CMS-1533-P-26 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Rick Pollack** **Date & Time:** **06/04/2007**

Organization : **American Hospital Association**

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Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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#26

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June 4, 2007

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Hubert H. Humphrey Building
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Washington, DC 20201

RE: CMS-1533-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72, No. 85), May 3, 2007

Dear Ms. Norwalk:

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) 2008 hospital inpatient prospective payment system (PPS).

While the AHA supports many of the proposed rule's provisions, we oppose the proposed "behavioral offset" cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

DRGs

The proposed rule would create 745 new Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs, and would overhaul the complication or comorbidity list. The proposed rule also **includes a 2.4 percent cut to both operating and capital payments in both FYs 2008 and 2009 – $24 billion over five years** – to eliminate what you claim will be the effect of classification changes that do not reflect real changes in case-mix. In addition, the rule proposes continuing the three-year transition to cost-based relative weights, with two-thirds of the FY 2008 weight based on costs and one-third based on charges.

However, payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Even with the DRG changes proposed by CMS, physicians will still have the ability and incentive to steer financially attractive patients to

facilities they own, avoid serving uninsured, Medicaid and other low-income patients, practice similar forms of selection for outpatient services and drive up utilization. We urge CMS to address the real issue of self-referral: to rigorously examine the investment structures of physician-owned, limited-service hospitals and consider our comments on CMS' interim report on the strategic plan required by the *Deficit Reduction Act of 2005*.

The hospital field supports meaningful improvements to Medicare's inpatient PPS. While we believe that the MS-DRGs provide a reasonable framework for patient classification, a transition is necessary given that the change redistributes between $800 million and $900 million among hospitals.

CAPITAL PAYMENT UPDATE

The proposed rule would eliminate the capital payment update for all urban hospitals (a 0.8 percent cut) and the large urban hospital capital payment add-on (an additional 3 percent cut). **These changes would result in a payment cut of $880 million over five years to urban hospitals.**

We are opposed to these unnecessary cuts, which ignore how vital these capital payments are to the ongoing maintenance and improvement of hospitals' facilities and technology. We also oppose your consideration of possible future cuts to the indirect medical education and disproportionate share hospital adjustments under the capital system. CMS should not make any cuts or other adjustments to the capital PPS.

CMS has gone well beyond its charge by recommending arbitrary and unnecessary cuts in this proposed rule. These backdoor budget cuts will further deplete scarce resources, ultimately making hospitals' mission of caring for patients even more challenging.

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

Sincerely,

Rick Pollack
Executive Vice President

American Hospital Association
Detailed Comments on the Proposed Rule
for the
FY 2008 Inpatient Prospective Payment System

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American Hospital Association
Detailed Comments on the Proposed Rule
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DRG REFORM AND PROPOSED MS-DRGS

In response to payment recommendations from the Medicare Payment Advisory Commission (MedPAC) to address the proliferation of physician-owned, limited-service hospitals, the Centers for Medicare & Medicaid Services (CMS) in fiscal year (FY) 2006 began significant efforts to reform the diagnosis-related groups (DRGs) and the calculation of the corresponding relative weights. While CMS adopted cost-based weights in FY 2007, it chose not to implement proposed adjustments to the DRG classification system to further recognize severity of illness. In FY 2008, CMS proposes continuing the transition to cost-based weights and offers a refinement to the current DRG system to better account for patient severity.

The hospital field supports meaningful improvements to Medicare's inpatient prospective payment system (PPS). We believe the AHA and CMS share the common goal of refining the system to create an equal opportunity for return across DRGs, which will provide an equal incentive to treat all types of patients and conditions. We also believe that the system should be simple, predictable and stable over time. One of the fundamental values of a *prospective* payment system is the ability of providers to reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions.

Another core feature of the PPS is clinically cohesive and meaningful DRGs that are intuitive for providers and coders to follow, and that reflect similar resource use within DRGs. Ultimately, the inpatient PPS should foster innovation and best practice in care delivery. We believe that these are essential characteristics of a well-functioning PPS, and it is within these policy goals that we evaluate CMS' proposal.

However, payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Even with the DRG changes proposed by CMS, physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving uninsured, Medicaid and other low-income patients, practice similar forms of selection for outpatient services and drive up utilization. We urge CMS to address the real issue of self-referral: to rigorously examine the investment structures of physician-owned, limited-service hospitals and consider our comments on CMS' interim report on the strategic plan required by the *Deficit Reduction Act of 2005* (DRA).

SEVERITY OF ILLNESS

For FY 2008, CMS proposes to refine the current DRG system by implementing Medicare-Severity DRGs (MS-DRGs), increasing the number of DRGs from 538 to 745. In addition, CMS has undertaken an overhaul of today's complication and comorbidity (CC) list and created up to

three tiers of payment for each DRG based on the presence of: a ***major*** complication or comorbidity (MCC), ***a*** complication or comorbidity, or ***no*** complication or comorbidity.

The AHA appreciates CMS' recognition and consideration of the issues we raised last year about the proposal to use consolidated severity-adjusted DRGs in crafting this year's proposal. Specifically, we asked CMS to: show evidence that the alternative resulted in an improved hospital payment system compared to the existing DRG system; test the degree to which the variation in costs within cases at the DRG level is reduced; consider whether there were easier ways to adjust for severity similar to the differentiation of patients in FY 2006 based on the absence or existence of a major cardiovascular diagnosis; maintain the improvements made to differentiate cases based on complexity in the existing system; and avoid creating a system that is proprietary and lacks transparency. CMS made a concerted effort to develop a system that incorporates these goals.

Hospitals support meaningful improvements to Medicare's inpatient PPS. MS-DRGs represent a reasonable approach to DRG refinement. CMS should commit to this system for the near future but build in the time needed to ensure that both the agency and hospitals are adequately prepared for this significant change.

We urge CMS to adopt the MS-DRGs over a four-year transition period, as the implementation of the more extensive classification system, though budget neutral, would redistribute somewhere between $800 million and $900 million among hospitals. Specifically:

- In FY 2008, the emphasis should be on preparation for and testing of the new classification system. This provides CMS with adequate time to finalize data and a CC list, introduce and test software for case classification and payment, including the definitions and instructions for case classification and payment, and train its fiscal agents. It also gives hospitals adequate time to implement and test the new system and adjust operations and staffing for predicted revenues. This also will allow vendors and state agencies time to incorporate such changes into their respective software and information systems.

- In FY 2009, DRG weights should be computed as a blend derived one-third from the MS-DRGs and two-thirds from traditional DRGs.

- In FY 2010, DRG weights should be computed as a blend derived two-thirds from MS-DRGs and one-third from traditional DRGs.

- In FY 2011, DRG weights should be derived using only the MS-DRGs.

The weights would be established by CMS running the "old GROUPER" from 2008 without any changes to the CC list to establish where cases originated, and running the "new GROUPER" from 2009 with the new CC list, then blending the two weights based on the schedule above. Since there is not a perfect crosswalk from the old DRGs to the new ones, the weight used for payment in a given year would be established by blending the MS-DRG weight with a volume-

weighted average of the CMS-DRG weights that feed into that particular MS-DRG. Thus, only one weight would be published in advance.

While there are many other ways to transition the system, we believe that this is easiest for CMS to implement, maintains the prospective nature of the system, is equitable across hospitals, does not require any sort of subsequent reconciliation, and does not require CMS or hospitals to run more than one GROUPER the entire year. We also believe that the length of the transition is appropriate given the large amount of money shifted within the system.

BEHAVIORAL OFFSET

Until MS-DRGs are fully implemented, and CMS can document and demonstrate that any increase in case-mix results from changes in coding practices rather than real changes in patient severity, there should be no "behavioral offset." We discuss this in more depth below.

The proposed rule includes a 2.4 percent cut in both FYs 2008 and 2009 to eliminate what CMS claims will be the effect of coding or classification changes that do not reflect real changes in case-mix. The 2.4 percent "behavioral offset" cut is based on assumptions made with little to no data or experience, and cannot be justified in advance of making the DRG changes. **The AHA opposes the "behavioral offset," which will cut payments to hospitals by $24 billion over the next five years. We do not believe that this cut is warranted – it is a backdoor attempt at budget cuts.**

Inpatient hospitals have operated under the current DRG system for 23 years. The proposed MS-DRGs would be a *refinement* of the existing system; the underlying classification of patients and "rules of thumb" for coding would be the same. There is no evidence that an adjustment of 4.8 percent over two years is warranted when studies by RAND, cited in the preamble, looking at claims between 1986 and 1987, at the beginning of the inpatient PPS, showed only a 0.8 percent growth in case mix due to coding. Even moving from the original cost-based system to a new patient classification-based PPS did not generate the type of coding changes CMS contends will occur under the MS-DRGs.

We provide detailed comments below on why the examples CMS uses to justify the coding adjustment are flawed. In addition, we also provide many reasons why we do not expect a significant increase in payment due to coding.

Maryland experience. In the rule, CMS uses the experience of Maryland hospitals moving to 3M's All-Patient Refined DRGs (APR-DRGs) as a basis for the behavioral offset. However, MS-DRGs and APR-DRGs are two completely different ways to classify patients, and generalizing from one system to the other cannot be done. The existing classification rules will change only marginally with the introduction of MS-DRGs, whereas they are very different under the APR-DRG system. Differences include:

- APR-DRGs consider multiple CCs in determining the placement of the patient and, ultimately, the payment. In fact, to be placed in the highest severity level, more than one high-severity secondary diagnosis is required.

- APR-DRGs consider interactions among primary and secondary diagnoses. Something that bumps one case type to a higher severity level might not affect another. This is not true for MS-DRGs.
- APR-DRGs consider interactions among *procedures* and diagnoses as well. MS-DRGs do not.
- APR-DRGs have four severity subclasses for *each* base DRG, while MS-DRGs have three tiers, and this is only for 152 base DRGs –106 base DRGs only have two tiers and 77 base DRGs are not split at all.
- Less than half the number of patient classifications in the MS-DRG system are dependent on the presence or absence of a CC – 410 for MS-DRGs versus 863 for APR-DRGs.

All of these differences greatly reduce the possibility for changes in coding to affect payment and make the Maryland experience an invalid comparison.

IRF PPS experience. CMS also draws on the example of the inpatient rehabilitation facility (IRF) PPS to justify the coding adjustment. This is an appropriate comparison. The coding changes seen under the IRF PPS were the result of moving from a cost-based system to a PPS, not the marginal difference of moving from the existing CMS-DRGs to the refined MS-DRGs.

In addition, coding under the IRF PPS is driven by the Inpatient Rehabilitation Patient Assessment Instrument (IRF-PAI). This provides an incentive for IRFs to code in a way that differs from the inpatient PPS, which does not utilize a patient assessment instrument. Coding for the IRF-PAI differs significantly from the long-standing coding rules that inpatient PPS hospitals have followed for the following reasons:

- The IRF-PAI introduced a new data item into coding – namely "etiological diagnosis." The definition of this new diagnosis and the applicable coding rules are significantly different than the "principal diagnosis" used to determine the DRG. More importantly, the Official Coding Guidelines that apply to all other diagnostic coding do not apply to the selection of the ICD-9-CM etiologic diagnoses codes.

- The Official Coding Guidelines do not consistently apply to the coding of secondary diagnoses on the IRF-PAI. Several different exceptions to the guidelines have been developed by CMS for the completion of the IRF-PAI.

- The definition of what secondary diagnoses may be appropriately reported differs under the IRF-PAI from the definition used by other inpatient coders.

Greater use of codes. Most hospitals are already coding as carefully and accurately as possible because of other incentives in the system to do so, such as risk adjustment in various quality reporting systems. Analysis of Medicare claims from 2001 to 2005 suggests that hospitals have been coding CCs at high rates for many years. More than 70 percent of claims already include CCs, and more than 50 percent of claims have at least eight secondary diagnoses (the maximum number accepted in Medicare's DRG GROUPER). Hospitals' assumed ability to use even more CCs under MS-DRGs is very low.

According to an article in the magazine *Healthcare Financial Management,* the level of coding on claims suggests that the presence of a CC on a bill is not strongly influenced by financial gain. The proportion of surgical cases with a CC code is higher for cases where there is no CC split and, thus, no financial benefit, than on those cases where there is a CC split and a corresponding higher payment. Thus, coding is driven primarily by coding guidelines and what is in the medical record rather than by financial incentives.

In addition, it must be recognized that many cases simply do not have additional CCs to be coded. For many claims, additional codes are simply not warranted and not supported by the medical record. Therefore, there is no opportunity for a coding change to increase payment.

Order of codes. We analyzed the all-payer health care claims databases from California, Connecticut, Florida and Michigan because, unlike the Medicare Provider and Review (MedPAR) files, these databases include all 25 diagnoses reported on the claims. This analysis showed that only 0.25 percent of claims had an MCC or CC appear for the first time in positions 10 through 25. This strongly suggests that hospitals will not be able to "re-order" their secondary diagnoses to appear higher on the claim so that CMS will pick them up and pay them a higher rate. Our coding experts note that most hospitals use software that automatically re-sorts the secondary diagnoses to ensure that those pertinent to payment are included in positions two through nine.

Specific codes. We examined secondary diagnosis codes and found that there were relatively few non-specific codes listed among the common secondary diagnoses of discharges without a CC/MCC. This means that hospitals cannot shift large numbers of discharges to CCs or MCCs based on putting in a more specific code to replace a non-specific code.

DRGs that do not split CCs and non-CCs. There is no opportunity for increased payment due to a change in coding for 77 base DRGs under the MS-DRGs systems, as there is only one severity class and no differentiation in payment.

Additionally, there are MS-DRGs that are now split between "w/MCC" and "w/o MCC" (a combined non-CC and CC MS-DRG) that have historically contained a single CC/non-CC split. These already required secondary diagnosis coding, thus, the codes to qualify the case as an MCC already would have been present. In these cases, it is very unlikely that the medical record would justify an MCC that is not already present. Coders are not able to interpret a case, but must code strictly based on what the physician notes in the chart. Therefore, it is highly unlikely that coding changes could move cases to the higher severity MS-DRG with MCC.

CMS should not implement a "behavioral offset" at this time. Once the MS-DRGs are fully implemented, CMS can investigate whether payments have increased due to coding rather than the severity of patients and determine if an adjustment is necessary. CMS is not required to make an adjustment at this time, and should not do so without an understanding of whether there will even be coding changes in the first few years of the refined system. CMS can always

correct for additional payments made as a result of coding changes in a later year when there is sufficient evidence and an understanding of the magnitude.

