



American Hospital
Association

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June 9, 2008

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

RE: CMS-1390-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Rule (Vol. 73, No. 84), April 30, 2008

Dear Mr. Weems:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2009 hospital inpatient prospective payment system (PPS).

While we support a number of the proposed rule's provisions, we have concerns about implementation of many of the new hospital quality measures, as well as payment cuts related to the wage index, capital payments and the post-acute care transfer policy.

HOSPITAL QUALITY DATA

The proposed rule would add 43 new quality measures for payment determination in FY 2010. This would, in one year, more than double the number of measures on which hospitals must report. **Adding such a large number of disparate measures is an unfocused approach to quality reporting that provides no direction to hospitals on quality improvement priorities.** Furthermore, this chaotic approach will adversely impact quality improvement efforts. In drafting this proposal, CMS has not followed the *Deficit Reduction Act of 2005* requirement that it choose measures that represent a "consensus among affected stakeholders," as it has proposed measures that are not endorsed by the National Quality Forum (NQF) and adopted by the Hospital Quality Alliance (HQA). It is important that any measures added to the pay-for-reporting program first go through the rigorous, consensus-based assessment processes of both the NQF and the HQA. **Of the proposed measures, only 10 have been adopted by the HQA. We do not believe that the other 33 measures proposed by CMS are ready for reporting at this time.**



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HOSPITAL-ACQUIRED CONDITIONS

In the FY 2008 inpatient PPS final rule, CMS adopted eight conditions for which it would no longer pay a higher diagnosis-related group rate beginning in FY 2009 if the conditions were not present on admission. This year, CMS proposes to expand the list and include nine additional conditions when the payment policy takes effect on October 1. **Of the 17 total conditions, only four are ready to include for FY 2009.** The remaining conditions should not be implemented for FY 2009 because either they are not reasonably preventable, it is difficult to determine whether they are present on admission, or the patient population included by CMS is too broad.

OTHER PROPOSALS

We also strongly oppose the following direct payment cuts:

- Raising the threshold for wage index geographic reclassification, thereby making it more difficult for hospitals to qualify;
- Applying budget neutrality for the rural floor, imputed rural floor and geographic reclassifications on a statewide basis;
- Phasing out the indirect medical education adjustment to capital payments, which cuts payments to teaching hospitals by \$1.3 billion over five years; and
- Expanding the post-acute care transfer policy to include patients receiving home health care services within seven days of discharge, which is estimated to reduce payments by \$50 million in FY 2009 and \$330 million over five years.

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

Sincerely,

Rick Pollack
Executive Vice President

**American Hospital Association
Detailed Comments on the Proposed Rule
for the
FY 2009 Inpatient Prospective Payment System**

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HOSPITAL QUALITY ISSUES

HOSPITAL QUALITY DATA

The *Deficit Reduction Act of 2005* (DRA) expanded quality reporting requirements for hospitals to be eligible to receive a full market basket update and provided the Secretary with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures on the basis that they are no longer appropriate. In the proposed rule for the fiscal year (FY) 2009 inpatient prospective payment system (PPS), the Centers for Medicare & Medicaid Services (CMS) puts forward 43 new measures to be included for the FY 2010 annual payment determination, which, in one year, would more than double the number of measures on which hospitals must report. To receive a full market basket update, hospitals would have to pledge to submit data on these and all measures currently included in the pay-for-reporting annual payment update program and pass the established data validation tests. The proposed measures include:

- One surgical care measure;
- Four nursing sensitive measures;
- Three readmission measures;
- Six venous thromboembolism measures;
- Five stroke measures;
- Nine patient safety and quality indicators from the Agency for Healthcare Research and Quality (AHRQ); and
- Fifteen cardiac surgery measures from the Society of Thoracic Surgeons registry.

Improvements in quality have been achieved by focusing on a few high-priority areas, understanding the steps that are critical to achieving the best outcomes, choosing measures that assess whether those steps are being performed reliably, testing and sharing strategies for enabling clinicians to reliably perform those necessary steps, and using the data to inform and motivate further action. Through the National Quality Forum (NQF), interested health care stakeholders come together to choose measures that are useful for these purposes. Through the Hospital Quality Alliance (HQA), public and private partners have come together to identify areas to focus on that are critical to hospitalized patients and, from among the NQF-endorsed measures, those that best assess quality in those selected areas. These two organizations are the primary consensus groups for hospital quality reporting. **In the proposed rule, CMS has not followed the DRA requirement that it choose measures that represent a “consensus among affected stakeholders,” as it has not proposed measures that are endorsed by the NQF and adopted by the HQA.**

Expansion of the quality measures. **Adding 43 disparate quality measures in one year is an unfocused approach to quality reporting that will be detrimental to quality improvement.** With this broad list of disparate measures, there is no indication that CMS thought carefully or

strategically about identifying the most important areas where resources and attention should be focused to advance quality and patient care.

Over the past few years, CMS has steadily incorporated a manageable number of new measures into the pay-for-reporting program. Hospitals have focused on each new measure and increased efforts in those areas each year. The results have been remarkable. Hospitals' overall performance has improved, sometimes rapidly, on every single measure added to the pay-for-reporting program. The national average score is now 85 percent or higher for more than half of the process measures that are currently reported. And those hospitals with the lowest baseline scores at the introduction of a measure have improved the most. This system has worked, and worked beyond expectations. By overwhelming hospitals with 43 new measures at one time, however, CMS is undermining that foundation of steady progress. Hospitals will not be able to make the same progress on these 43 measures that they have made previously. CMS' role is to provide hospitals with priority areas in which they should focus their quality improvement efforts, and the 43 measures in this proposed rule fail to do that.

Additionally, for performance measurement to foster quality improvement, the measures used must be actionable. Actionable measures are measures for which there are associated evidence-based practices that can improve patient outcomes. Such measures identify for providers exactly what evidence-based processes they did or did not follow, assisting them in interpreting and ascertaining where they can improve. If providers do not know what processes to change to improve patient care, measuring the care provided will make no difference. Some of the individual measures proposed by CMS are not actionable. Moreover, the very act of adding 43 new measures at once makes this whole set of measures unactionable for hospitals. **With this many measures, in a number of different areas of care, with different data sources, different degrees of reliability, different vendors with differing data collection instructions, different data collection schedules, and different validation processes, no organization can focus on where improvements are needed and implement the necessary changes.**

Hospitals are not the only audience that will struggle to make sense of this deluge of measures. The public already is struggling to understand and use the information on *Hospital Compare*. By adding many disparate measures, especially measures that are less reliable than those already on *Hospital Compare*, helping people understand what these data mean for their care, or for the care of a loved one, becomes an extraordinarily difficult task.

Even displaying data in a useful format lies beyond what *Hospital Compare* currently has the capacity to do. The current display of the data is not intuitive and is difficult for consumers to navigate. Through the HQA, we have been working with CMS on ways to improve the display of data on *Hospital Compare*, but opportunity remains to improve the Web site. With the addition of 43 new quality measures, the Web site will become even more cumbersome, and consumers may be discouraged as they try to find relevant information. Some of the proposed measures are very similar to existing measures and explaining the subtle difference between them to consumers will be a challenge. For example, with the addition of the 43 proposed measures, there would be five different measures that assess beta-blocker usage with slightly

different, and sometimes overlapping, patient populations. Making sense of why all five are needed and which measures are relevant to a particular patient will be a challenge for clinicians as well as the public. The current format of *Hospital Compare* cannot communicate these distinctions.

One way to attain the needed focus is to use the priorities developed by the NQF's National Priority Partners. We are disappointed that CMS makes no mention of the work of this group. **CMS should look to the Priority Partners' goals as a framework for the types of measures that should be included in the pay-for-reporting program.** The goal of the national priorities is to engage all stakeholders in a shared effort to make quality improvements in the most important areas of patient care. The HQA has agreed that the NQF's national goals should provide a foundation for its future work. CMS should follow these national goals as well.

To collect data for 43 new measures, hospitals will have to devote substantial resources toward data abstraction and submission. The vast increase in work required for data abstraction will take resources away from patient care and other quality improvement efforts. For example, most hospitals employ nurses to perform clinical data abstraction. Nurses that perform data abstraction are not providing patient care. The explosion of new measures for FY 2010 will dramatically and suddenly increase the amount of required data abstraction work and may pull a greater number of hospital nurses away from providing patient care and into these paperwork duties.

Proposed quality measures. Most of the measures put forward by CMS have not been endorsed by the NQF and adopted by the HQA. **It is necessary that any measures added to the pay-for-reporting program first go through the rigorous, consensus-based assessment processes of both the NQF and HQA. Of the proposed measures, only the surgical care measure, the six venous thromboembolism measures, and three of the nine AHRQ measures have been adopted by the HQA.** We do not believe that the other measures proposed by CMS are ready for reporting at this time. Our specific comments on each set of measures are included below.

- **Surgical care (perioperative beta blocker usage)** – This measure has been endorsed by the NQF and adopted by the HQA. We believe it is appropriate for inclusion for the pay-for-reporting program for FY 2010. It is an addition to the existing surgical care measures.
- **Nursing sensitive measures** – These measures were previously adopted by the NQF; however, they had not been tested to ensure that consistent and reliable data collection was possible. Therefore, they are not ready for implementation for FY 2010. They are currently undergoing appropriate field testing. Prior to inclusion in the pay-for-reporting program, all measures should undergo a field test to observe for any operational issues and assess the degree to which the measures can be implemented successfully by hospitals and data vendors. Those involved in the field testing of these nursing sensitive measures indicate that substantial modifications will be needed before they can be broadly used to generate comparable data.

The results of the field test will not be final until the end of this year. The results will lead to changes in the measures that may require NQF to re-examine the measures to ensure that they still meet the endorsement standards. We believe that these measures hold promise for future years, but because the field test is not complete, they are not ready for implementation for FY 2010. Additionally, we believe that the “failure to rescue” measure is identical to the AHRQ measure of “death among surgical patients with treatable serious complications.” We ask that CMS clarify any distinctions between these two measures.

- **Readmission measures** – The heart failure readmission measure has been recently endorsed by the NQF, but has not been adopted by the HQA. Therefore, it should not be included for hospital reporting in FY 2010. The heart attack and pneumonia readmission measures have not been endorsed by the NQF and should not be included for hospital reporting in FY 2010 either.

The HQA has adopted a measure of condition-specific readmission rates paired with condition-specific average length of stay (ALOS). As always, we urge CMS to look to the HQA as the source for applicable measures that are ready for inclusion in the pay-for-reporting program. CMS should incorporate the HQA-adopted readmission/ALOS measure into the pay-for-reporting program instead of the proposed readmission measures.

- **Venous thromboembolism measures** – The venous thromboembolism measures have been endorsed by the NQF and adopted by the HQA. They are ready for inclusion in the pay-for-reporting program. Venous thromboembolism is a major cause of mortality and morbidity for hospitalized patients, and hospitals have room for improvement in providing care for this condition. The Venous thromboembolism measures are a cohesive set and include both process and outcomes measures.
- **Stroke measures** – These measures have not been endorsed by the NQF nor adopted by the HQA. Although we are interested in examining the possibility of including care for stroke patients in future years, these measures are not ready for implementation for FY 2010.
- **AHRQ patient safety and quality indicators** – The HQA has adopted three of the nine AHRQ measures proposed by CMS, including postoperative wound dehiscence, accidental puncture or laceration and abdominal aortic aneurysm mortality rate. We believe these measures are appropriate for public reporting, although significant infrastructure challenges, outlined below, still exist to collect and transmit administrative data on patients of all payers. The other AHRQ measures may have value to hospitals for quality improvement purposes but, in their current format, they lack the sensitivity and specificity required for use as comparative, publicly reported measures. Because they are derived from administrative data, they are less sensitive than measures derived from

clinical chart abstraction at identifying relevant patients and excluding other patients. Some of the AHRQ indicators have very high false positive rates, meaning that they indicated potential problems, but further investigation showed the care was adequate and the indicator was wrong. To be considered for HQA adoption, and therefore be ready for implementation in the pay-for-reporting program, these measures would need extensive field testing and respecification.

CMS proposes that hospitals submit to the CMS data warehouse all-payer claims data to calculate these measures. However, CMS does not describe how this would be accomplished, and it is unclear how this could be done. The Joint Commission data vendors currently collect and submit most of the clinical data for the pay-for-reporting program. However, the vendors do not have the capability to process administrative data in a similar fashion. The data vendors have not been asked if they have the capacity to take on this task, nor has a contract been let to modify the CMS Abstraction & Reporting Tool (CART) to collect these additional data. We are unsure whether CMS expects the data vendors to develop these capabilities or whether a transmission mechanism would be built into the CART tool or another system. Thus far, the CART tool has been under-resourced and has been unable to keep pace with reporting demands. As an alternative means of transmission, CMS also proposes that other entities that collect data for the AHRQ measures, such as state agencies or state hospital associations, could transmit the data directly to CMS, thereby relieving hospitals of the task of submitting the same data to multiple different entities. Again, it is not clear how this would work or who would bear the costs for putting the data in the right format, running edits to check data accuracy and otherwise cleaning the data. There currently is no infrastructure to allow for the transmission of this type of information between outside entities and the CMS data warehouse. It is unclear how CMS would propose to build such an infrastructure.

It also is unknown how CMS would propose to validate the administrative claims data. All data posted for public display on the *Hospital Compare* Web site should be validated to ensure its accuracy. Data for measures similar to the AHRQ measures have never been collected or validated before. We urge CMS to clarify how it would validate the data for these measures.

We also have serious concerns about the security and privacy of the protected information that would have to be sent in such a transaction. CMS would need to ensure that a secure and protected infrastructure is in place and that it has been thoroughly tested prior to use.

It is not clear what patients who are not insured by a government payer would think about the Department of Health and Human Services (HHS) and its contractors having access to the sensitive information that is contained in their billing files. With the quality data, Congress enabled CMS to establish a data warehouse through which individual patient data is processed, and CMS is given aggregate information only. The proposed rule does not clearly delineate how the equally sensitive billing information would be collected so

that patient privacy would be protected. If the data go directly to CMS, would they be available through a *Freedom of Information Act* request or other means? How are they to be protected to preserve patient privacy?

- **Cardiac surgery measures from the Society of Thoracic Surgeons (STS) registry** – The STS cardiac surgery measures have been endorsed by the NQF, but they have not been adopted by the HQA. They should not be included for hospital reporting for FY 2010. The STS measures were developed for the purposes of quality improvement and patient safety. They were not developed for the purposes of public reporting or to encourage transparency and accountability. Therefore, they should not be used for public reporting until they are tested further to ensure the validity of the results of the comparisons between hospitals. Other testing should be conducted to determine whether these measures resonate with the public and whether patients find value in the data and can understand the importance of the measures.

We are very concerned that one of the measures, “participation in systematic database for cardiac surgery,” could be viewed as serving the financial interests of a third-party organization. To participate in the STS registry, hospitals must pay a fee to STS and use an STS data vendor. Participation in the program is costly. **It is inappropriate for CMS to institute a financial incentive through the Medicare pay-for-reporting program that would require hospitals to pay money to STS.**

CMS recognizes that hospitals not currently participating in the STS program would need to submit their data directly to CMS; however, the agency does not specify how this would occur. For those hospitals that participate in the STS registry, CMS states that an arrangement would be made for STS to directly submit the data to CMS. It also is unclear how this would work. For the CMS data warehouse to accept the data, all of the data elements would need to be specified in the same manner as the data elements for the existing measures. For example, for the current heart attack measure of receiving a beta blocker at discharge, a patient that receives a beta blocker is represented in the CMS dataset with a coded value of “E.” A patient who is eligible to receive the beta blocker, but did not receive it, is coded with a “D.” The STS measure set also contains a beta blocker at discharge measure. However, patients who received and who did not receive a beta blocker may be coded in the STS database with values of “Yes”/“No” or “Y”/“N” or “1”/“0,” or any combination of possible values. To bring the STS data into the CMS data warehouse, the differences in the specifications of the data elements would have to be eliminated. CMS makes no mention in the proposed rule of how this would occur, and the agency does not estimate the time and resources required to make it happen.

Similar to the AHRQ measures, CMS also does not address how the security and privacy of the data would be ensured during a data transfer from STS, and the agency does not provide any information on how the data would be validated to meet the same standards as the other pay-for-reporting measures.

