

>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

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>  
>Dear Ms. Norwalk:

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>On behalf of Freeman Health System and our 3,800 employees, we  
>appreciate 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).

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>  
>While Freeman Health System 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.

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>  
>DRGS

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>The proposed rule would create 745 new Medicare-Severity DRGs (MS-  
>DRGs)  
>to replace the current 538 DRGs, and would overhaul the complication  
>or  
>co- morbidity 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 FY2008 weight based on costs and one-third  
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>on charges.

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>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  
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>2005.

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>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.

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>CAPITAL PAYMENT UPDATE

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>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

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>hospitals.

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>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.

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>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.

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>Our detailed comments are attached. If you have any questions, please  
>feel free to contact Gary Duncan, President and CEO, at 417/347-6601  
>or

>gdduncan@freemanhealth.com.

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>

>Sincerely,

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**American Hospital  
Association**

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June 4, 2007

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***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:

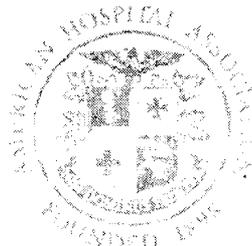
On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year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



Leslie Norwalk, Esq.  
June 4, 2007  
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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](mailto: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  
for the  
FY 2008 Inpatient Prospective Payment System**

**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

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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 renegeing 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

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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.

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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.

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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 as 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.

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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

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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., musculoskeletal 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

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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

**Steve Harwell**  
Healthcare Association of New York State

**Karen Heller**  
Greater New York Hospital Association

**Sponsoring Organizations**

**American Hospital Association**  
Danielle Lloyd  
Don May  
Caroline Steinberg

**Clara Kridle/Jose Robles**  
Price Waterhouse Coopers

**Todd Nelson**  
Grinnell Regional Medical Center

**Association of American Medical Colleges**  
Karen Fisher

**Kathy Reep**  
Florida Hospital Association

**Federation of American Hospitals**  
Steve Speil

**Trisha Schirmers**  
Allina Health System

**Participants**

**Pat Andersen**  
Oklahoma Hospital Association

**Mike Smith**  
Catholic Healthcare West

**George Arges**  
American Hospital Association/National  
Uniform Billing Committee

**Cecil Terry**  
BJC Healthcare

**Norman Belcher**  
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**Tim Wolters**  
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June 12, 2007

*VIA HAND DELIVERY  
FACSIMILE*

Ms. Leslie Norwalk  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

Re: **Comments to the Medicare Program; Proposed Changes to the  
Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008  
Rates [CMS-1533-P]**

Dear <sup>Leslie</sup> Leslie:

I am writing to flag a truly outrageous and indefensible flaw in the Fiscal Year ("FY") 2008 Hospital Inpatient Prospective Payment Systems Proposed Rule. This rule inadvertently exacerbates a truly egregious situation in the hospital labor market in Saginaw, Michigan. Without modification of the regulation, the Centers for Medicare and Medicaid Services ("CMS") will fail to afford any regulatory relief to a hospital that has been economically disadvantaged, through no fault of its own, by the accidental reporting error of another hospital in the region. The agency should use this rulemaking to rectify this competitive disadvantage that is poised to be perpetuated indefinitely in this market.

As you aware, the Saginaw area is served by two large hospitals, Covenant Healthcare ("Covenant") and St. Mary's of Michigan ("St. Mary's"). Covenant and St. Mary's are located within 1.4 miles of each other and have been located in the same statistical area (Saginaw) for area wage index calculations since FY 2000. Unfortunately, due to an inadvertent reporting error, Covenant, as the larger hospital with the highest level of indigent care in the area, currently has a wage index that is 18 percent lower than St. Mary's – a smaller facility with a "wealthier" patient population just one mile away.

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According to data published in the Federal Register, from FY 2003 to FY 2004, St. Mary's average hourly wage jumped from \$22.68 to \$29.20 – a spread of \$6.52, or four-and-a-half times the spread in previous years.<sup>1</sup> These anomalous data were brought to the attention of CMS but were not corrected. Based on these incorrect data, St. Mary's received approval from the Medicare Geographic Classification Review Board in early 2005 for reclassification into the Flint Core Based Statistical Area ("CBSA") for FYs 2006, 2007, and 2008. Covenant, on the other hand, was not successful in its reclassification application in 2005.

Having worked for over 25 years on hospital market issues, including dozens of wage index issues, I have never come across a situation that creates such an inequitable, and senseless, policy result. Literally overnight, the uncorrected error created a substantial financial disparity between the two hospitals. The spread in the area wage index between the hospitals as the result of the reclassification became 16.35 percent in FY 2006, 16.67 percent in FY 2007, and 20.25 percent for Proposed FY 2008. As the purpose of the wage index is to measure differences in hospital wage rates among labor markets, CMS surely did not intend such a sizeable differential between hospitals that compete literally for the identical labor pool.

The improper reclassification now gives St. Mary's a considerable and permanent competitive advantage over Covenant. For example, payment for a cardiac defibrillator implant (DRG 535) is now \$37,343 at Covenant and \$41,101 at St. Mary's. Similarly, payment for heart failure (DRG 127) is \$5,312 at Covenant and \$5,847 at St. Mary's. The overall DRG payment differential between the two hospitals is more than 10 percent per discharge.<sup>2</sup> Using the Occupation Mix Adjusted area wage indices for both providers, St. Mary's will be advantaged by \$27 million over the three-year period.<sup>3</sup>

As evidenced by these comparative payment data, the reclassification of St. Mary's has led to significant economic disparities between St. Mary's and Covenant. But for St. Mary's data reporting error, the two Saginaw hospitals would almost certainly still be reporting similar average hourly wages and, thus, receiving comparable reimbursements from Medicare. Because the reclassification and attendant economic disadvantage to Covenant occurred on account of St. Mary's mistake and through no fault of Covenant, there is a glaring inequity in the hospitals' situation.

Furthermore, the inequity in Covenant's situation is compounded by the structure of the reclassification system. Under this system, a hospital that has once been reclassified (even erroneously) can essentially guarantee its continued success in reclassification applications based on the way it spends the additional money received

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<sup>1</sup>69 Fed. Reg. 48916, 49295 et seq. (Table 2).

<sup>2</sup>70 Fed. Reg. 47278 (August 12, 2005), 47580 et seq. (Tables 4A and 4C); 71 Fed. Reg. 47870 (August 18, 2006) (Tables 4A and 4C).

<sup>3</sup>Economic impact analysis was prepared by RSM McGladrey, Inc., Davenport, Iowa and are calculated based on Occupational Mix Adjusted AWI's for both providers. 70 Fed. Reg. 47278 (August 12, 2005), 47580 et seq. (Tables 4A and 4C); 71 Fed. Reg. 47870 (August 18, 2006) (Tables 4A and 4C).

from the higher wage index payments, i.e., by using its increased revenue to raise employees' wages. Because reclassification decisions are based on the difference between the applicant hospital's wages and the wages paid by other hospitals in the default CBSA, the increased spread between the wages paid by the applicant hospital and by the hospitals in its former CBSA helps the applicant continue to meet this criterion for reclassification.

