hospitals should not be penalized for greater than average efficiency. Particularly, facilities in regions of the country where managed care has yielded lower lengths of hospital stay for *all* patients are disproportionately penalized.

The post-acute transfer policy is not necessary, as the perceived "gaming" hypothesis does not exist. When Congress first called for expansion of the transfer policy in the Balanced Budget Act of 1997 (BBA), data showed that Medicare inpatient lengths of stay were dropping, and that both use and cost of post-acute care by Medicare beneficiaries was growing. Since that time, however, inpatient length of stay has stabilized. Medicare spending on post-acute care has slowed as post-acute payment systems have moved from cost-based reimbursement to prospective payment. Additionally, studies by the AHA and others show that the majority of patients who use post-acute care have longer – not shorter – hospital stays than patients that don't use post-acute care, demonstrating that these patients are truly "sicker" and in need of additional care. In FY 2004, for instance, patients that were not transferred to post-acute care had an average length of stay of 4.93 days, while those who did receive post-acute care had an average length or stay of 7.51 days. If the agency is concerned about premature discharges, then we recommend it focus on improving the quality review process rather than further expand the transfer provision.

Section 1886(d)(5)(J) of the Social Security Act directs CMS to focus on those DRGs that have a high volume of discharges to post-acute care and a disproportionate use of post-discharge services. It is inherently impossible for all DRGs, or even 231, to have *disproportionate* use of post-discharge services. The 231 DRGs selected by CMS represent 88 percent of all DRGs with patients discharged to post-acute care in FY 2004. Clearly 88 percent of DRGs with *any* post-acute care use cannot have *disproportionate* use. Furthermore, CMS is also capturing DRGs that are not at all *high-volume*. For example, DRG 473 (acute leukemia without major operating room procedure age > 17) has 2070 discharges to post-acute care as compared to DRG 544 (major joint replacement or reattachment of lower extremity) 349,085 discharges to post-acute

care. It cannot be argued that while DRG 473 does not have a *high-volume* of discharges to post-acute care, it still has *disproportionate* use. Only 22.7 percent of the cases in DRG 473 were discharged to post-acute care versus 83 percent for DRG 544. **CMS' current criteria cast far too wide of a net and capture far more DRGs than authorized by current law.**

CMS has argued that the post-acute care transfer policy levels the playing field for rural hospitals that do not have comparable access to post-acute care. The AHA challenges this assertion. We compared the rates of discharge to post-acute care for the DRGs to which the post-acute care transfer policy would apply using the 2004 MedPAR data and found that urban hospitals discharged patients before the average length of stay 10.6 percent of the time, while rural hospitals discharged patients before the average length of stay 9.2 percent of the time. This demonstrates that the transfer policy will have fundamentally the same negative affect on rural hospitals as urban. Moreover, 4.5 percent of discharges from rural hospitals are to other acute-care facilities, while only 1.6 percent of discharges at urban hospitals are to other acute-care facilities. It is likely that some of the patients discharged from rural hospitals are then admitted at urban hospitals that then in turn discharge patients to post-acute care. **Thus, rural patients have essentially the same access to post-acute care as their urban counterparts. The policy does not create equity; rather it harms all hospitals and the patients they serve.**

Furthermore, transfer cases are weighted at less than 100 percent for the purpose of computing DRG weights. The substitute weight is the share of the full DRG payment that is represented by the transfer payment. This has the effect of maintaining the DRG weight at an artificially high level. By doing this, the natural weighting process is hampered and the relative nature of the weights is distorted.

The AHA objects to an expansion of the post-acute care transfer policy, which is not in the best interests of patients or caregivers. It undercuts the basic principles and objectives of the Medicare PPS and undermines clinical decision-making and penalizes hospitals for providing efficient care, at the most appropriate time and in the most appropriate setting. This provision must be withdrawn in the final rule.

Operating Payment Rates

Outlier Payments. The rule proposes to establish a fixed-loss cost outlier threshold equal to the inpatient PPS rate for the DRG, including IME, DSH, and new technology payments, plus $26,675. While this is not a particularly sizable increase from the FY 2005 payment threshold of $25,800, we remain very concerned that the threshold is too high. CMS states in the proposed rule that actual outlier payments for 2005 are estimated to be 0.7 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments and that the payments in 2004 were 1.6 percentage points lower than the funds withheld.

In the rule, CMS proposes to use a one-year average annual rate-of-change in charges per case from the last quarter of 2003 in combination with the first quarter of 2004 to the last quarter of 2004 in combination with the first quarter of 2005 to establish an average rate of increase. This results in an 8.65 percent rate of change over one year or 18.04 percent over two years.

The AHA appreciates that CMS is proposing this methodology in an effort to avoid using data prior to the major changes in the outlier policy. **However, using the proposed charge inflation methodology will only result in an inappropriately high threshold and a real payment cut to hospitals. The AHA strongly opposes using this methodology to estimate the outlier threshold.** Thus, the AHA conducted a series of analyses to identify a more appropriate methodology. Below we put forth for CMS' consideration a methodology that incorporates both *cost* inflation and *charge* inflation. The use of more than one indicator may make the threshold calculation more accurate and reliable.

First, we inflated 2004 charges by 18.04 percent (the inflation factor used by CMS in the proposed rule) and then reduced the charges to costs. Instead of using the cost-to-charge ratios (CCRs) from the CMS Impact File, we used the CCRs from the March 31, 2005 HCRIS release. In addition, we accounted for the nine-month lag from the end of a cost reporting period until the fiscal intermediary is able to update the CCR. We accomplished this by projecting forward from the most recent fiscal period in the March 31 HCRIS update to the fiscal period(s) expected to be used for the calculation of the CCR(s) determining federal FY 2006 outlier payments.

The cost inflation factor for projecting CCRs was determined from the cost reports of a cohort of 3,756 matched hospitals for periods beginning in federal FYs 2001, 2002 and 2003. All three costs reports were available for each hospital from the recent update of HCRIS. The 2001-2003 aggregate annual rate of increase in the cost per discharge for these hospitals was 6.57 percent[1]. This cost inflation factor and the CMS charge inflation factor of 8.65 percent were used to project CCRs over the time periods described above. The projected CCRs were applied to projected federal FY 2006 charges to simulate the determination of costs for federal FY 2006 outlier payments. **The estimated fixed-loss amount that would result in 5.1 percent outlier payments under this methodology is $24,050.**

The AHA strongly urges CMS to adopt this methodology. We estimate that the fixed-loss threshold to achieve 5.1 percent in FY 2005 should have been set at $21,640 as compared to the $25,800 actually utilized. CMS underspent the funds set aside for outliers by an estimated $610 million in FY 2005 and $1.3 billion in FY 2004. **If CMS leaves the threshold at $26,675, rather than dropping it to $24,050, we believe that CMS will again underspend by at least $510 million. We urge CMS to adopt our recommended methodology to lower the outlier threshold.** We would be happy to provide CMS with additional information on this analysis.