REVISED CC LIST

As part of the effort to better recognize severity of illness, CMS conducted the most comprehensive review of the CC list since the creation of the DRG classification. Currently, 115 DRGs are split based on the presence or absence of a CC. For these DRGs, the presence of a CC assigns the discharge to a higher-weighted DRG.

A condition was included on the revised CC list if it could be demonstrated that the presence of the condition would lead to substantially increased hospital resource use (intensive monitoring, expensive and technically complex services, or extensive care requiring a greater number of caregivers). Compared with the existing CC list, the revised list requires a secondary diagnosis to have a consistently greater impact on hospital resources. The revised CC list is essentially comprised of significant acute diseases, acute exacerbation of significant chronic diseases, advanced or end-stage chronic diseases and chronic diseases associated with extensive debility.

We commend CMS on the systematic way it reviewed 13,549 secondary diagnosis codes to evaluate their assignment as a CC or non-CC using a combination of mathematical data and the judgment of its medical officers. However, in our efforts to perform a meaningful review of the revised CC list, we disagree with the removal of many common secondary diagnoses.

We do not understand why significant secondary diagnoses have been removed from the CC list. Specifically, it is unclear what threshold levels were used and at what point in the analysis the CCs were removed. For example, what was considered "intensive monitoring"? Does intensive monitoring refer to additional nursing care on a daily basis, additional testing, intensive care unit care, extended length of stay, all of these factors, or some other factor? In some instances, we have noted that similar or comparable codes within the same group have remained a CC/MCC, while other clinically similar codes or codes requiring similar resources may have been omitted. Without greater transparency, and a code-by-code explanation, we are unable to determine why significant secondary diagnoses requiring additional resources have been removed from the CC list. For the most part, our analysis has concentrated on reviewing current CCs that have been omitted from the revised CC list.

We make the following overall recommendations with regards to the CC list:

- **CMS should make the final revised CC list publicly available as quickly as possible** so that hospitals may focus on understanding the impact of the revised CC list, training and educating their coders, and working with their physicians for any documentation improvements required to allow the reporting of more specific codes where applicable.
- **CMS should consider additional refinements to the revised CC list** and, in particular, address issues where the ICD-9-CM codes may need to be modified to provide the distinction between different levels of severity.
- **In situations where a new code is required, CMS should default to leaving the codes as CCs until new codes can be created.**

- **CMS should address the inconsistencies within the CC list identified by physicians and hospitals.** Where necessary, CMS should immediately obtain additional input from practicing physicians in the appropriate specialties to determine the standard of care and consequent increased hospital resource use.

Attachment I lists examples of many conditions that were removed from the revised CC list. We do not understand the rationale for their removal and urge CMS to maintain them on the CC list.

INPATIENT PSYCHIATRIC PPS

We urge CMS to carefully consider the implications of its proposed MS-DRG changes on the inpatient psychiatric facility PPS, specifically, the DRGs for alcohol/drug use and the changes to the CC list.

MEDICARE CODE EDITOR

We applaud CMS' removal of codes from Non-Specific Principal Diagnosis Edit 7 and Non-Specific O.R. Procedures Edit 10. These edits were created at the beginning of the inpatient PPS with the intent of encouraging hospitals to code as specifically as possible. We agree that these two edits have been misunderstood and claims have been erroneously denied, rejected or returned as a result.

RECALIBRATION OF DRG WEIGHTS

For FY 2008, CMS has not proposed any changes to the methodology adopted in FY 2007 for calculating cost-based DRG weights. The three-year transition from charge-based DRG weights to cost-based weights would continue, with two-thirds of each weight based on an estimation of costs and one-third based on charges.

However, during the transition to cost-based weights, two significant issues surfaced:

- First, there is a mismatch between the two data sources used in establishing the cost-based weights. These differing data sources, specifically the charges from the MedPAR files (an accumulation of Medicare patient claims filed by each hospital) and the cost-to-charge ratios (CCRs) from the hospital Medicare cost reports, can distort the resulting DRG weights. It is important to note that the cost report was not designed to support the estimation of costs at the DRG level.

- Second, hospitals mark-up different items and services within each cost center by different amounts. Higher-cost items often are marked up less than lower-cost items. When the same CCR is applied to charges for these items, costs can be underestimated for items with lower mark-ups and overestimated for items with higher mark-ups. This "charge compression" can lead to the distortion of DRG weights.

The AHA, Association of American Medical Colleges (AAMC) and Federation of American Hospitals (FAH) convened a workgroup made up of state association, cost report and billing experts to discuss these issues earlier this year. Our comments on the cost-based weighting methodology below are an outgrowth of this group's recommendations, which can be found in **Attachment II.**

Cost report changes. Under cost-based weights, the two sources of data that are used in establishing the DRG weights are the MedPAR files and the Medicare cost report. Charges are taken from the MedPAR files, grouped into 13 categories and reduced to cost using national CCRs calculated from the Medicare cost reports for these same 13 categories.

An examination of the cost-based weights developed for FY 2007 revealed that three problems occur by using these two different data sources together:

- First, the method used by CMS to group hospital charges for the MedPAR files differs from that used by hospitals to group Medicare charges, total charges and overall costs on the cost report.
- Second, hospitals group their Medicare charges, total charges and overall costs in different departments on their cost reports for various reasons.
- Third, hospitals across the country complete their cost reports in different ways, as allowed by CMS.

This mismatch between MedPAR charges and cost report CCRs can distort the resulting DRG weights.

CMS states that it is undertaking a comprehensive review of the Medicare cost report and plans to investigate this issue during that process but does not propose any short-term changes to alleviate this problem.

In RTI International's report to CMS on the cost-based weights, it recommends the incorporation of edits to reject cost reports or require more intensive review by auditors to resolve the lack of uniformity in cost reporting. However, this will not solve the mismatch problem because the reporting is consistent with the cost reporting instructions. Currently, cost report instructions included with the CMS Form-339 allow for three methods of reporting Medicare charges. The method selected by each hospital is specific to its information systems and based on the method that most accurately aligns Medicare program charges on Cost Report Worksheet D-4 (inpatient) and/or Worksheet D, Part IV (outpatient) with the overall cost and charges reported on Worksheets A and C. Many hospitals elect to allocate some or all of the Medicare program charges from the Medicare Provider Statistical and Reimbursement data (PS&R) to various lines in the cost report based on hospital-specific financial system needs. Under this scenario, total hospital CCRs are aligned with program charges, but will not match the charge groupings used in MedPAR. This mismatching may distort the resulting DRG weights under the methodology developed by CMS. Increased edits or cost report rejections would not provide a solution to a problem that is caused by cost report instructions that allow for multiple approaches.

Instead, the AHA, AAMC and FAH, along with the Healthcare Financial Management Association, are launching an educational campaign to help hospitals report costs and charges, particularly for supplies, in a way that is consistent with how MedPAR groups charges. This would allow for a consistent grouping of departments within the 13 categories identified in the August 18, 2006 final inpatient PPS rule that are currently used to create the cost-based weights, or any future expansion of the categories that may occur.

We believe that this is within the cost report instructions, but request that CMS communicate with its fiscal intermediaries (FIs) that such action is appropriate and encouraged. This will prevent FIs from unwittingly under-cutting an effort to bolster the cost-based weighting methodology. It should be recognized that the mismatching problem is not caused by the failure of hospitals to prepare their cost reports correctly, as appears to be suggested by the RTI study. In addition, CMS should recognize that some hospitals will be better situated to adopt certain cost report changes. It will be more expensive and time-consuming for some hospitals to successfully implement a different approach to cost reporting. Therefore, our education and training activities will take time.

Cost centers. As described above, in calculating the DRG weights, CMS currently groups charges into 13 cost centers and then applies national CCRs to convert the charges to costs. CMS is considering whether it would be appropriate to expand the cost center groupings to 19 in order to separate services that have substantially different CCRs from other services currently in the same cost center. Specifically, CMS is considering the following refinements recommended by RTI:

- Separating the emergency department and blood from "other services;"
- Splitting medical supplies into devices/implants/prosthetics and other medical supplies;
- Distinguishing between CT, MRI and other radiology; and
- Splitting drugs into IV solutions and other drugs.

Using existing cost report data, changes can be made to emergency departments and blood to separate them from other services. But further breaking out supplies, radiology and pharmacy would require either changes to the structure of the cost report or the application of a regression-based adjustment. The AHA and our workgroup agree that CMS' new approach for categorizing all charges and costs into 13 specific categories may not yield the most appropriate CCR for each cost category. As a result, we support the short-term educational efforts detailed above to resolve the mismatched data and CMS' long-term review of the cost report.

We do not believe that a temporary, regression-based adjustment that does not fix the underlying concerns with the cost report is appropriate. The AHA is concerned that, for the sake of expediency, the use of estimates (a regression analysis approach), as opposed to efforts to collect accurate data at the appropriate cost center level, would fail the objective. In addition, we are concerned that the use of a regression model may be difficult to validate, as the DRG weights are modified on an annual basis. We believe that once short-term educational efforts and CMS' long-term cost report evaluation are underway, we can have an informed discussion on which

cost-report changes are needed to alleviate the issue of charge compression. We do not, however, believe that the previously recommended hospital-specific relative value methodology is needed. As clearly stated in our comments last year, we believe that the method is flawed and do not support its implementation.

CAPITAL IPPS

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 currently adjusted by the same DRGs for each case, as is done under the operating PPS. Capital PPS payments also are adjusted for indirect medical education (IME), disproportionate share hospital (DSH) and outlier payments.

For FY 2008, CMS proposes eliminating the capital update for all urban hospitals (a 0.8 percent cut) and the large urban hospital add-on (an additional 3 percent cut). However, CMS proposes to update capital payments for rural hospitals by 0.8 percent (the capital input price index). In addition, CMS is considering discontinuing the IME and DSH adjustments to capital payments.

These cuts, based solely on the discretion of the administration with no congressional direction, are unprecedented. According to MedPAC, overall Medicare margins will reach a 10-year low in 2007 at ***negative*** 5.4 percent. These cuts would amount to a decrease in capital payments of $880 million over the next five years that urban hospitals cannot sustain in an already under-funded system.

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 would create significant financial difficulties and amounts to Medicare reneging on the full cost of caring for America's seniors and disabled. **The AHA is opposed to these unnecessary cuts, which ignore how vital these capital payments are to the ongoing maintenance and improvement of hospitals' facilities and technology.**

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 2004, is deficient in several respects. What hospitals experienced in 1996 is irrelevant to the operating environment today, 11 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 regression establishing the capital PPS was based on total costs, not just capital costs, so CMS should be looking at total margins. As noted earlier, MedPAC estimates an overall hospital Medicare margin in 2007 of negative 5.4 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 2004, the year when the margin dropped to its lowest point, 5.1 percent, in the time period CMS selected – 34 percent below the 2003 capital margin and 41 percent below the 2002 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 and steady decline since 2002 – from positive 2.4 percent to an estimated negative 5.4 percent in 2007.

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 modest capital margin (5.1 percent in 2004, and likely lower today) is excessive. In 1991, CMS even stated that hospitals must accrue profits to supplement payments in high spending years.

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 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.

The AHA also opposes possible future cuts to the IME and DSH adjustments under the capital system. 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.

DRGS: HOSPITAL-ACQUIRED CONDITIONS

The DRA requires CMS to identify by October 1, 2007 at least two preventable complications of care that could cause patients to be assigned to a CC 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. That is, the case would be paid as

though the secondary diagnosis were not present. Finally, the DRA requires hospitals to submit the secondary diagnoses that are present on admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding what is present on admission would be delayed until January 1, 2008 due to technical difficulties in software programming to accept the new information.

In the proposed rule, CMS seeks comments on how many and which conditions should be selected for implementation in FY 2009, along with justifications for these selections. CMS puts forward 13 conditions it is considering, but it recommends only six conditions for implementation at this time. The six conditions are:

- Catheter-associated urinary tract infections;
- Pressure ulcers;
- Object left in during surgery;
- Air embolism;
- Blood incompatibility; and
- Staphylococcus aureus septicemia.

This policy should be implemented starting with a small number of conditions because there are significant challenges to correctly identifying cases that meet the criteria laid out by Congress. There are further difficulties ensuring appropriate accuracy in the billing data that will enable the correct identification of the relevant cases. We ask CMS to carefully consider not only the criteria for selection set forth in the DRA, but also the ability of hospitals to accurately identify and code for these conditions. Some of the proposed conditions may not be feasible at this time.

Conditions to include for FY 2009. The AHA believes that three of the six conditions representing the serious preventable events identified by CMS – object left in during surgery, air embolism and blood incompatibility – are appropriate conditions to include for FY 2009. 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. America's hospitals are committed to patient safety and strive to ensure that these events do not happen.

Conditions not ready for inclusion for FY 2009. The other three conditions – catheter-associated urinary tract infections, pressure ulcers and staphylococcus aureus septicemia – present serious concerns for FY 2009. The correct identification of all three of these conditions will rely on the correct identification and coding of conditions that are present on admission. CMS proposes to rely on the present-on-admission coding that it had originally planned to implement starting October 1, 2007, but which has now been pushed back to January 1, 2008 due to technical difficulties. Implementing a present-on-admission coding indicator will be a major challenge for hospitals. The experiences of two states that already use present-on-admission coding show that it can be done, but that it takes several years and intense educational efforts to achieve reliable data.

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 pressure ulcers, urinary tract infections or staphylococcus aureus are present on admission. To date, we are unaware of any efforts by CMS to initiate such an education process. Only after reasonable reliability in physician identification and recording of the complications that are present on admission are achieved can claims be coded in such a way that CMS could accurately identify those cases that should not be classified into the higher-paying DRGs. The two states that have undertaken the use of present-on-admission coding have reported that such educational efforts have taken 24 months or more, making it highly unlikely that CMS' plan to use present-on-admission coding for payment purposes less than a year after initiating the coding, and without any education of clinicians, would lead to the correct identification of the cases envisioned in the DRA. **We urge CMS to delay implementation of the payment classification changes for cases involving pressure ulcers, catheter associated urinary tract infections and staphylococcus aureus until after it has taken the necessary steps to permit accurate identification of the relevant cases.**

In addition, these conditions are high cost or high volume, but they may not always be reasonably preventable. There is good evidence to suggest that, even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. There is concern among infection control experts that the definitions of some of these conditions need to be reviewed and updated before they can be implemented successfully in a hospital reporting program. Additionally, we believe that hospitals face significant challenges in diagnosing these conditions accurately on admission and coding for them at that time. Our specific concerns with each of the three conditions follow.