As a result, aberrant wage data and subsequent payment differentials will be permanently entrenched in the health care labor market. In Covenant's situation, these differentials are the direct result of an improper reclassification produced by a data error – an error that occurred through no fault of Covenant. Moreover, the current regulatory system will allow the improper reclassification and attendant payment differentials to be perpetuated year after year.

Covenant and its representatives have made repeated contacts with the agency to seek regulatory redress. More than once has Covenant been told that its situation is regrettable, and unfair, but that the agency is disinterested in changing its review process to address this likely unique problem because CMS “does not want to encourage any efforts to re-open its complex wage index rule on any front.” CMS, as an institution, exists for this very purpose – to assist health care providers in their efforts to serve patients and to design fair payment systems. I understand CMS' concern about discouraging complaints on wage index issues. But what is the point of having a rule, or even working at CMS, if you will not fix glaring policy errors?

I believe that CMS should take responsibility for the ways its regulations and review process have failed Covenant. To ignore the inequity experienced by Covenant is to shirk the agency's duties to base Medicare payments on accurate information and to treat providers in the same market fairly. An appropriate solution could entail the following: (1) implementation of a blended wage index rate for both Covenant and St. Mary's for the last year of this 3-year cycle; (2) regulatory changes that would allow for midyear corrections to wage index data in a situation like Covenant's; (3) adoption of a review process to mitigate the negative impacts of improper reclassifications.

The first component of the solution is specific to Covenant. In keeping with its prospective-only change policy, CMS could make this correction in one of three ways. First, CMS could reclassify Covenant to the Flint CBSA and thereby raise Covenant's wage index. Second, CMS could reduce St. Mary's wage index to the same non-reclassified rate as Covenant. Third, CMS could create a blended wage index for both hospitals, thus increasing Covenant's rate and decreasing St. Mary's rate to some extent. Applying a blended wage index to both Covenant and St. Mary's would treat both hospitals fairly in the period before St. Mary's improper reclassification expires. CMS indicated its willingness to consider this very type of mid-year action in the FY 2008 IPPS proposed rule by seeking comments on a similar situation.<sup>4</sup>

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<sup>4</sup>72 Fed. Reg. 24798.

Because this implementation of a one-year blended wage index would require CMS to make a midyear correction to wage index data, CMS should modify its regulations to specifically account for this situation. Currently, under § 412.64(k)(1), CMS makes such midyear corrections “only if a hospital can show that: (1) The fiscal intermediary or the MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the year.”<sup>5</sup> This regulation, as written, would not afford any relief to a hospital that is harmed by the effects of errors in another hospital’s wage data.

Thus, the second component of the solution would be for CMS to explicitly modify the set of situations in which it will make midyear corrections to an area’s wage index. The regulation found at § 412.64(k)(1) should be revised to allow CMS to make a midyear correction if the requesting hospital can demonstrate significant direct market competition with another hospital in the same MSA and can show a mistake in the submitted data of that hospital resulted in an improper reclassification which generated an AWI differential greater than 0.1 between the hospitals. Modifying the regulation to account for this unique situation would enable CMS to respond appropriately to truly inequitable situations without simultaneously opening the door to hospitals seeking to reduce other hospitals’ wage indices without having first suffered harm because of another hospital’s unjustified reclassification.

Finally, the third component of a proposed solution would be a procedural change intended to prevent the perpetuation of the harmful effects of improper reclassifications. To this end, we urge CMS to create a policy going forward in which it systematically monitors the impact of aberrant data that create a percentage differential in the health care market through the three-year cycle of reclassification. Should the error perpetuate an inequitable situation or further prevent a faultless hospital from reclassification, CMS should review this unique scenario with special consideration and redress. Such a review process would ensure that the effects of improper reclassifications are minimized and are revisited if necessary to ensure equity to hospitals harmed by unjustified reclassifications. It would allow for equitable adjustments, and would not unravel the wage index systems or open a “Pandora’s box” of assaults on the rule, as agency staff may fear.

We urge CMS to make these regulatory and subregulatory changes in order to provide fair treatment to hospitals that are harmed through no fault of their own by other hospitals’ erroneous data submissions. In my years as CMS’ Administrator, we fixed a number of wage index errors based purely on equity – including Savannah, Georgia – even though it “potentially” opened up the rules to other complaints. But we defended those decisions on the merits, and rejected others on the merits – because it was the right policy. Fixing the mess in Saginaw is unquestionably the right policy and CMS should not shirk its duty to equitably distribute payments. Not to address this situation is to

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<sup>5</sup>*Id.* at 24680, 24801.

June 12, 2007

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remain idle in the face of clear inequity. CMS can and should take action to remedy the injustice.

Again, I have never seen a more unfair situation within a single market, and I would truly hope CMS would thoroughly evaluate its options. I would be happy to discuss this further with you. I hope you will give this proposed solution serious consideration.

Best regards,

A handwritten signature in black ink, appearing to read "Tom Scully". The signature is written in a cursive style with a long, sweeping tail that extends downwards and to the right.

Tom Scully

cc: Herb Kuhn



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20 W. Stow Road, Suite 3  
Marlton, NJ 08053

June 4, 2007

Ms. Leslie V. Norwalk, Esq.  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1533-P

{ Address will vary depending on regular, overnight or hand courier. If sending via email then any of the addresses will be sufficient. }

Re: File Code CMS-1533-P

Dear Ms. Norwalk:

Please note that the following comments correspond to the "Imputed Floor" section contained in the FFY 2008 proposed IPPS rule published in the May 3, 2007 Federal Register.

West Jersey Health System continues to support the Centers for Medicare and Medicaid Services (CMS) proposal related to "Special Circumstances of Hospitals in All-Urban States" set forth in the FFY 2005 proposed Inpatient Prospective Payment System (IPPS) rule published in the May 18, 2004 Federal Register. Conversely, West Jersey Health System objects to the proposed expiration of the imputed floor for the following reasons:

- CMS does not give any substantive rationale as to the reason the imputed floor should expire. For comparative purposes, please note the following quote from CMS in the FFY 2005 final rule:

We think it is also an anomaly that hospitals in all-urban States with predominant labor market areas do not have any type of protection, or "floor", from declines in their wage index. Therefore, we are adopting the logic similar to that articulated by Congress in the BBA and are adopting an imputed rural policy for a 3-year period.

- CMS does not provide in the FFY 2008 proposed rule any change in either the existence or effect of the aforementioned "anomaly"; therefore, CMS does not provide any substantive support for the elimination of the imputed floor.
- We believe that it would be improper for CMS to include in the final rule any empirical analysis regarding the imputed floor, as that would constitute avoidance of public commentary.