Occupational Mix Adjustment

FY 2006 Adjustment. The occupational mix adjustment to the wage index is intended to control for the effect of hospitals' employment choices – such as the use of registered nurses versus licensed practical nurses or the employment of physicians – rather than geographic differences in the costs of labor. CMS proposes no changes to the methodology used in FY 2005 in the proposed rule, and indicates that nearly one-third of rural areas and more than half of urban areas would see a decrease in their wage index as a result of this adjustment. Given the potential financial impact of a full adjustment on hospitals, concerns regarding the data, and

1 An audit adjustment was applied to costs from "as submitted" cost reports. The audit adjustment was determined by comparing 1,881 "as submitted" cost reports from the December 31, 2003 HCRIS database with the settled reports of the same hospitals in the March 31, 2005 HCRIS update.

changes in the regulatory environment such as state-mandated minimum nurse staffing ratios, CMS is proposing to again limit the application of the occupational mix adjustment to 10 percent of the wage index. **Due to the concerns CMS expresses in the proposed rule, the AHA is supportive of this moderated implementation of the occupational mix adjustment.**

Future Data Collection. The AHA urges CMS to release a proposed survey for comment as soon as possible to ensure accurate and reliable data. We urge CMS to allow for an appropriate amount of time to develop the survey, provide clear instructions, adapt the systems, collect the data, prepare the survey responses, audit the data, correct the data, and calculate the adjustment. Given that CMS must have the adjustment ready for the FY 2008 adjustment (or the April 2007 proposed rule), **the AHA recommends that CMS release the proposed survey this summer to meet this timeframe and allow hospitals adequate time to prepare for the data collection and reporting.**

Wage Index

Wage Index Calculation Change. The inpatient PPS proposed rule contained a change in the wage index calculation. This change was made in step 4 of the Computation of the Proposed FY 2006 Unadjusted Wage Index on page 23373 in the *Federal Register*.

The change is in the calculation for Overhead Wage-Related Cost Allocation to Excluded Areas. This calculation is made up of three steps:

i. Determine the ratio of overhead hours to revised hours.
ii. Compute overhead wage-related cost by multiplying the overhead hour's ratio from step *i* by wage-related costs.
iii. Multiply the overhead wage-related costs by the excluded hour's ratio.

The change in the calculation occurred in the above step *i*. For 2006, the calculation for revised hours was changed to subtract excluded areas (Lines 8 and 8.01). This change results in a higher ratio for step *i*, which results in an increase in the overhead cost allocated to excluded areas. This change ultimately lowers the hospital's average hourly rate.

The AHA is concerned that CMS would make such a change to the calculation of the wage index without any discussion. We request that CMS explain the basis for the change and how a proper allocation can be achieved using the formula set forth in the proposed rule. Providers should be given an opportunity to comment on this revision to the methodology before it is implemented. The AHA believes that this methodological revision will have a significant impact on the wage indexes for some hospitals. **Accordingly, CMS should return to the established methodology and go through the full notice and comment process before making such a change. We further recommend that hospitals be given an opportunity to withdraw or reinstate their requests for geographic reclassification within 30 days of the publication of the final rule.**

Commuting Data. CMS should make available the hospital commuting data collected by the BLS and utilized by CMS in the out-commuting adjustment. While the data are supposed to be on the BLS Web site, we have been unable to locate it. This information will assist us in verifying the adjustment calculations and aid in our research of labor market areas.

Out-Migration Adjustment

Hospitals that qualify for an out-migration adjustment and do not waive the application of the adjustment are not simultaneously entitled to reclassification pursuant to Sections 1886 (d)(8) or (d)(10). Because significant changes to the wage index took place in FY 2005, CMS allowed hospitals to withdraw or reinstate their geographic reclassification applications within 30 days of the publication of the FY 2005 final rule. By doing so, CMS acknowledged that changes made between the proposed and final rules could affect whether a hospital was better off accepting the out-migration adjustment or whether it would be more advantageous for a hospital to waive the out-migration adjustment and pursue geographic reclassification.

Although the changes to the wage index are not as extensive for FY 2006, there is still a likelihood that revisions made between the proposed and final rules may impact a hospital's choice of whether to accept the out-migration adjustment or to apply for geographic reclassification. **Thus, the AHA requests that CMS implement a policy similar to last year's and allow hospitals to withdraw or reinstate their geographic reclassification applications within 30 days of the publication of the final rule.**

The AHA also notes that for FY 2006, the second year of the out-migration adjustment, CMS is applying adjustments that are identical in amount to the adjustments given in FY 2005. It appears that hospitals will receive the same adjustment in each of the three years of eligibility for the out-migration adjustment. The AHA does not believe that the governing statute, Section 505 of the MMA, requires that the adjustments be identical for all three years. The statute only requires that the adjustment be granted for a three-year period.

It is not logical or fair to freeze the amount of the adjustment for three years. Because of changes in the wage index each year, some hospitals will be receiving out-migration adjustments even though the wage index for their geographic area is now higher than the wage index for the county to which their residents are commuting. Likewise, there may be hospitals that would be entitled to a higher out-migration adjustment if it were recalculated based on the new wage indexes for FY 2006. The three-year eligibility period for the out-migration adjustment is similar to the three-year eligibility period for geographic reclassifications, but the wage indexes for the latter change each year despite the guaranteed three-year reclassification. **The AHA recommends that CMS revise its policy so that the out-migration adjustment will be recalculated each year based on updated wage data and the new wage indexes.**

Hospital Redesignations and Reclassifications

Urban Hospitals Redesignated as Rural. In adopting the CBSAs, a small number of hospitals that were classified as urban in FY 2004 became classified as rural in FY 2005. Because moving from a metropolitan statistical area (MSA) to the rural statewide average would have resulted in a significant decline in these hospitals' wage indexes, CMS implemented a three-year transition period (FYs 2005 - 2007). The AHA supports the continued transition for these hospitals to give them the opportunity and time to reclassify.

Hold-Harmless for Certain Urban Hospitals Redesignated as Rural. Last year, CMS discovered an instance where the approved redesignation of an urban hospital as rural resulted in the hospital's data adversely affecting the rural wage index. To address this concern, CMS

proposes for FY 2006 to apply its hold-harmless rule that currently applies when rural hospitals are reclassified as urban to situations where urban hospitals are reclassified as rural. Thus, wage data of an urban hospital reclassifying into a rural area would be included in the rural area's wage index, if including the urban hospital's data increases the wage index of the rural area. Otherwise the wage data are excluded. **The AHA supports this proposal to apply consistent hold-harmless provisions to both urban and rural areas for the purpose of geographic reclassifications.**

Urban Critical Access Hospitals Redesignated as Rural. The AHA requests CMS clarify the treatment of hospitals that are located in urban areas and apply for reclassification as rural. According to CMS statements in the proposed rule, "a hospital that is granted redesignation under section 1886(d)(8)(E) of the Social Security Act as added by section 401 BBA, is treated as a rural hospital for all purposes of payment under the inpatient PPS, including the standardized amount, wage index and disproportionate share calculations as of the effective date of the redesignation." CMS makes this statement in the context of a proposed policy change on the wage index in an effort "to promote consistency, equity and to simplify our rules with respect to how we construct the wage indexes of rural and urban areas when hospital redesignations occur."

However, this same consistency in policy has not occurred when these redesignations occur for critical access hospitals (CAHs) that are located in urban areas as of October 1, 2004 as a result of the use of the 2000 census data. Although the regulations were changed last fiscal year to allow CAHs in this situation to be temporarily reclassified as being located in a rural areas, CMS has not provided the same affirmative direction for CAHs in terms of treatment as rural for all purposes of Medicare payment. For example, the fiscal intermediary in one state has revoked the certified registered nurse anesthetists (CRNA) pass-through status for CAHs located in metropolitan areas as a result of the census change, citing the fact they are considered urban. Further, the fiscal intermediary has indicated the rural designation under section 1886(d) is only for provisions of 1886(d) and since the CRNA pass-through provision is outside of this section, the rural determination does not apply.