- **Catheter-associated urinary tract infections** – Many clinicians believe that urinary tract infections may not be preventable after several days of catheter placement, and prevention guidelines are still debated by clinicians.

- **Pressure ulcers** – It is difficult to detect stage I pressure ulcers on admission, as the skin is not yet broken, even though the tissue is damaged. The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers and included a new definition for a suspected deep tissue injury. Although difficult to detect initially, this condition may rapidly evolve into an advanced pressure ulcer, and it is especially difficult to detect in individuals with darker skin tones. We also are concerned that the present-on-admission coding of pressure ulcers will rely solely on physicians' notes and diagnoses, per Medicare coding rules, and cannot make use of additional notes from nurses and other practitioners. Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. There also is evidence of an increased risk of pressure ulcer reoccurrence after a patient has had at least one stage IV ulcer. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers because, in these cases, the condition may not be reasonably prevented.

- **Staphylococcus aureus septicemia** – Accurately diagnosing 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 or a urinary tract 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 presents 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.

  In addition, after talking with infectious disease experts, 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 been reasonably prevented.** We are happy to work with CMS in helping to more accurately identify these patients.

With regard to the seven conditions that CMS mentions in the proposed rule but does not recommend for implementation, we agree that these conditions cannot be implemented at this time because of difficulties with coding or a lack of consensus on prevention guidelines.

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 urinary tract infections that are present on admission may lead to excessive urinalysis testing for patients entering the hospital. The necessity to complete diagnostic tests before a patient is admitted to confirm present-on-admission status 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 complication or comorbidity DRG payment.

HOSPITAL QUALITY DATA

The DRA expanded quality reporting requirements for hospitals to be eligible to receive a full market basket update. The DRA provided the Secretary with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures on the basis that they are no longer appropriate. In the proposed rule, CMS puts forward five new measures – four process measures and one outcome measure – to be included for the FY 2009 annual payment determination. To receive a full market basket update, hospitals would have to pledge to submit data on these and all measures currently included in the Hospital Quality Alliance's (HQA) public reporting initiative for patients discharged on or after January 1, 2008.

In addition, hospitals would have to pass data validation tests for data submitted in the first three calendar quarters of 2006.

New quality measures. We are pleased that CMS has proposed adding only measures that have been adopted by the HQA for public reporting in FY 2009. The HQA's rigorous, consensus-based adoption process is an important step towards ensuring that all stakeholders involved in hospital quality – hospitals, purchasers, consumers, quality organizations, CMS and others – are engaged in and agree with the adoption of a new measure, and CMS should continue to choose from among the measures adopted by the HQA in linking measures to payment. The measures proposed for FY 2009 are well-designed, represent aspects of care that are important to patients, and provide insights into the safety, efficiency, effectiveness and patient-centeredness of care.

Adoption by the HQA is only one of three criteria that we believe all new measures included in the pay-for-reporting program should fulfill. In addition to HQA adoption, all measures should be endorsed by the National Quality Forum (NQF) through its consensus review process. We appreciate CMS' statement that, should any of the measures proposed for FY 2009 not receive NQF endorsement by the time of publication of the final rule, they will not be adopted for FY 2009. Finally, 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.

Because we believe that all measures for public reporting should be adopted by the HQA, endorsed by the NQF and tested in the field before implementation, we have concerns with some measures listed by CMS for possible implementation for FY 2009 or subsequent years because they do not fulfill these criteria. We urge CMS to carefully evaluate the value of the measures considered for reporting. Measures should be evidence-based, contribute to the comprehensiveness of performance measurement, be under a hospital's control and account for potential unintended consequences. We urge CMS only to propose and select measures that meet all of these conditions. **If the measures are NQF-endorsed and HQA-adopted, CMS can be assured that they meet these conditions. Therefore, CMS should only choose measures that have been selected by these two groups.**

The NQF currently is developing national quality goals. **We believe that CMS should look to the NQF goals as a framework for the types of measures that should be included in the pay-for-reporting program.** The HQA has agreed that the NQF's national goals should provide a foundation for its future work. CMS should indicate its intent to follow the national goals as well.

We commend CMS for including in the proposed rule the measures that hospitals will be required to report to receive their full FY 2009 inpatient payments, as this early notice allows hospitals sufficient time to establish the proper data collection processes. **We urge CMS to continue with this timely rulemaking to notify hospitals of the reporting requirements for the next fiscal year.**

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 that there may be a need to retire, replace or revamp reporting measures. Currently, CMS and the Joint Commission have a process for reviewing measures and identifying modifications that should be made as a result of changes in scientific evidence. **As a process is developed to retire or replace measures for the pay-for-reporting program, we urge them to include hospitals, data vendors and other stakeholders**. When amending measures, CMS and the Joint Commission should take into account the ability of hospitals, the data warehouse and data vendors to successfully and quickly implement changes in reporting measures. In particular, to understand the effects that reporting changes have on hospitals, CMS should seek input from hospital data collection personnel as a part of the measure review process.

In addition to establishing a process for retiring or replacing measures, **CMS should develop a policy for suspending measures when there is a change in science or an implementation issue** arises during a reporting period and needs to be addressed immediately. For example, in past years, influenza vaccine shortages have precluded hospitals' ability to perform well on a measure. More recently, the NQF endorsed as a measure the percentage of pneumonia patients receiving initial antibiotics within six hours of arrival at the hospital. This measure replaced a similar one regarding the receipt of antibiotics within four hours of arrival. The four-hour measure is no longer endorsed by the NQF due to clinical concerns that, within this shorter time frame, some patients whose pneumonia diagnoses were not yet confirmed were receiving antibiotics unnecessarily. Despite the fact that the four-hour measure is no longer endorsed by the NQF, it continues to be included as a measure for Medicare's pay-for-reporting program. We urge CMS to prioritize the development of a policy to address these situations. The AHA looks forward to working with CMS on this issue.

Data resubmission, validation and appeals. The proposed rule does not address the issue of data resubmission when the hospital or its vendor become aware of an error in the data that was sent to Q-Net exchange 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 options paper, but hospitals and the public should not have to wait for accurate data until a value-based purchasing system is implemented.

Recently, many hospitals have had difficulties with their data submission. These problems commonly have been due to errors in the software at the data warehouse, and have caused an undue administrative burden for hospitals. They have focused staff attention on data collection and reporting and away from quality improvement initiatives to provide better care to patients. **CMS needs to address these data issues in an expedited manner.** Specifically, the data specifications need to be articulated well in advance of the start of data collection so that both the vendors that assist hospitals in collecting and formatting data for submission and the data warehouse have an appropriate amount of time to adjust their software and test it to ensure it functions properly.

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 some variables used by CMS' contractors who are reabstracting patient-level data and comparing it to the data submitted by the hospitals. While the reabstraction of five charts per quarter for each hospital may have been a sufficient validation strategy when only 10 measures were being collected and reported, it is insufficient to ensure the reliability of the data as we continue to expand the number of measures and the number of patients on whom data are being collected. A more resilient and less resource intensive method of validation is needed. We are working with a well known research and data enterprise to explore alternatives and will share their recommendations about more effective, less cumbersome validation processes with CMS in the next few weeks.

Regardless of the validation process that is used, it may call into question the data submitted by a hospital, and that hospital should have the opportunity to file an appeal indicating why its data were correct. 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. For payments in FY 2007, approximately 130 hospitals filed appeals, and were told to expect a response within a few weeks. They did not get a response for several months, well into the payment year. This caused unnecessary cash flow problems, particularly for hospitals serving large numbers of uninsured patients. **CMS should use the experience in FY 2007 to construct a process for adjudicating appeals in a timely fashion and should clearly lay out that process for all hospitals to see prior to publication of the final rule.**

OCCUPATIONAL MIX ADJUSTMENT

By law, CMS must collect data every three years on the occupational mix of employees from hospitals subject to the inpatient PPS in order to construct an occupational mix adjustment to the wage index to control for the effect of hospitals' employment choices – such as greater use of registered nurses (RNs) versus licensed practical nurses or certified nurse aides – rather than geographic differences in the costs of labor.

Hospitals collected the hours and wages of employees from January 1 through June 30, 2006. CMS proposes to use these data in adjusting the FY 2008 area wage index. CMS also requested comments on what occupational mix adjustments to use for hospitals that did not turn in the data and whether to penalize such hospitals in the future.

For FY 2008, we believe that CMS' proposal to use the area's average adjustment for non-responsive hospitals and the national average adjustment for non-responsive counties is reasonable. For FY 2009 and beyond, because data from all hospitals is needed to construct an accurate national average hourly wage, full participation is critical. **We urge CMS to construct an application of the occupational mix adjustment that encourages hospitals to report but does not unfairly penalize neighboring hospitals. We also encourage CMS to establish**

some sort of appeal process for hospitals with extenuating circumstances (e.g., hospitals affected by Hurricane Katrina).

WAGE DATA

CMS expanded its collection of contract labor with cost reporting periods beginning on or after October 1, 2003 to include administrative and general (A&G), housekeeping, dietary and management and administrative services. The FY 2008 wage index, based on FY 2004 cost report data, marks the first year CMS can determine what the impact would be if it included such costs in the wage index. CMS contends that the data are reasonable and accurate and that the vast majority of hospitals would not be affected by the change. Thus, CMS proposes to include such contract labor costs in the wage index for FY 2008.

However, we believe that the impact is greater than suggested by CMS due to an error in the calculation. We agree that lines 22.01 (Contract A&G Services), 26.01 (Contract Housekeeping Services) and 27.01 (Contract Dietary Services) are and should be included in Step 4. The purpose of Step 4 is to allocate a portion of overhead wages and wage-related costs to the excluded areas, and then to subtract a commensurate amount from wages and wage-related costs included in the wage index. However, while line 9.03 (Contract Management and Administrative) was included in the total wages in Step 2, lines 22.01, 26.01 and 27.01 were not. This results in a double negative effect. First, the contract labor for those three lines was never included. And second, a portion of those same costs are being subtracted from the wages and wage-related costs included in the wage index.

CMS should fix the calculation and then reassess the impact on hospitals. While the AHA supports the inclusion of contract labor, as it discourages outsourcing in order to raise average wage levels and thus wage indices, a transition should be considered if the impact on any individual hospital is great.

WAGE INDEX

In FY 2009, CMS is required by law to consider changes to the area wage index. The AHA agrees that the wage index is not functioning and alternatives should be considered. Thus, we would like to take this opportunity to describe some of the fundamental concerns our members have with the wage index, as well as with MedPAC's recommendation for CMS' deliberation over the next year. Our workgroup, comprised of state, regional and metropolitan hospital association executives as well at other national hospital associations, ranked their concerns as follows:

1. Volatility of wage index year to year.

2. Self-perpetuating – hospitals with low wage indices are unable to increase wages to become competitive in the labor market.

3. Unrealistic geographic boundaries.

4. Geographic boundaries create "cliffs" where adjacent areas have very different indices.

5. Inaccurate measure of actual labor costs.

6. Fiscal intermediaries are inconsistent in their interpretations.

7. Hospitals can be penalized for erroneous data submitted by other hospitals in the same geographic area.

8. Exclusion of some personnel from the wage index calculation – outsourcing of low-wage workers raises an area's wage index.

Regarding MedPAC's recommendation, which will be released in its June report, our members had the following concerns.

Data source. MedPAC considered the use of Bureau of Labor Statistics (BLS) data rather than the hospital-reported data collected on CMS' Medicare cost reports. While this approach may be significantly less burdensome for hospitals, there are critical differences between the two data sets that must be carefully evaluated. The new data source is the cornerstone of the MedPAC approach and represents a fundamental change. Many of the other aspects of the draft proposal possibly could be applied using hospital wage data as it is currently collected. Key differences between the CMS and BLS methodologies include:

- **Inclusion of non-hospital employers** – The BLS wage data for a particular occupation are collected from *all employers*, not just short-term, acute-care hospitals participating in Medicare. Wage rates, however, vary depending on the type of employer (hospital, nursing home, physician office, insurance company, university, etc.), and the mix of employers varies by market. Thus, wage rates will be influenced by the specific mix of hospital vs. non-hospital employers of the same occupations. For example, the mean hourly wage of an RN working in a general medical and surgical hospital in 2005 was $27.80 compared to $24.76 for an RN working in a nursing care facility, according to BLS. Consequently, the BLS data may not be an accurate reflection of labor costs experienced by hospitals in communities with a higher proportion of other types of health care organizations.

  In addition, section 1886(d)(3)(E) of the *Social Security Act* specifies that the wage index must be based on data from "subsection (d) hospitals." The BLS data set would need to be altered to remove the wages and hours for non-inpatient PPS providers to satisfy this requirement, or the law would have to be changed to accommodate the use of BLS data.

- **Different treatment of certain types of personnel in wage data collection** – Wages paid by companies that offer temporary employees to health care providers are included

in the BLS sample. Thus, contract workers are included. However, their wages reflect the lower rate that the employees are paid *by* the agency as opposed to what the hospitals pay *to* the agency for the contract workers. This may understate labor costs in shortage areas with high use of registry nurses.

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. This may materially affect wage estimates in areas with a high penetration of teaching hospitals, particularly those that have provider-based clinics where employed physicians provide care not associated with teaching residents.

- **Process to review/verify data** – Unlike CMS' public process for review and correction of wage data at the hospital level, BLS has a strict confidentiality policy that ensures that the sample composition, lists of reporting establishments and names of respondents are kept confidential. Hospitals would be unable to verify the accuracy of the data.

- **Not designed to capture differences in wage growth between geographic areas** – 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. The data collected at each of these different points in time is combined on a rolling basis to create the annual estimate. For example, the May 2005 release of wage data is built from data collected in November 2002, May and November 2003, May and November 2004, and May 2005.

  Before estimates can be released, the five previous panels must be adjusted to the current reference period. Using the example above, the data collected in November 2002 and for each subsequent panel would need to be inflated to May 2005. This is done using a "single national estimate" of wage growth for broad occupational divisions, called the *Employment Cost Index*. This approach fails to account for any differences in wage growth between markets over the three-year period. As BLS notes, *"This procedure assumes that there are no major differences [in wage growth] by geography, industry, or detailed occupation."*

- **Pay-period rather than full-year data** – While CMS collects wage data for a 12-month period, the BLS survey captures only two payroll periods per year – one in May and the other in November – each capturing data from one-sixth of the total number of sampled establishments. (As noted above, data from six panels – with one survey every six months – are combined on a rolling basis over a three-year period to create the annual estimate.)