**Ms. Norwalk**

**6/5/2007**

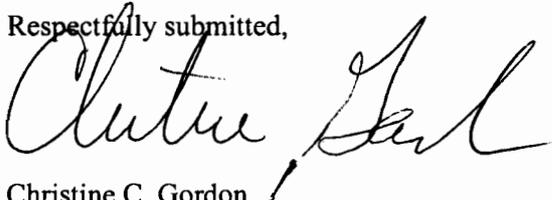
**Page 2 of 2**

- CMS has contradicted itself by stating in the FFY 2008 proposed rule that “we believe the policy should apply only when required by statute.” However, in the FFY 2005 final rule, CMS responded to commenters’ contention at that time that “any special provision for urban-only States should be subject to legislative action.” Citing Social Security Act (SSA) section 1886(d)(3)(E) as the authoritative basis for establishing the imputed floor, CMS correctly noted that the agency “does have the discretion to adopt a policy that would adjust wage areas” in the manner established by CMS at that time; that is, the policy reflected in the imputed floor regulation.
- In addition, in the past CMS has repeatedly utilized SSA section 1886 (d)(5)(I)(i) to implement wage index adjustments absent specific statutory authority. Furthermore, CMS is currently relying on this section of the SSA for another proposed wage index matter in these proposed regulations.
- CMS notes in the proposed rule that “Urban providers in ... the Mid-Atlantic Region (NJ) will experience a decrease ... by 0.2 percent ... from the imputed rural floor no longer being applied” in New Jersey. We respectfully request that CMS provide the public, during the public comment period, with the rationale that supports the agency’s conclusion in this regard. We request that the agency furnish this information during the public comment period so that interested parties will have due opportunity to review the rationale and comment, as they deem appropriate.
- On an individual hospital level the reduction in funds under the expiration of the imputed floor would have the following impact on our hospital. West Jersey Health System feels that this change would greatly limit the growth ability for any current and/or new programs.

As noted above, the expiration of the imputed floor would have a detrimental impact on West Jersey Health System. As such, West Jersey Health System does not support the expiration of the imputed floor due (among other things) to the fact that the rationale for implementing the imputed floor three years ago has not changed since the inception of the imputed floor regulation. Therefore, we urge CMS to extend the imputed floor regulation.

Thank you for considering these important comments and we look forward to your response.

Respectfully submitted,



Christine C. Gordon  
Manager of Reimbursement



# Saint Raphael Healthcare System

Sponsored by The Sisters of Charity of Saint Elizabeth

104

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New Haven, Connecticut 06511

**Paul D. Storable**

Vice President and Chief Financial Officer  
Saint Raphael Healthcare System and  
Hospital of Saint Raphael  
(203) 789-3713 Fax: (203) 789-3107

June 5, 2007

Leslie V. Norwalk, Esq.  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1533-P  
P.O. Box 8011  
Baltimore, MD 21244-1850

**Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective  
Payment Systems and Fiscal Year 2008 Rates: Proposed Rule**

Dear Ms. Norwalk:

On behalf of the Saint Raphael Healthcare System, we appreciate the opportunity to comment on CMS' proposed rule on the FY 2008 Medicare Inpatient Prospective Payment System ("IPPS") published in the May 3, 2007 Federal Register. The comments that follow explain some significant effects that the proposed operational and policy changes will have on our System and its primary subsidiary, the Hospital of Saint Raphael ("Saint Raphael's" or "the Hospital").

**Capital PPS**

As you know, CMS is required to pay for a portion of the capital-related costs of inpatient hospitals and does so through a separate capital PPS. For FY2008, CMS proposes freezing Medicare capital payments for all urban hospitals, of which the Hospital of Saint Raphael is one. In addition, the proposal eliminates today's additional capital payments, and combined with the freeze proposal, represents a 3.8% cut for large urban hospitals.

Saint Raphael's along with nearly half of its Connecticut counterparts, has had successive years of operating losses, generated in part by a severe under-funding of our Medicaid program (Connecticut ranks 47<sup>th</sup> of the 50 states) and Medicare increases that have not kept up with the reality of operating in one of the costliest labor markets in the country. Consequently, there have been precious few resources to invest in new capital equipment and technology in the current operating environment. Compounding this lack of resources with further cuts that are vital to the Hospital's capital requirements will ultimately deny the community we serve with the needed replacement of technology and infrastructure of a modern healthcare facility.

Ms. Leslie V. Norwalk  
Centers for Medicare and Medicaid Services  
June 5, 2007  
Page 2

Dealing in an environment of insufficient governmental reimbursement, Saint Raphael's has had to self-impose a limited freeze on capital expenditures dating back to December 2005, deferring much-needed replacement of even the basic technology requirements within its operating rooms. This deferral has caused the Hospital's average age of plant to far exceed any reasonable benchmarks for the industry, a situation that will only be exacerbated by further cuts or freezes in Medicare capital reimbursement.

We urge CMS to leave capital PPS for urban hospitals in tact without freezes and without elimination of the additional payments.

**Severity-adjusted DRG Changes**

The most significant change in the IPPS proposes creating 745 new Medicare-Severity DRGs ("MS-DRGs") to replace the current 538 DRGs. While we applaud the concept of attempting a fairer methodology of applying DRG payments across the spectrum of severity, there is a disturbing aspect to the imposition of this methodology. The proposed rule contains a "behavioral offset", ostensibly to eliminate what CMS believes will be the effect of coding or classification changes it anticipates rather than real changes in case-mix.

Saint Raphael's, like all other hospitals, has used established coding protocols and practices for so long now that there is virtually no capacity to alter its coding and classification methodologies. Coders code what is documented in the charts-no more and no less. This "behavioral offset" is nothing more than an imposition of an additional, unwarranted cut in the Medicare program that most hospitals can ill afford. Furthermore, the assumption of behavioral adjustments for coding practices related to a brand new program without any empirical evidence yet to support it, lends additional credence to the supposition that it is merely a payment reduction disguised as a refinement of the payment system.

We strongly urge that if MS-DRGs are ultimately adopted, this "behavioral offset" component be eliminated from the final rule. Once there is experience with the use of MS-DRGs, CMS can study any significant movement that may have occurred to determine if there is a coding cause-and-effect relationship, and then make adjustments accordingly. Better yet, consider a phase-in of the MS-DRG system over a three to four year period, and use the studied data to make adjustments in the out years, if necessary.

Ms. Leslie V. Norwalk  
Centers for Medicare and Medicaid Services  
June 5, 2007  
Page 3

**Wage Index**

While we understand the broader need to revise across the board the methodology for applying area wage index reclassifications, we support the extension of Section 508 of the Medicare Modernization Act and respectfully request continued support of extending this provision through the legislative process until such time as a broader wage index revision takes place. It is our hope that this broader revision, scheduled for implementation in FY2009, has significant input from experts within as well as outside the healthcare industry.

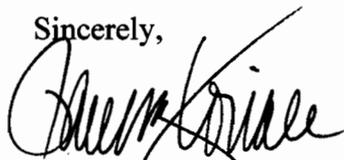
Additionally, there are thirty-five (35) hospitals, including the Hospital of Saint Raphael, that received a Section 508 extension under Section 106 of the Tax Relief and Health Care Act of 2006 ("TRHCA") and have been denied the rate relief that was intended by TRHCA, based on a faulty interpretation of this law by CMS. This was never the intent of the Congressional delegations that fought so hard on our behalf for this relief and we urge that the final rule correct this inequity for these 35 hospitals.