The HQA recently adopted several other measures that CMS did not propose to include for FY 2010. In particular, the HQA has adopted two measures of infection rates: surgical site infection and central line catheter-associated blood stream infection. The HQA believes that these measures are ready for public reporting. They have been thoroughly specified, are currently used in other reporting initiatives, are salient to consumers and hold important information that hospitals can use for their quality improvement programs. CMS lists both of these measures as possible measures for FY 2011 or beyond; however, we believe they are ready for inclusion in the pay-for-reporting program now. **We urge CMS to reconsider implementing them for FY 2010.** In addition, the HQA has adopted measures on the care provided in pediatric intensive care units. The quality measures for pediatric populations, as well as maternity patients and other patient populations not currently represented by the selected measures, should be supported for collection, validation and posting by CMS. As appropriate and fitting with the identified national goals, we urge CMS to take a broader view of the patient populations represented by the measures.

In summary, we support the addition of the following 12 measures that have been adopted by HQA for use in the pay-for-reporting program:

- Surgical site infection rate.
- Central line catheter-associated blood stream infection rate.
- Perioperative beta blockers for surgical patients.
- Six measures of venous thromboembolism care.
- Three AHRQ patient safety and quality indicators: postoperative wound dehiscence, accidental puncture or laceration and abdominal aortic aneurysm mortality rate.

Program procedures. CMS proposes to allow hospitals that have fewer than five heart attack, heart failure, pneumonia or surgical care patients in a calendar quarter to not submit quality measures data for those patients beginning in FY 2010. Hospitals that have fewer than five HCAHPS-eligible patients in any month will not be required to submit HCAHPS surveys for that month. The AHA supports this approach as a sensible way to reduce the reporting burden on hospitals with a very small number of cases; however, we believe hospitals should always be able to voluntarily report on quality measures if they want to do so.

For the first time, CMS proposes to use staggered start dates and data submission time frames for the measures in the pay-for-reporting program. We believe this proposal would add unnecessary confusion and additional complexity to an already complicated system. CMS proposes four different start dates, from January 2009 to October 2009, for the group of new measures and does not specify when reporting would begin for the readmission measures. Some of these start dates are delayed because the specifications for the measures and the data collection and transmission infrastructure will not be ready for hospitals to begin collecting data with January 2009 discharges. This is a clear acknowledgement by CMS that not all of these measures are ready for implementation in FY 2009 for the FY 2010 annual payment update. For example, CMS proposes that hospitals begin data collection on the AHRQ measures with discharges beginning in October 2009 and that the first quarter of data would be due by April 2010. Both of these

dates are in FY 2010. This should be proposed and discussed in next year's rule; it is not relevant now, as CMS is not ready to implement data collection for these measures in this fiscal year.

CMS also proposes to stagger the data submission time frames for the new measures. Currently, hospitals must submit the data for all measures within four and a half months of the close of the reporting quarter. CMS proposes a similar time frame for the surgical care, nursing sensitive, venous thromboembolism and stroke measures, but proposes that the AHRQ and STS cardiac measures be submitted within four months of the close of the quarter. We believe that the staggered submission dates are unnecessary and increase the potential for data submission errors to be made. **We urge CMS to adopt one, consistent submission time frame of four and a half months for all pay-for-reporting measures.**

Using alternative data sources. In the proposed rule, CMS seeks comments on what alternative data sources for quality measures could be used in place of chart abstracted data. CMS lists the Continuity Assessment Record & Evaluation (CARE) tool, electronic laboratory test results and clinical data registries as examples of alternative data sources. We believe this is a misguided discussion. Quality measures should not be selected for the pay-for-reporting program simply because there is a readily available data source that can provide information on a particular area of care. Measures should be selected solely on their merit, for their importance, validity and relevance.

In reference to the CARE tool, we believe that it is too early to judge whether the tool may be of value for quality measurement and public reporting purposes. The demonstration project with the CARE tool is in its very beginning stages. We do not know how successfully hospitals can implement the tool, much less whether it has any value for quality measurement purposes.

Infrastructure problems. Recently, CMS has experienced multiple problems with the quality reporting data infrastructure. There have been delays in data submission and reporting timelines. The data warehouse has, at times, lacked the capacity to receive data and has been unable to track the data it has received. There has been inadequate communication to hospitals and their data vendors on many steps of the process. For example, some hospitals have received data validation reports for other organizations. In regular practice, hospitals receive notification only two to three days before a reporting period deadline that they are "missing" one patient case and are in jeopardy of losing their annual payment update. On multiple occasions, the data warehouse had to reprocess files due to programming errors and did not confirm to hospitals whether their cases were accepted during the reprocessing or whether they needed to be resubmitted.

We were disappointed that CMS did not discuss these challenges in the proposed rule, nor did the agency ask for comment on how the process could be improved. In the proposed rule, there was no indication by CMS that more resources would be devoted to improving the infrastructure and increasing its capacity. Although CMS proposed adding 43 new quality measures, it did not discuss how this would be managed by a system that is barely able to meet its current demands.

We urge CMS to devote more resources to the data infrastructure and to seek comment through the regulatory process for what changes should be made most urgently.

Measure maintenance. The AHA believes it is critical that the measures included in the pay-for-reporting program represent best clinical practice. Therefore, we are pleased that CMS recognizes the need to retire measures if they are no longer relevant or important in distinguishing opportunities to improve care. We agree that the pneumonia oxygenation assessment measure may no longer be necessary for reporting, and we concur with its retirement. However, as the method used to retire or replace measures for the pay-for-reporting program is developed and refined, we urge CMS to include hospitals, data vendors, other stakeholders and the public in the process.

All changes to existing measures should be made through the regulatory process, which allows for public comment. No changes should be made to existing measures through a sub-regulatory process as CMS suggests in the proposed rule. We understand that CMS is planning to respecify the pneumococcal and influenza vaccination measures without consulting the HQA or seeking public input. This is unacceptable. At times, it may be necessary to temporarily suspend measure reporting due to a change in science or an implementation issue, such as with past influenza vaccine shortages. **However, all permanent changes to revise existing measures must be made through the regulatory process to allow for public input.**

Data resubmission, validation, and appeals. The proposed rule does not address the issue of data resubmission when a hospital or its vendor becomes aware of an error in the data that was sent for posting on *Hospital Compare*. **The AHA urges immediate adoption of an effective mechanism for allowing hospitals and their vendors to resubmit quality measure data if they discover an error.** The point of public reporting is to put accurate and useful information into the hands of the public, and this is facilitated by allowing known mistakes to be corrected. CMS recognized this in its value-based purchasing report to Congress. There is no reason why this should not be implemented now in the pay-for-reporting program.

In addition, improvements must be made to the current validation process. Many hospitals have been notified that there have been problems validating the data they submitted. In several instances, these validation problems have been due to inconsistencies in the definitions of variables used by CMS' contractors who are reabstracting patient-level data and comparing it to the data submitted by the hospitals. In other instances, a mismatch between single data elements unrelated to the quality of care provided by a hospital, such as the patient's birth date, have caused hospitals to fail validation. The reabstraction of five charts per quarter for each hospital is insufficient to ensure the reliability of the data. A more resilient and less resource-intensive method of validation is needed. We believe that the ideas for reforming the data validation process that were put forward by CMS in its value-based purchasing report to Congress hold promise as an improved approach toward data validation. We were disappointed that CMS did not propose similar changes for the pay-for-reporting program in the proposed rule. **We urge CMS to propose an alternative data validation process for the pay-for-reporting program as soon as possible.**

A hospital should have the opportunity to file an appeal if it believes it wrongly failed the data validation process. The appeals process should be straightforward, transparent and timely. **Hospitals should have clear guidance on how to submit their appeals, and CMS should provide timely appeals decisions.** In the proposed rule, CMS states that it will provide hospitals with a decision within 60 to 90 days of their appeal. This delay is burdensome and unnecessary. Because CMS decreases a hospital's payments during the appeals process, it may cause unnecessary cash flow problems for hospitals whose validation results are later overturned. This could be particularly harmful for hospitals serving large numbers of uninsured patients. In 2008, CMS was able to process all appeals within 60 days. **There is no reason why this timeline must be expanded to 90 days for FY 2009.** In its value-based purchasing report to Congress, CMS outlines an appeals process through which hospitals that initially fail validation will not receive lower payment while their appeals are ongoing. Only after a final decision is reached would any payment adjustments be made. This logical process should be established now in the pay-for-reporting program.

DRGs: HOSPITAL-ACQUIRED CONDITIONS

The DRA required CMS to identify by October 1, 2007 at least two preventable complications of care that could cause patients to be assigned to a complication or comorbidity (CC) diagnosis-related group (DRG). The conditions must be either high-cost or high-volume or both, result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and be reasonably preventable through the application of evidence-based guidelines. The DRA mandates that for discharges occurring on or after October 1, 2008, the presence of one or more of these preventable conditions would not lead to the patient being assigned to a higher-paying DRG.

In the FY 2008 inpatient prospective payment system (PPS) final rule, CMS adopted eight conditions for which it would no longer pay a higher DRG rate beginning in FY 2009 if the conditions were not present on admission. Those eight conditions were:

- Object left in during surgery;
- Air embolism;
- Blood incompatibility;
- Pressure ulcers;
- Falls and trauma;
- Catheter-associated urinary tract infections;
- Vascular catheter-associated infections; and
- Surgical site infection – mediastinitis after coronary artery bypass surgery.

This year, CMS proposes to expand the list to include nine additional conditions when the payment policy takes effect on October 1. The nine conditions are:

- Surgical site infections following elective procedures;
- Legionnaires' Disease;
- Glycemic control;
- Iatrogenic pneumothorax;
- Delirium;
- Ventilator-associated pneumonia;
- Deep-vein thrombosis/pulmonary embolism;
- *Staphylococcus aureus* septicemia; and
- *Clostridium difficile*-associated disease.

Most of the conditions selected by CMS do not fulfill the statutory requirement that they be reasonably preventable through the application of evidence-based guidelines. **To be reasonably preventable, there must be solid evidence, published in peer-reviewed literature, that by engaging in a certain set of practices, clinicians can reduce the occurrence of an event to zero, or near zero, among a typically broad and diverse patient population.** Currently available evidence indicates that for many conditions, even when all appropriate care is given, we do not yet know how to reduce the rates of these conditions to zero or near zero. Some patients, particularly high-risk individuals, may still develop the conditions on the list.

Where guidelines and proven strategies exist, hospitals strive to ensure that serious, adverse events do not occur. While we endeavor to do the best for patients through the use of sophisticated systems, information technology and care protocols, human error can and does occur. When serious events occur, hospitals believe that information about the error should be quickly and openly communicated to patients and their families, and that the purchasers of those health care services – patients, insurers or employers – should not be billed for that care. The AHA has asked all hospitals to review their current billing policies and practices and ensure that they reflect their organizations' internal policies about foregoing payment for costs associated with care made necessary due to a preventable medical error that occurred during the course of care in that organization.

CMS could provide leadership to the hospital field in identifying where solid evidence exists that certain conditions can be prevented and by helping hospitals focus on the efforts they can take to prevent them. However, the implementation of a list of 17 conditions does not provide that leadership. A recent report by the Government Accountability Office found that the HHS is lacking the leadership to prioritize recommended practices and help guide implementation of evidence-based practices in hospitals. This proposed list of conditions is another example of a disjointed approach to quality improvement. The inclusion of some of these conditions on the list leads us to believe that CMS did not obtain the necessary clinical and expert input on what conditions may be appropriate for this policy.

We recommend that CMS develop an advisory panel of clinicians and scientists to provide the agency with guidance on which conditions are appropriate for inclusion under this policy. The advisory panel should include both academic researchers and clinicians who are actively providing patient care in the inpatient hospital setting. The role of the advisory panel

should be to review the scientific evidence on the preventability of the conditions on the list and help CMS more specifically define the particular patient populations to whom the payment policy should be applied. For example, there is solid research showing the benefits of controlling blood glucose levels among certain surgery patients. However, for patients with many other conditions, there is no established scientific evidence around this practice. If CMS were to choose to include glucose control as a condition, it would be more reasonable to apply the payment policy only for those patients where there is solid evidence that controlling blood glucose levels is a best practice. The technical advisory panel also should review the experiences and results from those states that have already implemented present-on-admission coding or adverse-event reporting. States such as California and Minnesota have experience implementing policies related to CMS' hospital-acquired conditions policy. We recommend that CMS examine the outcomes from these states and the lessons learned in refining its own policy.

For this policy to be implemented fairly, some adjustment must be made to account for the differences in patient populations among hospitals. Without using a risk-adjustment methodology, hospitals that admit a higher proportion of sicker patients, who are more at risk for some of the conditions, will unfairly bear a larger financial penalty. Additionally, certain high-risk patient populations should almost always be excluded from this policy. Trauma patients and patients near the end of life receiving palliative care are examples of high-risk patient populations that should not be included in this payment policy for most of the proposed conditions.

Additionally, we believe that hospitals will face significant challenges in diagnosing these conditions accurately on admission and coding for them at that time. Coding accuracy can only be achieved when physicians have been educated about the need to carefully identify and record, in an easily interpretable manner, whether these conditions are present on admission. To date, CMS has done little to initiate such an education process.

Conditions to include for FY 2009. The AHA believes that four of these conditions are appropriate to include for FY 2009. These include three serious, adverse events – object left in during surgery, air embolism and blood incompatibility – and vascular catheter-associated infections. Because these conditions are identified by discrete ICD-9 codes, they can be coded by hospitals. More importantly, these are events that can cause great harm to patients and for which there are known methods of prevention. However, the AHA requests that CMS provide technical guidance on how it would address certain situations of retained foreign objects. In some circumstances, it may be in the best interest of the patient not to remove the object. Leaving a patient under anesthesia for a prolonged period of time and displacing internal organs in a search for a microscopic surgical object left in the body may be more harmful than leaving the object inside the patient and completing a surgery in an expedited fashion. We suggest that CMS clearly specify that the policy applies to an *unintended* retention of a foreign object, to allow physicians to exercise their clinical judgment regarding the relative risk of leaving an object in versus removing it. Additionally, we would appreciate guidance on how CMS would address a situation in which a foreign object left in the body after surgery is found by the same hospital, but in a different fiscal year, or by another hospital.

Conditions not ready for inclusion for FY 2009. The other conditions, including those adopted in the FY 2008 inpatient PPS final rule and those proposed in the FY 2009 proposed rule, should not be implemented for FY 2009.

Our specific concerns with each of the conditions follow.

- **Pressure ulcers** – We do not believe that pressure ulcers should be included in this policy because they do not meet the definition of “reasonably preventable.” Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. The best method of preventing pressure sores is to turn the patients. But patients who have suffered trauma or have underlying conditions that make turning inadvisable are at greater risk of pressure ulcers. Some patients have fragile skin that puts them at greater risk. There also is evidence of an increased risk of pressure ulcer reoccurrence after a patient has had at least one stage IV ulcer. Other patients may be at risk for a pressure ulcer, but it may be more harmful to the patients’ overall health to move them than to take the risk of a pressure ulcer developing. For example, an obese patient with a serious spinal injury may be at a high risk to develop a pressure ulcer, but due to the nature of the spine injury, it is safer for the patient to remain in one position.

In addition, it may not always be possible, or in the best interest of the patient, to examine the patient for pressure ulcers when they arrive at the hospital. For example, a patient who arrives in coronary distress, with traumatic injury or with any other life- or function-threatening condition requires immediate care for their urgent condition, which should not be delayed by a search for skin breakdowns.

In the proposed rule, CMS clarifies that, with the development of new ICD-9 codes that capture the staging of pressure ulcers, hospitals must code both the staging and the site of a pressure ulcer. CMS has proposed, however, to remove the CC and major complication or comorbidity (MCC) classifications from the current pressure ulcer codes that show the site of the ulcer (ICD-9-CM codes 707.00 through 707.09). Therefore, hospitals will only be able to indicate CC/MCC classifications if they include one of the new codes indicating the stage of the ulcer. Further, only stage III and stage IV pressure ulcers would be included under the hospital-acquired conditions policy and have these CC/MCC classifications.

We recommend that CMS collect sufficient data before implementing the proposal to remove the CC/MCC classifications from the current pressure ulcer codes that show the site of the ulcer. Hospitals will need time to learn to correctly use the new staging codes and adjust their processes to ensure these stages are documented in their records. Additionally, we believe that CMS’ proposal that only stage III and stage IV pressure ulcers would have CC/MCC designations is inconsistent with CMS’ long-standing tradition of treating new codes in the same manner as the predecessor codes. CMS has

traditionally not moved conditions across DRGs, or changed the CC/MCC status of a code, until sufficient claims data are available to determine the impact on hospital resources. Therefore, we recommend that CMS recognize the codes for stage II pressure ulcers (707.22) and unstageable pressure ulcers (707.25) as a CC and stage III and IV pressure ulcers as an MCC until sufficient claims data are available to determine the impact on hospital resources.