- **BLS excludes the cost of benefits** – According to the AHA Annual Survey, benefits represent over 25 percent of hospitals' labor costs nationally. Looking across states, this percentage varies from a low of 18 percent to a high of 31 percent. Therefore, any adjustments made to include benefit costs would have to be market-specific. If benefits information is to be added, it would have to be collected on CMS' Medicare cost report

in order to adjust the BLS data. This would negate the potential benefit of eliminating the collection of hospital-specific wage data.

- **BLS excludes pay counted by CMS** – The BLS data excludes shift differentials, overtime pay and jury duty – all of which CMS includes. Overtime pay can be a cost associated with local labor shortages and shift differentials can vary as well, depending on local labor market conditions.

- **Full-time and part-time employees are equally weighted** – While CMS collects both wages and hours, BLS collects a count of workers within a series of wage ranges. The survey makes no distinction between full-time and part-time workers in estimating wage rates from the data collected. To the extent that the use of part-time versus full-time workers varies by market or type of employer, this could distort the wage calculation if part-time hourly wages are lower than full-time wages.

- **Data subject to sampling error** – Estimates using a sampling methodology like the BLS approach are going to be less reliable than using the entire universe of PPS hospitals, as is done by CMS. Both surveys would be subject to non-sampling error (e.g., errors from respondents providing incorrect data). However, the CMS process allows for extensive public scrutiny of the data while the BLS approach does not.

Geographic boundaries.

- **Current geographic boundaries** – 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.

  In addition, MedPAC plans to use the decennial Census to determine variation between the counties. So, for 2008, MedPAC would use the 2000 Census data to establish the relationship between counties within a metropolitan statistical area until the 2010 Census is available. Using data this old may create differences in wage indices that are inconsistent with the actual difference experienced in wages.

- **Single 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. While varying the wage indices within rural areas may make sense, we recommend further examination of MedPAC's approach as to whether the decennial

census data – now seven years old – produces accurate estimates of current area wage differences.

- **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.

We look forward to a full discussion of possible changes to the wage index in the FY 2009 rulemaking process and appreciate CMS' consideration of the issues raised in the meantime.

RURAL FLOOR

CMS proposes applying the budget-neutrality adjustment associated with the rural floor to the wage index rather than the standardized amount in FY 2008. While it considered both an iterative process and a uniform reduction, the agency said the uniform reduction is operationally easier and results in the same wage indices.

The AHA supports this move assuming that it removes the compounding affect of applying the budget-neutrality adjustment for the rural floor to the standardized amount annually since 1998. We believe that 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. We also suggest that CMS remove the effects of the adjustments made from 1999 through 2006 by increasing the positive budget-neutrality adjustment proposed to the standardized amount intended to just reverse the 2007 adjustment.

PHYSICIAN OWNERSHIP IN HOSPITALS

The proposed rule would require that that all physician-owned hospitals at the beginning of an admission or outpatient visit disclose to patients that physicians have an ownership interest or investment in the hospital and offer to make a list of physician investors available on request. The beginning of an admission or outpatient visit is defined to include pre-admission testing or to require registration. Such hospitals also would have to require, as a condition for medical staff privileges, that physician investors disclose to their patients that they have an ownership interest when they refer patients to the hospital for services. **The AHA supports implementation of a physician-ownership disclosure requirement.**

There are several specific aspects of the proposal that deserve comment:

- **Locus of requirement** – CMS asked whether the requirement should be located in the provider agreement or conditions of participation. **We recommend that the ownership disclosure requirement be incorporated into provider agreements** because the conditions of participation should be focused on care delivery standards.

- **Scope of requirement** – CMS asked whether the definition of a "physician-owned hospital" should exclude physician ownership or investment interests based on the nature of the interest, the relative size of the investment, or the type of investment (e.g., publicly-traded securities and mutual funds). **We recommend that the only exception to the definition of a "physician-owned hospital" be when physician ownership is limited to holding publicly-traded securities or mutual funds that satisfy the requirements for the exception under §411.356(a),(b). We oppose any exception based on the size of investment.** It is important for patients to know whenever there is a duality of interest on the part of their physician that could cause a conflict of interest in making decisions about their care. The size of that interest is immaterial to the fact that the conflict may exist.

- **Definition of the beginning of an admission or outpatient visit** – The "beginning of an inpatient admission or outpatient visit" specifically includes pre-admission testing and registration. **We recommend that the definition be clarified to include scheduling as well as pre-admission testing and registration.** Patients should receive these disclosures at the earliest opportunity so that they have an ability to act on the information if they choose.

- **Provision of list of physician investors** – The proposal would require that physician-owned hospitals offer to provide patients with a list of the physician investors on request, but does not establish any time frame for doing so. **We recommend that the list be provided to patients at the time the request is made.** We believe providers should be able to provide the list immediately upon inquiry, so that patients would get the information in time to consider it.

PATIENT SAFETY MEASURES

As part of the DRA-required report to Congress, CMS also raised the issue of the safety of patients in physician-owned specialty hospitals. Recent events and media coverage of safety concerns also have highlighted problems. The proposed rule would address these issues in several ways:

- Require a written disclosure to patients of how emergencies are handled when the hospital does not have a physician available on the premises 24 hours a day, 7 days a week; and
- Seek comment on whether current requirements for emergency service capabilities in hospitals both with and without emergency departments (EDs) should be strengthened in certain areas, including required staffing competencies, certain equipment availability, and required 24-hour-a-day, 7-day-a-week ED availability.

While these requirements may sound reasonable, we believe they miss 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 reason: The safety concerns that have been raised with physician-owned specialty hospitals occur because these facilities operate outside the traditional network of care delivery in this country. They are free-standing facilities, are generally not part of a larger system of care, most often have no 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 network of care in their community, 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. Small and rural hospitals also 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. **Applying additional requirements for this group of hospitals is unnecessary and costly.**

The broader network of care delivery, of which full-service community hospitals are a part, is the best way to ensure that care is provided to patients at the right time and in the right setting.

The kinds of requirements discussed in the proposed rule can be used to assure that physician-owned facilities, in the absence of being a part of the broader care network, meet minimum standards for patient safety.

IME ADJUSTMENT

In the FY 2007 final rule, CMS finalized a policy to exclude residents' time spent in non-patient care activities from the resident count for purposes of IME (in all settings) and direct graduate medical education (in non-hospital settings) payments. Since that time, the agency has received questions about the treatment of vacation or sick leave and orientations. While recognizing that this time is neither devoted to patient care nor non-patient care, but rather a third category, the proposed rule would treat vacation and sick time differently than it would treat orientation time. Orientation time would continue to be included as part of the full-time equivalent (FTE) count, as it always has.

Under the proposed rule, vacation and sick time would be removed from the total time considered to constitute an FTE resident. Thus, it would be removed from both the numerator and denominator of the FTE calculation. CMS acknowledges that this would result in lower FTE counts for some hospitals and higher counts for other hospitals, solely because of this regulatory change.

The AHA appreciates CMS' efforts to clarify its policies, and its attempt to not penalize hospitals for offering sick and vacation leave for its residents. However, CMS' proposal is operationally impractical. Hospitals would not only have to keep track of the leave for each resident, but then somehow apportion the leave to each of the hospitals the residents' rotate through. **We recommend that CMS instead treat sick and vacation leave similarly to how it proposes to treat orientation time as part of the FTE count.** We do not believe that it is necessary for CMS to parse each hour of residents' time; otherwise lunch hours and other exceptions would have to be considered. The vast majority of time counted in the FTEs is related to patient care, and any further changes would have minor affects, nationally speaking, while having major implications at the individual hospital level.

REPLACED DEVICES

In the calendar year 2007 outpatient PPS final rule, CMS adopted a policy that requires a reduced payment to a hospital or ambulatory surgical center when a device is provided to them at no cost. Similarly, CMS believes that payment of the full inpatient PPS DRG in cases in which the device was replaced for free or at a reduced cost effectively results in Medicare payment for a non-covered item.

Unlike the current outpatient PPS policy (which applies only when a device is provided at no cost), CMS proposes to reduce the amount of the Medicare inpatient PPS payment when a full or partial credit towards a replacement device is made or the device is replaced without cost to the hospital or with full credit for the removed device. However, CMS proposes to apply the policy only to those DRGs under the inpatient PPS where the implantation of the device determines the base DRG assignment (22 DRGs), and situations where the hospital receives a credit equal to 20 percent or more of the cost of the device.

CMS also proposes to use new condition codes to report the use of such devices to trigger manual processing by the FIs. The hospital would be required to provide paper invoices or other information to the FI (or Medicare Administrative Contractor) indicating the hospital's normal cost of the device and the amount of the credit received. In cases where the device is provided without cost, CMS proposes that the normal cost of the device will be subtracted from the DRG payment. In cases where the hospital receives a full or partial credit, the amount credited will be subtracted from the DRG payment.

CMS justifies this change by noting that "in recent years, there have been several field actions and recalls with regard to failure of implantable cardiac defibrillators and pacemakers." Although the AHA does not dispute this fact, we believe it ignores the underlying concept of the DRG payment system.

DRG payments are fundamentally based on averages of historical costs and charges. To reduce the payment for cases involving replacement of a medical device assumes that either these types of cases have not occurred in the past or are occurring at such a dramatic increase as to

materially skew the averages used to develop the DRG weights. In fact, CMS notes that "we believe that incidental device failures that are covered by manufacturers' warranties occur routinely." This statement acknowledges that incidental device failure has occurred in the past and was likely covered by the manufacturer warranty. If so, this practice is part of the historical cost and charge data used to develop the current DRG weights for cases involving implantation. Reducing payment for certain cases involving a re-implantation would ignore the average DRG weight for those cases that already implicitly include this reduction. **Therefore, we ask CMS to reconsider implementing this proposal.**

However, if CMS implements this policy, we agree that it should limit the number of DRGs to which the policy applies. In addition, we agree that insignificant credits or refunds should not trigger this policy. However, CMS should consider raising the proposed threshold from 20 percent to greater than 50 percent or the majority of the cost of the device. Given the administrative burden of manually processing these claims, it is not worth the burden on the hospitals' or FIs' part if only a nominal portion of the cost of the device is at issue. In addition, inpatient PPS payments are often less than costs. If CMS implements this policy, **estimated costs should be calculated from the charges on the claims and only reduce the DRG payment by the device cost if the payment is greater than the cost of the case less the cost of the device.**

NEW TECHNOLOGY

Section 503 of the *Medicare Modernization Act* (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 the inpatient PPS 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. **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.**

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

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

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in committee language for the MMA, recommended that the Secretary undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential

reimbursement policies for inpatient services, including new health technology, as required under the *Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000.*

To date, despite these recommendations, as well as the recommendations of several federal health care agencies and offices and health care trade and professional associations, the Department of Health and Human Services (HHS) has not yet moved forward to adopt the ICD-10 classification upgrades. Absent a switch to ICD-10 soon, hospitals will experience significant coding problems that will affect the efficiency of the current coding process, adding significant operational costs. In addition, failure to recognize this looming problem will only impede efforts to speed the adoption of electronic health records.

At the April 2005 ICD-9-CM Coordination and Maintenance (C&M) committee meeting, many expressed the need to start limiting the creation of new procedure codes in order to allow the classification system to last at least two more years. ICD-9-CM procedure code categories 00 and 17 were created to capture a diverse group of procedures and interventions affecting all body systems. The establishment of these code categories represented a deviation from the normal structure of ICD-9-CM and a stopgap measure to accommodate new technology when no other slots in the corresponding body system chapters (e.g., musculosketal system, circulatory system, etc.) were available. The plan was to use codes in chapter 00 first and then begin populating chapter 17.

Category 00 is now full, and the C&M committee is entertaining proposals for codes in category 17. At the April 2005 C&M meeting, a proposal was presented that would, in effect, leave only 80 codes available in this category. In order to conserve codes, this proposal was rejected and replaced instead with three codes that did not provide information as to what part of the body the surgery was performed on. Many of the specific body system chapters are already filled (e.g., cardiac and orthopedic procedures). In recent years, as many as 50 new procedure codes have been created in a single year. This means that it is possible for ICD-9-CM to completely run out of space in less than a year. We concur with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10. We also would support an implementation period of at least two years.

We strongly recommend that the Secretary 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 to 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. It is imperative that the rulemaking process start immediately.

ATTACHMENT I – Revised CC List

SPECIFIC COMMENTS ON THE COMPLICATION AND COMORBIDITY (CC) LIST

The following list represents conditions currently proposed for removal from the CC list. **These conditions should be reinstated as CCs.**

Category 250.xx Diabetic manifestations.
Currently, all diabetes mellitus codes in category 250 are considered CCs except for those with a fifth-digit subclassification of 0 (diabetes type II or unspecified type, not stated as uncontrolled). We agree that there may not be significant additional hospital resources required for a long-standing diabetic patient who is clinically stable and consistently under diet, oral or insulin control and without diabetic manifestations affecting major organ systems. However, we fail to understand why the CCs for diabetic manifestations are being removed. Patients whose diabetes has advanced to renal manifestations (250.4x), ophthalmic manifestations (250.5x), neurological manifestations (250.6x), peripheral circulatory disorders (250.7x) or other specified manifestations, including hypoglycemia shock (250.8x), require additional care and monitoring.

For example, a patient with diabetic nephropathy may require additional blood tests to monitor renal function, careful coordination of medications so as not to further compromise renal function and possibly even dialysis if the disease has progressed to stage V chronic kidney disease or end-stage renal disease. Diabetic manifestations can significantly increase the length of stay of patients suffering from infections, trauma, myocardial infarction or any other serious illness. The fact that diabetes is present may even result in patients who otherwise might be managed on an outpatient basis requiring admission. For example: patients with infections, who have undergone outpatient surgery or chemotherapy; or may require rapid initiation of rigorous control of the diabetes to improve outcome; or the primary medical problem or the therapeutic intervention can cause a major deterioration in diabetes control; or if there is acute onset of retinal, renal, neurological or cardiovascular complications of diabetes.

More importantly, chronic, stable diabetic patients may develop uncontrolled diabetes (codes 250.x2 and 250.x3), which would require close monitoring of the patient to determine the etiology of the control problem and subsequent modification of therapy. Frequent monitoring of blood sugars and medication adjustments may be required until the patient is stabilized.