**IME Adjustment**

Under the proposed rule, vacation and sick time would be removed from the numerator and the denominator of the FTE calculation to determine what actually constitutes an FTE resident. Although we clearly understand the intent of this proposal and appreciate the effort, it is not practical to implement, particularly for residents who rotate through multiple hospitals. Attempting to apportion these types of time off through the various hospitals poses a logistical nightmare that is simply not necessary. Instead, an alternative is to treat these time elements similarly to the treatment for orientation time for residents.

Finally, on behalf of Saint Raphael's, we want to thank you for the opportunity to comment on the proposed FY 2008 IPPS rule and ask that you kindly consider these comments prior to publishing the final rule.

Sincerely,



Paul D. Storiale  
Vice President & Chief Financial Officer

PDS/

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

May 30, 2007

Dear Madam/Sir:

Thank you for the opportunity to comment on the Quality and Safety Provisions of Medicare Inpatient Prospective Payment System Proposed Rule for FY2008. The proposed rule specifically seeks comments on:

1. The proposed adoption of the five new measures for FY2009 RHQDAPU program. We would comment that including four more SCIP measures will be time-consuming and will require more training for the data collectors, medical records coders in our case. All the information is already present in the medical record, so the task will not be daunting. The measures should all receive NQF approval prior to being required by CMS. As for the fifth new measure, Pneumonia 30-day mortality, that will require no additional effort on our part since the data will come from Medicare claims data. The new methodology utilized for the AMI and HF 30-day mortality measures is an improvement on earlier methodology. We presume that the same methodology will be utilized for Pneumonia mortality.
2. Potential new measures to be adopted beyond FY2009. We will leave it to the clinical experts to comment on each measure specifically, but a general comment would be that there is still considerable controversy about most of the measures. From an administrative point of view, it is worth pointing out that not all of the potential new measures are included in the medical record consistently, e.g., Stress Ulcer Disease Prophylaxis, CAP and ACOS protocols. Readmission rates would have to be captured from Medicare claims data. A glaring weakness of Leapfrog data is that it is self-reported and becoming ever more complicated, which will certainly lead to disparities in data interpretation. While it is a useful exercise for an individual provider to work through the Leapfrog questions, it is ridiculous to assume that providers' responses can be compared to each other meaningfully. Among the AHRQ data measures, Failure to Rescue is a terrible measure of quality. The data come from administrative files, are subject to coding disparities, and do not adequately consider co-morbid or chronic conditions. For some of the proposed measures the documentation exists in the medical record now but is not currently being abstracted. Thus, it would take considerable extra effort to find and report it. We would expect that before any new measure would be adopted, it would already have achieved wide consensus as a quality measure.

3. Criteria and a mechanism for retiring or replacing measures in the current RHODAPU program. On the one hand, if a quality measure has been achieved by a majority of providers, that success should be reported and maintained. If that measure were dropped, providers could backslide and the regression would not be apparent. On the other hand, it is not practical to keep adding measure after measure forever. The process of collecting and reporting the data is very labor intensive. We would suggest that if a given measure is maintained at some threshold level for a defined period of time, then it should be retired.
4. Quarterly submission of data. This will be a hardship on small providers that only have one person collecting and reporting quality measures now. Nevertheless, we think quarterly submission makes sense.
5. Attestation of data. It is critical that every provider be given the opportunity to attest each quarter to the completeness and accuracy of their data.
6. Six priority conditions and other additional conditions (7) being considered as evidence that a provider should not be paid "extra" unless the condition were present on admission. The DRA specified that at least two conditions that are high cost/high volume be identified by October 1, 2007. It is shortsighted to think that every possible diagnosis will be identified upon admission. For instance, it is often not clear whether a urinary tract infection or septicemia is present on admission or not. This proposal demonstrates a lack of understanding of the need to assess a patient through a differential diagnosis and appropriate diagnostic testing. This testing often identifies the source of the patient's chief complaint. Moreover, pressure ulcers can develop even with the best possible care. MRSA is becoming more frequently acquired in the community than ever before and it is prohibitively expensive to test every patient upon admission to determine if they already have it. The same applies to c-diff. Some patients are so compromised that they will develop an infection regardless of our efforts to prevent it. The only possible events on the list that should never happen are wrong surgery and giving the wrong type of blood (blood incompatibility). All of the other events on the list should receive rigorous attention by every provider to minimize their occurrences, but if they should develop, providers should certainly be paid. If there are quality concerns at any particular provider, there are other mechanisms in place to address those concerns. We think that this entire effort should be dropped as a specious "quality" effort. This is nothing more than another attempt to decrease payments to providers.

Thank you for the opportunity to comment.



Alice L. Polley  
Vice President for Clinical Services  
Sturdy Memorial Hospital  
Attleboro, MA



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June 7, 2007

Mr. Tzvi Hefter  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 1488-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: Comments on Medicare Program; Proposed Changes to the Hospital  
Inpatient Prospective Payment Systems (IPPS) and Fiscal Year 2008 Rates;  
Proposed Rule

Dear Mr. Hefter:

We have the following comments on the proposed rule for changes to the hospital IPPS for fiscal year 2008, published in the May 3, 2007, Federal Register.

#### Indirect Medical Education (IME) Adjustment

In the proposed rule, CMS proposes to amend the regulations at 412.105(f)(1)iii(A) and 413.78(b) to specify that vacation and sick leave are not included in the determination of full-time equivalency (FTE) for IME and direct graduate medical (GME). This proposal was made because vacation and sick time does not meet the requirements of patient care time. The vacation and sick time would not be counted in either the numerator or the denominator used to determine a FTE.

We recommend that CMS allow vacation and sick time to be included in the determination of an FTE and that the regulations remain unchanged.

While the removal vacation and sick time from the numerator and the denominator of the FTE calculation may seem simple, it will prove to be impossible to make these calculations in many circumstances.

First, the determination of an FTE for medical education purposes is based on the amount of time it takes to fill one approved slot, so the denominator is not standard among specialties. Sometimes an FTE is measured in weeks, sometimes by days and sometimes by months. How would one day of sick time be taken from the FTE count? This could be done as a reduction based on a

Tzvi Hefter  
June 7, 2007  
Page 2

reduction of number of days in a week or a reduction to the entire days in a month. The results could be different, based on the assumption of how the denominator is counted.

Second, a teaching hospital may not have the documentation to make the reduction to the denominator. If this policy is to be applied, all sick and vacation time for the year would have to be removed from the numerator and denominator. While a hospital would presumably have documentation regarding the sick and vacation time spent by a resident during the rotation to that hospital, the hospital would not have the information for sick and vacation time taken by the resident during other rotations. Records for sick time and vacation time are kept by the sponsoring institution. If the denominator must be reduced for all sick and vacation time incurred by a resident, a hospital with resident rotations would have to obtain these records for the entire year in order to determine the denominator for its FTE count. We do not believe that CMS intends an annual reconciliation of vacation and sick time spent for each resident in order to determine the denominator of each resident FTE.

In addition, you have indicated that some providers would lose and some gain. We can only see providers losing. If a provider happens to have residents taking vacation or sick time at their facility, they will lose compared to prior year. We cannot see where any provider will gain over the prior year.

You have also indicated that vacation and sick time is a third category of time. We agree. We see the time as a fringe benefit which each intern and resident is entitled to under their employment contract. We believe this time should be included in both IME and DGME as it has been in the past. If necessary, an exception can be included in the regulations.