- **Falls and trauma** – This condition should not be included in this policy because it does not meet the definition of reasonably preventable. Not all patient falls are the result of a mistake by the hospital, and not all falls can be prevented by the hospital. In some cases, even though the hospital can provide the best care, come swiftly to the patient's assistance when the patient calls for help, and minimize the use of restraints, the patient may get out of bed on her own and suffer from a fall.
- **Catheter-associated urinary tract infections** – This condition should not be included because prevention guidelines for catheter-associated urinary tract infections are still debated by clinicians. Additionally, many clinicians believe that urinary tract infections may not be preventable after several days of catheter placement, and certain patients, such as trauma patients, may need catheters for extended periods of time. Clinicians may not always know upon admission if a patient has a bladder infection. The only method to verify present-on-admission status would be to institute universal screening upon admission, which would be unnecessarily burdensome to patients, costly to hospitals and would not necessarily identify those patients with infections.
- **Surgical site infection – mediastinitis after coronary artery bypass graft** – Although mediastinitis should not occur after the surgeries of uncomplicated patients, patients with comorbid conditions, such as diabetes or obesity, will be at higher risk for any infections after surgery, and not all infections may be preventable. Patients with serious comorbidities should be excluded from the patient population for this condition.
- **Surgical site infections following elective procedures** – We agree that there are evidence-based practices that should prevent most surgical site infections. However, several of the surgeries selected for inclusion under this policy do not seem appropriate. Varicose vein ligation and stripping is typically performed as an outpatient procedure. The other surgeries are typically short-stay procedures. Any infections occurring post surgery would likely not be identified during the initial hospitalization, but would cause a patient to seek medical care after discharge. These events would not be captured under CMS' hospital-acquired conditions policy. Those patients undergoing a laparoscopic gastric bypass are obese and, therefore, are already at higher risk for a surgical site infection or other complication.

Of these surgeries, only the total knee replacement surgery was included in the Surgical Care Improvement Project (SCIP). We would support the inclusion of this condition in the future as long as the payment penalty was applied only in those instances when not all

of the recommended perioperative surgical processes were carried out. This would require CMS to implement some level of medical record or case review in deciding whether or not to lower the hospital's payment rate.

However, we note that almost all knee replacement surgeries fall into three DRGs that are solely dependent on the presence or absence of an MCC: "Major joint replacement or reattachment of lower extremity without MCC" (470); "Major joint replacement or reattachment of lower extremity with MCC" (469); and "Bilateral or multiple major joint procedures of lower extremity without MCC" (462). The codes proposed by CMS to identify hospital-acquired conditions for knee replacement surgery include only CCs, "Infection and inflammatory reaction due to internal joint prosthesis" (996.66) and "Other postoperative infection" (998.59), and no MCCs. Thus, knee replacement surgery patients' DRG assignments will be the same whether or not these selected hospital-acquired condition codes are present.

- **Legionnaires' Disease** – Similar to the other infections included on this list, a patient may come into the hospital already colonized with Legionnaires' Disease. There is no way to be sure whether the condition is present on admission other than to screen all patients, which would be unnecessary and costly. There are no clinical differences between Legionnaires' Disease acquired outside of the hospital setting and Legionnaires' Disease acquired within the hospital, so determining the site of the infection would be technically impossible.

There is no consensus opinion among experts on how to prevent Legionnaires' Disease due to the lack of evidence-based recommendations, the questionable validity of environmental monitoring, and remaining questions on how to perform active disinfection of a water system. The Centers for Disease Control and Prevention (CDC) does not recommend routine environmental screening in hospitals for the bacteria that cause Legionnaires' Disease. The primary reason against routine testing is that the relationship between water culture results and the risk to patients of contracting Legionnaires' Disease remains undefined. The bacteria that cause Legionnaires' Disease can be present in the water systems of buildings without being associated with known cases of the disease. Thus, conducting environmental surveillance, which the CDC does not recommend, would obligate hospitals to initiate water-decontamination programs if the bacteria are identified, even if there have been no identified case of Legionnaires' Disease.

- **Glycemic control** – CMS also selects "extreme aberrations in glycemic control" as a condition. However, the agency does not provide a clinical definition of "extreme aberrations." Clinicians we spoke with were unable to determine exactly what CMS meant by this phrase. While there is scientific evidence to suggest that controlling blood glucose levels can prevent infections for surgery patients, tightly controlling blood glucose levels for all patients has not been scientifically validated. In fact, under certain conditions, blood glucose levels that are too tightly controlled could put the patient in

danger of hypoglycemia, which is at least as dangerous as hyperglycemia. For example, because blood glucose levels are responsive to hormones, if a patient is experiencing anxiety before surgery, the patient's blood glucose level may increase. The clinician may try to control the elevated blood glucose level and bring it down during the perioperative period. However, post surgery, when the patient is no longer experiencing stress, the blood glucose level may naturally decrease. Without careful monitoring, the patient could become hypoglycemic simply because the blood glucose level had been previously controlled.

Some diabetics have poorly controlled blood sugar levels that are not a result of any care the hospital did or did not provide. If a diabetic patient with poorly controlled blood glucose levels is admitted to the hospital for immediate, necessary surgery, the hospital may have to take the risk that the patient's blood glucose levels will become even more elevated during the surgery. Balancing the risks and benefits for each treatment for each patient is a fact of providing care. Just as there is no one-size-fits-all way to practice medicine for all patients, this condition cannot be applied to all patients under this policy.

- **Iatrogenic pneumothorax** – Iatrogenic pneumothorax is not reasonably preventable. In emergency situations, it may be necessary to place a central line in an access point, such as the subclavian or jugular veins, with a higher risk of pneumothorax. However, if these sites are the only access points available to the clinician to place the central line, they must be used. Additionally, there is anatomical variation among all patients that makes it possible that a pneumothorax could happen during a medical procedure, regardless of the skill with which the procedure is performed.
- **Delirium** – There is no clear clinical definition of delirium, particularly as a patient comes into or out of a state of delirium; therefore, its inclusion on the list is problematic. Further, as CMS acknowledges in the proposed rule, evidence-based practices may only prevent 30 to 40 percent of cases, meaning most cases cannot be prevented. This does not meet the definition of reasonably preventable.

Delirium is an unfortunate side effect that can occur for a number of reasons, most of which are not within the control of the hospital or the result of a mistake made by the hospital. For example, many patients with Alzheimer's disease or dementia experience delirium when they are placed in a new, unfamiliar environment, such as a hospital. Simply changing the environment from one the patient was accustomed to can induce the delirium. While this symptom is very difficult for the patient's family to cope with, the symptoms almost always subside and disappear completely once the patient is adjusted to the new environment or returned to her usual residence. Many physicians believe that it would do no good, and could be potentially harmful, to over-medicate patients in this condition in an attempt to reverse the delirium. In another example, it is sometimes necessary to withdraw patients from certain medications prior to surgery. This may cause temporary delirium. However, the temporary delirium is less harmful to the patient than completing the surgery while the patient has the potentially harmful drug in his system.

- **Ventilator-associated pneumonia** – Certain patients, such as trauma or immunocompromised patients, may be at a high risk for developing ventilator-associated pneumonia. For some patients, their medical conditions make it more difficult or impossible to implement all evidence-based practices. For example, trauma patients with certain injuries might not be able to have the head of the bed elevated as suggested in some guidelines. CMS states in the proposed rule that the scientific evidence suggests that 60 to 80 percent of ventilator-associated pneumonia cases *cannot* be prevented, which again, does not meet the definition of reasonably preventable.

We also are concerned over the lack of standardized clinical definitions or criteria for ventilator-associated pneumonia. The fact that the definition is open to interpretation means that clinicians may diagnose it differently in similar patients. These differences would be reflected in the medical record documentation and might unfairly penalize those organizations that more liberally diagnose ventilator-associated pneumonia. Hospital coders will need detailed instructions on the assignment of the newly created code 997.31. The *Official Guidelines for Coding and Reporting* requires that code assignment for postprocedural complications be based on the provider's documentation of the relationship between the infection and the procedure. We believe that the same should hold true for all complication codes, including the new ventilator-associated pneumonia. Coders are not allowed to code on the basis of abnormal lab findings alone, nor are they allowed to interpret clinical findings or diagnose patients.

Therefore, we are concerned that the codes listed in the proposed rule “to identify cases in current Medicare data” for ventilator-associated pneumonia seem to imply that the mere fact that a patient is on a ventilator (code 96.70-96.72) and has a pneumonia code would constitute ventilator-associated pneumonia. Some of the pneumonia codes included would not be routinely associated with a ventilator, such as 073.0 (Ornithosis with pneumonia) or 136.3 (Pneumocystosis). Code 073.0 refers to pneumonia that results from an infectious disease that is usually transmitted to humans from birds. Code 136.3 refers to pneumonia due to a fungal organism *Pneumocystis carinii* (now renamed *Pneumocystis jiroveci*) that is common in the environment and does not cause illness in healthy people, but can cause a lung infection in people with a weakened immune system due to conditions such as cancer, HIV or transplant status.

- **Deep-vein thrombosis/pulmonary embolism** –This condition is similar to pressure ulcers in that there may be certain trauma patients who are at risk for developing a clot, but their condition is such that they cannot be moved from one stationary position. Additionally, patients with clotting disorders or who are in a hypercoagulated state may be more likely to develop a blood clot that could not be prevented even with the best of care. Blood clots can be difficult to detect on admission if the typical symptoms of swelling and inflammation are not yet apparent, even though the clot has already formed.

- ***Staphylococcus aureus* septicemia** – Accurately identifying the presence of *staphylococcus aureus* septicemia on admission will be a challenge. Patients may be admitted to the hospital with a *staphylococcus aureus* infection of a limited location, such as pneumonia, urinary tract infection or skin infection. Subsequent development of *staphylococcus aureus* septicemia may be the result of the localized infection and not a hospital-acquired condition. Additionally, the proliferation of changes in coding guidelines for sepsis in recent years present further challenges to hospital coding personnel to accurately capture present-on-admission status. Finally, there is still some debate among clinicians regarding the prevention guidelines for *staphylococcus aureus* septicemia.

We believe the category of *staphylococcus aureus* septicemia is simply too large and varied to be able to say with confidence that the infections were reasonably preventable. We urge CMS to narrow this category to include only patients for whom it is reasonably clear that the hospital was the source of the infection and that it could have reasonably been prevented.

We disagree with the range of codes identified for *staphylococcus aureus* septicemia. The only code needed to represent this condition is 038.11, *staphylococcus aureus* septicemia. We disagree with all other codes listed under this condition in the proposed rule because they do not uniquely identify this condition, one of CMS' criteria for selection of a hospital-acquired condition. For example, 995.91 and 995.92, respectively, identify sepsis and severe sepsis resulting from any infectious condition, not just *staphylococcus aureus*. Code 998.59, other postoperative infection, is not for septicemia and is not specific to *staphylococcus aureus*. In fact, code 998.59 does not indicate a systemic infection, as it could be applicable to a localized infection such as a postoperative abscess. In addition, subcategory 999.3, other infection, includes code 999.31 (infection due to central venous catheter, which has already been selected as a hospital-acquired condition) and 999.39 (infection following other infusion, injection, transfusion, or vaccination).

- ***Clostridium difficile*-associated disease (CDAD)** – CDAD can be an unfortunate side effect from the use of antibiotics among individuals whose health is compromised. However, when patients are put on strong antibiotics it is because they are fighting a serious infection. That infection is likely to be far more dangerous to the patient's overall health than the uncomfortable side effects of CDAD. In another example, a hospital may give a surgical patient an antibiotic during the perioperative period, as is recommended by the SCIP and the quality reporting measures. Such a patient may experience CDAD. Thus, following one set of evidence-based guidelines could result in a side effect that causes a hospital to be penalized under the hospital-acquired conditions policy.

Many individuals are already colonized with CDAD. Therefore, it is not acquired in the hospital nor the result of a mistake made by the hospital. Some clinicians have pointed out that clearly distinguishing community-acquired CDAD from healthcare-associated

CDAD can be difficult. We do not believe all patients entering the hospital should be tested on admission to determine if they are colonized with CDAD. Nor do we believe physicians should withhold prescribing antibiotics to patients who need them because there is a chance the patient may experience CDAD. We do not believe CDAD is reasonably preventable or appropriate for inclusion on this list.

In the proposed rule, CMS also discusses the public health concerns of Methicillin-resistant *staphylococcus aureus* (MRSA), but it proposes not to include MRSA as a hospital-acquired condition for payment purposes under the inpatient PPS. We support this decision because of the inconclusive evidence base on the preventability of MRSA, and we agree with CMS that the presence of MRSA as a colonizing bacterium does not always result in harm to the patient.

Payment changes based on present-on-admission coding. The payment changes for hospital-acquired conditions will apply only when the selected conditions are the only CCs or MCCs present on a claim. Under this policy, CMS would not make higher payments for the selected conditions if they are coded as not present on admission or if the medical record documentation is insufficient to determine whether the condition was present on admission. In other words, CMS would not make a higher payment if the condition is coded on the claim with an “N” (not present on admission) or a “U” (medical record documentation is insufficient). CMS proposes to not pay a higher payment amount when the medical record documentation is insufficient because it believes this will foster better medical record documentation.

The reporting of present-on-admission indicators is still new, and hospitals continue to learn how to apply them, as well as educate their physicians on the required documentation without which present-on-admission reporting is impossible. **We urge CMS not to implement the proposal not to pay for hospital-acquired conditions coded with the “U” indicator.** According to the *Official Guidelines for Coding and Reporting*, the “U” reporting option “should not be routinely assigned and used only in very limited circumstances.” Coders are encouraged to query the providers when the documentation is unclear. We agree that there should be limited circumstances when “U” is reported. However, those circumstances are more likely to be due to lack of physician availability or lack of physician response to a hospital query for more specific information. It is important to distinguish these circumstances from those where the physician is not able to provide more specific present-on-admission information (even after a hospital query) because the patient expired or was transferred before a clinical evaluation could be completed to determine whether a condition was present on admission or not. We believe such situations should be reported with a present-on-admission indicator of “W,” or clinically undetermined. We recommend that CMS analyze the reporting of option “U” and determine whether there is a problem with over-reporting before a decision is made not to pay for CC/MCC reported with a “U.”

Unintended consequences. The AHA encourages CMS to consider the unintended consequences that might arise from implementing the hospital-acquired conditions policy. Trying to accurately code for some of these conditions that are present on admission may lead to excessive testing for patients entering the hospital. The necessity to complete diagnostic tests before a patient is

admitted to confirm whether a condition was present on admission could lead to delayed admissions for some patients and disrupt efficient patient flow.

Other technical clarifications. The AHA would like clarification from CMS on how hospitals may appeal a CMS decision that a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher DRG payment. A process for hospitals to appeal a decision about specific patient cases is vitally necessary to ensure accountability.

Enhancement and future issues. CMS asks for comment on several potential future refinements to this policy. In particular, CMS asks for comments on whether rates should be collected to measure the incidence of these conditions and whether information learned from the present-on-admission coding could be used for quality improvement purposes. CMS also asks for comment on whether the adoption of ICD-10 codes could facilitate more accurate identification of hospital-acquired conditions.

Information on the incidence rates of these conditions learned through present-on-admission coding should not be publicly reported. All information used for public reporting should continue to proceed through the established mechanism. Measures must first be endorsed by the NQF and then adopted by the HQA. Measures that fulfill those criteria may then be considered for inclusion by CMS in the pay-for-reporting program. For example, the HQA has adopted measures of surgical site infection rates and central-line associated bloodstream infection rates. These measures are ready for inclusion in the pay-for-reporting program. A separate reporting site outside of *Hospital Compare* should not be developed, and measures that are not NQF-endorsed and HQA-adopted should never be used.

We encourage CMS to explore how information learned from present-on-admission coding could be used to better understand and prevent certain hospital-acquired conditions. Improving care for patients should be the end goal of this policy. We urge CMS to use the new information available to examine ways that care can be improved.

ICD-10-PCS and ICD-10-CM. We strongly agree with CMS that the adoption of ICD-10 could facilitate more precise identification of hospital-acquired conditions. However, we believe that there may have been a typographical error in referring to ICD-10-PCS (which contains procedure codes), rather than ICD-10-CM in relation to diagnosis codes. We agree that ICD-10 (both diagnosis and procedure codes) are more precise and capture information using more current medical terminology.

The need to replace ICD-9-CM diagnoses and inpatient procedure codes has been under discussion since the early 1990's. The ICD-9-CM classification system is close to exhausting codes to identify new health technology and current medical terminology, and is in critical need of upgrading.