Code 276.6, Fluid overload.
Patients with fluid overload require intravenous diuresis and/or renal dialysis, depending on the etiology of the fluid overload. These patients require increased nursing care through repeated assessment of signs and symptoms of congestion and changes in body weight. Monitoring of daily weight, intake and output is recommended to assess clinical efficacy of diuretic therapy. In addition, they require careful physical and symptom assessment and monitoring of vital signs, body weight and laboratory results to optimize fluid status. They also require careful observation for development of a variety of side effects, including renal dysfunction, electrolyte abnormalities and symptomatic hypotension, especially when diuretics are used at high doses

and in combination. Patients need to undergo routine laboratory studies and clinical examination, as dictated by their clinical response. Serum potassium and magnesium levels need to be monitored at least daily and maintained in the normal range. More frequent monitoring may be necessary when diuresis is rapid.

Overly rapid diuresis may be associated with severe muscle cramps, which should be treated with potassium replacement, if indicated. Patients treated with diuretics need to be monitored carefully for excessive urine output, development of hypotension and reductions in serum potassium, magnesium and renal function. Serial determinations of creatinine and blood urea nitrogen (BUN) are particularly important when these side effects are present or anticipated. Diuretic therapy must be highly individualized based on the degree of fluid overload present and the degree of volume loss produced to minimize these side effects.

All this points to increased monitoring and hospital resources, and we believe this condition should remain a CC.

Code 276.51, Dehydration.
Dehydration is a condition in which the body contains an insufficient volume of water for normal functioning. It can be caused by a wide range of diseases and states that impair water homeostasis in the body. Causes can include infectious diseases and malnutrition, as well as other external or stress-related causes. Vomiting and diarrhea are common causes. Dehydration can be classified as mild, moderate or severe based on how much of the body's fluid is lost or not replenished. Severe dehydration is a life-threatening emergency. Treatment of moderate-to-severe dehydration may require hospitalization and intravenous fluids with replacement of electrolytes and continuing assessment of electrolyte status.

We do not understand why dehydration (code 276.51) is being removed from the CC list. If the intent is to exclude cases of mild dehydration that may not require significant additional resources, the ICD-9-CM codes currently do not distinguish levels of severity. A revision to the ICD-9-CM codes to provide further specificity on the level of severity would be required to recognize the significant additional resources required to treat moderate and severe dehydration.

Code 276.52, Hypovolemia.
Hypovolemia is a state of decreased blood volume; more specifically, a decrease in volume of blood plasma. Common causes of hypovolemia can be dehydration, bleeding and severe burns. Drugs such as diuretics or vasodilators are typically used to treat hypertensive individuals. Treatment is dependent on the underlying cause. If the hypovolemia is due to bleeding or severe burns, these patients may require blood transfusions, which are costly and require more intensive nursing monitoring.

Code 276.9, Electrolyte and fluid disorders.
Patients with electrolyte and fluid disorders are treated with intravenous fluids and require more frequent monitoring of electrolyte levels.

Code 282.69, Other sickle-cell disease with crisis.
We believe that code 282.69, Other sickle-cell disease with crisis, should be a major complication or comorbidity (MCC), consistent with the other sickle-cell disease with crisis codes (282.42, 282.62, and 282.64). The main symptoms are crisis or sudden pain in joints or organs. The affected joints or organs vary from patient to patient. The most common areas are the chest, back and torso, leading to difficulty breathing during the crisis. A crisis may last from only a few hours to weeks. We believe that the fact that this code includes "crisis" indicates of an acute flare up of the disease and could require antibiotics, pain management, intravenous fluids, blood transfusion, surgery and psychosocial support. These patients also are best managed in a comprehensive multi-disciplinary program of care, indicating increased hospital resource use.

Code 284.8, Aplastic anemias, NEC.
This code includes aplastic anemia due to chronic systemic disease, drugs, infection, radiation, aplasia of bone marrow, red cells, panhematopenia, panhemocytopenia, acquired bone marrow failure, toxic aplastic anemia or other specified type not elsewhere classified (NEC). Treating aplastic anemia involves suppression of the immune system, which may be achieved by daily medicine intake or, in more severe cases, a bone marrow transplant or platelet transfusions. Medical therapy of aplastic anemia often includes a short course of anti-thymocyte globulin (ATG) or anti-lymphocyte globulin and several months of treatment with cyclosporin to modulate the immune system. Mild chemotherapy with agents such as cyclophosphamide and vincristine also may be effective. Antibodies therapy such as ATG targets T-cells, which are believed to attack the bone marrow. Medical treatment also requires evaluation of renal and liver functions often by measuring BUN, serum creatinine, serum bilirubin and liver enzymes. All of these therapies represent significant additional hospital resources. In addition, increased patient monitoring is required to determine a patient's response to treatment and to prevent any possible complications.

Code 285.1, Acute posthemorrhagic anemia.
This code is assigned when a physician documents acute posthemorrhagic anemia. It also includes acute postoperative anemia if the physician documents significant amount of blood loss resulting in anemia but does not label it as a postoperative complication. Treatment is dependent on the source of bleeding. If the source of bleeding is not identified, significant resources may be devoted to determining and controlling the source of bleeding. Even if the source of the bleeding is known and controlled, blood transfusions may be necessary. Blood transfusions represent additional resources in terms of the cost of blood storage and processing, blood administration and the significant monitoring required of these patients.

Codes 287.30, 287.39, 287.4, 287.5, Thrombocytopenia.
Thrombocytopenia is a serious medical problem involving low platelets. It may be caused by a number of different factors such as chemotherapy, medications, infection or immune problems. Treatment depends on the cause of the condition. In some cases, a transfusion of platelets may be required to stop or prevent bleeding. As previously stated, we believe that transfusions of blood and blood products represent a significant increase in hospital resources.

For the sake of consistency, we believe that the following codes should remain as CCs:

- 287.30 Primary thrombocytopenia, unspecified;
- 287.4 Secondary thrombocytopenia; and
- 287.5 Thrombocytopenia, unspecified.

This would be consistent with the other specific thrombocytopenia codes that have remained as CCs:

- 287.31 Immune thrombocytopenic purpura;
- 287.32 Evans' syndrome; and
- 287.33 Congenital and hereditary thrombocytopenia purpura.

303.00-303.02, Acute alcohol intoxication.
Acute alcohol intoxication has the potential to adversely affect almost every organ system. However, cardiovascular, gastrointestinal and neurologic problems are of particular concern. Alcoholic intoxication also may affect morbidity and mortality through the development of cardiac arrhythmias and tachyarrhythmias, particularly idiopathic atrial fibrillation. Ventricular tachyarrhythmias also may be provoked, and heavy drinking may increase the risk of sudden cardiac death from fatal arrhythmias. Patients with acute alcohol intoxication require additional monitoring, even if the more serious potential complications do not materialize. Airway assessment and protection also are crucial because of the suppressed protective reflexes that can result from intoxication and the increased potential for vomiting secondary to gastric irritation. Therapeutic intervention priorities include hydration with intravenous fluids, symptomatic control of nausea and vomiting, and correction of electrolyte imbalances such as hypomagnesemia. In severe cases – those of severe stupor and coma – the patient may even need intubation to support respirations (which may stop spontaneously) and to protect the lungs from filling with vomit. Acute alcohol ingestion is particularly likely to complicate the management of trauma patients. Agitated patients must be protected from themselves and require more intensive nursing supervision and care. Evaluation of an acutely intoxicated patient may require repetitive examinations and a quantitative assessment of intoxication. There also may be a need for social service interventions including counseling, treatment or shelter referrals.

Codes 402.xx, Hypertensive heart disease.
We believe combination codes within a category should be handled consistently. For example, codes 402.00, 402.01, 402.11 and 402.91 are considered CCs. This range of codes includes hypertensive heart disease without heart failure (402.00), as well as those with heart failure (402.01, 402.11 and 402.91). Based on the ICD-9-CM classification, code 402.x1 is assigned when there is hypertensive cardiomegaly, cardiopathy, cardiovascular disease or heart disease **with** heart failure (including congestive heart failure 428.0). However, independently, neither benign or unspecified hypertension (401.1 or 401.9), nor congestive heart failure (428.0) are CCs. We are unable to determine whether the inclusion of 402.00 or the omission of 428.0 was an oversight. We recommend that code 402.00 be removed from the CC list and code 428.0 be reinstated as a CC.

Codes 403.90 and 403.91.
We believe combination codes within a category should be handled consistently. Codes 403.00, 403.01 and 403.11, representing the malignant and benign forms of hypertension associated with chronic kidney disease (CKD), have remained on the revised CC list, while codes 403.90 and 403.91, representing unspecified hypertension, have been removed. Most physicians fail to specify hypertension as benign and often will assume the hypertension to be benign when not specifically documented as "malignant." The hospital resources utilized in addressing patients with benign or unspecified hypertensive CKD are the same. However, ICD-9-CM rules require that these cases be coded to the "unspecified" form of the code. We believe that the original intent was to recognize the additional resources involved in the treatment of patients with Stage IV CKD (585.4), Stage V CKD (585.5) or end-stage renal disease (585.6). Additional increased monitoring and resources for these patients includes renal dialysis and possibly care of any dialysis-related arteriovenous fistulae. Codes 585.4 and 585.5 are considered CCs, while code 585.6 is considered an MCC in the current proposed CC revision.
An additional coding problem is that the current fifth digits for category 403, Hypertensive chronic kidney disease, are divided as:

- "0" with chronic kidney disease stage I through stage IV, or unspecified; and
- "1" with chronic kidney disease stage V or end-stage renal disease.

The proposed CC revision list has grouped the chronic kidney disease codes as follows:

- 585.4 CKD, stage IV (severe) – CC;
- 585.5 CKD, stage V – CC; and
- 585.6 End-stage renal disease – MCC.

The breakdown of the fifth digit "0" for category 403 makes it difficult to split these conditions in a consistent manner since CMS could be including the less-severe stages of CKD in 403.x0 in an effort to also recognize CKD stage IV. There also is a problem in determining whether 403.x1 should be a CC or an MCC since the fifth-digit of "1" includes CKD stage V (a CC), as well as end-stage renal disease (an MCC).

Until a change to the ICD-9-CM classification is made, we recommend that code 403.90 be considered a CC and code 403.91 an MCC.

Code 413.9, Angina pectoris.
Angina requires medical treatment with beta-blockers, nitroglycerin, calcium channel blockers, vasodilators, ACE inhibitors or statins. Patients with this condition require evaluation and monitoring to ensure that they do not progress to more significant cardiovascular problems.

Code 426, Conduction disorders.
We have found some inconsistencies in whether heart blocks are considered as CCs. It is unclear whether this is for clinical reasons or whether this was an accidental oversight. We recommend that CMS seek input from the appropriate clinical specialties as to the current treatment of heart blocks. For example, some heart blocks have remained as CCs (namely 426.0, Atrioventricular

block, complete; 426.12, Mobitz (type) II atrioventricular type; and 426.89, Other specified conduction disorders), while other similar heart blocks, including complete heart blocks, have been removed, such as:

- 426.13, Other second degree atrioventricular block;
- 426.53, Other bilateral bundle branch (this is considered a complete heart block);
- 426.54, Trifascicular block (this also is a form of complete heart block);
- 426.6, Other heart block (includes intraventricular block, sinoatrial block, sinoauricular block); and
- 426.9, Conduction disorder, unspecified.

Code 427.31, Atrial fibrillation.
Atrial fibrillation (AF) is a significant medical condition that requires treatment to prevent stroke. The American Heart Association recommends aggressive treatment of this heart arrhythmia. Anticoagulant and antiplatelet medications thin the blood and make it less prone to clotting. Warfarin is the anticoagulant now used for this purpose, and aspirin is the antiplatelet drug most often used. Long-term use of warfarin in patients with AF and other stroke risk factors can reduce stroke by 68 percent. Medications are used to slow down rapid heart rate associated with AF. These treatments may include drugs such as digoxin, beta-blockers (atenolol, metoprolol, propranolol), amiodarone, disopyramide, calcium antagonists (verapamil, diltiazam), sotalol, flecainide, procainamide, quinidine, propafenone, etc. Electrical cardioversion may be used to restore normal heart rhythm with an electric shock when medication does not improve symptoms. Drugs (such as ibutilide) can sometimes restore the heart's normal rhythm. These drugs are given under medical supervision and are delivered through an IV tube into a vein, usually in the patient's arm. These patients also require repeated blood tests and additional nursing care.

Patients with atrial fibrillation require more intensive resources, including admission to the intensive care unit if symptoms do not abate. In more severe situations, radiofrequency ablation or atrial pacemaker insertion may be required when medical treatment is unsuccessful.

Code 428.0, Congestive heart failure, unspecified.
Currently, ICD-9-CM codes do not distinguish between acute, chronic or acute exacerbation of chronic congestive heart failure (CHF). All forms of this condition are assigned to code 428.0. Medical record documentation may not typically include information on whether the CHF is systolic or diastolic (acute versions of heart failure with this specificity are considered MCCs). **We request that 428.0 be added as an MCC until a new code can be created to identify acute exacerbation of CHF.**

Based on advice published in *Coding Clinic for ICD-9-CM*, Fourth Quarter 2002, pp. 52-53, and confirmed in Fourth Quarter 2004, p. 140, even if the information available specifies systolic or diastolic heart failure, code 428.0 is assigned as an additional code to identify the fact that this is a "congestive" episode. CHF is not an inherent component of either systolic or diastolic heart failure. When the diagnostic statement lists CHF along with either systolic or diastolic heart failure, two codes are required.

The fact that there is "congestion" is medically more problematic and more resource intensive than either systolic or diastolic dysfunction. Uncompensated CHF leads to pulmonary edema, which may necessitate care in the intensive care unit and a prolonged hospital stay. Coding guidelines necessitate that acute pulmonary edema of cardiac origin be assigned code 428.0, Congestive heart failure, unspecified.

Category 451, Thrombophlebitis.
We fail to understand why certain codes for thrombophlebitis have remained as CCs (e.g., 451.19, 451.81, 451.83 and 451.89), while the similar codes listed below have not:

- 451.0, Thrombophlebitis of superficial vessels of lower extremities;
- 451.11, Thrombophlebitis of femoral vein (deep) (superficial); and
- 451.2, Thrombophlebitis of lower extremities, unspecified.