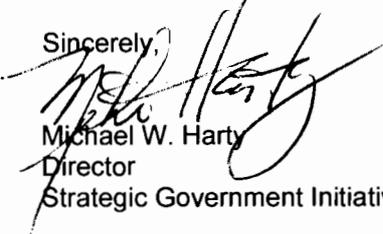
We reiterate our recommendation that the regulations remain unchanged with regard to vacation and sick time.

If CMS does make this change to the regulations, we recommend that the rule be date-specific as Oct 1, 2007, instead of for cost reporting periods beginning on or after Oct. 1, 2007. As we noted above, we do not see situations where a hospital would be advantaged by the policy, only situations where it would be disadvantaged. Hospitals with cost reporting periods beginning on Oct. 1, 2007, would receive the disadvantage for a longer time period than hospitals with other cost reporting periods. If the effective date was date-specific, any reimbursement effect would be experienced by all hospitals at the same time.

We appreciate the opportunity to comment on the proposed rule.

If you have any questions, please contact me at 312.297.5876.

Sincerely,



Michael W. Harty

Director  
Strategic Government Initiatives

107  
JUN 12 2007



Recovering hearts. Saving lives.

June 11, 2007

Ms. Leslie Norwalk  
Centers for Medicare and Medicaid Services  
ATTN: CMS-1533-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: Comments on CMS-1533-P, Changes to the Hospital Inpatient Prospective Payment System (“IPPS”) for Fiscal Year 2008**

Dear Ms. Norwalk:

ABIOMED welcomes the opportunity to provide the following comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule for changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 [CMS-1533-P], (hereinafter referred to as “proposed rule” or “NPRM”).

ABIOMED, Inc. develops, manufactures and markets medical technology designed to restore, recover or replace the pumping function of the failing heart. Established in 1981, ABIOMED is committed to putting patients first by providing a range of therapeutic medical devices aimed at supporting patients through acute heart failure and if necessary, through the final stages of life. Currently, ABIOMED manufactures and sells the AB5000™ Circulatory Support System and the BVS® 5000 Biventricular Support System for temporary support of patients with reversible acute heart failure. ABIOMED also manufactures and markets the IMPELLA® RECOVER® technology under the CE Mark outside the US. This family of technology includes minimally invasive cardiovascular support systems designed for circulatory support in the cardiac cath lab for high risk percutaneous coronary intervention (PCI) patients and devices for more aggressive support intraoperatively following cardiomy. ABIOMED is conducting clinical trials of the 2.5LP and 5.0LP IMPELLA in the U.S. The company’s AbioCor® Implantable Replacement Heart received designation as an HDE (“humanitarian device exemption”) in 2006.

**I. “DRG Reclassification” Abiomed supports CMS’ decision to propose a Medicare Severity Diagnosis-Related Group (MS-DRG) patient classification system to capture the variations in patient diagnosis and severity.** Abiomed is acutely aware of the complications and co-morbidities evidenced in patients who benefit from advance mechanical support for heart failure. Often, patients in acute heart failure present with a myriad of clinical conditions that advance quickly to multiple organ system failure without intervention. The proposed MS-DRG system is an effective method of capturing the complexity of patients who present with multiple conditions often associated with heart failure and we believe it is a much more reasonable and accurate system than proposed in FY 07.

Abiomed supports the inclusion of acute heart failure within the category of “Major Complications and Co-Morbidities” (“MCC”) and related efforts by CMS to track and publish hospital-specific mortality rates for acute myocardial infarctions. Abiomed does, however, ask that CMS clarify why certain MCC codes, e.g., 4275 (cardiac arrest) and 78551 (cardiogenic shock), require that the patient be discharged alive to be considered in the MCC category. On its face, it would seem that these patients are some of the most complicated patients to treat and should be classified among other MCC categories regardless of mortality. We are concerned that linking coding to survival outcomes will preemptively determine the choice of treatment and aggressiveness in clinical decision making should a hospital be concerned that valuable resources for heart failure patients will not be reimbursed if the patient dies. Hospitals may do less to revive patients with myocardial infarctions, for example, if they fear that expenditures will not be reimbursed. We strongly recommend that CMS provide further clarity and justification for its position that a very limited number of diagnoses – some representing the most significant hospital admissions and resource utilization – are to be linked to survival outcomes for coding.

**II. “New Technology” Abiomed believes it is critical that CMS maintain and improve incentives for the advancement of, and access to, innovative technologies in the context of new technology add-on payments.** One mechanism that would serve CMS’ goal of ensuring that the latest medical technology continues to be available to Medicare beneficiaries would be to increase the add-on payment levels to the levels recommended in the Medicare Modernization Act Conference Report to raise the add-on payment level from 50 to 80 percent of the difference between the standard DRG payment and the cost of the procedure with the new technology. Increasing the payment percentage would offer some stability and consistency for hospitals providing Medicare patients access to new technologies, and better ensure that the Medicare patient population continues to benefit from the latest medical technology that improves care.

**III. Abiomed recommends that CMS re-evaluate DRG 525 and take the following two actions:**

**(a) Abiomed recommends that CMS re-evaluate the appropriateness of including ICD-9 37.62 (“insertion of non-implantable heart assist system”) in DRG**

**525 (proposed MS-DRG 215), clarify what procedures ICD-9 37.62 includes, and re-assign ICD-9 37.62 to more accurately reflect hospital resource consumption of services involving mechanical support for cardiovascular failure.**

DRG 525 was created in the FY 03 Final Rule<sup>1</sup> to encompass a category of mechanical assist devices that had matured to reflect advanced support of the failing heart, both in acute and chronic states. Upon its creation, implantation of both pulsatile external (ICD-9 37.65) and implantable (ICD-9 37.66) devices were include in DRG 525. At the time, comments were raised as to whether it was appropriate to include ICD-9 37.62 within this DRG considering it reflected the use of centrifugal pumps in the operating room, a procedure more similar to cardio-pulmonary bypass. In recent years, there has been confusion as to the appropriate use of this code as other codes have been “created” from it. Abiomed appreciates that questions regarding this code back to the FY 95 Final Rule<sup>2</sup>; therefore, Abiomed requests that CMS once again clarify what procedures are to be coded by ICD-9 37.62 and if these procedures are to be limited to use in the operating room.

Commenters in the FY 03 Final Rule also raised concerns that including ICD-9 37.62, allegedly a centrifugal pump, in DRG 525 would lower the average reimbursement cost of DRG 525 due to its temporary support intra-operatively in contrast to other technologies in DRG 525 for longer term ventricular support. CMS’ response at the time was to continually review the DRG as new devices gained approval for use.<sup>3</sup>

Two subsequent changes to the inpatient rule have compounded the original concern of including ICD-9 37.62 in DRG 525: 1) the removal of ICD-9 37.66 (“insertion of implantable heart assist system”) from DRG 525 to DRG 103 in the FY 05 Final Rule; and 2) the removal of ICD-9 37.65 (“implant of external heart assist system”) with ICD-9 37.64 (“removal of heart assist system”) to DRG 103 in the FY 06 Final Rule. Both changes resulted in higher cost procedures moving out of DRG 525.