We urge the Secretary to expeditiously undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS. HHS should take the necessary steps to avoid being

unable to create new diagnosis or procedure codes that reflect evolving medical practice and new technology. It is easier to plan for this migration than to respond to the significant problems that will likely result in unreasonable implementation time frames. **The AHA still believes that the health care field will need a minimum of two years to implement ICD-10-CM and ICD-10-PCS. It is imperative that the rulemaking process start immediately so as to not jeopardize the two-year implementation time frame required.**

VALUE-BASED PURCHASING

The DRA mandated that CMS develop a plan to implement value-based purchasing for hospitals under the Medicare program. CMS submitted its plan to Congress on November 21, 2007. In the proposed rule, CMS outlines its development of the plan and discusses the plan's components.

Implementation of value-based purchasing requires action by Congress. However, CMS intends to test the potential impact of its value-based purchasing plan by conducting a simulation of hospitals' performance under the program and assessing the performance scores and the financial impact of the proposal. CMS is seeking comments as to whether and how the results of this testing should be made public.

The simulation testing will be done to better understand the impact of the proposal on hospitals with a variety of characteristics to ensure that no group of hospitals is put at an unfair disadvantage by the design of the plan. We believe this can best be determined through a three-step process.

- 1) **Hospitals should see their own data and comments should be solicited.** Each hospital should be able to see its own results from the simulation and a comparison to the state and national average results. Opportunities should be created for hospital leaders to ask questions and provide feedback. The AHA would be happy to work with other national and state hospital associations to assist CMS in soliciting this feedback.
- 2) **Simulation results should be made publicly available by various categories of hospitals.** All health care stakeholders need to understand the impact of value-based purchasing on different categories of hospitals, including by size, geographic region, state, teaching status, the relative acuity of the patient population and the degree to which the hospital serves a disproportionate share of low-income patients. National averages also should be shared publicly. The testing information should not be posted on the *Hospital Compare* Web site, but instead should be posted on another section of CMS' Web site. *Hospital Compare* is devoted to the display of hospital quality information to share knowledge with hospitals, clinicians, payers and the public. It should not be used as a venue for other information.
- 3) **CMS should bring together a technical advisory panel.** This technical advisory panel should be allowed access to the complete set of simulation results in order to help enhance

our understanding of the proposed value-based purchasing system and potential design improvements. Researchers, hospital leaders and systems experts may help identify elements of the proposed design that put particular hospitals at an advantage or disadvantage.

If we are going to engage in a large, national experiment with value-based purchasing, one that has the potential for substantial intended and unintended consequences, we should have as much knowledge as possible about the predicted impact of the system so that wise public and institutional policies can be made. This is far too important a change in payment policy to make without fully exploring its potential ramifications. We urge CMS to employ all three of the strategies articulated above to more completely understand the potential impact of value-based purchasing.

APPLICATION OF INCENTIVES TO REDUCE AVOIDABLE READMISSIONS TO HOSPITALS

While not proposing any changes related to hospital readmissions at this time, CMS is requesting public comment on three approaches that would give hospitals an incentive to reduce avoidable readmissions. According to a 2005 Medicare Payment Advisory Commission report, approximately 18 percent of Medicare patients discharged from hospitals are readmitted to hospitals within 30 days, costing approximately \$15 billion. CMS is interested in applying incentives to encourage the reduction of avoidable readmissions. The three approaches discussed include:

- A direct adjustment to the hospital DRG payment for avoidable readmissions.
- An adjustment to hospital DRG payments through a performance-based methodology.
- Public reporting of readmission rates.

There are three key questions that must be answered to address these options:

- 1) To what extent is it possible to identify avoidable readmissions?
- 2) Are there effective strategies for reducing or eliminating these avoidable readmissions?
- 3) What is the likelihood that each approach will promote and encourage the use of those effective strategies while avoiding undesirable consequences?

Without this information, we are only speculating on what policy approach is most attractive. CMS has incorporated work on reducing readmission rates into the ninth Scope of Work of the Medicare quality improvement organizations (QIOs). We believe the QIOs are uniquely qualified to perform this work, given their close working relationships with hospitals, as well as home health agencies and skilled-nursing facilities. **We urge CMS to give the QIOs time to explore this issue and further develop the knowledge base in this area.**

As part of the HQA, the AHA is supporting public reporting of a readmission measure that has been endorsed by the NQF and adopted by the HQA. This measure reports on condition-specific

readmission rates paired with condition-specific ALOS. This effectively addresses one potential unintended consequence – extended length of stay – as a method of avoiding readmissions. We urge CMS to use this measure for reporting rather than the three readmission measures proposed in this rule. **Measures that are not NQF-endorsed and HQA-adopted should never be used for measurement and reporting or the pay-for-reporting program.**

Any NQF-endorsed and HQA-adopted readmission measures chosen by CMS should be displayed on the *Hospital Compare* Web site with the other quality measures. *Hospital Compare* is the national source for the public display of hospital quality information, and we believe it should continue to be the single source for this information.

We caution CMS against making changes in payment policy until we more fully understand the answers to the three questions articulated above. Hospitals need to gain experience with any new readmission measures. The first step should be the initiation of calculations of new measures related to readmission. Then, the data should be publicly reported, and hospitals should be given a period of time to analyze their data and develop ways to improve in this area. We have seen from our experience with reporting for other measures that these two steps alone have served as a tremendous catalyst for hospitals' improvement in delivering care. It is likely that the public reporting of readmission rates also will drive improvement.

Further, we believe there may be other, better incentives available to further decrease hospital readmissions, besides simply changing hospital payment rates. Many patients are readmitted to the hospital because our health care system is not structured to promote chronic care management. Many patients do not have a medical home outside of the hospital. Hospitals, physicians and other providers all play a role in managing the health and health care of patients and patients' roles in complying with their care instructions is vitally important. Yet, the silos in our health care system fail to allow providers to work together to provide continuity of care to patients. Preventable readmissions to hospitals are a complex, system-wide problem. A simple approach to solving it, such as changing hospital payment rates, will be ineffective. Hospitals cannot do this alone, and they certainly cannot do it with less funding. **We urge HHS to focus efforts instead on developing tools and mechanisms to help hospitals, physicians, other health care providers and patients work together to improve care coordination and disease management.**

HOSPITAL PAYMENT ISSUES

CHANGES TO MS-DRG CLASSIFICATIONS AND RELATIVE WEIGHTS

In response to payment recommendations from the Medicare Payment Advisory Commission (MedPAC), in fiscal year (FY) 2006, the Centers for Medicare & Medicaid Services (CMS) began significant efforts to reform the diagnosis-related groups (DRGs) and the calculation of the corresponding relative weights. CMS started a transition to cost-based weights beginning in FY 2007 and a transition to Medicare-Severity DRGs (MS-DRGs) in FY 2008. CMS also undertook an overhaul of the complications and comorbidity (CC) list in FY 2008 to support three tiers of payment under the MS-DRGs based on the presence of: a major complication or comorbidity (MCC), a CC or no CC. For FY 2009, CMS proposes to complete this transition with minimal methodological changes.

The hospital field continues to support meaningful improvements to Medicare's hospital inpatient prospective payment system (PPS). We believe that the AHA and CMS share the common goal of refining the system to create an equal opportunity for return across diagnostic groups, which will provide an incentive to treat all types of patients and conditions. We also believe that the system should be simple, transparent and predictable over time. One of the fundamental values of a PPS is the ability of providers to reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions. **We are pleased that CMS has not proposed any major refinements to the methodology for the MS-DRG weights for FY 2009.**

MS-DRG DOCUMENTATION AND CODING ADJUSTMENT

Potential Additional Payment Adjustments in FYs 2010 through 2012. The FY 2009 proposed rule applies the documentation and coding adjustment of negative 0.9 percent as required by the *TMA, Abstinence Education and QI Programs Extension Act of 2007*. This law also specifies that to the extent that the required adjustments for FY 2008 and FY 2009 result in overpayments or underpayments relative to the actual amount of documentation and coding-related increases, the Secretary will correct the overpayments or underpayments in FYs 2010 through 2012.

The AHA is extremely concerned about the potential recoupment required by law. Determining how much of the total increase in case mix is due to changes in documentation and coding will be difficult and, if this determination is not made appropriately, it could result in overly large reductions to the standardized amount, which would ignore real changes in patient acuity and cause undue financial stress on hospitals.

The AHA applauds CMS for recognizing the importance and challenges of this task by describing its preliminary analysis plans in the proposed rule and inviting public comment. **Although the analysis plan CMS described is a good start, we believe that it is entirely insufficient to evaluate and quantify the various sources of case-mix change.** It does not

reflect the methodological rigor used in the work that CMS has cited on numerous occasions as providing the best estimate of how much case-mix change is due to real changes in case-mix and how much is due to changes in coding and documentation.¹

To determine how much case-mix change is due to changes in coding and documentation, CMS states that it plans to conduct a thorough retrospective claims analysis. It will apportion case-mix change between actual patient severity and documentation and coding improvements under the MS-DRG system. To separate the two effects, CMS plans to isolate the effect of shifts in cases *among* base DRGs from the effect of shifts in the types of cases *within* base DRGs. The proposed rule observes that shifts among base DRGs are the result of changes in principal diagnoses, while the shifts within base DRGs are the result of changes in secondary diagnoses. It also notes that CMS expects most of the documentation and coding improvements under MS-DRGs to occur in the secondary diagnoses, making the shifts among base DRGs unlikely to be due to the implementation of MS-DRGs. The AHA supports this part of the analysis plan and believes that it could provide useful information about how much of the overall case mix increase may be related to documentation and coding changes. **In particular, isolating the impact of within-DRG case-mix change could provide an upper bound for the amount of case-mix change that is related to documentation and coding. Clearly, some of the within-DRG case-mix change will represent real change in patient severity. Thus, this analysis will not be sufficient to determine what portion of the case-mix change, if any, is related to coding and documentation change.**

CMS also plans to look at past claims data to identify the specific MS-DRGs and diagnoses that contributed significantly to the within-DRG case-mix increase. This step will entail analysis of the secondary diagnoses driving the shifts in severity within specific base DRGs. **The AHA believes that this analysis also may provide valuable information about the DRGs experiencing the greatest case-mix change, but we emphasize that not all of the increased incidence of secondary diagnoses within a base DRG can be attributed to changes in documentation and coding.** A portion of the increase will be real.

Finally, if additional analyses are warranted, the proposed rule states that CMS may decide, if feasible, to use historical data from the Hospital Payment Monitoring Program (HPMP) to corroborate the within-base DRG shift analysis. The HPMP is supported by the Medicare Clinical Data Abstraction Center (CDAC). From 1999 through 2007, the CDAC obtained medical records for a sample of discharges as part of CMS' hospital monitoring activities, collecting data on a random sample of between 30,000 to 50,000 hospital discharges per year. CMS states that the historical CDAC data could be used to develop "an upper-bound estimate" of the trend in real case-mix growth (that is, real change in underlying patient severity) prior to implementation of the MS-DRGs. **The AHA believes that the CDAC data, including 2008**

¹ For example, see CMS, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates," Federal Register 72:85 (3 May 2007) pp. 24708 and 24842, and "Medicare Program; Prospective Payment System for Long-Term Care Hospitals RY 2009: Annual Payment Rate Updates, Policy Changes, and Clarifications; and Electronic Submission of Cost Reports: Revision to Effective Date of Cost Reporting Period," Federal Register 73:91 (9 May 2008) p. 26805-26808.

data, could provide the best data source to evaluate case-mix change because it includes a statistical sample of medical records over several years. However, in the proposed rule, CMS does not commit to using these data.

Many factors can contribute to case-mix change and careful analysis is required to determine the contribution of each factor. Changes in medical practice, demographics and health status over time affect case-mix growth, including:

- shifts in the site of service to hospital outpatient departments or ambulatory surgery centers, which could lead to higher hospital inpatient case mix if the patients shifted to other sites of service have fewer co-morbidities;
- aging of the Medicare population leading to increased co-morbidities;
- increasing severity of illness unrelated to aging of the Medicare population, such as rising rates of co-morbidities associated with higher levels of obesity; and
- changes in medical practice affecting average length of stay and the distribution of length of stay by MS-DRG or the intensity of services by MS-DRG.

While the above factors lead to gradual change over time, more sudden shifts in case mix can occur because of specific policy changes. **The AHA believes that a host of significant CMS policy changes occurring simultaneously with the implementation of the MS-DRGs has likely accelerated the case-mix growth rate.** For example:

- The implementation of present-on-admission coding is leading hospitals to assess patients for a broader array of conditions. This is likely to result in additional secondary diagnoses being identified, treated and coded, which involves a real increase in resource use and, therefore, real case-mix change.
- The permanent expansion of the Recovery Audit Contractor program is encouraging hospitals to even more carefully scrutinize low-acuity patients and shift care to the outpatient setting to avoid short-stay admissions. This change in practice will increase the average acuity of patients that remain in the inpatient setting.
- The implementation of Medicare Part D has resulted in acceleration of beneficiaries moving to Medicare Advantage. Medicare Advantage has been shown to attract the younger and healthier segment of the Medicare population, thereby increasing the average acuity level of the population that remains in fee-for-service Medicare.²
- Effective in calendar year 2008, CMS made dramatic changes in the criteria for procedures that can be done in an ambulatory surgery center, thereby adding hundreds of additional procedure types. We believe that these changes will accelerate the move of lower-acuity patients to the outpatient setting, again resulting in increased acuity in the inpatient setting. The majority of ambulatory surgery centers involve physician

² See Landon BE, Zaslavsky AM, Bernard SL, et al.: Comparison of performance of traditional Medicare vs Medicare managed care. *JAMA*, April 14, 2004;291(14):pp 1744-1752; Call KT, Dowd B, Feldman R, et al.: Selection experiences in Medicare HMOs: pre-enrollment expenditures. *Health Care Financing Review*, Summer 1999;20(4):pp 197-209; and Morgan RO, Virniq BA, DeVito CA, et al.: The Medicare-HMO revolving door: the healthy go in and the sick go out. *New England Journal of Medicine*, July 17, 1997;337(3):pp 169-175.

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

Many of these types of factors were rigorously examined in the 1980's. **The AHA does not believe, however, that the results of these old studies can be presumed to remain valid today in view of the magnitude of changes that have occurred both over the last 20 years and in the very recent past in Medicare policies, disease, technology, site of service, length of stay, post-acute care and other practice patterns.** The AHA opposes any attempt by CMS to estimate real case-mix change based on old research or trends immediately prior to the implementation of MS-DRGs that assumes any residual change is the result of documentation and coding. **CMS must conduct new rigorous and comprehensive analysis examining the factors listed above and replicating the RAND case-mix analysis using CDAC data. While we recognize that considerable resources might be required to undertake this work, it is critical to have the best case-mix measurement possible to ensure payment accuracy.** Whatever the investment in this study, it will be minor relative to the size of the payments at risk to hospitals.

Application of the Documentation and Coding Adjustment to the Hospital-specific Rates and Puerto Rico-specific Standardized Amount. The FY 2009 proposed rule invites public comment on two specific issues pertaining to application of the coding adjustment. First, CMS had previously rescinded its application of the coding adjustment to the hospital-specific portion of the PPS payments for sole community and Medicare-dependent hospitals. At that time, CMS stated that it had decided that application of the adjustment to the hospital-specific rates was not consistent with the plain meaning of section 1886(d)(3)(A)(vi) of the Act, which only mentions adjusting "the standardized amount" and not the hospital-specific rates.

However, in the FY 2009 proposed rule, CMS states that it believes it has the authority to apply the documentation and coding adjustment to the hospital-specific rates using the special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. CMS intends to examine the FY 2008 claims data for evidence of significant increases in case-mix for patients treated in these hospitals. If significant increases are found, CMS will consider proposing application of the documentation and coding adjustments to the FY 2010 hospital-specific rates.

Second, CMS is seeking comments about whether to apply the coding adjustment to the 25 percent Puerto Rico-specific portion of the PPS payment for hospitals in Puerto Rico. Similar to the question of applying the adjustment to the hospital-specific rate, CMS believes it could apply the adjustment to the Puerto Rico-specific amount using its special exception authority. It will evaluate FY 2008 claims data and consider application of the adjustment to the Puerto Rico standardized amount in FY 2010.

The AHA opposes use of the special exceptions and adjustment authority under section 1886(d)(5)(I)(i) to apply the coding adjustment to the hospital-specific and Puerto Rico-specific portions of the MS-DRG payments. As CMS itself observes, application of the

adjustment to these portions of the rates is not consistent with the plain meaning of section 1886(d)(3)(A)(vi) of the Act, which only mentions adjusting “the standardized amount.”