Treatment of thrombophlebitis includes medicines to ease pain and inflammation and anticoagulants to break up clots and keep new clots from forming. Blood tests and dosage adjustments are required at least daily. Depending on the severity of the condition, and the patient's response to treatment, care also may involve removal of the thrombus and application of compression bandage. Additional nursing care also is required to keep the leg elevated. Additional testing such as echocardiograms may be required to ascertain the extent and location of the thrombophlebitis.

459.0, Hemorrhage, unspecified.
Generally, this code would only be reported when there is insufficient information to report a more specific code to identify the source of bleeding. Nevertheless, the presence of this code could reflect that significant workup was conducted to identify the source of bleeding but none was found.

Category 630-677, Complications of pregnancy, childbirth and puerperium.
We are concerned about the number and wide breadth of codes from Chapter 11 of the ICD-9-CM, Complications of pregnancy, childbirth and puerperium (categories 630-677), that are being removed from the CC list. According to CMS, due to the low volume in the Medicare population, diagnoses related to newborns, maternity and congenital anomalies were classified using All-Patient Refined DRGs (APR-DRGs). According to this methodology, APR-DRG default severity 1 (minor) diagnoses were classified as non-CCs. We are concerned about the lack of public comment and widespread clinical validation of whether these conditions are assigned to the appropriate severity level. Of special concern are conditions such as infections, acute renal failure, air and pulmonary embolism, cardiac arrest, shock, etc. that are CCs or MCCs and would be coded as such if not for the fact that the ICD-9-CM classification considers problems associated with pregnancy, childbirth and the puerperium to be so clinically significant that they require special combination codes. The combination codes are intended to identify that the presence of the pregnancy complicates the condition. For example, code 415.19, Other pulmonary embolism and infarction is an MCC, while code 673.20, Obstetrical blood-clot embolism, unspecified, is not even a CC.

We recommend that codes in Chapter 11 be carefully evaluated and validated with clinical experts, similar to the process to which the codes in other chapters were submitted. Combination codes should be treated consistently. If the condition is considered a CC or MCC in a non-pregnant patient, the corresponding pregnancy-related combination code also should be a CC or MCC.

Category 765.0, Extreme immaturity.
Codes in category 765.0, Extreme immaturity, represent infants with a birthweight of less than 1000 gm. Common problems with very low birthweight babies are low oxygen levels at birth; inability to maintain body temperature; difficulty feeding and gaining weight; infection; breathing problems, such as respiratory distress syndrome; neurological problems, such as intraventricular hemorrhage; gastrointestinal problems, such as necrotizing enterocolitis; and sudden infant death syndrome (SIDS). While some of these problems have unique ICD-9-CM codes that could be reported, not all of them do (e.g., inability to maintain body temperature). Nearly all very low birthweight babies need specialized care in the neonatal intensive care unit until they can gain weight and are well enough to go home. Care for very low birthweight babies often includes temperature-controlled beds, special feedings – sometimes with a tube into the stomach if a baby cannot suck – as well as other treatments for complications. These codes would always be secondary diagnoses in newborn cases. The survival of these newborns is directly related to their weight at birth. Even after discharge from the hospital, the risks for long-term complications and disability are increased for babies with very low birthweight. Generally, the lower the birthweight, the greater the chances for developing intellectual and neurological problems, which affect the child's care.

V45.1, Renal dialysis status.
We believe that patients on renal dialysis should be recognized for the additional resources required to provide dialysis and to care for the arteriovenous fistula.

Diagnoses associated with patient mortality.
In the proposed rule, CMS noted that diagnoses that were closely associated with patient mortality were assigned different CC subclasses, depending on whether the patient lived or died. These diagnoses are:

- 427.41, Ventricular fibrillation;
- 427.5, Cardiac arrest;
- 785.51, Cardiogenic shock;
- 785.59, Other shock without mention of trauma; and
- 799.1, Respiratory arrest.

We agree that these diagnoses should be considered MCCs for patients who are discharged alive. However, we disagree with CMS' proposal to make these diagnoses non-CCs when a patient dies. We urge CMS to consider the patient's length of stay. We agree that a patient who expires soon after admission may not have significant resources associated with these conditions, but we believe that this is not true when a patient has been hospitalized at least a week.

ATTACHMENT II – Recalibration of DRG Weights

COST REPORT CHANGES TO IMPROVE THE ACCURACY OF "COST-BASED" WEIGHTS

Recommendations of the Cost Report Workgroup

April 2007

BACKGROUND

On August 18, 2006, the Centers for Medicare & Medicaid Services (CMS) published the final rule for the inpatient Medicare prospective payment system (PPS) implementing a change in how diagnosis-related group (DRG) weights would be developed. CMS modified the previous system, which relied solely upon hospital charge data, and developed an approach that would establish weights based on hospital "cost" data. CMS suggested that this type of revision would lead to the creation of DRG weights that more accurately reflect the relative resource use by DRG. Recognizing the financial impact of changes to the weights on some hospitals, and the possible need for further refinements, the final rule allowed for a three-year transition using a blend of the "charge-based" system and the "cost-based" system.

Under the cost-based system, the two sources of data that are utilized in establishing the DRG weights are the Medicare Provider and Review (MedPAR) files (an accumulation of claims filed by each hospital) and the Medicare cost report (MCR). Charges are taken from the MedPAR files, grouped into 13 categories and reduced to cost from cost-to-charge ratios (CCR) calculated from the MCRs for these same 13 categories.

An examination of the cost-based weights developed for fiscal year 2007 revealed that some significant problems occur by combing these two data sources:

- First, the method used by CMS to group hospital charges for the MedPAR files differs from how hospitals group Medicare charges, total charges and overall costs on the cost report.
- Second, hospitals group their Medicare charges, total charges and overall costs in different departments on their cost reports for various reasons.
- Third, hospitals across the country complete their cost reports in different ways, as allowed by CMS.
- Fourth, CMS' new approach for categorizing all charges and costs into 13 specific categories may not yield the most appropriate CCR for each cost category.

This mismatch between MedPAR charges and cost report CCRs can distort the resulting DRG weights. It is important to note that the cost report was not designed to support the estimation of costs at the DRG level.

As a result, the American Hospital Association, Association of American Medical Colleges and the Federation of American Hospitals convened a workgroup of hospital experts to evaluate the current MCR and other elements that provide input into the cost report – such as the Uniform Billing form and related codes, Medicare paid claims summaries (PS&Rs), and hospital accounting structures and reports – to discuss how they affect the above issues. The group's charge was to identify what changes might be made to the MCR and/or other related inputs to ensure CMS' approach yields more accurate weights. Workgroup participants are listed at the end of this section.

WORKGROUP RECOMMENDATIONS

- **In order to achieve more accurate DRG cost-based weights, all hospitals should prepare their MCRs so that Medicare charges, total charges and overall costs are aligned with each other and with the categories currently utilized in the MedPAR file.** This allows for a consistent grouping of departments within the 13 categories identified in the August 18, 2006 final inpatient PPS rule that are used to create the cost-based weights. The workgroup recommends that the medical supplies category be the primary area of focus.

  The workgroup recognizes that hospitals will need to consider how MCRs are used by Medicare and other payers as they look at how best to make these changes.

- **The workgroup recommends that this approach be supported by educational materials to be developed and disseminated by the national, state, regional and metropolitan hospital associations in collaboration with the Healthcare Financial Management Association.** The recommended approach will augment the current cost report instructions, but still follow existing cost reporting requirements. The workgroup recognizes that some hospitals will be better situated to adopt these changes; as a result, it will be more expensive and time-consuming for some hospitals to successfully implement this recommendation. However, the workgroup believes that the investment is worth the effort in order to lessen distortions in cost-based DRG weights that affect all PPS hospitals' Medicare reimbursement.

- **The workgroup suggests that the national associations inform CMS of the group's recommendations to ensure fiscal intermediary (FI) cooperation.** While many hospitals will be able to accomplish the recommended changes to the cost report from general ledger data, other hospitals will have to use cost estimation techniques. Without assurance from CMS that it will instruct the FIs to accept these computations, some hospitals may be unwilling to make these changes.

- The workgroup considered changes to the Uniform Bill, MCR, revenue codes and MedPAR, but determined that these changes would require a multi-year process with involvement beyond the hospital field. However, the recommendations outlined above do not fix all of the problems identified by the workgroup. **The workgroup recommends that the hospital field work with CMS to identify whether changes**

should be made to the cost report and other inputs to address other areas of potential distortion.

RECOMMENDED APPROACH FOR MODIFYING COST REPORTS TO ACHIEVE CONSISTENT REPORTING

The approach outlined below addresses two problems identified by the workgroup:

- First, hospitals do not always consistently categorize their Medicare charges, total charges and total costs into departments on the cost reports, causing a mismatch within the CCR and/or a mismatch between the CCR and the Medicare charges. Medicare charges, total charges and total costs should be reported consistently.

- Second, a significant number of hospitals do not categorize their Medicare charges, total charges and total costs on the cost report in the same manner as CMS categorizes Medicare charges on the MedPAR file. This creates a mismatch of MedPAR and cost report data that may distort cost-based DRG weights.

The workgroup recommends that hospitals evaluate their reporting of charge and cost data in their cost reports to ensure that they consistently categorize overall hospital costs, charges and Medicare charges.

Currently, cost report instructions included with the CMS Form-339 allow for three methods of reporting Medicare charges. The method selected by each hospital is specific to its information systems and based on the method that most accurately aligns Medicare program charges on Cost Report Worksheet D-4 with the overall cost and charges reported on Worksheets A and C. Many hospitals elect to allocate some or all of the Medicare program charges from the Medicare PS&R to various lines in the cost report based on hospital-specific financial system needs. Under this scenario, total hospital CCRs are aligned with program charges but will not match the charge groupings used in MedPAR. This mismatching may distort the resulting DRG weights under the methodology developed by CMS.

The workgroup has identified the reporting of medical supplies costs and charges on the cost report as the most significant problem area because of two issues:

- First, many hospitals include medical supply charges in different ancillary departments (e.g., the operating room (OR), the emergency department (ED), etc.) These charges are billed on the UB92 bill using the 27X revenue code series for medical supplies. Ultimately, the medical supply charges for the Medicare program are either mapped to line 55 (the Medical Supply Cost Center) in the cost report or allocated to various other departments. If the 27X charges on the Medicare PS&R are allocated to various departments on the MCR, and not all of the total charges and total costs have been reclassified to the same departments on Worksheets A and C, the CCR for medical supplies will be misstated (generally understated), which will distort the "cost-based"

weights for DRGs containing significant medical supply charges. Inconsistencies in reporting can cause this type of distortion.

- Second, problems can occur when hospitals choose (as allowed by CMS) to allocate the MCR total charges and costs for some medical supplies to the departments where the supplies are used. Supply costs and charges might be allocated to the OR and the ED in addition to the Medical Supply Cost Center. Many of these hospitals achieve consistency in their cost reports by allocating the Medicare charges on the PS&R to the OR, ED and Medical Supply Cost Center. This practice is allowed by cost report instructions but will result in charge groupings that do not match the way charges are grouped in the MedPAR file. MedPAR groups ALL medical supplies on line 55 of the cost report. Since the MedPAR groupings are used to establish the 13 categories used to set the cost-based DRG weights, the practice described above will result in CCRs that do not match the charges to which they are applied.

Therefore, we are urging hospitals to examine how they complete their cost reports and adopt the approach of classifying all **billable** medical supply costs and charges to line 55 of the cost report and mapping the 27X Revenue Summary codes from the PS&R only to line 55. While it is preferable to accomplish this within the hospital's accounting systems, it can be accomplished through a reclassification on Worksheet A-6 of the cost report. It is our understanding that most, if not all, hospital revenue accounting systems have the ability to report charges by Revenue Summary code by department. Charges containing the 27X Revenue Summary codes would be reclassified to line 55 from any department mapped to lines other than 55. In addition, the cost of the **billable** medical supplies also should be reclassified to line 55 from any department mapped to lines other than line 55.

Cost Report Workgroup Participants

Facilitator

Steve Clark
Clark, Koortbojian and Associates

Sponsoring Organizations

American Hospital Association
Danielle Lloyd
Don May
Caroline Steinberg

Association of American Medical Colleges
Karen Fisher

Federation of American Hospitals
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Participants

Pat Andersen
Oklahoma Hospital Association

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American Hospital Association/National Uniform Billing Committee

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Montefiore Medical Center

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Universal Health Services Inc.

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Healthcare Association of New York State

Karen Heller
Greater New York Hospital Association

Clara Kridle/Jose Robles
Price Waterhouse Coopers

Todd Nelson
Grinnell Regional Medical Center

Kathy Reep
Florida Hospital Association

Trisha Schirmers
Allina Health System

Mike Smith
Catholic Healthcare West

Cecil Terry
BJC Healthcare

Tim Wolters
BKD, LLP

CMS-1533-P-27 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Date & Time:** **06/04/2007**

Organization :

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

adding monitoring of these measures does not help safe care. It is just making sure you have good documentation. All these measures do not have intese research to support evidence at this time. For those organization with small sample size can be at disadvantage with the implementation of these measures. We can see articles that suggests that US healthcare has not been ranked highest in outcomes or safety and by adding more publicly reported data for organization is not the solution.

CMS-1533-P-28 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Karen Schneider** **Date & Time:** **06/04/2007**

Organization : **Health Systems Consultants, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

See attached letter dated June 4, 2007

CMS-1533-P-28-Attach-1.DOC

#28

CMS-1533-P

Submitter: Karen C. Schneider
Organization: Health Systems Consultants, Inc.
Category: Health Care Industry

June 4, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: DRG Reform and Proposed MS-DRGs

Dear Ladies and Gentlemen:

Health Systems Consultants, Inc. (HSC) respectfully submits this comment on the proposal to reform the DRGs by creating Medicare Severity-DRGs (MS-DRGs) to better address severity of illness and resource use based on case complexity. We agree that refining the DRG system using a severity-of-illness methodology will make possible more accurate Medicare IPPS payments.

Our concern, however, is with the development by CMS of a completely new and untested severity system while there are several systems currently being evaluated by the Rand Corporation (under contract with CMS) that have been successfully used for many years. For example, our RDRG® Severity System, the HSC-DRGs in the Rand report, has been in continuous use for 18 years. It is based on the original Yale University methodology developed under contract with the Health Care Financing Administration, now CMS, between 1986 and 1989.

We strongly urge that CMS continue with CMS DRGs for one more year. CMS states in the May 3, 2007 Federal Register that it is not ready to propose using one of the alternative DRG systems being evaluated by Rand. Introducing a new temporary severity system, the MS-DRGs, and then expecting hospitals to switch to yet another system for FY 2009 will create unnecessary havoc for the hospital industry.