A review of the 06 MedPAR data indicates that only three codes are currently reflected in DRG 525 for a total of 150 procedures (see Chart 1). Nearly one-half of all procedures mapped to DRG 525 are in ICD-9 37.62 and the median total charges is less *than one half* that of other procedures. Abiomed recommends that CMS re-evaluate including ICD-9 37.62 in DRG 525 and requests that ICD-9 37.62 be moved in order that DRG 525 more accurately reflect the resource consumption of procedures involving ventricular support.

**Chart 1: Charge and LOS Comparisons for  
DRG 525**

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<sup>1</sup> 67 Federal Register 49990.

<sup>2</sup> 59 Federal Register 45330 (Sept. 1, 1994)

<sup>3</sup> 67 Federal Register 49991.

Principle Procedure	Number of Cases	LOS			Total Charges		
		Mean	Median	Max	Mean	Median	Max
3762	66	12	8	61	178,378	134,659	548,092
3763	25	13	9	39	310,377	248,123	1,133,422
3765	59	11	4	93	317,808	235,619	1,428,167

FY 2006 MedPAR data

**(b) Abiomed recommends that CMS move ICD-9 37.52 (“implantation of total replacement heart system”) from DRG 525 to DRG 103 (proposed MS-DRG 1 or MS-DRG 2) to more accurately reflect the grouping of procedures for the implantation of a total replacement heart system with heart transplantation and destination therapy to more accurately capture hospital resources for the care and treatment of end-stage heart failure and end-of-life care.**

The AbioCor® is the world’s first completely self-contained, internal replacement heart. The AbioCor® sustains the body’s circulatory system and mimics the function of the human heart. The complete system consists of an internal thoracic unit, an internal rechargeable battery, an internal miniaturized electronics package and an external battery pack, handheld alarm monitor and sophisticated computer console. The thoracic unit of the AbioCor®, weighing approximately two pounds, includes two artificial ventricles with corresponding proprietary artificial valves which provide a seamless blood path, as well as a motor-driven hydraulic pumping system.

AbioCor® was designated as a Humanitarian Use Device by the FDA’s Office of Orphan Product Development in September 2003. In September 2006, ABIOMED obtained approval of an HDE to market AbioCor®. The device— “[I]s indicated for use in severe biventricular end stage heart disease patients who are not cardiac transplant candidates and who

- are less than 75 years old
- require multiple inotropic support
- are not treatable by [Left Ventricular Assist Device] destination therapy, and
- are not weanable from biventricular support if on such support.”<sup>4</sup>

This indication limits the availability and use of AbioCor® to patients with end stage cardiac failure who are at imminent risk of death and for whom other treatment options are not available, including *heart transplantation or traditional “destination therapy.”* It is estimated that approximately 85% of all AbioCor patients will be Medicare beneficiaries.

Implantation of the device is to begin in the fall of 2007 under a post-market study at three U.S. facilities. Despite its very recent approval for market, ICD-9 codes for the implantation of a “total replacement heart system” pre-existed and pre-dated the

<sup>4</sup> H040006 approved September 5, 2006

<<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm>> [accessed May 3, 2007]

HDE designation; however, its inclusion in DRG 525 is inappropriate.<sup>5</sup> Based upon economic data from 14 patients in a clinical trial between 2001 and 2004, in-hospital costs per patient can average \$500,000 to \$1,000,000 with a length of stay approximately four to five months. Based upon our experience in the clinical trial and the common knowledge that AbioCor patients are as sick, if not sicker, than those suitable for transplantation or destination therapy, Abiomed recommends that CMS reassign ICD-9 37.52 (“implantation of total replacement heart system”) to DRG 103 (proposed as MS-DRG 1 or MS-DRG 2).

The following (see Chart 2) summarizes the mean and median charges associated with heart transplantation (ICD-9 37.51), external recovery devices (ICD-9 37.65 and 37.64) and implantable heart assist devices (ICD-9 37.66) all of which are included in DRG 103 and all of which more closely align with the charges and length of stay for AbioCor use.

**Chart 2: Performance of Heart Assist Devices and Heart Transplantation Procedures in DRG 103**

DRG	ICD9	Number of Cases	LOS			Total Charges		
			Mean	Median	Max	Mean	Median	Max
103	37.64 & 37.65	34	51	27	237	710,685	645,263	2,011,232
103	37.66 only	339	41	34	153	583,308	475,505	3,319,946
103	37.51 only	544	30	19	281	433,861	308,740	6,923,637
103	all 37.66	372	46	36	327	645,607	497,353	5,813,702
103	all 37.51	578	34	20	327	481,214	319,631	6,923,637

Abiomed notes that should CMS implement both recommendations for DRG 525 presented herein, that a very few remaining procedures would remain in DRG 525. To that end, Abiomed recommends that should CMS remove ICD-9 37.62 (“insertion of non-implantable heart assist system”) and ICD-9 37.52 (“implantation of total replacement heart system”) from DRG 525 that it concurrently consider removing the only remaining implant procedure, ICD-9 37. 65 (“implant of external heart assist system”) to DRG 103. This would result in DRG 525 remaining essentially a “repair” or “replacement” category of procedures which are increasingly important as mechanical devices are designed and used for longer periods of time.

Abiomed appreciates the opportunity to comment on the NPRM for the FY 08 inpatient rule and looks forward to working with CMS towards improvements in care for Medicare beneficiaries in need of advanced cardiac technology.

<sup>5</sup> No cases were coded to ICD-9 37.52 (“implantation of total replacement heart system”) in FY 06 MedPAR data.

Please contact me at [gmayes@abiomed.com](mailto:gmayes@abiomed.com) or 202-652-2281 should you have any questions regarding these comments.

Sincerely,

A handwritten signature in cursive script that reads "Gwen Mayes".

Gwen Mayes, JD, MMSc  
Director of Government Relations/Reimbursement  
ABIOMED, INC.



## Baxter Regional Medical Center

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The Ahrens Clinic  
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Foundation

*Member:*

Baxter Regional PHO, Ltd.

108

JUN 12 2007

June 8, 2007

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1533-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: CMS-1533-P  
May 3, 2007, IPPS Proposed Rule  
Submission of Comments

Dear Sir or Madam:

We appreciate this opportunity to comment on the inpatient PPS fiscal 2008 proposed rule published in the May 3, 2007, **Federal Register**. We are a rural referral center/sole community hospital located in north-central Arkansas. We operate 221 general inpatient beds and have over 60% Medicare inpatient utilization each year. Our comments are as follows:

### **DRG Reform and Proposed MS-DRGs**

CMS proposes a massive restructuring of the DRG system to comprehensively adjust DRGs for severity of illness. It is apparent CMS has done a tremendous amount of analysis to develop MS-DRGs, and it is difficult to argue with the logic of adjusting DRGS to better reflect the severity of patient illnesses.

CMS is charged by statute with making adjustments to standardized amounts to eliminate the effect of changes in coding or classification of discharges that do not reflect real changes in case-mix. We understand CMS has discretion to make standardized amount adjustments for changes that are likely to occur. However, absent strong evidence that such changes are likely, we urge CMS to avoid making negative adjustments to the standardized amount.