REFINEMENT OF THE MS-DRG RELATIVE WEIGHT CALCULATION

Regression-based Adjustments. The FY 2009 proposed rule discusses continued studies commissioned by CMS to analyze the use of a regression-based approach for addressing charge compression. Drafts of two such studies have been released during the comment period; however, neither provides evidence that this approach improves payment accuracy. **The AHA opposes such a regression-based approach for the following reasons:**

- As CMS has stated, there has not been time to evaluate the impact of a regression-based approach on either inpatient or outpatient services or on the MS-DRGs.
- The approach is excessively complicated and we are concerned that it may be difficult to validate, given that the MS-DRG weights are modified annually.
- The regression-based approach will be based on faulty data if the mismatch between MedPAR charges and cost report costs and charges is not corrected.
- The regression-based approach could be a possible substitute for the use of real data if there were urgency to addressing the issue of “charge compression.” However, we do not believe such urgency exists. Our members have indicated that the increases and/or decreases in the resulting MS-DRG weights will, in most cases, produce a minimal dollar impact. The RAND report also states that they believe this adjustment would not have a material impact on payment accuracy. As a result, any rush to address “charge compression” by this means is not warranted.

We believe that more accurate and uniform reporting within cost centers, combined with the approach outlined below, is the best method of calculating accurate payments.

Refining the Medicare Cost Report. The AHA supports CMS’ efforts to improve the calculation of the cost-based MS-DRG relative weights through the collection of actual data at the appropriate cost-center level. However, we are concerned that CMS is using a “piecemeal” approach for addressing the broader problem that cost report data were not designed to support the current methodology for setting relative weights. **While we prefer more comprehensive reform of the cost report, the AHA supports CMS’ proposal to split the “Medical Supplies and Equipment” cost-to-charge ratio (CCR) into one CCR for “Medical Supplies Charged to Patients” and another for “Implantable Devices Charged to Patients” as a short-term solution.** We agree that this short-term approach may help address the issue of charge compression in setting cost-based weights for MS-DRGs that contain medical supplies.

CMS proposes to split supplies and devices between the two new cost centers using specific revenue codes as well as additional criteria, such as the existing criteria for the type of device that qualifies for pass-through payment under the outpatient PPS. **The AHA opposes this proposal. Instead, we suggest that CMS work within the context of hospitals’ existing billing and accounting systems – specifically, exclusive use of existing revenue codes and**

associated definitions established by the National Uniform Billing Committee (NUBC). CMS is not the only payer bound by the definitions and codes established by NUBC. If the agency introduces exceptions to what hospitals include in certain revenue codes, these codes must either be redefined or new ones created, both of which create administrative burden because they require NUBC approval and necessitate significant changes to hospital billing and accounting systems.

The Medical Supplies and Equipment cost center should be separated into two cost centers based exclusively on the following revenue code criteria:

- **Implantable Devices Charged to Patients:** Revenue codes—275 (pacemaker), 276 (intraocular lens), 278 (other implants) and 0624 (FDA investigational devices). Except for revenue code 0624, this is consistent with the proposed rule and would eliminate the need to modify or add revenue codes, as required under the proposed rule. Our members tell us that revenue code 0624 is mostly comprised of higher-cost implants. This code could be refined at a later point to separate implants from other medical supplies, which would require NUBC approval.
- **Medical Supplies Charged to Patients:** All remaining 27x revenue codes and other revenue codes currently reported on the medical supply line, such as 0621, 0622 and 0623 (supplies incidental to radiology, other diagnostic services and surgical dressings).

We acknowledge that this approach will not completely separate high- and low-cost items, but believe that it will go far enough to warrant the effort. A more refined approach would yield only incremental improvements for what our members indicate would be a significant impact on hospital accounting and billing systems, assuming that the changes were ultimately approved by the NUBC.

Over the past year, we have recommended that hospitals prepare their Medicare cost reports so that Medicare charges, total charges, and total costs are aligned with each other, and with the current categories in the MedPAR file. We continue to believe that this is an important effort. Our proposed methodology for splitting supplies and devices is consistent with these past recommendations. We appreciate CMS' efforts to inform the fiscal intermediaries (FIs) and Medicare Administrative Contractors (MACs) to work with hospitals to accomplish this goal (CMS transmittal #321). **However, we are concerned that the transmittal letter failed to address the need by some hospitals to elect a cost-estimation approach to ensure costs and charges for supplies are aligned. We urge CMS to instruct the FIs/MACs not to reverse or undo reporting that relies on estimation approaches to achieve this alignment, provided that hospitals submit adequate documentation of their methodology.**

In addition, CMS solicited comments on how to treat supplies that are part of "surgical kits," since the costs of all of the components are not often separated or distinguishable. The AHA again recommends utilizing a revenue code-based approach. Specifically, if the kit is billed with one of the device revenue codes listed above, its cost should be included in the device cost

center. This approach will not separate out all low-cost items, but will still reduce charge compression.

Finally, we urge CMS to provide adequate notice before it implements any changes to the cost report, whether the AHA's recommendations are accepted or not. Under CMS' proposed approach, hospitals will need to make significant changes to their billing and accounting systems prior to the beginning of their fiscal year. Even under our recommended revenue code approach, hospitals will need adequate time to make the necessary changes.

Timeline for Revising the Medicare Cost Report. CMS stated that it has begun a review of the Medicare hospital cost report and plans to issue its proposed changes in the future. The Medicare cost report has become an antiquated instrument that no longer meets the needs of the current PPS or fits with the current accounting and management practices of hospitals. We agree that a re-examination is warranted and could help achieve simplicity by collecting only necessary information and ensuring that the cost report aligns with the current reimbursement methodology. In addition, we continue to believe that comprehensive cost report reform must be conducted in collaboration with the hospital field. However, we are unaware of CMS soliciting participation from either the AHA or other hospital field representatives. **In the past, we have suggested that efforts to comprehensively revise or replace the cost report should be mutual and are concerned that such an effort has occurred unilaterally. We are disappointed in CMS' failure to work with the hospital field from the outset on such an important endeavor.**

Although the AHA cannot comment on potential revisions to the Medicare cost report other than the medical supply issue, we urge CMS to avoid making piecemeal changes that do not fully align with the current hospital protocols and reimbursement methodology. Doing so would not help accomplish our mutual goal of improving the accuracy of the cost-based MS-DRG weights. Further, depending upon the type of changes CMS proposes, it may not be possible for hospitals to alter their billing and accounting systems to capture the new data requirements after the start of their fiscal year. CMS must give adequate notice to hospitals to review and analyze comprehensive changes before they are implemented.

RAND: Evaluation of Alternative Methods to Establish DRG Relative Weights. CMS asked the RAND Corporation to evaluate refinements to the way the inpatient PPS calculates the relative weights used to determine payment rates. They compared the current method proposed in FY 2007 (and put in place for FY 2008) to five other methods. RAND's analyses ultimately found that, while there were large redistributions in payment across DRGs and hospitals, "...none of the alternative weight methodologies represent a marked improvement over the current system" in terms of the ability to predict costs at the discharge or hospital level. **We agree with RAND's overall assessment that it would be premature to consider further refinements to the methodology for setting relative weights, including both regression-based adjustments to CCRs and the hospital-specific relative value (HSRV) methods of standardization, until data from FY 2008 or later can be evaluated.**

We hope that the results of this report will encourage CMS to drop any further consideration of the HSRV method. As we have stated in earlier comments, we have never believed that the HSRV method is appropriate for use in a cost-based methodology. We believe it is only applicable in charge-based systems to remove the effects of different mark-up practices. When applied in a cost-based system, other RAND research has found evidence that the HSRV approach inappropriately compresses the weights.

DRG RECLASSIFICATIONS

Given the major changes to MS-DRGs last year, we believe it is appropriate for CMS to propose a limited number of changes for FY 2009. **In general, the AHA has no objections to CMS' proposed changes to certain codes, which seem reasonable given the data and information provided.**

Pressure Ulcers: Proposed Changes in Code Assignments. Despite the fact that we generally support CMS' proposed code changes, we have one specific concern regarding the current pressure ulcer codes. We believe that CMS' proposal to classify the new ICD-9-CM codes 707.23 (pressure ulcer stage III) and 707.24 (pressure ulcer stage IV) as MCCs is inconsistent with CMS' long-standing practice of treating new codes in the same manner as their predecessor codes. In addition, CMS has traditionally not moved conditions across DRGs, or changed the CC/MCC status of a code until sufficient claims data are available to determine the impact on hospital resources. Hospitals will need time to learn to correctly use the new codes and adjust their processes to ensure the stages of the pressure ulcers are documented in the records. **We recommend that CMS collect sufficient data before implementing the proposal to remove the CC/MCC classifications from the current pressure ulcer codes that show the site of the ulcer (ICD-9-CM codes 707.00 through 707.09).**

WAGE INDEX

The *Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006* (MIEA-TRHCA) required CMS to, taking MedPAC's wage index recommendations into account, include one or more proposals for revising the wage index in the FY 2009 proposed rule.

Revision of the Reclassification Average Hourly Wage Comparison Criteria. Each year, many hospitals apply for reclassification to another geographic area to receive a higher wage index. As part of its effort to propose wage index changes, CMS re-evaluated the average hourly wage (AHW) criteria for reclassification for the first time since they were established in FY 1993. Based on this analysis, CMS is proposing to change the criteria for FY 2010 and after so that an urban hospital would need an AHW that is 88 percent (up from 84 percent) of the area to which they want to reclassify. A rural hospital would need an AHW that is 86 percent (up from 82 percent) of the area to which it wants to reclassify. Hospitals applying for group reclassification would need an AHW that is 88 percent (up from 85 percent) of the area to which they want to

reclassify. In addition, CMS is proposing to re-evaluate, and if warranted, recalibrate these criteria in the future when there are significant changes to labor market area definitions.

While CMS' proposal uses the most recent data, which the AHA supports, it also raises the threshold for reclassification, thereby making it more difficult for hospitals to qualify. Making such a revision impedes hospitals' ability to offer competitive salaries to qualified individuals and, thus, provide the highest quality care and adequate access to beneficiaries. In addition, making these revisions without including additional funding simply moves the system's deficiencies around, rather than eliminating them. The wage index is highly volatile from year-to-year, is self-perpetuating (in that hospitals with low wage indices are unable to increase wages to become competitive in the labor market), and is based on unrealistic geographic boundaries. These fundamental problems warrant a comprehensive re-evaluation of a system that CMS itself acknowledges is burdensome and of questionable integrity. **Therefore, we oppose CMS' proposal to recalibrate the AHW criteria, both now and in the future, and instead urge the agency to continue its study of the wage index in favor of future changes that create a more equitable system and adequately reimburse hospitals for providing quality care to beneficiaries.**

Within-state Budget Neutrality Adjustment for the Rural and Imputed Floors. By law, the wage index for a hospital in an urban area of a state cannot be less than the wage index for a hospital in the rural area of a state. In addition, in 2006, CMS temporarily adopted an "imputed" rural floor measure by establishing a wage index floor for those states that did not have rural hospitals. Both the rural floor and the imputed rural floor are funded through a nationwide budget neutrality adjustment. For FY 2009, CMS proposes to apply a statewide (rather than a nationwide) rural floor budget-neutrality adjustment to the wage index. The agency also is proposing to extend the imputed rural floor through 2011.

CMS has stated that the intent of the rural floor is to afford some measure of protection to urban-rural states; it created the imputed rural floor to do the same for all-urban states – a policy that we support extending as proposed. However, despite the fact that these floors only affect certain states, they are nationwide policies. Applying budget neutrality on a nationwide basis minimizes the policy's impact on payments and results in the nation funding a nationwide policy. In contrast, applying budget neutrality on a statewide basis maximizes the policy's impact on the payments of a few hospitals, and results in several states funding a national policy.

Accordingly, the AHA opposes CMS' proposal to apply budget neutrality on a statewide basis. We also remain very concerned that CMS is continuing to introduce additional intricacies and changes to a system that is already burdensome, inequitable and volatile. We again urge the agency to continue its study of the wage index system.

In addition, in FY 2008, CMS began applying the budget-neutrality adjustment related to the rural floor to the wage index, rather than the standardized amount, while the adjustment related to the imputed rural floor is currently applied to the standardized amount. For FY 2009, CMS proposes to also apply the imputed rural floor budget-neutrality adjustment to the wage index.

In FY 2008, when CMS began applying the rural floor budget neutrality-adjustment to the wage index, it made a positive budget-neutrality adjustment to the standardized amount that was intended to reverse the FY 2007 standardized amount budget-neutrality adjustment. However, we are very concerned that CMS did not also make positive budget-neutrality adjustments to reverse the FY 1999 through FY 2006 standardized amount budget-neutrality adjustments. We recommend that CMS do so in order to remove the compounding effect of applying the budget-neutrality adjustment to the standardized amount annually from FY 1999 through FY 2006.

In addition, we support applying the budget-neutrality adjustment associated with the imputed rural floor to the wage index rather than the standardized amount in FY 2009, assuming that CMS removes the compounding affect of applying the adjustment to the standardized amount annually since 2006. We believe it was an unintended error to repeatedly apply the rural floor budget-neutrality adjustment without first reversing the prior year's adjustment, as is done with the outlier calculation each year.

Within-state Budget Neutrality Adjustment for Geographic Reclassification. Budget neutrality related to geographic reclassifications also is applied on a nationwide basis. However, CMS supports a legislative proposal that would apply this budget neutrality on a statewide basis. **We oppose statewide budget neutrality related to geographic reclassifications for the same reasons that we oppose statewide budget neutrality related to the rural floor.** Geographic reclassifications are necessary because the wage index system as a whole does not adequately reimburse hospitals their costs – its deficiencies necessitate numerous exceptions. Individual states – the very states where the wage index is most inequitable – should not be held accountable for paying for the entire system's deficiencies.

MedPAC's Wage Index Recommendations. CMS has hired Acumen, LLC, to review MedPAC's recommendations for changing the area wage index and to analyze other options to revise the area wage index for hospitals and other Medicare providers. CMS stated that it will present any analyses and proposals in the FY 2009 inpatient PPS final rule or in a subsequent special notice. Thus, we would like to take this opportunity to describe some of the hospital fields' fundamental concerns with MedPAC's recommendations.

MedPAC recommended using wage data from all employers and industry-specific occupational weights, as well as adjusting for geographic differences in the ratio of benefits to wages. It used an analysis of Bureau of Labor Statistics (BLS) data to support these recommendations. Therefore, our comments pertain to using BLS data rather than the hospital-reported data collected on CMS' Medicare cost reports that are currently used. While using BLS data may be less burdensome for hospitals, there are critical differences between the data sets that must be carefully evaluated. The new data sources are the cornerstone of the MedPAC approach and represent a fundamental change. Many of the other aspects of the recommendations possibly could be applied using hospital wage data as it is currently collected. Our detailed comments on the key differences between and our concerns about the CMS and BLS methodologies can be found in our comment letter on the FY 2008 inpatient PPS proposed rule. In brief, these differences and concerns include:

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

We also have several other concerns about MedPAC's approach, including:

- **Geographic boundaries and smoothing** – The current wage index methodology, with the exception of some commuting pattern adjustments, assumes that there is no inter-relationship between areas. By simply being on opposite sides of a geographic boundary, two hospitals can have very different reimbursement, even though they are competing for the same workforce. More refined areas – as in MedPAC's proposal to vary wage indices by county – may be more realistic and less arbitrary. On the other hand, the “smoothing” approach, whereby wage index values or wages of neighboring areas are artificially constrained to allow only a 10 percent difference in wage indices, may mask actual variation in wages between areas. For example, there may be real, greater differences between outlying counties and an urban core.