However, in examining the authority for the CRNA pass-through at 42 USCA §1395k note, the rural definition references section 1886(d) of the Social Security Act. In section 1886(d)(2)(D)(ii), "urban area" is defined as an area within a Metropolitan Statistical Area and "rural area" is defined as any area outside such an area or similar area. However, a further section of 1886(d) at 1886(d)(8)(E) allows a hospital to be treated as being located in a rural area if it meets the qualifications in this section. Since the annotated code refers broadly to section 1886(d), the rural determination made under 1886(d)(8)(E) does apply for the purposes of the CRNA pass-through as directed by the code.

The AHA urges CMS to make an affirmative statement that all hospitals granted a redesignation should be treated rural for all purposes of Medicare payment.

Geographic Reclassifications

Urban Group Reclassifications. The AHA is pleased that CMS is proposing to allow counties that are included in a Combined Statistical Area (CSA) to reclassify to a contiguous metropolitan

division of the CSA using the 2000 standards. We believe that this is an appropriate policy approach and acknowledges the realities of areas that are just outside major metropolitan areas and must meet the competitive salary scales in order to attract and retain competent health care professionals.

The AHA further urges CMS to modify its policy to allow hospitals located in counties that are in the same Core Based Statistical Area (CBSA), as well as CSA, as the county to which they seek redesignation to be considered to have met the proximity requirement. By failing to include CBSAs in the proximity criteria, CMS has excluded one group of hospitals, those located in Palm Beach County, Florida, from being able to reclassify to the Fort Lauderdale-Pompano Beach-Deerfield Beach division of the Miami CBSA. The AHA assumes that it was not the intention of CMS to exclude this one county group. Since CBSAs are actually more refined classifications than CSAs, we believes that inclusion of CBSAs in the proximity criteria would be consistent with CMS' policy goals to both transition to the new labor market area definitions and to protect hospitals from unintended unfavorable consequences.

In addition, the AHA is concerned that group reclassifications will be affected by the timing of section 508 of the MMA. In section 508 for instance, Ventura, California, Nassau Suffolk, New York and Providence, Rhode Island will all be prevented from reclassifying for 2007 because an individual hospital that is getting section 508 payments that is ineligible to reclassify. We do not believe that Congress intended for the section 508 hospitals to prevent group reclassifications. In addition, section 508 is not budget neutral, thus it would be inappropriate to encourage such hospitals to forgo the section 508 funding to join a group reclassification at the expense of all other hospitals. **The AHA urges CMS to allow section 508 hospitals to commit to a group reclassification and join after the section 508 funding expires.**

Multi-Campus Hospitals. Multi-campus hospitals have one provider number and thus one cost report. An individual campus cannot apply for reclassification, currently, because the wage data are not broken down by campus on the cost report. CMS proposes to allow individual campuses to complete the manual version of the S3 form in order to have the information necessary to reclassify. In addition, CMS suggests that the data from all campuses be used as a proxy for individual campuses that wish to reclassify for FY 2007 as a result of the labor market changes included in the FY 2005 final inpatient PPS rule and do not have the appropriate individual campus data.

The AHA believes that the use of the manual S3 would be appropriate to collect the necessary data. **However, this option should only be available for campuses that were redistricted into different MSAs as a result of the adoption of the 2000 census data. We further assert, that campuses should only be allowed to reclassify to an area where another one of the campuses is located.**

Rural Urban Commuting Areas. The Office of Rural Health Policy (ORHP) began using the rural-urban commuting areas (RUCAs) rather than updating the Goldsmith modification for defining rural areas. While we understand that CMS is simply updating its regulatory references in the proposed rule, the AHA is concerned with using RUCAs to define rural areas. Although the definition works for most areas of the country, there are some anomalies. **We urge CMS to**

work with ORHP to rectify the problems in the methodology and ensure that rural areas are not inadvertently classified as urban.

New Technology Applications

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. This important provision was enacted to ensure that the inpatient PPS would better account for expensive new drugs, devices and services. Despite this, CMS is essentially proposing to reject all eight applications (six new and two re-evaluations) and only maintain payment for one currently approved technology. The AHA is concerned that CMS continues to resist approving new technologies for add-on payments. **The AHA also is disappointed that CMS did not propose to increase the marginal payment rate to 80 percent rather than 50 percent consistent with the outlier payment methodology, which it has the authority to do without reducing payments to other services.**

Moreover, we are concerned about CMS' ability to implement add-on payments for new services and technologies in the near future. Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. The ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading.

Since the early 1990s, there have been many discussions regarding the inadequacy of ICD-9-CM diagnoses and inpatient procedure classification systems. ICD-10-CM and ICD-10-PCS (collectively referred to ICD-10) were developed as replacement classification systems.

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in the committee language for the MMA, recommended that the Secretary of Health and Human Services (HHS) undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology as required under the Benefits Improvement and Protection Act of 2000.

To date, in spite of these recommendations, as well as the recommendations of several federal health care agencies and offices, and health care trade and professional associations, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. We believe that without a change to ICD-10 soon, there will be a significant data crisis in the U.S. This coding crisis will affect the efficiency of the current coding process, adding significant operational costs. Additionally, failure to recognize this looming problem will only impede the efforts to achieve President Bush's goal for an electronic health record by 2014.

At the April 2005 ICD-9-CM Coordination and Maintenance (C&M) committee meeting, there were many impassioned discussions on the need to start limiting the creation of new procedure codes in order to allow the classification system to last at least two more years. ICD-9-CM procedure code categories 00 and 17 were created to capture a diverse group of procedures and interventions affecting all body systems. The establishment of these code categories was a

deviation from the normal structure of ICD-9-CM and a stopgap measure to accommodate new technology when no other slots in the corresponding body system chapters (e.g. musculoskeletal system, circulatory system, etc.) were available. The plan was to use up codes in chapter 00 first and then start populating chapter 17.

We have now reached the point where category 00 is full and the C&M committee is entertaining proposals for codes in category 17. At the April C&M meeting a proposal was presented that would in effect leave only 80 codes available in this category. Many of the specific body system chapters are already filled (like cardiac and orthopedic procedures). In recent years, as many as 50 new procedure codes have been created in a single year. This means that it is possible for ICD-9-CM to completely run out of space in one-and-a-half years. We concur with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10. We also would support an implementation period of at least two years following issuance of a final rule. Without the publication of even a proposed rule, the prospect of being unable to recognize new major surgical procedures and entirely new medical technology is a certain grim reality.

The AHA strongly recommends that the Secretary undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS expeditiously. HHS should take the necessary steps to avert this crisis and avoid the situation of being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than respond to a crisis that will likely result in unreasonable implementation timeframes. It is imperative that the rulemaking process starts immediately.

DRG Reclassifications

In general, the AHA supports CMS' proposed changes to the DRG system, as the revisions appear rational given the data and information provided. However, we do have concerns about some of the proposals as detailed below.