Several studies have shown that hospitals in general and rural hospitals in particular are suffering negative margins from treating Medicare patients. Hospitals cannot continue to sustain such negative margins without quality of care being impacted. Wherever CMS has discretion to adjust hospital payments, we urge restraint be used to avoid further damaging hospitals' financial conditions.

We recognize the difficulty CMS has in estimating the changes in case-mix that could occur under MS-DRGs due to improved documentation and coding by hospitals. However, hospitals have been documenting and coding secondary diagnoses since the implementation of DRGs in the early 1980s. To assume any significant increase in the coding of secondary diagnoses under MS-DRGs is, we believe, unwarranted.

CMS is proposing dramatic reductions in the standardized amount of 2.4% per year for the next two years to reflect the possible increase in case-mix under MS-DRGS

due to improved documentation and coding. CMS bases this proposal on an analysis of the changes in case-mix experienced by Maryland hospitals after implementing APR DRGs.

We are concerned with the magnitude of the proposed adjustment, based on the hypothetical assumption that implementation of MS-DRGs nationwide will mirror the implementation of APR DRGs in Maryland. We believe the differences between the two systems are significant enough that it is improper to conclude the case-mix changes will be similar under the two systems. In particular, CMS notes that APR DRGs are an all-payer system, applying to all third party payers, and that Maryland hospitals were provided with training and extensive feedback during the implementation of APR DRGs.

As hospitals have known for several years that CMS has been evaluating severity-adjusted DRGs, we believe some increase in coding is already built into the MS-DRG weights CMS proposes. The short timeframe between publication of a final rule in August 2007 and implementation on October 1, 2007, leaves little time for any additional improvement in coding within the next year.

CMS will be able to evaluate the first few months' data under MS-DRGs to determine the need for adjustment to FY2009 standardized amounts in next year's proposed rule. Such an adjustment could be based on actual data, rather than speculating on the need for such a dramatic adjustment for FY2008.

If after evaluating public comments this year, CMS determines an adjustment to the standardized amount is warranted, we recommend CMS reevaluate the approach used to determine the 4.8% adjustment proposed over the next two years. CMS has noted a dramatic case-mix increase of 9.6% for two teaching hospitals in Maryland, compared to a modest case-mix increase of only 3.2% for the rest of Maryland. CMS blends these two increases together based on 25% weighting for the teaching hospitals and 75% for other hospitals to arrive at the final 4.8% adjustment proposed.

If there is in fact such a dramatic difference between the improved documentation (and case-mix) experienced by teaching hospitals compared to nonteaching hospitals, CMS should develop separate factors for adjusting payments to each category of hospitals, rather than penalizing nonteaching hospitals. To maintain a single set of standardized amounts, CMS could remove the penalty on nonteaching hospitals either through a separate payment add-on for nonteaching hospitals, or through negative adjustment to MS-DRG weights for those MS-DRGs expected to be experienced disproportionately by teaching hospitals.

Smaller, nonteaching hospitals, and rural hospitals in general, will suffer particularly from the proposed FY 2008 changes. We believe that many of our patients do not have the additional complications to code, thus we will not participate in the anticipated coding creep. CMS' proposal will result in us being **penalized first** by the basic implementation of the MS-DRGs, and **penalized again** by the across the board 4.8% reduction in the standardized amount. We will be penalized for anticipated coding creep to which we will not contribute. Thus, we believe we should be protected from any adjustment to standardized amounts for anticipated documentation or coding improvements. This could be accomplished, at least for the rural hospitals, by a rural add on as is now present in other prospective payment systems.

Because of these various concerns with the MS-DRG proposal, we support the recommendation of the American Hospital Association for the adoption of a four-year transition period for these changes, to ensure that rural hospitals are adequately prepared for these significant changes.

One additional aspect of the documentation and coding adjustment is the impact on the hospital-specific rate update for sole community and Medicare-dependent hospitals. CMS does not formally state a budget neutrality factor for the hospital-specific rate and omitted it from the October 11, 2006 Final IPPS Rule.

As a general comment for future years, we request CMS formally state this factor in the IPPS proposed and final rules.

As a specific comment this year, we request CMS not apply the 2.4% documentation and coding adjustment to the hospital-specific rate. The biggest factor influencing this adjustment is the increased case-mix experienced by Maryland teaching hospitals. As very few sole community and Medicare-dependent hospitals are teaching hospitals, they should not be subjected to this adjustment in determining the budget neutrality factor applied to their hospital-specific rates.

Finally, CMS proposes an outlier fixed-loss cost threshold of \$22,940, compared to the current threshold of \$24,485. This reduction is due to the expected increased accuracy under the MS-DRG system. CMS reduces the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases, which CMS has estimated to be 5.1% for the last several years. As MS-DRGs should result in a significant improvement in payment accuracy, there should be a significant reduction in the number of outlier cases. We are concerned that CMS has not reduced the threshold enough. As actual payments have now been less than the 5.1% estimate for several years, we request CMS revise its approach and further reduce the fixed-loss cost threshold for fiscal 2008.

#### **DRGs: Relative Weight Calculations**

CMS reviews the results of the RTI study on charge compression. While we believe using cost report information to establish cost-based DRG weights represents an improvement over the previous charge-based weights, we recognize changes can be made to improve the cost reporting process.

We believe the flexibility to establish new standard cost centers can provide more accurate data for future DRG weight determinations. We also believe adjustment to revenue codes reported on standard UB-04 claims forms may also be appropriate to better match charges on claims forms with the charges (and costs) reported on the Medicare cost report.

With any proposed revisions to the Medicare cost report, we encourage CMS to recognize the primary use of the cost report is to determine an individual hospital's costs of treating Medicare patients. Over 1,200 critical access hospitals must be allowed the ability to properly report their costs to receive accurate reimbursement. Sole community and Medicare-dependent hospitals periodically are provided opportunities for new base years to determine hospital-specific payment rates, and many state Medicaid plans and other payers rely on cost report data to determine hospital reimbursement rates.

Thus, we ask CMS to proceed cautiously with any cost report changes to avoid unintended consequences for CAHs or other hospitals for which cost reports still determine a significant portion of current reimbursement.

#### **Replaced Devices**

CMS proposes to reduce the DRG payment in certain cases where a device is replaced without cost to the hospital for the device or with full or partial credit for the removed device. CMS proposes to apply this policy only to those DRGs where the implantation of the device determines the base DRG assignment and where the hospital receives a credit equal to 20 percent or more of the cost of the device.

The IPPS is, by design, a system of averages. The payments hospitals receive are designed to approximate the costs of treating an average patient with a specific condition. These averages already consider the true net costs incurred by hospitals to treat patients with replaced devices, without the need for a reduced DRG payment for such services. We request CMS not finalize this policy.

## **Wage Index**

In the Wage Data section of the proposed rule, CMS proposes to include contract labor for indirect patient care services in the FY2008 wage index. However, in the Wage Index section of the proposed rule, CMS does not appear to include these sections of the wage survey in the wage index computation. Specifically, Lines 9.03, 22.01, 26.01 and 27.01 of Worksheet S-3 should be included in Steps 2 and 3 of the wage index computation, if not already included.