- **Use of Census data** – MedPAC plans to use Census data to determine variation between the counties. While doing so may make sense, we recommend further examination of whether Census data produce accurate estimates of this variation, for two reasons. First, it is Census protocol to suppress statistics for which less than three people report values and, in certain cases, rural counties had less than three persons reporting wages for an occupation. Therefore, MedPAC had to estimate occupation-specific wage data for these counties, which could be inconsistent with actual wages. Second, for 2008, MedPAC would use the 2000 Census data to establish the relationship between counties within a metropolitan statistical area until the 2010 Census data are available. Using data this old may create differences in wage indices that are inconsistent with the actual difference experienced in wages.
- **Rural area wage index** – While a single wage index for all rural areas of a state may be reasonable for small states, it may not adequately reflect wage variation in large states. Varying the wage indices within rural areas may make sense. However, we recommend further examination of whether Census data produce accurate estimates of current area wage differences, for the same reasons cited above. Specifically, we are concerned that Census data for certain counties are missing, and that the data are eight years old.
- **Year-to-year volatility** – Volatility in wage indices from one year to the next makes it difficult for hospitals to estimate Medicare payments for budgeting purposes. While the three-year rolling average employed by BLS may reduce volatility, alternative approaches should be examined, including those that do not rely on BLS data.
- **Exceptions process** – MedPAC states that its BLS approach eliminates the need for an exceptions process because it automatically adjusts the market area (metropolitan statistical area and statewide rural) index values to remove large differences between adjoining areas. It also recommends that the Congress repeal the existing hospital wage index statute, including reclassifications and exceptions. **The AHA opposes eliminating exceptions processes from the wage index system.** Exceptions are necessary for hospitals with labor costs atypical for their local area or for local areas compared to other areas. Developing a single wage index to accurately capture differences in labor costs across hospitals is a complex task and likely to understate the costs in some areas. Exceptions processes allow hospitals in areas with misrepresentative indices to seek redress.

MIEA-TRCHA required CMS to include one or more proposals for revising the wage index in the FY 2009 proposed rule. We believe that because CMS has done so, it has met its statutory obligation – it is not necessary to implement its proposals to satisfy MIEA-TRCHA.

We look forward to a full discussion of possible changes to the wage index in a future proposed rule and appreciate CMS' consideration of the issues raised in the meantime.

CAPITAL INPATIENT PPS

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

In the FY 2008 final rule, CMS made two changes to the structure of payments under the capital PPS, claiming that payments under the capital PPS exceeded what was required for hospitals to provide inpatient services. First, the agency eliminated the 3.0 percent additional payment that had been provided to hospitals located in large urban areas. Second, the agency adopted a policy to phase out the IME adjustment to teaching hospitals over three years. In FY 2008, teaching hospitals receive their full IME adjustment to capital payments; in FY 2009 they will receive half their adjustment; and in FY 2010 and beyond, the adjustment will be eliminated.

CMS' elimination of the add-on payment for hospitals in large urban areas cut payments to hospitals by \$600 million from FY 2008 through FY 2012. Elimination of the IME adjustment will reduce payments to teaching hospitals by an additional \$1.3 billion over five years. These cuts are based solely on the discretion of the administration with no congressional direction and are unprecedented. According to MedPAC, overall Medicare margins will be *negative* 4.4 percent in 2008. These cuts to an already under-funded system result in a decrease in capital payments that urban hospitals cannot sustain.

As we stated in our comments last year, capital cuts of this magnitude will disrupt hospitals' ability to meet their existing long-term financing obligations for capital improvements. Hospitals have committed to these improvements under the expectation that the capital PPS would remain a stable source of income. Reducing capital payments will create significant financial difficulties and amounts to Medicare renegeing on the full cost of caring for America's seniors and disabled. CMS has no analysis of the impact of these proposed changes on the high-caliber medical education of our future physicians and the community-wide services on which hospitals often lose money providing, such as burn and neonatal units. It is irresponsible of CMS to make such changes without a clear understanding of the broader ramifications. **The AHA reiterates its opposition to these unnecessary cuts, which ignore how vital these capital payments are to investments in the latest medical technology, ongoing maintenance and improvement of hospitals' facilities and medical education.**

CMS justifies the cuts based on an analysis that purports to show that hospitals are experiencing substantial positive margins under the capital payment framework. The analysis, which averages hospital inpatient Medicare capital margins for the period from 1996 to 2005, is deficient in several respects. What hospitals experienced in 1996 is irrelevant to the operating environment today, 12 years later. Looking at a snapshot rather than a full capital cycle of 15 to 20 years is

misleading. The averaging system is meant to balance the high-spending cycles of some hospitals with the low-spending cycles of others over time, but isolating any given portion of the cycle may not achieve this. In addition, the analyses establishing the capital PPS were based on total costs, not just capital costs, so CMS should be looking at total Medicare margins. As noted earlier, MedPAC estimates an overall hospital Medicare margin in 2008 of negative 4.4 percent. Whether or not hospitals experience a narrow positive margin for their capital payments is of small consequence to the hospital losing money, on average, every time it treats a Medicare beneficiary. Moreover, this should not be discussed in isolation from the overall payment effect in an effort to mask the fact that these are significant capital cuts.

CMS' analysis concludes in 2005, the year when the margin dropped to its lowest point, 3.7 percent, in the time period CMS selected. This 2005 margin is 30 percent below the 2004 capital margin and 51 percent below the 2003 capital margin. Extending that trend line projects that capital margins today are negative, which should not be a surprise because it is the very same overall Medicare margin trajectory that MedPAC has documented – a sharp decline since 2002 – from positive 2.4 percent to an estimated negative 4.4 percent in 2008.

Hospitals must make a healthy positive margin in low-spending years in order to access loans and take on large, long-term financial obligations. Yet, CMS is suggesting that a very modest capital margin (3.7 percent in 2005, and likely lower today) is excessive. In developing the capital PPS in 1991, CMS even stated that hospitals must accrue capital “profits” in some years to supplement payments and offset losses in years when capital spending is higher.

In addition, CMS has not fully considered the ramifications of dramatic capital cuts on the use of technology and the quality of hospital infrastructure. Reduced capital payments would make buying the advanced technology and equipment that patients expect much more difficult for the nation's hospitals, and could have the effect of slowing clinical innovation. These changes disadvantage large urban and teaching hospitals, where much of the innovation and cutting-edge research is generated. These hospitals will be even more challenged to keep up with leading technology, facilities and patient care. Moreover, for many hospitals, investing in information technology such as electronic health records and computerized physician order entry would become even more challenging. Without these facility and technological improvements, *all* patients will be deprived of these advances. At a time when the administration and Congress are pushing for such investments, this proposal may have the opposite effect of slowing needed adoption of health information technology.

POST-ACUTE CARE TRANSFER POLICY

The AHA opposes expanding the post-acute care transfer provision to include patients receiving home health care services within seven days – rather than three days – of discharge, as it inappropriately penalizes hospitals for efficient treatment and ensuring that patients receive the right care at the right time in the right place.

Since FY 1999, Medicare beneficiaries in certain qualifying DRGs who are discharged to a post-acute care setting – including rehabilitation hospitals and units, long-term care hospitals and units, cancer hospitals, psychiatric hospitals, children’s hospitals and skilled-nursing facilities – or are discharged within three days to a home health agency, are defined as transfer cases if their acute-care length of stay is at least one day less than the national average. These cases are paid a daily (per-diem) rate, rather than a fixed DRG amount, not to exceed the full PPS rate. Thus, if a patient has a shorter-than-average inpatient stay for certain DRGs, even by just one day, the hospital is paid less than the full DRG rate.

In general, this policy penalizes hospitals for the efficient treatment of patients. The Medicare inpatient PPS is a system of averages. Cases with longer-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. Expansion of the transfer policy further undercuts the basic principles and objectives of a PPS and only penalizes hospitals further. And, facilities in regions of the country where managed care has yielded shorter lengths of stay are disproportionately penalized.

The law states that the Secretary can pay as transfers those cases that are discharged to home health services “if the services are related to the condition or diagnosis for which the individual received inpatient hospital services, and if the home health services are *provided within an appropriate period* (as determined by the Secretary)” [emphasis added]. In 1999, the Secretary determined that three days was an appropriate period. CMS indicated that it was appropriate because it “mitigated the incentive to delay home health services to avoid the application of the post-acute care transfer policy, and because a three-day time frame was consistent with existing patterns of care.”

The data and analyses that CMS present to suggest that the current three-day time frame is inappropriate are out of date and incomplete. First, CMS’ analysis is based on home health agency claims from 1999 through 2003. However, in calendar year 2008, the home health PPS was substantially revised, in large part to address what CMS stated were “undesirable incentives from the 10-visit therapy threshold.” CMS also stated that its analysis suggested that the 10-visit therapy threshold might have distorted service-delivery patterns. **Given that the home health PPS has recently undergone major modifications that will likely change future service-delivery patterns, we believe that CMS’ use of data from the prior home health PPS in justifying a change to the transfer policy is inappropriate.**

Additionally, CMS stated that Medicare patients who are subject to the transfer policy are discharged earlier, and that it therefore expects that these patients should be less sick and thus less costly to the home health program. It then stated that this is not what the data show, as average Medicare payments per home health visit for patients subject to the transfer policy are consistently higher than patients not subject to the transfer policy. CMS stated that it found some evidence that hospitals may be discharging patients subject to the transfer policy earlier than advisable and providing less than the optimal amount of acute inpatient care. We find CMS’ analysis deficient. The agency presents no analysis of patient case mix to support its claim. Instead, it presents evidence that payments per visit for patients subject to the transfer

policy are higher than patients not subject to the transfer policy. We remind CMS that a “payments-per-visit” statistic is affected not only by total payments, but also by number of visits. Patients subject to the transfer policy could very well be less sick, which would necessitate fewer home health visits, and in turn result in a higher payment-per-visit number when compared to their counterparts that were not subject to the transfer policy.

In the proposed rule, CMS suggests that hospitals are delaying the start of home health care past the three-day window in order to receive the full PPS payment. Yet there are a number of reasons home health services may be delayed to four days past discharge, or later. **The hospital discharge process is multifaceted and is influenced by a number of factors, including patient preferences, family availability, insurance coverage and access to post-acute care treatment options.** A delay in receiving home health services may occur because a patient’s family is available to care for them the first few days after discharge. Or patients – especially medically complex patients – may need to wait for placement, as not all home health agencies have the capacity to take these patients. And, it is common for patients to be discharged on Friday and not receive a home health visit until Monday or Tuesday of the following week, given the intervening weekend.

This policy penalizes hospitals for making sound clinical judgments about the best setting of care for patients – and this setting is more and more frequently outside of the hospital’s four walls. Home health services beyond the three-day window are not a substitute for inpatient acute care. Delaying services by seven days can not be viewed as a “continuation of the inpatient admission,” the justification Congress used in creating the post-acute care transfer policy. It is unreasonable to assume that a patient can go without professional care for a full week and then receive a nursing visit at home and suggest that the patient is now continuing their inpatient acute care treatment, but in a different setting.

This proposal significantly expands the liability of hospitals for decisions that are not within their control. Hospitals often do not even know when a “transfer” to a post-acute setting occurs after a patient is discharged. This is because physicians, not hospitals, typically order and arrange such care. Patients may request that their primary care physician (someone other than their doctor taking care of them while they were in the hospital) arrange for home health services. And, it is not uncommon for a patient to be discharged home from the hospital, then to visit their physician a day or two later, only to have the physician order home health services that take another day or two to begin – again pushing the start of home health services past the three-day window. Patients discharged home, but who later receive a visit from a home health agency, should not be viewed as “transferred to home under care of a home health service organization in anticipation of covered skilled care.” These patients have been discharged, and hospitals should not be penalized when valuable and cost-efficient, follow-up care is provided to these patients.

Expansion of this unreasonable provision actually creates perverse incentives to either keep patients longer, so that hospitals may retain the full DRG payment, or to delay home health services to after seven days of discharge – and neither is in the best interest of the patient. CMS suggests that some providers are “gaming” the system and intentionally delay ordering home

health services until after the three-day window. If this were true, what evidence does CMS have that pushing the window to seven days would make a difference? There are other mechanisms in place to identify such providers (if they exist). Expansion of the transfer policy, which penalizes all hospitals, is not the right answer. **The cost savings to the Medicare program of this proposal is minimal, yet the impact to patients and hospitals is very real.**

OUTLIER PAYMENTS

The rule states that CMS' proposed outlier thresholds for FY 2009 will yield outlier payments equal to 5.1 percent of operating DRG payments and 5.73 percent of capital payments. We have been unable to successfully reproduce the cited capital outlier percentage of 5.73 percent. Instead, our analysis results in a capital outlier percentage of 5.37 percent. **Therefore, we recommend that CMS re-evaluate its calculation to ensure that the capital outlier percentage is correct.**

The AHA appreciates that CMS has used a methodology that incorporates both cost inflation and charge inflation. **However, CMS outlier threshold estimates continue to be overstated, resulting in significant and unreasonable payment cuts to hospitals.** CMS is estimating that it spent only 4.64 percent, or about \$400 million less than what it set aside in FY 2007, and only 4.8 percent, or about \$300 million less than what it set aside in FY 2008. **Using the proposed CCR-inflation methodology will continue to generate an inappropriately high outlier threshold as has occurred repeatedly in the past. The AHA urges CMS to address the flaws in the methodology for estimating the outlier threshold and recommends two improvements that will yield a more accurate threshold.**

First, in the proposed rule, CMS states that it is appropriate to apply a one-year adjustment factor to the CCRs. However, we believe that for many hospitals, CCRs should be projected over periods of time other than one year to more accurately reflect the actual CCRs used in FY 2009. For example, as CMS states in the rule, we assumed that CCRs are updated nine months after the end of hospitals' fiscal periods. Therefore, the December 31, 2007 Provider Specific File that CMS used for the outlier analysis contains the 2007 CCRs of hospitals with fiscal periods ending in January 2007. These hospitals will be paid using this 2007 CCR for the first month of FY 2009 (October 2008). In November 2008, however (nine months after the end of the hospitals' fiscal year), the hospitals' FY 2008 CCRs will become available and will be used for payment for the remaining 11 months of FY 2009. Therefore, the actual 2007 CCRs that CMS used in analyzing these hospitals should be used for one month of FY 2009. These 2007 CCRs should then be projected over one year to 2008 CCRs for the remaining 11 months of FY 2009. In contrast, when doing its analysis, CMS used the projected CCRs for all 12 months of FY 2009. See table 1 our recommended for projection periods for hospital fiscal periods ending in January through March.

Table 1: Recommended Projection Periods for 2007 CCRs for Hospital Fiscal Periods that End in January 2007 through March 2007

End of hospital fiscal period	Months of use for actual 2007 CCR	Months of use for 2007 CCRs projected to 2008 CCRs
January	1	11
February	2	10
March	3	9

The situation is different for hospitals with fiscal periods ending in April through December. For example, the December 31, 2007 Provider Specific File that CMS used for this analysis contains the 2006 CCRs of hospitals with fiscal periods ending in April 2007. However, in January 2008, these hospitals' 2007 CCRs will become available and used for payment for the first four months of FY 2009 (October 2008 through January 2009). Therefore, the actual 2006 CCRs that CMS used in analyzing these hospitals should be projected over one year to 2007 for four months of FY 2009. For the remaining eight months of FY 2009, these hospitals will be paid using their 2008 CCRs. Therefore, for the 2006 CCRs that CMS used should be projected over two years to 2008 for the remaining eight months of FY 2009. In contrast, when doing its analysis, CMS used CCRs projected over one year for all 12 months of FY 2009. See Table 2 for our recommended projection periods for hospital fiscal periods ending in April through December.

Table 2: Recommended Projection Periods for 2006 CCRs for Hospital Fiscal Periods that End in April 2007 through December 2007

End of hospital fiscal period	Months of use for 2006 CCRs projected to 2007 CCRs	Months of use for 2006 CCRs projected to 2008 CCRs
April	4	8
May	5	7
June	6	6
July	7	5
August	8	4
September	9	3
October	10	2
November	11	1
December	12	0

Using this approach for projecting CCRs, we estimate that the FY 2009 fixed-loss threshold would be \$20,775 (compared to CMS' proposal of \$21,025).

Second, CMS estimated the rate of change in CCRs by assuming the relationship between actual costs and the hospital market basket stays constant over time. An alternative approach to estimating the rate of change in CCRs is to use a recent historical industry-wide average rate of change as the projection factor, which is exactly how CMS projects charge inflation. In analyzing such an approach, we used the two most recent points in time separated by one year for which sufficient data were available: October 1, 2006 and October 1, 2007. Data were available for 3,248 out of the 3,528 hospitals used for outlier projections; these hospitals

represent over 92 percent of all MedPAR inpatient PPS cases. We found that for these hospitals, the average change in the operating CCRs from October 1, 2006 through October 1, 2007 (weighted by the number of inpatient PPS cases) was 0.9791, or negative 2.09 percent. The average change in the capital CCRs was 0.9864, or negative 1.36 percent.

Using this methodology of calculating rates of change in CCRs, we estimate that the FY 2009 fixed-loss threshold would be \$20,085 (4.5 percent less than CMS' proposal of \$21,025). If we use this approach in addition to our CCR projection methodology described above, we estimate that the fixed-loss threshold would be even lower, at \$19,775 (5.9 percent less than CMS' proposal).