MDC 1 (Diseases and Disorders of the Nervous System) – Strokes. CMS reviewed the possibility of creating a new DRG with a recommended title "Ischemic Stroke Treatment with a Reperfusion Agent." The data reviewed by CMS suggested that the average standardized charges for cases treated with a reperfusion agent are more than $16,000, or $10,000 higher than all other cases in DRGs 14 and 15, respectively. Although the data suggested that these patients are more expensive than all other stroke patients, CMS proposed not to make a change to the stroke DRGs because the conclusion was based on a small number of cases. CMS believed that the administration of tissue plasminogen activator (tPA) identified by ICD-9-CM procedure code 99.10 may be underreported because it currently does not affect DRG assignment.

The AHA requests that CMS create a new DRG to recognize the additional resources associated with strokes and tPA administration even if the data analyzed did not have a large number of cases.

While it may be true that code 99.10 is underreported because it currently does not affect DRG assignment, the number of patients meeting the clinical indications for receiving tPA administration is low. Published clinical data show that only 2 percent of patients with stroke receive intravenous tPA nationally (*Archives Neurology*, 2004, March; 61) and the rate among

community hospitals may be slightly less at 1.6 percent (*Strok*e, 2001 August; 32). These statistics are only slightly higher than the 1.16 percent rate found in CMS data for patients in DRG 14 without intracranial hemorrhage with code 99.10.

The effective administration of tPA requires that treatment be administered within three hours of onset of a stroke, and only after ruling out hemorrhagic stroke by computed tomography. Intravenous thrombolytic agents are not recommended when the time of stroke onset cannot be ascertained reliably, including strokes recognized on awakening. These indications significantly limit the number of patients eligible for tPA administration.

According to published clinical studies, administering tPA in clinical practice has proved very difficult. The biggest challenge is the ability to determine that symptom onset occurred less than three hours prior to the time of the tPA infusion. Patients need to be educated to recognize the symptoms of a stroke and to seek early treatment. Administration of tPA in stroke patients requires that the patient recognize that something is wrong, is transported to a hospital equipped to provide this therapy, undergoes a history and physical examination and CT scan, and has this scan read by a qualified radiologist—all within the three hours of initial onset of symptoms.

For all the clinical reasons noted above, it is unlikely that the number of stroke cases reported with code 99.10 will increase significantly in the near future. **Regardless, the additional resources required to treat these patients should be recognized with a new DRG.**

Complication/Comorbidity List. CMS has indicated that they are planning a comprehensive and systematic review of the complication/comorbidity (CC) list for the inpatient PPS rule for FY 2007. CMS considers this review to be consistent with the Medicare Payment Advisory Commission's (MedPAC) recommendation that CMS improve the DRG system to better recognize severity.

We applaud CMS' efforts to keep refining the DRG system to better recognize severity of illness, and the resources required to treat those illnesses. However, we believe that this is a temporary fix and a more refined DRG system can only be accomplished with more specific clinical classification systems, capable of painting a more complete picture of a patient's condition and the services provided to treat those conditions - namely ICD-10-CM and ICD-10-PCS. We strongly agree with CMS' assessment in the May 9, 2002 hospital inpatient PPS notice of proposed rulemaking, that ICD-10 is an improvement over ICD-9-CM and that it will provide greater specificity and detail. Thus, we again urge CMS to implement ICD-10.

Furthermore, we are concerned that CMS may not be evaluating all diagnoses and procedures that could possibly affect a patient's severity of illness and/or the resources utilized. The current DRG grouper only considers nine diagnoses and up to six procedures. Hospitals submit claims to CMS in an electronic format. The HIPAA compliant electronic transaction 837i standard allows up to 25 diagnoses and 25 procedures. Many fiscal intermediaries are ignoring or omitting the additional codes submitted by hospital providers since these additional diagnoses and procedures are not needed by the grouper to assign a DRG. While it is important for inpatient acute hospitals, it is even more crucial for long-term care hospitals (LTCHs) whose patients are medically complex and have multiple illnesses beyond the nine diagnoses allowed

by CMS. Moreover, a list of CCs qualifying for comorbidity adjustments for inpatient psychiatric facilities' services was only recently introduced under the new PPS. Thus, these hospitals have not historically utilized the software available to sort and rearrange secondary diagnosis codes so that all CCs possibly affecting the DRG grouping are prioritized.

We urge CMS to modify the DRG grouper and instruct fiscal intermediaries to expand the number of diagnoses from nine to 25, and the number of procedures from six to 25, in order to include all reportable diagnoses and procedures in the DRG calculation.

MedPAC Recommendations

The MedPAC recommendations discussed in the proposed rule grew out of concern that limited-service providers were given an unfair advantage under the inpatient PPS. However, it is unclear how such changes will affect the remaining PPS hospitals. While the AHA supports refining the PPS, care should be taken in such an endeavor given that the majority of hospitals are losing money under the Medicare inpatient PPS. Therefore, the AHA urges CMS to proceed slowly and deliberately with extensive research as a foundation for any proposed changes.

Critical Access Hospitals

Rural Hospitals Redesignated as Urban. One of the requirements for CAH designation is that the hospital must be located in or reclassified to a rural area. As a result of the most recent labor market changes, some counties that were previously considered rural were redesignated as urban. Per the MMA, a rural county that is adjacent to one or more urban counties is considered to be located in the urban MSA to which the greatest number of workers in the county commutes, if certain conditions are met. These are known as "Lugar counties." Thus, some CAHs are now located in Lugar counties and are unable to meet the rural location requirement, even though they were in full compliance at the time they were designated as critical access.

In response, CMS proposes that CAHs in counties that were designated Lugar counties effective October 1, 2004 because of the new labor market definitions will be allowed to maintain their CAH status until September 30, 2006. **The AHA supports the continued transition for these hospitals to give them the opportunity to reclassify.**

Necessary Provider Status Relocations. Currently, a governor may certify a hospital as a "necessary provider," which allows that hospital to become a CAH even if it fails to meet the distance requirement of being more than 35 miles (or 15 miles in mountainous areas or by secondary roads) away from a PPS hospital or another CAH. The MMA terminates a state's authority to grant necessary provider status as of January 1, 2006; however, it includes a provision allowing any CAH that is designated as a necessary provider in its state's rural health plan prior to January 1, 2006 to maintain its necessary provider designation.

The AHA believes that CMS is exceeding its authority and independently developing a policy that is in conflict with the law. The MMA clearly established the intent of Congress to exempt current facilities from the expiration of the necessary provider waiver. Yet, for FY 2006 and beyond, CMS proposes extremely restrictive guidelines that are tantamount to barring CAHs with necessary provider status from relocating. Specifically, the rule would allow hospitals to rebuild within 250 yards of their existing site or relocate onto a contiguous piece of property if it

was purchased by December 8, 2003. For a hospital that moves any further, the hospital will have to show that it:

- Submitted an application to the state agency for relocation prior to January 1, 2006;
- Meets the same criteria for necessary provider status that it did when it originally qualified (e.g., in a health professional shortage area (HPSA) and remains in a HPSA);
- Serves the same community (75 percent of same population, 75 percent of same services, 75 percent of the same staff);
- Complies with the same conditions of participation; and
- Was "under development" as of December 8, 2003 using similar criteria as the specialty hospitals guidelines (architectural plans, financing, zoning, construction bids, etc).