We are pleased with the work CMS has done recently to review 13,549 secondary diagnosis codes to refine the CC list, which has not been changed except for new diagnosis codes in over 25 years. We believe the use of a new, thoroughly examined CC list will produce a greatly improved DRG grouper. This is another reason to continue with the CMS DRGs during FY 2008 while awaiting final results of the Rand report. The updated CMS DRGs with the new CC list will immediately improve the accuracy of Medicare payments.

Unfortunately, Rand's comparison of the MS-DRG system with the five alternate systems will not include the benefit of the new FY 2008 CC list. For example, the new CC list will greatly improve HSC's RDRG system, since it is heavily based on this list of diagnoses. A comparison of the FY 2008 MS-DRGs (with the new CC list and new codes) with FY 2006 and FY 2007 alternative severity systems using the unrevised CC

list is not really a fair comparison. We therefore recommend that CMS produce Version 25 CMS DRGs with the new CC list and new codes and allow the vendors of the alternative severity systems until November or December to incorporate this information into updated versions of their systems. This would provide a much fairer evaluation of the available severity systems. The Rand report deadline could be extended beyond September 1, 2007.

Rand in its final evaluation will undoubtedly discuss the new MS-DRG system in detail, but we want to take this opportunity to point out some of its more obvious shortcomings.

- Although CMS' chief concern is Medicare patients, it is shortsighted to ignore non-Medicare patients in the proposed MS-DRG system, as the healthcare industry often focuses its attention on the Medicare relative value system for all of its hospital patients.

- The DRG system has always been comprehensive, including all possible ICD-9-CM diagnoses and procedures. We assume it will continue to be, but consolidating low-volume procedures and procedures now performed primarily in an outpatient setting creates confusion in the MS-DRG classification system. Procedures such as tonsillectomies, carpal tunnel release, and cataract extractions are in different MDCs and are treated by different medical specialists. They are similar only with respect to historical cost data and only for the time being.

- We also believe that eliminating newborns, maternity and congenital anomalies from the usual MS-DRG severity level approach does not provide a comprehensive severity system.

Finally, we believe that whichever software system is ultimately chosen for the public in September, it should be provided in a modern and accessible software language and format. We recommend a C version. To continue to put CMS software into the public domain written in IBM assembler and distributed through the National Technical Information Service (NTIS) on 9-track tapes or 3480 cartridges seems hard-to-imagine. This technology is over 40 years old.

In sum, we propose that CMS wait for the Rand Corporation's final report before adopting a severity system. In the interim, we suggest that CMS update the CMS DRGs using the proposed DRG reclassifications and the revised CC list and provide the resulting software in a C version on CD's or DVD's.

Sincerely yours,

Karen Schneider
President
Health Systems Consultants, Inc.
340 Whitney Avenue
New Haven, CT 06511
Tel: 203-785-0650
Email: karen.schneider@healthsyst.com

CMS-1533-P-29 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Starr West** **Date & Time:** **06/04/2007**

Organization : **Texas Hospital Association**

Category : **Hospital**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

See attachment

CMS-1533-P-29-Attach-1.DOC

#29

TEXAS HOSPITAL ASSOCIATION

June 4, 2007

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1533-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS-1533-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems; DRGs: Hospital-Acquired Conditions

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Dear Sir/Madam:

The Texas Hospital Association, on behalf of its more than 500 member hospitals, is pleased to submit comments on the hospital inpatient prospective payment systems rules published in the May 3, 2007, *Federal Register*. In the proposed rule, the Centers for Medicare & Medicaid Services seeks comments on how many and which hospital-acquired conditions should be selected for implementation in FY 2009. CMS outlines 13 conditions it is considering, but it recommends only six conditions for implementation at this time, including three serious preventable events. The six conditions are:

- catheter-associated urinary tract infections;
- pressure ulcers;
- object left in during surgery;
- air embolism;
- blood incompatibility; and
- Staphylococcus aureus septicemia.

The conditions must meet three criteria as required by section 5001(c) of Pub.L. 109-171: (a) high cost or high volume or both; (b) result in the assignment of the case to a DRG that has a higher payment when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidence-based guidelines. In addition, the Present on Admission indicator is required in order to determine which of the selected conditions developed during a hospital stay.

Serving Hospitals and Health Systems
6225 U.S. Highway 290 East – Post Office Box 15587 – Austin, Texas 78761-5587 – 512/465-1000 – Fax: 512/465-1090

There are significant challenges enabling the correct identification of relevant cases:

- Correctly identifying cases that meet the criteria using only the documentation of physicians or qualified health care practitioners as prescribed in the *ICD-9-CM Official Guidelines for Coding and Reporting* is a challenge that has not been fully resolved since implementation of the DRG system. Frequently, the necessary information is documented by other members of the health care team.
- Additional complexity arises for hospital coding personnel to accurately capture the present on admission status enabling the correct identification of the conditions that are present on admission.

While the use of POA will bring increased accuracy to administrative data, the experience of California and New York in collecting POA data indicates that it may be several years before the use of the indicator accurately reflects whether a condition is a complication or a comorbidity. CMS carefully should consider not only the criteria for selection set forth in the Deficit Reduction Act, but the ability of hospitals to identify and code the present on admission status accurately.

THA supports the initial selection of the three serious preventable event conditions: leaving an object in during surgery, air embolism as a result of surgery, and providing incompatible blood or blood products. The three events meet the selection criteria and should never occur during an inpatient stay. All are high cost, are preventable through prevention guidelines and are classified as CCs under the current CMS DRGs. In addition, the three conditions are not as dependent upon use of POA as the other proposed conditions.

The other conditions proposed for selection have potential challenges as outlined below.

Catheter-Associated Urinary Tract Infections: Many clinicians believe that urinary tract infections may not be preventable after several days of catheter placement, and prevention guidelines still are debated by clinicians. Trying to accurately code for urinary tract infections that are present on admission may lead to excessive urinalysis testing for patients entering the hospital.

Pressure Ulcers: Some patients, especially those with vascular insufficiency, may develop pressure ulcers regardless of preventive measures. Identifying which patients fall into this category remains a challenge. Hospitals may stop accepting patients at risk for pressure ulcers if they believe patients are entering their hospitals with undetected early-stage pressure ulcers.

Staphylococcus aureus bloodstream infection/septicemia: Accurately diagnosing 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 or a urinary tract infection. Subsequent development of Staphylococcus aureus septicemia may be the result of the localized infection and not a hospital-acquired condition. Additionally, the changes in coding guidelines for sepsis in recent years presents further challenges to hospital coding personnel to accurately capture present on admission status.

THA recommends that CMS proceed cautiously, starting with the three serious preventable event conditions. Other conditions should be adopted as hospitals have time to develop and implement processes to accurately capture POA, and for consensus to build regarding prevention guidelines. Time is needed to determine whether unintentional consequences will arise as a result of implementing the hospital-acquired conditions policy at the same time that dramatic changes are being made to the CMS DRG system.

THA appreciates the opportunity to make comments on the proposed changes to the hospital inpatient prospective payment systems rules.

Sincerely,

Starr West
Director, Policy Analysis

Copy: Dan Stultz, M.D., FACP, FACHE, President/CEO Texas Hospital Association

CMS-1533-P-30 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Ann Langan** **Date & Time:** **06/04/2007**

Organization : **St. Cloud Hospital**

Category : **Hospital**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Please see attached comments.

CMS-1533-P-30-Attach-1.DOC

#30

We agree with CMS that the proposed MS-DRGs represent a substantial improvement over the current CMS DRGs in their ability to differentiate cases based on severity of illness and resource consumption. However, we ask CMS to delay any change to the current CMS DRGs until the RAND Corporation has completed its evaluation of the alternative DRG systems (which now includes the MS-DRG system). If CMS implements the MS-DRGs as proposed in this rule for FY 2008 and then changes to another DRG system for FY 2009 based on the RAND Corporation final report which will be released in September, the difficulty of implementing two new DRG systems in two years is beyond measure.
At a minimum, providers would incur the additional costs of two different DRG groupers. The amount of staff and physician training time and cost would be immense. In addition, the comparability by DRG between years would be lost.
We recommend that CMS retain the current CMS DRG system for FY 2008 and refine it if necessary by using split DRGs as they have done in the last two years. This would minimize the staff and physician training to the new split DRGs for FY 2008 and allow CMS the time necessary to implement the RAND Corporation's recommendations for a new DRG system for FY 2009.

We are also very concerned about CMS' proposal to reduce the inpatient PPS standardized amount by 2.4% for each year for FY 2008 and FY 2009 due to the proposed implementation of the MS-DRGs. CMS made this proposed reduction based on the hospital data of the state of Maryland. We do not believe CMS' review of the hospital data of the state of Maryland is representative of all hospitals in the nation. We have included below the text of a document obtained from *hfm* magazine of April, 2007 which lists the findings of an analysis performed by Ingenix:

A review of the percentage of Medicare discharges in 2005 that contained one or more CCs among secondary diagnoses discloses that hospitals already code CCs on most of their bills. This finding suggests that presence of a CC on a bill may not be as influenced by financial incentives as some would suggest. Although the proportion of cases containing a CC among medical DRGs that do not currently have a CC split is slightly smaller than the proportion among medical DRGs with a CC split (77.3 percent versus 84 percent), the pattern is actually reversed among surgical cases. That is, the proportion of cases with a CC is actually higher among surgical cases where there is no current CC split--and no financial incentive to code CCs--than among surgical cases where there is such an incentive (73 percent versus 71.9 percent). Indeed, data suggest that hospitals have been coding CCs at high rates for years, although there does appear to be a slight upward drift over time.

Trends in CC Coding Rates by Type of Case and Presence of a CC Split in Current CMS DRG Structure, 2001-2005

	2001	2002	2003	2004	2005
Medical cases w/ CC split	81.8%	82.6%	83%	83.5%	84%
Medical cases w/o CC split	72%	73.1%	74.9%	76.1%	77.3%
Surgical cases w/ CC split	71.7%	72.4%	73.4%	72%	71.9%
Surgical cases w/o CC split	71.8%	72%	72.3%	73%	73%

These findings suggest that the potential for upcoding in response to the introduction of severity-adjusted DRGs may be relatively small. They also suggest that coding practices may be less influenced by financial incentives than by coding guidelines and professional standards that are designed to ensure that hospitals record as much clinically significant information as possible on their bills.

Based on the findings listed in this article, we believe the 2.4% reduction in the inpatient PPS standardized amount each year for both FY 2008 and FY 2009 is not necessary since the potential for upcoding is relatively small.

In summary, we again recommend that CMS retain the current CMS DRGs for FY 2008 and not reduce the inpatient PPS standardized amount by 2.4%. This would allow CMS the time

necessary to implement the RAND Corporation's recommendations for a new DRG system for FY 2009. This would also allow CMS the time necessary to evaluate the percentage of Medicare discharges in 2006 that contained one or more CCs among secondary diagnoses to determine if there will truly be any upcoding in response to the introduction of severity-adjusted DRGs.

CMS-1533-P-31 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Ann Langan** **Date & Time:** **06/04/2007**

Organization : **St. Cloud Hospital**

Category : **Hospital**

Issue Areas/Comments

DRGs: Relative Weight Calculations

DRGs: Relative Weight Calculations

Please see attached comments.

CMS-1533-P-31-Attach-1.DOC

#31

CMS has asked for public comment on whether they should proceed to adopt the RTI International (RTI) recommended changes for FY 2008 in the absence of a detailed analysis of how the relative weights would change if they were to address charge compression while simultaneously adopting an HSRVcc methodology together with the proposed MS-DRGs.
We recommend that CMS not implement the MS-DRGs for FY 2008 as explained in our comment under the DRG reform section. We also recommend that CMS not implement an HSRVcc methology but instead use the analytic technique of using regression analysis to identify adjustments that could be made to the cost-to-charge ratios (CCRS) to better account for charge compression for FY 2008 and until the Medicare cost reports would include a separate cost center for implantable medical devices. This would allow CMS to address the RTI finding that of all the adjusted CCRs, the largest impact on weights came from accounting for charge compression in medical supplies for devices and implants. This would also allow CMS to apply the regression method to the combined inpatient and outpatient services for FY 2008.

CMS-1533-P-32 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Ann Langan** **Date & Time:** **06/04/2007**

Organization : **St. Cloud Hospital**

Category : **Hospital**

Issue Areas/Comments

Wage Data

Wage Data

Please see attached comments.

CMS-1533-P-32-Attach-1.DOC

#32

CMS has asked for public comment on whether they should revise future cost reports to collect contract labor data for the remaining indirect patient care cost centers on worksheet S-3, Part II for inclusion in the wage index. We ask that CMS add a line 25.01 to worksheet S-3, Part II to collect the contract labor costs and hours for contracted laundry services. We base our request upon the wage index public use file dated February 22, 2007. Of the 3,605 providers listed, 1,503 had no amount listed in Laundry salaries for line 25. This is 42% of the total providers that have no amount listed in Laundry salaries for line 25. We believe this public use file shows the need to include the contract labor data for laundry for the wage index computation for future cost reports in order to improve the accuracy of the wage index to account for the area differences in the cost of labor.

CMS-1533-P-33 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Ann Langan** **Date & Time:** **06/04/2007**

Organization : **St. Cloud Hospital**

Category : **Hospital**

Issue Areas/Comments

Rural Floor

Rural Floor

Please see attached comments.

CMS-1533-P-33-Attach-1.DOC

Rural Floor:
CMS has asked for public comment on whether it would be appropriate for them to establish a policy under its authority to preclude the arrangement described in the proposed rule of critical access hospitals converting to IPPS status solely to raise the State's rural floor. We ask CMS to implement such a policy since the increased payments to the hospitals in the one state would be at the expense of all other IPPS hospitals nationwide.

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am the president and founder of the **Musella Foundation For Brain Tumor Research & Information, Inc,** a 501(c)(3) non-profit public charity dedicated to improving the lives of families dealing with brain tumors.

I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

CMS-1533-P-34 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Albert Musella** **Date & Time:** **06/04/2007**

Organization : **Musella Foundation For Brain Tumor Research**

Category : **Consumer Group**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

See attached file

CMS-1533-P-34-Attach-1.DOC

#34

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am the president and founder of the **Musella Foundation For Brain Tumor Research & Information, Inc,** a 501(c)(3) non-profit public charity dedicated to improving the lives of families dealing with brain tumors.