We examined CMS' estimate that actual outlier payments for FY 2008 will be approximately 4.8 percent of total payments, which is 0.3 percent lower than the 5.1 percent it intended. Using CMS' assumptions that resulted in its 4.8 percent figure, we estimate that to have hit the 5.1 percent target, CMS should have set the FY 2008 fixed-loss threshold at \$20,650, instead of the \$22,185 that it actually set. If we apply our two alternative methodologies to FY 2008, we estimate the FY 2008 fixed-loss threshold at \$20,410. We also examined the FY 2007 outlier amounts actually paid, which were significantly lower than CMS' intended level of 5.1 percent. We estimate that to have hit the 5.1 percent target in FY 2007, CMS should have set the fixed-loss threshold \$21,235 instead of \$24,485. We note that CMS set the FY 2007 fixed-loss threshold using projected 2006 to 2007 rates of change in operating and capital CCRs of negative 0.27 percent and negative 4.26 percent, respectively. These projections turned out to be substantially different from the now available actual values of negative 2.09 percent (operating) and negative 1.36 (capital). **Therefore, we believe our methodologies represent a substantial improvement. Given that the agency has significantly overestimated the outlier threshold, and thereby significantly underspent on outlier cases for many years, we urge CMS to adopt our suggested methodologies and more accurately estimate the outlier threshold.**

NEW TECHNOLOGY

Section 503 of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS to ensure that it would better account for expensive new drugs, devices and services. However, CMS continues to resist approval of new technologies and considers only a few technologies a year for add-on payments. Further, in FY 2008, it did not approve the only application under consideration. **The AHA also is disappointed that CMS has not increased the marginal payment rate to 80 percent rather than 50 percent, consistent with the outlier payment methodology, as we previously requested.**

VOLUME DECREASE ADJUSTMENT FOR SCHs AND MDHs: UPDATED DATA SOURCES

The AHA is pleased that CMS has moved forward in publishing both the occupational mix and AHA annual survey data that will allow a sole-community hospital (SCH) or Medicare-dependent hospital (MDH) to complete its application for special payments if it experiences a decrease (that was out of its control) of 5 percent or more in the total number of inpatient discharges from one cost-reporting period to another. The adjustment is intended to cover the fixed costs that the hospital is unable to reduce in the year following the volume decrease.

Because there are very few of these applications in any given year, we ask that CMS be clear in its final rule in identifying the data that can be used for each year of the adjustment. The AHA amended its 2006 survey so it could be used for these adjustments moving forward. Therefore only the 2006 data is currently available. We will continue to provide CMS with updated AHA annual survey data for these specific calculations, and 2007 data will be available later this fall. Once CMS makes the calculations, it should post them on its Web site rather than waiting for another regulatory cycle to be concluded in order for these hospitals and the FIs/MACs to move efficiently in making those adjustments to hospitals.

In addition, we urge CMS to clearly articulate what specific data were used in calculating the Occupational Mix Survey numbers. For example, were nurse managers included or excluded in the methodology?

EMTALA, PHYSICIAN SELF-REFERRAL AND PATIENT DISCLOSURE ISSUES

HOSPITAL EMERGENCY SERVICES UNDER EMTALA

In the fiscal year (FY) 2009 proposed rule for the inpatient prospective payment system (PPS), the Centers for Medicare & Medicaid Services (CMS) proposes a number of changes to the *Emergency Medical Treatment and Labor Act* (EMTALA) regulations, most of which derive from recommendations made by the EMTALA Technical Advisory Group (TAG).

Applicability of EMTALA Requirements to Hospital Inpatients. CMS proposes to revise EMTALA so that when an individual covered by EMTALA is admitted as an inpatient and remains unstabilized with an emergency medical condition, a receiving hospital with specialized capabilities has an EMTALA obligation to accept that individual, assuming that the transfer of the individual is an appropriate transfer and the participating hospital with specialized capabilities has the capacity to treat the individual.

We urge CMS not to finalize this proposal. We believe that this proposal represents a substantial change in policy, not merely a clarification of current regulation as CMS suggests. Specifically, this policy change contradicts the current regulation regarding the non-applicability of EMTALA to inpatients that was finalized in September 2003. The regulation at 42 CFR 489.24 (d)(2)(i) clearly sets out that once an individual presenting to the hospital's emergency department has been screened and admitted as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its EMTALA obligations for that individual. CMS' proposed "clarification" contradicts the regulation in that it re-opens EMTALA. The hospital to which the patient has been admitted is again subject to EMTALA (obligations for conducting an "appropriate transfer" (42 CFR 489.24 (e)(2))); and other hospitals take on an EMTALA obligation unrelated to a patient who is presenting to a hospital for emergency care. As CMS explained in its 2003 rule, once an individual becomes an inpatient, they have the same legal protections as all other patients.

Further, such a change in policy is simply unnecessary. We do not know why a hospital would knowingly admit a patient with an unstabilized emergency medical condition to an inpatient unit if it did not have the capacity or capability to medically stabilize the patient's condition. However, even if a hospital were to do so, once admitted as a patient to an inpatient unit, current regulations and state law already impose a legal and clinical responsibility on the hospital to provide appropriate care to the patient. As 42 CFR 489.24 (d)(2)(iii) indicates, the following hospital conditions of participation (CoPs) regulations, as well as the associated CMS interpretive guidelines, provide an appropriate foundation for safe care of all inpatients, including inpatients who have an unstabilized emergency medical condition:

- *Physician On Duty or On Call* (42 CFR 482.12(c)(3))
- *A Responsible Physician for Each Patient* (42 CFR 482.12(c)(4))
- *RN Supervision & Availability 24/7* (42 CFR 482.23(b))
- *Right to Care in a Safe Setting* (42 CFR 482.13(c)(2))
- *Governing Body Ensures Accountability* (42 CFR 482.12(a)(5))
- *Medical Staff - Organized & Accountable* (42 CFR 482.22(b))
- *Quality Assessment and Performance Improvement (QAPI)* (42 CFR 482.21(e))
- *Discharge Planning* (42 CFR 482.43 and 42 CFR 482.43(a))

We also do not believe that CMS has adequately demonstrated that its current policy needs to be reversed. The discussion in the proposed rule's preamble does not establish that a problem exists with regard to the inability of hospitals to transfer unstable inpatients. Nor does it address why the existing CoPs are not sufficient to protect hospital inpatients. Instead, CMS states it is relying on the recommendation of the EMTALA TAG, which offers no compelling description of an existing problem in this area, to justify the need for a change in policy.

Further, the preamble includes no reference to or summary of the TAG's lengthy and heated discussion on this recommendation. CMS fails to note that this recommendation was strongly contested within the TAG and that the recommendation passed with only a slim majority, with most of the physician and hospital representatives voting against the proposal. The support for this recommendation came largely from the TAG's government representatives. During TAG discussions, a brief description of a single relevant patient case, provided by one of the government representatives, was entered into the record. After the meeting ended, letters to the chairman of the TAG from groups of its members were sent indicating concern that this recommendation, if implemented, would adversely affect patient care and potentially increase the number of unnecessary patient transfers. In addition, two of the physicians who voted in favor of the recommendation subsequently sent a letter expressing concern that its implementation could have "potential for abuse (i.e., patient dumping)" and that they "...fear that the potentially unintended consequence may be the transfer of EMTALA patients for reasons other than those related to emergency care of the problem for which the patient was originally admitted when these services could have been provided at the sending hospitals."

Most importantly, this proposal is simply poor public policy. Through its 30-month term, the TAG heard a great deal about the larger issues affecting the emergency department related to overcrowding, patient boarding, ambulance diversion and the precarious operational and financial situation in which many trauma centers and psychiatric hospitals find themselves. In fact, the TAG dedicated an entire chapter of its final report to acknowledging the many issues that impinge on emergency department operation. Trauma center and psychiatric hospital representatives testifying before the TAG stressed the difficulties that their facilities faced due to the increasing numbers of EMTALA transfers from other hospitals, many of which were felt to be of questionable added value ("over-triage"). Over-triaging of patients and related transfers have adverse consequences; they limit access for patients who truly require the level of care provided at trauma centers, and result in financial strain that limits trauma centers' ability to

meet the needs of their communities. Individuals testifying and TAG members noted insufficient attention paid to unnecessary transfers in the enforcement of EMTALA. From many recent reports, ranging from the Institute of Medicine's report, *Hospital-Based Emergency Care at the Breaking Point*, to the recently released House of Representatives Oversight and Government Reform report, *Hospital Emergency Surge Capacity: Not Ready for the Predictable Surprise*, the public has heard the message of the crisis in emergency care loud and clear.

Therefore, it is all the more troubling that CMS has decided to move forward with the most controversial recommendation of the TAG; one that TAG members indicate has potential to worsen this situation facing the nation's emergency departments. The minutes of the September 2007 TAG meeting reflect these concerns, stating that "[s]everal members of the TAG argued that requiring hospitals with specialized capabilities to accept inpatient transfers under EMTALA would adversely affect patient care and increase the number of unnecessary patient transfers."

For these reasons, the AHA urges CMS not to finalize this proposed policy.

Shared/Community Call. CMS proposes that, as part of the obligation to have an on-call list, hospitals may choose to participate in a community call plan to provide on-call coverage for an area. A community call plan must be a formal plan among the participating hospitals and include, at a minimum, a number of specific elements outlined in the proposed regulations.

The AHA supports CMS' proposal to allow hospitals to meet their on-call list obligations through a shared or community call plan. Such an approach would allow communities to provide for access to specialty care in a more reasoned, expedited and efficient manner. However, we caution CMS against being too prescriptive in the requirements imposed on hospitals in such a plan. In particular, we believe that the element located at the proposed new 489.24 (j)(2)(iii)(E) requiring "evidence of engagement of the hospitals participating in the community call plan in an analysis of the specialty on-call needs of the community for which the plan is effective" is overly prescriptive and is likely already subsumed under the element (G), the "annual assessment of the community call plan by the participating hospitals." Therefore, we recommend that CMS delete this element (E) from the regulation.

Relocation of Regulatory Provisions for On-Call List Requirements. CMS proposes to move the regulation discussing the obligation of a hospital to maintain an on-call list from the EMTALA regulations to the hospital provider agreement regulations and amends the language to be more consistent with the EMTALA statute. We support this change but note that in the process of moving and amending the on-call list language, CMS has removed the "in a manner that best meets the needs of the hospital's patients" language from the current paragraph (j)(1) without explicitly describing its rationale for doing so. Given that this language was controversial when it was originally proposed in 2002 and remained so during the TAG deliberations, we recommend that CMS explain why it has removed this language from the regulation. The AHA believes that an explanation is important so that the change is not misconstrued as undermining the ability of hospitals to set expectations for physicians agreeing to serve on-call to the hospital emergency department.

Non-applicability of EMTALA Provisions in an Emergency. CMS proposes to make technical corrections regarding the non-applicability of EMTALA provisions in an emergency area during an emergency period. We support this change because it makes the regulations consistent with the requirements of the statute and will allow hospitals to provide timely and appropriate care to patients in disaster situations without fear of sanction under EMTALA.

PHYSICIAN SELF-REFERRAL

In the proposed rule, CMS includes several proposals related to the Stark regulations that address highly specific and technical aspects of their enforcement. The comments below address those proposals. They also address the need for a more comprehensive CMS effort to modernize how federal laws manage potential physician conflicts of interest. The physician self-referral law is one of several federal laws focused on prohibiting or limiting interactions between hospitals and physicians that might have monetary value to either party. While the intent is honorable – to avoid conflicts of interest – it is important that the net effect not impede hospitals’ and physicians’ ability to work together using appropriate incentives to improve quality, patient safety and community access to services. **We urge CMS to view the application of physician self-referral prohibitions not only from the perspective of controlling abusive behavior, but also from the perspective of encouraging care improvement initiatives that would benefit patients, hospitals and physicians.**

Stand in the Shoes Provisions. In the proposed rule, CMS revisits the “stand in the shoes” policy and regulations issued in Phase III of its Stark regulations. In these regulations, certain contracts between a provider of designated health services and a physician practice or group practice were treated as arrangements directly with the physicians, members, employees or independent contractors of that practice, with these physicians “standing in the shoes” of their physician organizations. As a result, the regulatory exception related to indirect compensation arrangements was no longer applicable and some existing arrangements were required to meet a different exception in order to be permissible under the physician self-referral statute.

CMS’ decision to revisit these regulations was motivated by expressed concerns about their scope and impact, particularly as applied to compensation arrangements involving “mission support payments” and similar payments. Such payments are intended to support the overall mission of an academic medical center or maintain the operations of an integrated delivery system and usually are not tied to specific items or services provided the physician or group practice. They likely do not satisfy the fair market value requirement that is a typical component of most existing exceptions to the physician self-referral regulations. As a result, while support payment arrangements were required under the Phase III regulations to satisfy a direct compensation arrangement exception to be permissible, there was no applicable exception available.

CMS' stated goal in revisiting the "stand in the shoes" provisions is to simplify the analysis of many financial arrangements and reduce program abuse by bringing more financial arrangements within the scope of the physician self-referral law, "such as certain potentially abusive arrangements between designated health services entities and physician organizations that may not have met the definition of an 'indirect compensation arrangement.'" In the proposed rule, CMS puts forth two alternative approaches for revising the physician "stand in the shoes" provisions. Under the first approach, a physician would be deemed *not* to stand in the shoes of the physician organization if the physician's compensation arrangement with his or her physician organization satisfies the requirements of any of the current exceptions for bona fide employment relationships, personal services arrangements or fair market value compensation.

While there is no proposed regulatory text, CMS' alternative approach would leave the Phase III provisions as promulgated and, using its general authority, the agency would create a new exception specific to "nonabusive payments or arrangements that warrant protection not otherwise available under any existing exceptions," with conditions necessary to protect against program and patient abuse.

On the designated health services entity side of the financial arrangement, CMS repropose, with some modifications, the previous "stand in the shoes" provisions that were part of the calendar year 2008 physician fee schedule proposed rule published in the November 27, 2007 *Federal Register* but never finalized. Comments suggested that the proposal was unclear and potentially overly broad. Under the proposal, an entity that provides designated health services would be deemed to stand in the shoes of *any* organization in which it has a 100 percent ownership interest and would be considered to have the same compensation arrangements with the same parties and on the same terms as the organization that it owns.

We believe that CMS' proposals are inconsistent with the stated goal of simplification. The proposals are overly complex, requiring an organization to have intimate knowledge and conduct analysis of arrangements that are internal to its "partner" organization and substantially beyond its own control. The complexity of CMS' proposals also is evident from the preamble discussion in which CMS details – without proposing regulatory text – several complex conventions that must be used in order to apply the proposed "stand in the shoes" provisions to a chain of financial relationships between a physician and a designated health services entity. As CMS acknowledges, these conventions are necessary to ensure that at least one compensation arrangement between the referring physician and the designated health services entity remains, in order to analyze the chain arrangement under the physician self-referral rules.

The "stand in the shoes" provisions and the complex conventions to be used in their application are just one of the many moving parts of CMS' strategy to bring more financial arrangements within the scope of the physician self-referral law, especially those arrangements that may not meet the definition of an "indirect compensation arrangement." CMS specifically indicates in the preamble discussion that it intends to amend the regulatory text, as appropriate, to codify the conventions for applying the "stand in the shoes" provisions when they are finalized. In addition, CMS specifically states that, because of concerns that the elements of the definition of

“indirect compensation arrangements” are being interpreted too narrowly, it may provide additional guidance on the application of the elements in the definition as part of the FY 2009 inpatient PPS final rule.

With all of these moving parts, **it is critical that CMS take a more holistic view of the issues involved and consider the interrelationship of all of its related proposals**, rather than taking the piecemeal approach that it appears to have adopted. Clarifications to the definition of “indirect compensation arrangements,” for example, necessarily will directly affect the “stand in the shoes” policy and provisions and, in fact, may lessen the need for the complex regulatory construct CMS now proposes to apply. A proposal developed as a result of a more integrated consideration also will enable a more thorough evaluation of the impact of any proposed changes.

Period of Disallowance. CMS proposes to amend the physician self-referral provisions to specify a “period of disallowance” (i.e., the time period for which a physician could not refer patients for designated health services to an entity, and for which the entity could not bill Medicare where a financial relationship between the referring physician and the designated health services entity failed to satisfy the requirements of an exception to the general self-referral prohibition) for certain noncompliant arrangements. CMS received few public comments in response to an earlier solicitation included in the calendar year 2008 physician fee schedule proposed rule. The current proposals generally would place an outside limit on the period of disallowance in limited circumstances:

- Where the reason for noncompliance does not relate to compensation (e.g., a signature is missing or an agreement is not in writing), the period of disallowance would end no later than the date the arrangement was brought into compliance.
- Where the reason for noncompliance relates to payment of either too little or too much compensation, the period of disallowance would end no later than the date the shortfall is made up or the excess compensation is returned by the party who owes the shortfall or has received the excess compensation, provided that the arrangement otherwise satisfies all requirements of an applicable self-referral exception.