The date restrictions proposed by CMS are unrealistic and unreasonable. December 8, 2003 is simply the date the MMA was signed into law and has no connection to a CAH relocation deadline in law. The ability of governors to newly approve necessary providers expires January 1, 2006, more than two years later than the date arbitrarily chosen by CMS for the relocation deadline. Regardless, the law expressly allows those existing providers to maintain their status after that date with no articulated restrictions. **Consequently, we insist that CMS remove the arbitrary date restrictions for relocations that have no basis in law.**

CAHs are often housed in old buildings that are in desperate need of renovations, but prior to converting, these facilities could not gain access to capital due to their poor financial situation. After stabilizing their finances, many CAHs are able to establish the worthiness of investment in them and proceed with rebuilding their aged plants. Once financially stable, CAHs can become creditworthy, not because of excessive profits, but because of the stability of Medicare reimbursements covering certain allowed costs. In many cases, CAHs are relocating to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or other essential upgrades. **Such improvements will undoubtedly result in higher quality care, better patient outcomes, and more efficient service.**

Many facilities need to, or choose to, rebuild on a new site to be closer to a highway, connect to municipal water and sewer, because of seismic safety concerns, or other reasons that again, will improve patient safety and the quality of care provided. In addition, many CAHs are landlocked with little or no room for expansion, thus they have no choice but to relocate if they must rebuild. **Facilities that must relocate to make critical safety improvements should not be penalized for circumstances beyond their control and barred from moving.**

The AHA believes CMS has gone too far in trying to paint hospitals that are moving a few miles from their current location as having ceased business and reopened as a *new provider*. This shows a general lack of knowledge about rural areas. These CAHs are integral to their communities and often one of the biggest employers. Moving down the road will not demonstrably change the population served. **We further assert that CMS automatically should consider any CAH that moves within five miles to be rebuilding and not relocating and thus the same provider.** We would not, for example, support the use of city limits as the measure of whether a hospital is rebuilding or relocating. In many areas, the city limits are a

political boundary that may not change regularly to reflect the changing population and may not be consistent with the health district boundaries. Moreover, it is difficult in many areas to find a large enough piece of land, possibly 40 acres, within the city limits and at an affordable price. Furthermore, one of the objectives of many relocating facilities is to move to the edge of town where EMS access is easier.

If a CAH moves further than five miles, and CMS is concerned about whether the same population is being served, then we would recommend an approach similar to the 75 percent test described earlier. However, given that these criteria would have to withstand the changing health care landscape for the indefinite future, we believe some modifications to the test of whether the newly relocated provider is serving 75 percent of the same population, with 75 percent of the same staff, and providing 75 percent of the same services are warranted.

For instance, natural changes in demographics and the practice of medicine will occur over time that may necessitate a change in services when a hospital is rebuilt. Or, a greater reliance on new technology may limit the number or change the type of staff needed at a newly built facility. **Some flexibility in the measures is needed to allow for such expected changes in the needs of the community.**

Therefore, the AHA recommends that CMS expand its measures and alter its criteria to allow three out of five to be satisfied. In addition to the staff, services and population measures, CMS should consider adding a needs assessment and cost comparison. For example, if a CAH can show through a needs assessment that the change in services provided would be appropriate, then the test of 75 percent of the services should not need to be met. If a CAH has undertaken a cost comparison that shows that a new facility on another site would be less expensive than rebuilding on the current location, then only two other measures should need to be satisfied. **A combination of the criteria suggested would offer CAHs some flexibility and allow for the natural development and maturation of the CAH and the community.**

We also encourage CMS to consider special provisions for hospitals that are merging. Under these circumstances, the two hospitals may not be able to meet the criteria. In these cases, CMS should make determinations on a case-by-case basis. If the merger meets the needs of the communities, then CMS should consider it an appropriate and allowable relocation.

Regardless of what criteria are chosen, CMS should clearly delineate them in advance. For example, when counting the staff, how should the hospital ascertain if the staff would continue employment at the new location? How would a CAH compare the population they serve to a hospital that has yet to be built? Would the services be considered based on departments or actual individual services? Is the fact that you plan to provide lab services in general sufficient? Moreover, the comparison between the old facility and the soon-to-be built facility should be a one-time comparison based on the facts at the time of the application. **CAHs need clear expectations and advanced warning of the standards to which they will be held.**

CAHs are the sole providers of inpatient acute-care services in their communities and often outpatient and long-term care services. Facilities that convert to CAH status do so because of their dire financial conditions under the prospective payment systems. Thus, it is unlikely that

they would be able to successfully convert back to the inpatient PPS. In addition to the lower reimbursement there would be other hurdles, such as getting licensed for additional beds in certificate of need states or hiring additional staff to expand services when there are shortages in many areas that would need to be surmounted in an effort to build volume to survive under the PPS. For many of these CAHs, loss of their status would force them to close. **Given the role of these facilities in their communities, such closures would have devastating affects on rural health care access.**

We urge CMS to rescind its overly restrictive relocation policy and allow necessary provider critical access hospitals to relocate as needed to improve the care and meet the needs of their communities. Instead, CMS should expand and use the criteria recommended above.

Pending Necessary Provider Status Applications. The AHA is concerned about the hospitals that are currently in the process of converting to CAH status under the necessary provider program. We have heard reports from some states that the queue to be surveyed is growing and despite a hospital's best efforts and advanced planning, the survey to obtain the new provider number may not occur by January 1, 2006. It also is possible that the survey will occur, but the plan of correction will not be accepted by the deadline if one is needed. States have an enormous survey workload that is further exacerbated by Emergency Medical Treatment and Labor Act (EMTALA) surveys that take priority. **Providers that have gotten to the stage of requesting a survey in advance of the January 1, 2006 deadline, but are unable to get the state to complete the survey have clearly demonstrated a good faith effort and should be considered as meeting the deadline.**

Low-Volume Hospital Payment Adjustment

Section 406 of the MMA created a payment adjustment under the inpatient PPS to account for the higher costs per-case of low-volume hospitals. The law defined eligible hospitals as those located more than 25 miles from another facility with fewer than 800 total discharges during the year. The rule proposes to maintain a 25 percent increase, the maximum allowable, in payments to hospitals with fewer than 200 discharges. For those hospitals that have between 200 and 800 discharges, CMS proposes to maintain its current policy, applying no payment increase. Only 10 hospitals currently are receiving this adjustment. **The AHA is concerned that CMS is ignoring congressional intent and denying a group of hospitals – those with over 200 discharges but less than 800 discharges – access to this necessary payment increase.**

Rural Community Hospital Demonstration Program

Section 410 of the MMA requires CMS to conduct a demonstration program in rural areas where qualifying hospitals with fewer than 51 beds would receive cost reimbursement, rather than PPS payment, for inpatient acute care and swing-bed services for a five-year period. To satisfy the law's budget neutrality requirement, CMS proposes to offset inpatient PPS payments to other hospitals by $12.7 million. Given that the demonstration was clearly designed to provide higher payments to these facilities, **the AHA agrees that the law intended for the program to be budget neutral to the entire inpatient PPS rather than within the demonstration.**

DSH Adjustment Data

Section 951 of the MMA required CMS to furnish the necessary data for hospitals to compute the number of patient days included in the DSH formula. The AHA believes that this requirement encompasses the Medicare, Medicaid and Supplemental Security Income (SSI) data used in the DSH calculation. Hospitals can use this information to determine a more accurate calculation of their Medicare DSH adjustment and to determine whether the data based on the federal fiscal year or their own fiscal year is advantageous. **The AHA supports CMS' plans to release a MedPAR limited data set for both SSI and Medicare.**

The AHA, however, strongly objects to CMS' decision not to make available Medicaid information. Congressional intent on the inclusion of Medicaid information is clear. The explanatory report language accompanying the final legislative language for the MMA states that the Secretary must arrange to provide information hospitals need to calculate the Medicare DSH payment formula. This same section in the version of the MMA passed by the House of Representatives states specifically that the Secretary is required to provide the information to hospitals so they can calculate the number of Medicaid patient days used in the Medicare DSH formula. The hospital field has brought this issue regarding the difficulty in obtaining Medicaid information from the states to CMS' attention for several years. Efforts were made through the Medicare Technical Advisory Group to find ways to remedy this problem. CMS then as now, continues to ignore this problem.