I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

CMS-1533-P-35 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Dave Snow** **Date & Time:** **06/04/2007**

Organization : **Hall Render Killian Heath**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Rural Floor

Rural Floor

See Attachment

CMS-1533-P-35-Attach-1.PDF

#35

HALL RENDER
KILLIAN HEATH & LYMAN

Professional Corporation
One American Square, Suite 2000
Indianapolis, IN 46282
www.hallrender.com

June 4, 2007

Via Electronic Submission to: http://www.cms.hhs.gov/eRulemaking

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1533–P
P.O. Box 8011
Baltimore, MD 21244–1850

Re: Comment On Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule published in the May 3, 2007 Federal Register

Dear Sirs:

We hereby submit our comments on the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule ("Proposed Rule").

Reference: RURAL FLOOR

Hall, Render, Killian Heath & Lyman represents approximately 800 hospitals in appeals of the rural floor budget neutrality adjustment for federal fiscal year ("FY") 2007 and prior years. We are submitting these comments on their behalf.

In Proposed Rule, CMS proposed 1) applying the rural floor budget neutrality adjustment to the wage index instead of the standardized amount, and 2) applying a rural floor adjustment of 1.002214 to the FY 2008 standardized amount calculation. Our concerns and comments for each of these items are discussed below.

1. **CMS proposed applying the rural floor budget neutrality adjustment to the wage index instead of the standardized amount.**

CMS proposed applying the rural floor budget neutrality adjustment ("BNA") to the hospital wage index for FY 2008. This proposed change is not sufficiently explained, and we disagree with CMS' approach. At best, it appears that this change will shift the impact of the rural floor BNA among providers, from what it has been under the standardized amount method used since the rural floor was first implemented in FY 1998. At worst, if applied as described in the example, it will not be budget neutral.

We believe that CMS wishes to abandon the historical treatment of applying the rural floor budget neutrality adjustment to the standardized amount, because under the historical approach CMS failed to reverse the impact of this adjustment from year to year. As a result, the rural floor adjustment is cumulative (that is, it is budget *negative* rather than budget *neutral*), and CMS has excessively and inappropriately reduced Medicare PPS payments since the rural floor was implemented in FY 1998. This error has been brought to CMS' attention because many hospitals filed appeals with the PRRB on this issue.

CMS' proposal to apply the rural floor budget neutrality adjustment to the wage index rather than the standardized amount appears to be an acknowledgment that something is wrong with the historical practice. What is wrong, it would appear, is the budget negative compounding resulting from CMS' failure to reverse these budget neutrality adjustments from year to year.

For the reasons described below, we believe that applying the rural floor BNA to the standardized amount is the correct approach.

First, CMS has already acknowledged that the application of the rural floor adjustment to the wage index will not be equitable because hospitals have different labor-related shares (62% for hospitals with wage indices less than or equal to 1; 69.7% for hospitals with wage indices greater than 1). See page 24792 of the May 3, 2007 Federal Register. Changing from a method that is equitable, (i.e., applying the rural floor budget neutrality adjustment to the standardized amount) to a method that has known inequities is not appropriate.

Second, it is also unclear from the explanation and examples in the Federal Register whether CMS calculated the rural floor budget neutrality adjustment for the wage index based on the total standardized amount or just the labor component. Either way, the calculation has flaws when compared to the current methodology of applying the budget neutrality adjustment to the standardized amount.

A. The example in the Proposed Rule at pages 24,791-92 appears to calculate the BNA based on the total standardized amount (in the example, $1,000). It then determines the budget neutral impact by applying the BNA to reduce the wage indices which are then multiplied by the same $1,000 standardized amount. This is not how the wage index is applied in the actual payment system, however.

In actuality, the wage index and therefore (under CMS' proposed methodology) the BNA, is only applied to the labor component of the standardized amount. This will likely cause the methodology to not be budget neutral in application. This can be demonstrated by adding a step to the final calculation on page 24,792 that splits the $1,000 standardized amount into separate labor and non-labor components with the BNA adjusted wage index applied only to the labor component. The disparity will vary based on the relative case-mix, number of discharges, and comparative wage indices. In the example, this results in the proposed methodology reducing payments to hospitals from what they would be without the rural floor.

B. Even if CMS calculated the rural floor BNA using only the labor component payments, the adjustment affects hospitals differently than if the BNA were applied to the standardized amount as CMS has done historically. For example, hospitals with a larger wage index will absorb more of the impact of the BNA than hospital with a smaller wage index. While this is also true when the rural floor BNA is applied to the standardized amount, the impact is compounded because the entire adjustment is made to the labor component through the wage index.

Third, we fail to understand why CMS would handle the rural floor BNA differently than other adjustments related to the wage index. There are a number of wage index adjustments that must be made budget neutral, and all are applied to the standardized amount. For example, the hospital reclassification adjustments are applied to the standardized amount. Without sufficient justification for a difference, the rural floor budget neutrality adjustment should be applied consistently.

Fourth, the methodology for calculating the wage indices is already a complicated process because the calculation incorporates many factors and determinations (including reclassification decisions, out migration adjustments, and occupational mix adjustments). Incorporating the rural floor budget neutrality adjustment into the wage indices will only make it more difficult to calculate and understand the wage indices.

CMS does not sufficiently explain why it is proposing this change, and for the reasons described above we believe that the rural floor BNA should continue to be applied to the standardized amount. However, we also comment that CMS must apply the rural floor BNA to the standardized amount only for the fiscal year to which that year's rural floor payments apply; CMS must not carry the rural floor BNA forward from year to year.

We further ask CMS to clarify the reason for the proposed departure from the historical practice, and to acknowledge that CMS is proposing this change because CMS carried forward the rural floor budget neutrality adjustment from year to year since FY 1998, resulting in an in appropriate compound reduction in the standardized amount.

2. CMS applied a rural floor adjustment of 1.002214 to the FY 2008 standardized amount calculation without explanation.

CMS proposed to apply a rural floor adjustment of 1.002214 to the calculation of the FY 2008 standardized amount on page 24,839 of the Proposed Rule. Specifically, CMS included a line item in the calculation of the FY 2008 standardized amount simply titled "Rural Floor Adjustment." This line item increases the standardized amount by a factor of 1.002214. CMS directs readers to section III.G.4 of the preamble to the proposed rule "for a complete discussion" of this line item, but section III.G.4 does not mention the 1.002214 adjustment at all.

The FY 2008 proposed rule appears to be the first time CMS has ever suggested implementing a rural floor BNA greater than one. Because of the nature of the rural floor adjustment (*i.e.*, a reduction of the FY's total PPS payments to neutralize the impact of that year's rural floor adjustment), a BNA for a single year's impact should never be greater than one. The only apparent reason for a rural floor BNA greater than one would be to reverse the impact of a prior year adjustment. Since CMS is proposing to apply the FY 2008 rural floor BNA to the wage indices rather than the standardized amount, this adjustment must be some type of reversal of prior year(s) rural floor BNA. Such a reversal has not been discussed in prior guidance on the rural floor.

Since it would appear that this line item is intended to reverse one or more adjustments from prior year(s), we ask CMS to 1) clarify the reason for the 1.002214 line item adjustment to the standardized amount, and 2) specifically address the extent to which CMS has identified an improper reduction to the standardized amount from the historical practice of applying the rural floor budget neutrality adjustment to standardized amount without reversing the effect of the adjustment from year to year. Further, if CMS is reversing one or more adjustments from prior years, CMS should provide an explanation of how the amount was computed and whether the practice was applied consistently in prior years.

Sincerely,

HALL, RENDER, KILLIAN, HEATH & LYMAN, P.C.

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571981v3

CMS-1533-P-36 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Claudia Siegel** **Date & Time:** **06/04/2007**

Organization : **Dr. Claudia Siegel**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new code for such cases. The current proposed rules removes the code you created to solve this problem and we may go back to loss of access to this standard of care. This can be corrected by changing the wording of the new codes to allow cases involving the implantation of devices to be assigned to DRG 23, even without a MCC.

This would remove an economic barrier to the use of Gliadel for brain cancer.

I lost my sister and my father in law to Glioblastomas. Gliadel was not used for either of them. They both died after the FDA approved Gliadel but before Medicare created the billing code for Gliadel. I hate to think that the decision to not use Gliadel may have been motivated by economics.

I would like to request a change to the wording of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent, such as Gliadel, would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

CMS-1533-P-36 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Claudia Siegel** **Date & Time:** **06/04/2007**

Organization : **Dr. Claudia Siegel**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new code for such cases. The current proposed rules removes the code you created to solve this problem and we may go back to loss of access to this standard of care. This can be corrected by changing the wording of the new codes to allow cases involving the implantation of devices to be assigned to DRG 23, even without a MCC.

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MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

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MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Brain tumor patients have enough problems to worry about without having to be concerned that Medicare rules may prevent them from receiving the standard of care.

CMS-1533-P-37 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Susan Anderson** **Date & Time:** **06/05/2007**

Organization : **Susan Anderson**

Category : **Individual**

Issue Areas/Comments
DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am the sister of a former brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

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MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

CMS-1533-P-37 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Susan Anderson** **Date & Time:** **06/05/2007**

Organization : **Susan Anderson**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am the sister of a former brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

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MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

CMS-1533-P-38 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Date & Time:** **06/05/2007**

Organization :

Category : **Academic**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am a former caregiver of a brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

CMS-1533-P-39 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Laurel Joyce** **Date & Time:** **06/05/2007**

Organization : **Ms. Laurel Joyce**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am a brain tumor patient, and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

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Thank you for your consideration of this important matter!

CMS-1533-P-40 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Diana Gillis** **Date & Time:** **06/05/2007**

Organization : **self**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

I am the caregiver of a brain tumor patient and am active in a brain tumor support group in my area. I am very concerned that Medicare is now about to make it very difficult for brain tumor patients to get access to the Gliadel wafer. What I have learned is that there is not a lot of hope for those unlucky enough to be diagnosed with a malignant brain tumor. Each patient responds in a different way to available treatments. For some, the Gliadel wafer has been a good treatment. We need more new treatments for this devastating disease. Reducing coverage for the existing options we have is a very bad idea.

Please reconsider this proposed change and the effect it will have on those with few options.

Thank you.

CMS-1533-P-41 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Esther Marshall** **Date & Time:** **06/05/2007**

Organization : **Esther Marshall**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am a family member and caregiver to a brain tumor patient . I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS- DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

CMS-1533-P-42 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Matthew Ewend** **Date & Time:** **06/05/2007**

Organization : **University of North Carolina at Chapel Hill**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

My name is Matt Ewend, MD. I am the Chief of Neurosurgery at the University of North Carolina, and I treatment primarily patients with brain tumors. I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Patients treated under these codes are fighting the most malignant of cancers, a primary brain tumor. At present, there are few therapies available that have been shown to have efficacy and prolong survival for these patients. If the DRG changes go forward, most patients would no longer be able to receive BCNU-polymer wafers for treatment of their cancer despite the existence of three randomized, placebo controlled, doubled blinded studies that show the wafers can prolong survival.

In my experience, most patients who survive longer than expected (greater than 24 months) are treated with multiple therapies. It is a shame that DRG regulations will remove one of the important tools from our bag. It would be like taking away the carpenter's hammer and telling him to go to work missing one of his/her key tools.

I hope the committee overseeing this will reconsider this decision. Treatment of this cancer is tremendously challenging. We do our patients a great disservice when we legislate away important treatment options. We are talking about and FDA approved therapy.

Thank you for your consideration

Matthew G. Ewend, MD
Chief, Division of Neurosurgery
Program Director, Neuro-Oncology
University of North Carolina at Chapel Hill
3013 Burnett-Womack, Campus Box 7060

CMS-1533-P-43 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Leslie Gunther** **Date & Time:** **06/05/2007**

Organization : **Mrs. Leslie Gunther**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am the wife and caregiver of a brain tumor patient, and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

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MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the actual costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

The maze of insurance issues a family has to navigate is already overwhelming.... clarifying this billing issue and insuring that our beloved family members can receive the standard of care that is called for by their doctors is a critically important act.

Thank you for your consideration of this important matter!

CMS-1533-P-44 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : elise ziv **Date & Time:** 06/05/2007

Organization : elise ziv

Category : Individual

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am a spouse of a brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

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MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

Sincerely,

Elise A. Ziv

CMS-1533-P-45 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Amy Ross** **Date & Time:** **06/05/2007**

Organization : **Mrs. Amy Ross**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am the widow of a brain tumor patient and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

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Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

My husband was diagnosed with Glioblastoma January 2007 and passed away on April 22, 2007. He was never offered this Gliadel wafer. If he had, would he have had a better chance of survival? I guess we will never know. His course of treatment was radiation and Temodar. After 33 radiation treatments and Temodar during the radiation, recurrance of the tumor occurred. If this is the standard treatment, then it should be available to all patients.

Thank you for your consideration of this important matter!

CMS-1533-P-46 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Rick Nall** **Date & Time:** **06/05/2007**

Organization : **Mrs. Rick Nall**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Re: CMS-1533-P. Request for modification to MS-DRG 23 and MS-DRG 24

I am a spouse of a brain tumor patient,and I would like to request a change to the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

I propose the following titles for these MS-DRGs:

MS-DRG 23: Craniotomy with major device implant or acute complex CNS PDX with MCC

MS-DRG 24: Craniotomy with major device implant or acute complex CNS PDX without MCC

I would like to suggest that the DRGs be restructured so that their titles are the following:

MS-DRG 23: Craniotomy with acute complex CNS PDX with MCC or major device implant

MS-DRG 24: Craniotomy with acute complex CNS PDX without MCC

Rationale: The proposed titles do not take into account the costs involved in implanting a device such as the Gliadel Wafer (and other new treatments in the pipeline). Gliadel is a device implanted into the brain which slowly releases chemotherapy. It is now considered the standard of care for malignant brain tumors.

When Gliadel was first approved by the FDA, the payment for a brain tumor surgery with Gliadel was so low that many community hospitals could not afford to use the treatment and many patients lost access to it. CMS corrected the problem a few years later, by creating a new DRG for such cases (DRG 543). This removed the major barrier to access for Gliadel and put the decision on its use back into the hands of the doctors. (Thank you for that DRG!)

The current proposed rule removes the DRG that you created to solve this problem, and without modifications to the new replacement MS-DRGs, we may go back to loss of access to this standard of care. This can be corrected by changing the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!