But CMS does not propose to establish a definitive period of disallowance, or more generally applicable guidelines, when:

- The parties to a noncompliant financial relationship do not or cannot bring the arrangement into compliance (e.g., the relationship already has expired under the terms of the underlying agreement or has ended earlier or later than the expiration date in the underlying agreement); or
- A party owing a shortfall or receiving excess compensation never makes up the shortfall or repays the excess compensation.

Rather the determination of the period of disallowance, CMS states, must depend on the specific facts and circumstances involved.

The AHA appreciates that, in advancing these proposals, CMS is attempting to offer greater clarity about making referrals and billing the Medicare program in the case of noncompliant financial relationships. However, we are concerned that the proposals rely heavily on a “pay back” concept or otherwise resort to a specific facts-and-circumstances test in determining the period of disallowance. Both notions are problematic because they reach beyond the duration of the relationship, creating consequences that stretch far into the future in complex and unknowable ways. As a result, the proposals would seem to inhibit self-reporting and self-correction of compliance problems rather than establishing the certainty and finality necessary to encourage them.

In addition, the seemingly piecemeal approach to addressing the issues raised in these circumstances heightens concerns about the current proposal’s level of clarity and usefulness. In the preamble discussion, CMS notes that consideration of a related proposed “alternative method of compliance” from the calendar year 2008 physician fee schedule proposed rule remains under consideration. Additionally, CMS specifically states that it “may propose rulemaking on [a period of disqualification during which the parties to a noncompliant financial relationship would be prohibited from using a particular exception due to that relationship] in the future,” although the current proposal does not impose such a period. Finally, CMS highlights that the current proposal does not address whether the anti-kickback statute is implicated and/or whether civil monetary penalties under the physician self-referral statute are potentially applicable due to the noncompliant financial relationships.

Because these issues and concerns are closely intertwined and must be considered together to ensure a coherent and workable regulatory approach, the **AHA urges CMS to consider all of these issues together to develop and publish a more comprehensive proposal that will allow organizations to consider the full impact of any proposed changes.** In developing such a comprehensive proposal, **CMS should work together with the Office of Inspector General (OIG) to coordinate efforts to address the full range of concerns raised** regarding these arrangements.

Gainsharing. The AHA and its members believe that clinical integration is essential to delivering the quality and efficiency gains patients, employers and insurers demand, and that alignment of financial incentives is essential to maximizing those gains. We appreciate CMS’ acknowledgment at 73 Fed. Reg. 23694 of “the value to the Medicare program and its beneficiaries where the alignment of hospital and physician incentives results in improvements in quality of care” and agrees that the physician self-referral prohibition and its implementing regulations may create statutory and regulatory impediments to gainsharing. However, we are concerned that by focusing the current inquiry solely on gainsharing arrangements, any resulting exception could inadvertently impede the development of a broader range of structures necessary for clinical integration.

While gainsharing arrangements are known as relationships intended to develop and promote cost efficiencies, we have come to learn that clinical integration can seek measurable

improvement in a variety of other categories. Our members report a strong desire amongst their administrators and staff or physicians to integrate functions and incentives to achieve those non-cost goals, as well financial efficiencies. Private insurers have long recognized that numerous types of incentives bring about desired gains in health care quality, patient safety and community access and are emulating pay-for-performance programs that currently are not available in the Medicare context, but clearly are being considered for adoption by the Medicare program. Encouraging adherence to scientifically based clinical protocols proven to improve outcomes and the quality of care, or rewarding providers for achieving desirable patient outcomes, are just some of the ways private insurers are collaborating with providers to improve the quality of care.

Not only does the Stark law restrict the ability to share on cost savings but it, as well as other laws, impedes the ability of hospitals and physicians to work together using incentives to improve quality, patient safety and community access to services. The time is ripe to modernize the concept of gainsharing and focus on the broader goal of fostering hospital-physician arrangements that provide incentives for care improvement. An exception narrowly tailored to traditional gainsharing arrangements would not relieve the OIG of the burden of responding to continued advisory opinion requests as hospitals and physicians struggle to fit performance goals – common in the private insurance industry – within the existing legal framework. Moreover, much the way that CMS and OIG took a coordinated approach to developing the E-prescribing and electronic health records Stark law exceptions and anti-kickback law safe harbors, any work in this area needs to be coordinated, so as to fully recognize the potential value to the Medicare program and its beneficiaries when the alignment of hospital and physician incentives results in improvements in quality of care.

For example, earlier in our comments, we addressed CMS' desire to develop incentives under hospital payment rules to reduce hospital readmissions. However, hospital readmissions are the result not only of hospital performance but also of physician and post-acute care provider actions. Furthermore, the potential savings associated with reduced hospital readmissions would accrue directly to the Medicare program, not to hospitals. The adoption of any hospital payment change related to hospital readmissions would need to enable relationships between hospitals and physicians (and potentially other post-acute care providers) that use incentives appropriately without conditioning those incentives on "savings" to the hospital. The current concept of gainsharing is simply too narrow.

The federal requirements that regulate hospital-physician relationships, as they stand, inhibit the necessary evolution in physician-hospital relationships needed to improve health care delivery and enable productive responses to the increasing reliance on performance-based payment systems being adopted by Medicare, Medicaid and private payers. Specifically, we believe federal laws and/or regulations that affect hospital-physician relationships should be amended to foster hospital-physician incentive arrangements that are designed to:

- Improve or maintain community access to services, or to achieve one or more of the six aims for health care delivery articulated by the Institute for Medicine in its report, *Crossing the Quality Chasm*. The six aims are health care that is safe, effective, patient-centered, timely, efficient and equitable.
- Achieve needed improvements in the health care delivery system, even if they do not produce immediate cost savings.
- Sustain community access to services that are essential. With physicians less dependent on hospitals as a place to practice, new incentives should be allowed in order to maintain community access to services (such as trauma and emergency department services), support community outreach efforts, provide care for the uninsured, and support other aspects of hospital operations that require physician support.
- Promote the integration of clinical care across providers, across settings and over time to better coordinate the care provided to patients, especially the growing numbers of those with chronic conditions.
- Enhance organizational or practitioner productivity, or achieve other efficiencies.

In addition, federal laws and/or regulations that affect hospital-physician relationships should be amended to establish a simpler, consistent set of rules for how hospitals and physicians construct their working relationships. The complexity, inconsistency and sometimes conflicting interpretations of federal laws and regulations affecting hospital-physician relationships are a significant barrier. Few arrangements can be structured without very significant legal expense.

FINANCIAL RELATIONSHIPS BETWEEN HOSPITALS AND PHYSICIANS

CMS for the third time proposes an "information collection request" (ICR) that would require approximately 500 hospitals to report information, supply documents and make certain legal certifications regarding their relationships with physicians. With the exception of an increase in the estimated burden (still greatly understated), the proposal is identical to the one submitted to the Office of Management and Budget in September 2007 and withdrawn in April 2008 in the face of serious objection to the burden and scope of the request by the AHA and others on behalf of the adversely affected community hospitals.

We again object to the proposed ICR, as it affects community hospitals that would be subject to the intrusive and burdensome demand for information regarding compensation arrangements. CMS' explanation of the purpose and need continues to be insufficient to justify the time, effort and dedication of resources that would be required of community hospitals.

CMS continues to blur the congressional directive in the *Deficit Reduction Act of 2005* (DRA) that CMS "develop a strategic and implementing plan" to address issues of concern to Congress regarding "physician investment in specialty hospitals" with its interest in collecting compensation information from community hospitals. The AHA supports and encourages CMS to complete the work it started and any additional work that may be needed to meet the DRA

mandate. The DRA did not, however, mandate and does not justify the ICR regarding community hospitals' compensation arrangements.

There are two fundamental problems with this proposal and the initiative: the objective is too abstract (evaluate compliance) and the demand for information is, not surprisingly, too sweeping. After two rounds of notice and comment, the third proposal still effectively asks for the maximum amount of information and effort and treats the response as ministerial.

There is no description of a compliance problem that might merit the burden created. Likewise, there is no explanation of how all the information being requested would be used in evaluating compliance. There also is no recognition of the significance of what is being asked. Executive management is required to make certifications regarding the completeness of the submission, compliance with specific provisions of the law and explanations of noncompliance. Yet CMS asserts that the task can largely be handled by administrative staff. The Disclosure of Financial Relationships Report (DFRR) begins with the maximum burden and no articulation of objectives against which the manner and method can be evaluated, and no exploration of a less costly and burdensome approach.

The burden estimate and the CMS description of what a response will require are at odds with current recordkeeping processes in hospitals. Record keeping is predominantly manual, not electronic; documents are decentralized, not centralized; and there is no "self-referral law" filing system required. The number of physicians on staff will affect the number of potential contracts. Having been told that the request will sometimes lead to hundreds of contracts being identified, located, reviewed and copied – manually to the largest extent – CMS offers no explanation of why this is justified. While CMS has increased the estimate of burden in this third proposal, it has made no adjustment in the substance of what it proposes.

Why should a small, medium or large hospital be asked to divert resources to this request? While CMS makes the point that it is proposing a 10 percent sample of hospitals be included in the first stage of the request, it never explains why it needs 100 percent of files, relationships and information.

CMS requests information on nine different categories of compensation arrangements. For those categories most commonly engaged in (e.g., recruitment arrangement), it asks for copies of every contract in effect during a calendar year. Depending on the size of the hospital, documents will be required for hundreds or thousands of contracts. And the number of contracts only begins to describe how many pieces of paper will need to be copied.

Anecdotally, the burden estimates for hospitals include:

- The number of contracts affected can include: 400; 500-600; 800-1,000.
- At least 200 hours will be needed just to identify and assemble all the relevant contracts.
- Three to four weeks will be required to fully respond, assuming no vacations or holidays for involved staff.

- Two to three months to respond with one full-time equivalent employee's time.
- Smaller hospitals will have fewer contracts, with fewer staff to complete the work, and a greater need for outside attorneys or auditor support.
- Hospitals with a fiscal year that is not a calendar year are required to provide documents for two fiscal years, doubling their workload.

Copying the documents will be the last step and the least of what it will take for a hospital to comply. They must identify all the relevant contracts, where they are located and assemble them in a central location. Only then can the kind of review and analysis be completed that will be necessary to answer the specific questions asked and to enable a CEO to make the certification that is required. Some questions require information on arrangements for which a simple review of the agreement will not be sufficient. For example, knowing which specific exception an arrangement relied on when more than one may be applicable will not necessarily be noted in the contract. Only an attorney's review will allow a hospital to determine that information.

Under the current rule, routine mandatory reporting is not required. In fact, it was included in the proposed rule on reporting. And, after hearing from the field that it would be unduly burdensome, CMS made a conscious decision not to use that approach. It also made clear that it was not developing any forms or record-keeping requirements specific to reporting. The DFRR, therefore, would circumvent CMS' own rulemaking decision.

There is nothing in the regulations to support imposition of the broad-based, all-encompassing demand of the DFRR. While CMS reserved the right to make requests on an individual basis, the DFRR is much different. This is a wholesale mandatory request. An individual request would have to be justified on grounds specific to the circumstances of the entity from which the information was requested. The DFRR is not a reasonable exercise of agency discretion and is outside the scope of the current rule, whether judged as a mandatory reporting system or an individual request.

CMS should not proceed with this intrusive, costly and very burdensome demand on community hospitals.

DISCLOSURES TO PATIENTS BY CERTAIN HOSPITALS AND CRITICAL ACCESS HOSPITALS

In the FY 2008 inpatient PPS final rule, CMS imposed two requirements for disclosures to patients by certain hospitals and critical access hospitals (CAHs). The first requirement was for a hospital to disclose to all patients whether it is physician-owned and, if so, the names of its physician owners. This requirement applies only to those hospitals with physician ownership. In this year's inpatient PPS proposed rule, CMS seeks to make several changes to that requirement, some of which are technical in nature. **The AHA supports the following proposed changes to the physician ownership disclosure requirement:**

- Revising the definition of a physician-owned hospital to make it consistent with the definitions in the physician self-referral law and regulations regarding inclusion of ownership interests held by the immediate family members of a referring physician.
- Revising the definition of a physician-owned hospital to exclude those hospitals where none of the physician owners refer to the hospital.
- Requiring that a hospital provide the list of physician owners to a patient at the time a request is made.
- Requiring that referring physicians disclose in writing to all patients who they refer to the hospital any ownership or investment interest in the hospital held by themselves or by an immediate family member at the time they refer patients to the hospital.

The second requirement adopted in the FY 2008 inpatient PPS final rule was that those hospitals and CAHs that do not have a physician present in the hospital 24 hours per day, seven days per week provide a written notice to all inpatients and outpatients stating as much. The notice also must describe how the hospital or CAH would meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present in the hospital. The proposed changes clarify enforcement actions in the event of noncompliance and make technical changes.

The AHA believes that CMS should use this opportunity to revisit issues that we and others have raised regarding the overly burdensome approach of this second disclosure regarding on-premises physician availability. These issues relate to the applicability of this requirement to small, rural hospitals and CAHs and the requirement that the written notice be provided to *all* outpatients in addition to inpatients. The AHA has addressed these issues in comments to CMS on the FY 2008 inpatient PPS proposed rule, and to both CMS (on June 22, 2007) and the Office for Management and Budget (on September 14, 2007) in connection with CMS' request for approval of the paperwork requirements associated with the disclosures.

As indicated in our earlier comments, **the AHA believes that the physician availability disclosure requirement is being applied much too broadly and, as such, creates an unnecessary burden on small, rural hospitals and CAHs and, more generally, on the delivery of outpatient services.** While the requirement may sound reasonable, we believe it misses the mark on the real issue to be addressed: safety concerns in physician-owned specialty hospitals.

It makes sense to apply special requirements like these to physician-owned specialty hospitals, but not to all hospitals. The safety concerns raised by physician-owned specialty hospitals occur because these facilities operate outside the traditional network of care delivery. These facilities are free-standing, generally not part of a larger system of care, most often lack transfer agreements with other hospitals or providers of care in a community, and tend to specialize in one type of care delivery, challenging their ability to treat the unexpected event or emergency.

This is not the case with full-service community hospitals. Full-service community hospitals are part of a community network of care, involving referrals from local physician practices, reliance

on local trauma-support networks, participation in local emergency medical transport systems and transfer agreements among facilities. Even small and rural hospitals located in more remote areas are part of a planned network of care and patient triage. Small and rural hospitals often stabilize and transport patients to other facilities, but that transport is communicated, the receiving hospital is alerted, and the patient's clinical information collected at one hospital goes with the patient to the next hospital. In addition, small and rural hospitals are often connected to a system of care through telemedicine, which allows for access in more remote areas to specialists and other clinical expertise available at larger, more urban hospitals. Furthermore, the capabilities of these hospitals are well known in their communities and they are looked to as a local entry point into the health care system. **Applying additional requirements for this group of hospitals is unnecessary and costly.**

Participation in the broader network of care delivery, of which full-service community hospitals are a part, is the best way to ensure that the right care is provided to patients at the right time, in the right setting. This requirement can be used to assure that patients scheduled for admission to a physician-owned specialty hospital understand that, in the absence of being a part of the broader care network, the ability of these facilities to handle complications on-site may be limited.

The burden associated with this requirement should be further reduced by not applying the requirement to all outpatient visits. **The AHA recommends that this requirement be limited to inpatient admissions and only those outpatient visits that include surgery, other invasive procedures, the use of general anesthesia or other high-risk treatment. Emergency department services should specifically be excluded.**

Patients being admitted to a hospital expect that the hospital can handle emergencies that arise, and patients undergoing outpatient surgery or other procedures that are invasive, involve anesthesia or are higher risk, expect that related complications can be handled. A patient coming for a mammogram or going to an arthritis clinic has a different set of expectations. Therefore, we do not believe it makes sense to give every outpatient this disclosure notice. Furthermore, providing the notice to emergency department patients seems fruitless because the decision to seek care at the hospital already has been made. **Other than high-risk or invasive procedures, AHA believes that the goal of broadly expanding community understanding of a hospital's limitations through outpatient encounters would be more efficiently accomplished through signs in hospital emergency departments and outpatient clinics.**