CMS states in the rule that it believes hospitals are best situated to provide and verify Medicaid eligibility information and that the mechanisms are currently in place to enable hospitals to obtain the data necessary to calculate their Medicaid fraction. The process for obtaining, reporting, and justifying the Medicaid days is problematic in many states. While some improvements have been made in the process for obtaining Medicaid eligibility and payment information from the states, there is still wide variation in the breadth of information provided as well as its accessibility and reliability. In addition, the information from the states still must be processed to match claims data with eligibility data and then manipulated to develop reports that are acceptable to the fiscal intermediary. This is a complex process that is time-consuming and labor intensive. As a result, hospitals often find it necessary to hire consultants that have the required expertise and computer programs. Moreover, the penetration of Medicaid managed care can add an additional layer of complexity in some states that can further diminish the accuracy of the data provided to hospitals.

Therefore, the AHA recommends that CMS impose a state Medicaid plan requirement to meet the terms of the MMA provision that requires states to provide timely, accurate Medicaid information. The AHA further recommends that CMS require states to provide provisions in their contracts with managed care plans that require the submission of accurate and reliable utilization data to the state, and that the state make this information available to the providers and contractor audit staff.

Provider-Based Entities

Rural Health Clinics. CMS' proposed rule would add rural health clinics with 50 or more beds to the list of specific types of facilities and organizations for which determinations of provider-based status would not be made. **The AHA supports this change.**

Neonatal Intensive Care Units. The provider-based requirements were designed to prevent physician offices or clinics with little to no integration with a hospital from providing relatively low-level services and receiving the higher hospital-based Medicare outpatient rates. The 35-mile requirement was introduced as one of a number of measures of integration between a general-acute care facility's main campus and its provider-based entities. However, unlike general acute-care facilities, children's hospitals are fewer in number and tend to cover wider catchments areas. In the case of the provider-based neonatal intensive care units (NICUs) located in host hospitals described in the rule, there is no question of the level of services or integration with the parent hospital regardless of the distance to the parent hospital. The type of inpatient services provided requires specialized equipment, staff and support that the host hospital could not provide on its own.

We are currently aware of only one children's hospital that is providing such services through this model. While the off-campus NICUs meet all of the other provider-based criteria, they are more than 35-miles away from the main campus. However, the intent of these NICUs is to bring specialized services closer to the outlying areas that the parent hospital serves. Such small units are not profitable, but are still supported by the parent facility to meet the needs of an economically-impoverished and medically-underserved community that is largely rural.

Options one, three and four described in the rule are problematic. Option one, would simply expand the mileage limitation and create an additional blunt measure that does not fully account for the appropriate provision of crucial services in underserved areas. Option three, would require changes to each state's Medicaid plan, which would be difficult for individual hospitals to achieve. Option four, would require the NICUs to covert to hospital-within-hospitals, which is unrealistic for six-to-eight bed units that require the support of a full-service children's hospital. **The AHA believes that the best approach to address this problem and ensure access to these critical services in underserved areas is option two, which would exempt off-campus NICUs from only the distance limitation where all other provisions of the provider-based requirements under Sec. 413.65 are satisfied.**

Graduate Medical Education

Initial Residency Period. Last year, CMS instituted a new policy for weighting the direct graduate medical education (GME) resident count for residents that pursue specialties requiring an initial year of broad-based training, such as anesthesiology. The new policy allows the initial residency period to be based on the period of board eligibility for the specialty, rather than the clinical-base year. CMS now further proposes to base the initial residency period on the period of board eligibility for the specialty when a resident matches directly to an "advanced program" without regard to fact that the resident did not match for an initial clinical base-year training program. This would allow hospitals to be paid an entire full-time equivalent (FTE), rather than half of an FTE for such residents until they are board eligible. **The AHA supports this change.**

Affiliation Agreements. Previously, rural hospitals that began residency training programs on or after January 1, 2005 were able to establish affiliation agreements with hospitals that had existing residency programs. CMS now proposes to allow urban hospitals that create a new residency program to establish an affiliation agreement with another hospital so long as the agreement results in a positive adjustment to the hospital's resident FTE cap. This would prevent hospitals from creating new residency programs and then moving most or all of its residents over to an existing program. **The AHA supports the expansion of the hospitals that may enter into affiliation agreements.**

IME Adjustment

No IME FTE count was calculated for those hospitals that were exempt from the inpatient PPS for cost-reporting periods ending on or before December 31, 1996. Thus, for inpatient PPS exempt hospitals that wish to covert to the inpatient PPS, CMS proposes to establish the IME FTE count on the GME FTE count based on the cost reports ending on or before December 31, 1996.

With regard to the period used for determining the cap amount (whether for a converting hospital or a converting unit), it is inappropriate to use nearly 10-year-old data for the establishment of an IME resident cap. We acknowledge that an audit by the fiscal intermediaries was performed for *direct* GME purposes and the data may be available at this late date to establish an IME resident cap using that data. That said, teaching hospitals have made educational and program decisions regarding expansions of residency training rotations within those hospitals (and units) since 1996 with the understanding that the teaching hospital will not be penalized for Medicare reimbursement purposes apart from a penalty associated with possibly exceeding the hospital's direct GME cap. For CMS to state now, nine years later, that converting entities will revert all the way back to the 1996 resident cap levels for IME purposes and possibly be immediately above their IME resident cap when these program decisions and commitments have already been made to residents is inappropriate.

There is ample precedent for CMS to use a more updated data source for establishing the IME cap for hospitals and units converting to the inpatient PPS without an accompanying legislative change. The inpatient psychiatric PPS developed by CMS established an IME cap for those facilities *and units* based on the most recent cost reporting period prior to November 15, 2004, and the inpatient rehabilitation PPS proposed rule recently published by CMS contemplates the last cost reporting period ending on or before November 15, 2003 for the establishment of an IME cap for those facilities and units. **The AHA recommends that CMS use either or both of these cost reporting periods for the establishment of the IME cap in situations where a hospital or unit is converting and will be newly subject to the inpatient PPS.**

Specialty Hospitals

In the inpatient PPS notice, CMS reported that some limited-service hospitals (CMS refers to them as "specialty hospitals") might not meet the Medicare statutory definition of a hospital and therefore were not eligible for Medicare certification as a hospital. If physician-owned limited-service providers are not hospitals, then their physician-owners also are not eligible for the protection of the "whole hospital" exception under the federal physician self-referral law. This

conclusion appears to be drawn from CMS' review of applications for grandfathering under Sec. 507 of the MMA that imposed an 18-month moratorium on physician self-referrals to certain new limited-service hospitals. It undoubtedly also was drawn from the fact that both the MedPAC and CMS congressionally-mandated studies of physician-owned limited-service hospitals have been unable to include surgical and orthopedic hospitals in many of their analyses because these facilities had so few inpatient admissions. It appeared that many of these hospitals – especially surgical and orthopedic hospitals – were focused predominantly on outpatient surgery.

Subsequently, in testimony before Congress, CMS announced its plan to revisit the procedures by which applicant hospitals are examined to ensure compliance with relevant federal standards, as well as an examination of how limited-service hospitals should be treated under EMTALA. Further, CMS indicated that its fiscal intermediaries had been instructed to refrain from processing Medicare participation applications from limited-service hospitals until a comprehensive review of its hospital provider enrollment process was completed. This process is expected to take at least six months. On June 9, the day after the congressional moratorium expired, CMS issued a fact sheet outlining next steps. The fact sheet provided additional details on CMS' plans to solicit input on these issues. It also indicated that the instructions to fiscal intermediaries included suspension of authorization for initial surveys by state survey agencies during the review period. Finally, it indicated that the suspension would not apply to limited-service hospitals that had submitted an enrollment application or requested an advisory opinion regarding grandfathering under the physician self-referral moratorium prior to June 9, 2005.

The AHA commends CMS for recognizing this issue, undertaking this review, and suspending limited-service hospital enrollment applications in the interim. We would like to take this opportunity to comment on the issues raised by this action, not only in the inpatient PPS notice but also in CMS' subsequent notices. We will address:

- Application of (COPs) statutory definition of a hospital and the Medicare hospital conditions of participation to limited-service hospitals.
- Treatment of physician-owned limited-service hospitals during the review process.

Application of the Definition of a Hospital and Medicare COPs. We appreciate the complexity of CMS' task in applying the statutory definition of a hospital, especially the requirement that the entity be primarily engaged in providing services to inpatients. While it has been amended across time, it is still a 40 year-old definition that is not necessarily reflective of current medical care and technology. Of necessity, we believe CMS will need to exercise some flexibility. Also, the Medicare hospital COPs have been undergoing a process of updating and revision for several years that is not yet completed.

First and foremost, **the AHA recommends that CMS focus on what the public expects of any entity labeled a "hospital" whether it is a full-service or limited-service hospital.** All Medicare-certified hospitals should have to meet all relevant Medicare COPs. With respect to limited-service hospitals, we believe most of the **core requirements that CMS should stress are already in place but require more rigorous enforcement. The area that we believe needs to be addressed with new requirements is the handling of patients with complications**

and the transfer of patients from limited-service hospitals to full-service community hospitals. Specifically, we recommend the following core requirements for limited-service hospitals:

- **An adequately staffed inpatient capacity**, including a fully-functioning quality monitoring and improvement system. The Medicare COPs already require this.

- **The ability to deal with complications that may arise during or after a surgical procedure in a way that protects the patient's well-being**. That means internal teams capable of handling complications typical to the procedures normally performed in that hospital and, when transfers are needed to access other specialties or services at another hospital, EMTALA-like provisions should apply with respect to how the transfer is executed and communicated with the receiving hospital. (Other comments related to the application of EMTALA to limited-service hospitals will be addressed separately in comments to the EMTALA Technical Advisory Group.) In the case of limited-service hospitals, we also believe that **specialty hospitals should disclose to their patients upfront that if complications occur outside their limited capability, patients would be transferred to another hospital**.

- **The ability to appropriately respond to emergencies.** Current hospital COPs related to emergencies should be strictly enforced. This does not require that every hospital have an emergency department. Under the COPs, hospitals that do not offer emergency services are required nonetheless to ensure that they have the ability to appraise emergencies, initially treat, and refer when appropriate. This requires more than simply dialing 911 and waiting for an ambulance to arrive. Hospitals that do offer emergency services (whether by choice or by state requirement) should be required to fully meet the provisions of 42 CFR 482.55. As identified by MedPAC's March 2005 report, some physician-owned limited-service hospitals have what they call an emergency department in order to meet state hospital licensure requirements but, given MedPAC's description of what they found, some of those hospitals cannot possibly be in compliance with the provisions of Sec. 482.55. If a hospital holds itself out as having emergency services, that proffer must be real or the public's health and safety will be endangered.

- **A fully-functioning discharge planning process and relationships with post-acute providers in the community**. The AHA believes this current Medicare requirement is especially important for Medicare beneficiaries given CMS' finding that physician-owned limited-service hospitals have shorter lengths of stay and higher readmission rates. While discharge planning is required of all hospitals, CMS' findings suggest that some physician-owned limited-service hospitals may have inadequate discharge planning processes and, as a result, Medicare patients are being sent home too quickly or without adequate post-discharge support.

We would urge caution, however, with respect to how CMS judges whether a hospital is primarily engaged in providing services to inpatients. The delivery of health care has changed significantly in the 40 years since Medicare was enacted. Many hospitals are now health care systems that provide a wide range of inpatient and outpatient care. **The AHA recommends that**

CMS look at a hospital's operation comprehensively to ascertain whether the facility is *significantly* (or *seriously* if you will) engaged in providing inpatient hospital care and avoid adopting any rigid standard for the proportion of inpatient versus outpatient care. There is a significant difference between a hospital with 278 hospital beds that has 14,400 inpatient discharges and 94,500 hospital inpatient days a year that provides almost 80 percent of its care to outpatients because of the scope of services offered, and a limited-service hospital with eight beds, only 537 inpatient discharges and 1,200 hospital inpatient days a year that also provides almost 80 percent of its care to outpatients. The fact that most physician-owned surgical and orthopedic hospitals' performance often could not be measured under the MedPAC and CMS studies due to insufficient numbers of inpatient discharges is telling.

CMS also should consider whether the inpatient component of the hospital, even if small, represents a vital health care resource as in the case of a small rural hospital or a highly specialized center of excellence.

Treatment of Physician-Owned Limited-Service Hospitals During the Review Process. The AHA was surprised to see in the June 9 notice that CMS would not be applying the suspension of the enrollment process for limited-service hospitals across the board. Despite the fact that many of these hospitals have had their applications pending during review of whether they were eligible for grandfathering under the physician self-referral moratorium, it is difficult to understand how CMS plans to act on those applications when it has not yet completed its review of standards and the hospital provider enrollment process. Consequently, **the AHA recommends that CMS apply the suspension of processing enrollment applications for all limited-service hospitals until its review is completed and appropriate revisions adopted.**

As indicated in our May 24 letter to CMS, **the AHA also recommends that the agency use its authority granted under 1861(e)(9) and 1877(d)(3) of the Social Security Act to extend the application of the physician self-referral moratorium's conditions for grandfathering of existing physician-owned limited-service hospitals until CMS completes its review and Congress acts on pending legislation regarding self-referral to physician-owned limited-service hospitals.** In addition to overall patient health and safety concerns, there are several important reasons for CMS to administratively extend the application of the growth limitations under the moratorium:

- It would maintain the status quo while CMS conducts its review and Congress is deciding what action it will take.
- It would avoid any significant growth in volume prior to implementation of expected payment changes.
- It would avoid unnecessary administrative complications that could arise if currently grandfathered physician-owned limited-service hospitals take significant steps to grow or change when there is a possibility that congressional action will reach back to the June 8 sunset of the original moratorium.

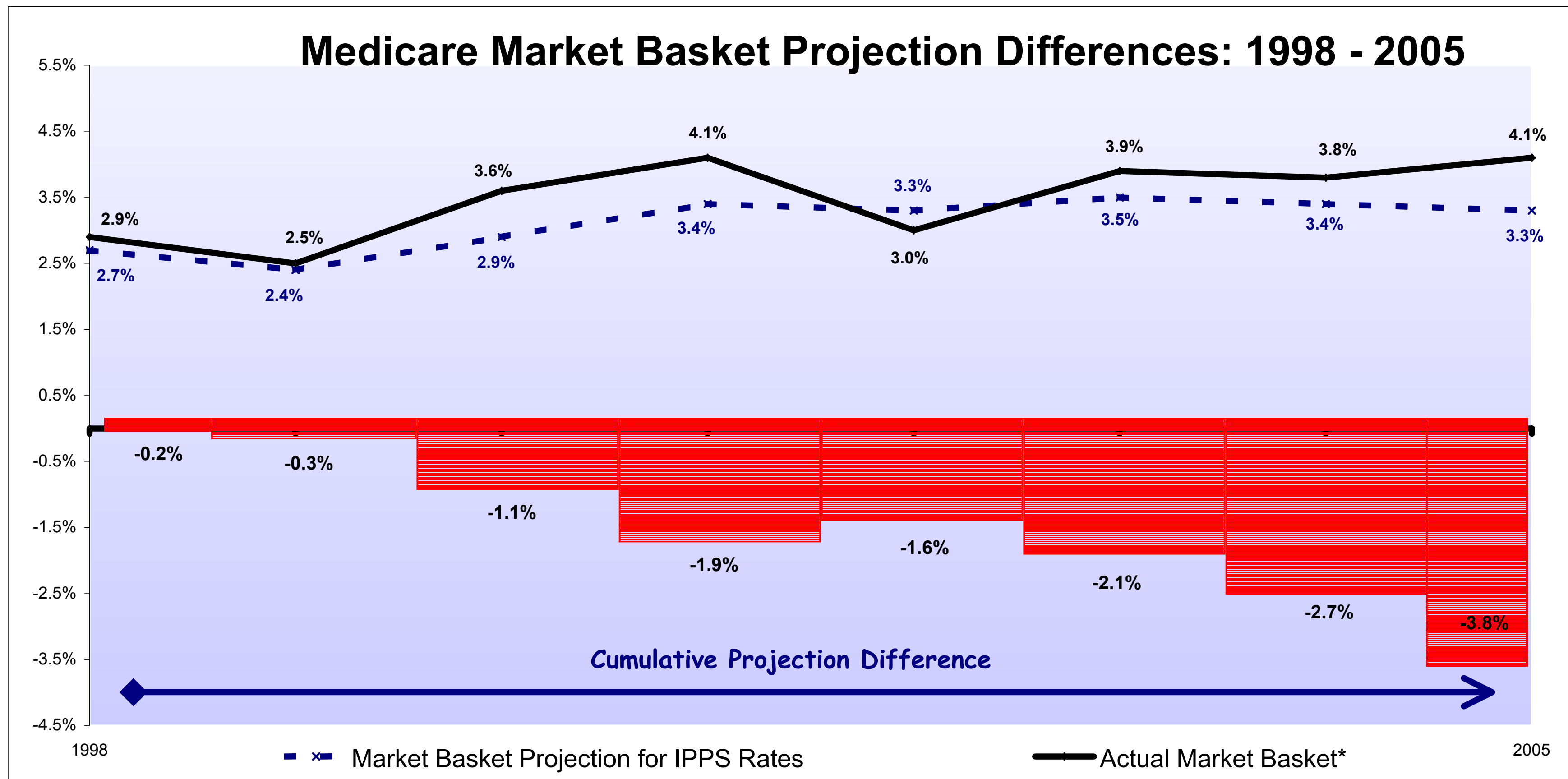
LTCH DRG Relative Weights

The proposed rule includes the recalibrated weights for the long-term care hospital (LTCH) DRGs, which CMS estimates would reduce Medicare payments to LTCHs by $135 million in FY 2006. When calculating the proposed weights, CMS used a new methodology that removed statistical outliers and cases with a length of stay of up to seven days from the reweighting calculation. In the proposed rule, CMS said that outlier cases were removed from the calculation because they “may represent aberrations in the data that distort the measure of average resource use” and that short-stay cases were removed since they “do not belong in a LTCH because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH.” The AHA is concerned that the proposed methodology inappropriately removes too many LTCH patients from the reweighting calculation. By narrowing the pool of cases used to determine the relative weights for LTCH DRGs, the agency would erode a fundamental feature of the prospective payment system – the principle of averaging.

Further, the AHA is concerned that the LTCH DRG reweighting methodology would not achieve an adequate level of accuracy and that two types of cases may be under-represented in the data. A Lewin Group analysis of the December 2004 MedPAR file, in combination with data validation by a sample of LTCH providers, indicates that interrupted-stay patients and patients who transition from Medicare to Medicaid status during an LTCH stay are under-counted in the LTCH DRG reweighting. **The AHA urges CMS to re-examine these categories of cases to ensure that charges for these and all cases are fully accounted for in the proposed weights to avoid any unwarranted lowering or redistribution of the weights.**

The reweighting of the DRGs also raises concerns since the new weights are not being introduced in a budget neutral manner, even though the statutorily-required budget-neutral transition of the LTCH PPS is still underway. While we recognize that most LTCHs have already opted to transition to the PPS rather than be paid under a blended PPS/cost-based rate, it should not be overlooked that Congress established a five-year transition for the implementation of the LTCH PPS in order to avoid instability and disruption. Yet the proposed FY 2006 reweighting of the LTCH DRGs would generate a substantial reduction in Medicare payments to LTCHs.

In order to mitigate the substantial impact of this provision – estimated by CMS to be a 4.7 percent reduction and by The Lewin Group to be a 6.7 percent reduction – CMS should limit large swings in the LTCH DRG weights as it did in FY 2003 for the outpatient PPS. In that situation, CMS adopted a dampening policy that applied when an APC’s weight decreased by more than 15 percent. In those cases, any decrease greater than 15 percent was reduced by half. **The AHA strongly encourages CMS to implement a similar transition or dampening method as part of the recalibration of the LTCH DRG weights.**



Notes: Market basket projections are used by CMS to calculate the Medicare hospital inpatient rates for each federal fiscal year. The actual market basket is the value of the market basket as calculated after the end of the fiscal year according to the methodology for that year. For the time period of this analysis two different methodologies were in effect. From 1998 to 2002 the "1992 methodology" was used and from 2003 to 2005 the "1997 methodology" was used.

The projected and actual market baskets for the years 1998 through 2002 can be found in the following Federal Register: 67 FR 50040. The projected market baskets for the years 2003 through 2005 can be found in the following Federal Registers: 2003: 67 FR 50288; 2004: 68 FR 45479; 2005: 69 FR 49189. Actual market baskets for 2003 and 2004 were provided by CMS and can be found on the CMS Web site at: http://www.cms.hhs.gov/statistics/market-basket/.

* The actual market basket for 2005 is a revised projection calculated by Global Insight, Inc. for CMS as of the fourth quarter 2004.