## **Hospital Reclassifications and Redesignations**

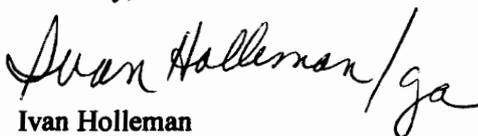
CMS has provided a great deal of flexibility to hospitals seeking reclassification to another area for wage index purposes. However, one problem remains over which the hospitals have no control. If hospitals qualify to reclassify to two different areas, they must choose one area as the primary reclassification location. Given fluctuations in wage index values, the primary area chosen one year may not be the preferable reclassification location in the actual year the reclassification takes effect. CMS should use its discretion to allow a hospital to reclassify to the best eligible location based on the proposed reclassified wage index published in the applicable IPPS proposed rule.

## **Hospital Quality Data**

While we see the value of reporting quality data, we are also concerned that hospitals should not be overwhelmed with continual expansion of the number and types of elements to be reported. As previously mentioned, hospitals are suffering from increasingly negative margins serving Medicare patients, and do not have the financial resources to comply with ever-increasing reporting requirements. Thus, we urge CMS to use restraint by not proposing any additional expansion to the quality reporting requirements in 2009.

We appreciate this opportunity to comment on these important proposals. If you have any questions concerning our comments or require further information, please contact me at 870-508-1003.

Sincerely,



**Ivan Holleman**  
Chief Financial Officer



JUN 12 2007  
109

VERMONT ASSOCIATION OF  
HOSPITALS AND HEALTH SYSTEMS

June 11, 2007

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS -1533 - P  
Mailstop: C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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 Sir or Madam:

I am commenting on behalf of the Vermont Association of Hospitals and Health Systems. Although our Association supports many of the proposed rule provisions we have significant concerns related to the implementation of the Medicare-Severity Diagnosis-related Groups (MS-DRGs). Additionally, we strongly oppose the behavioral offset and contend that there is no evidence which supports this payment reduction.

In Vermont there are fourteen acute care hospitals, of which eight are Critical Access Hospitals. The remaining six are reimbursed based on the prospective payment methodology, including one teaching hospital. The remaining five hospitals range in size from 50 to 100 beds. These five hospitals are at significant risk as they typically do not qualify for special payment provisions and have little ability to absorb cuts in reimbursement.

By moving to the MS-DRG system in conjunction with the behavioral offset the six Vermont hospitals reimbursed under the prospective payment system stand to lose approximately \$5 million in Medicare reimbursement. Although this may not seem like a large number in the "big picture," cuts of this magnitude combined with annual Medicare underpayments of \$50 million and annual Medicaid underpayments of \$64 million will create undue financial pressure on Vermont's health care delivery system.

Vermont hospitals strongly support the American Hospital Association's recommendations as outlined below and would ask you adopt these recommendations prior to implementing the MS-DRG system.

**Medicare-Severity Diagnosis-related Groups (MS-DRGs)** - We believe the MS-DRGs are a reasonable framework for patient classification, provided they are used for several years and other severity systems are no longer considered by CMS. We also recommend a four-year transition:

- FY 08 - No changes to payment; instead use the time to prepare: release a GROUPER and complication or co-morbidity list, test systems, give other payers like Medicaid a chance to catch up, and educate the hospital field.
- FY 09 - Pay based on one-third MS-DRGs and two-thirds "old" DRGs.
- FY 10 - Pay based on two-thirds MS-DRGs and one-third "old" DRGs.
- FY 11 - Pay based fully on MS-DRGs.

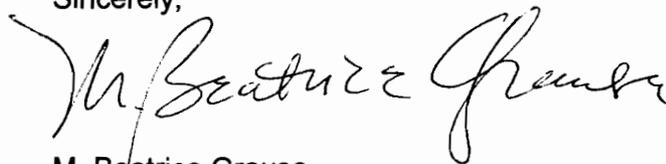
**Behavioral Offset** - We are opposed to the "behavioral offset," which will cut payments nationally to hospitals by \$24 billion over the next five years. We do not believe that this cut is warranted - it is a backdoor attempt at budget cuts. Hospitals have operated under the current inpatient DRG 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.

**Capital PPS** - We oppose the cuts to the capital inpatient PPS and the possibility of future capital indirect medical education and disproportionate share hospital payment cuts. These cuts are unprecedented, were not asked for by Congress, and will disrupt hospitals' ability to meet their existing long-term financing obligations for capital improvements. The cuts also could impede the adoption of information technology, clinical research and upgrades to hospital infrastructure.

We understand and appreciate the Administration's desire to create a fair, accurate Medicare payment system. We believe that an essential component of a fair, accurate payment system is payment that covers the cost of care. Medicare PPS payments to Vermont hospitals however, already fail to cover the cost of care. If this rule goes into effect, Medicare payments to our PPS hospitals will overall be significantly reduced. We plan to work with CMS to address our overall payment issue. Delaying this proposed rule is an important part of trying to preserve current Medicare payment levels until payment improvements can be more fully understood and implemented.

If you have any questions, please do not hesitate to contact M. Beatrice Grause, VAHHS President and CEO at (802) 223-3461 ext. 112 or [Bea@vahhs.org](mailto:Bea@vahhs.org). In addition, Michael Del Trecco, VAHHS VP of Finance can be contacted as well. His email is [Mike@vahhs.org](mailto:Mike@vahhs.org) and his extension is 103. Thank you for your time and consideration of these important issues.

Sincerely,



M. Beatrice Grause,  
President and CEO

June 11, 2007

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1533-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: CMS-1533-P  
May 3, 2007, IPPS Proposed Rule  
Submission of Comments

Dear Sir or Madam:

We appreciate this opportunity to comment on the inpatient PPS fiscal 2008 proposed rule published in the May 3, 2007, **Federal Register**. We are a rural referral center/Medicare-dependent hospital located in central Missouri. We operate 100 beds and have approximately 65% Medicare inpatient utilization each year. Our comments are as follows:

### **DRG Reform and Proposed MS-DRGs**

CMS proposes a massive restructuring of the DRG system to comprehensively adjust DRGs for severity of illness. It is apparent CMS has done a tremendous amount of analysis to develop MS-DRGs, and it is difficult to argue with the logic of adjusting DRGs to better reflect the severity of patient illnesses.

CMS is charged by statute with making adjustments to standardized amounts to eliminate the effect of changes in coding or classification of discharges that do not reflect real changes in case-mix. We understand CMS has discretion to make standardized amount adjustments for changes that are likely to occur. However, absent strong evidence that such changes are likely, we urge CMS to avoid making negative adjustments to the standardized amount.

A recent study commissioned by the Missouri Hospital Association demonstrated that the 80 general acute-care hospitals in the state lost an average of \$1.9 million each on Medicare inpatient services during the most recent year of data available, for cost reporting periods beginning in federal fiscal 2005. This represents a deterioration of 40% over the negative inpatient margin experienced in the previous year. The negative Medicare outpatient, skilled nursing and home health margins average an additional \$2.1 million for each Missouri hospital.

Hospitals cannot continue to sustain such large negative margins serving Medicare patients without quality of care being impacted. Wherever CMS has discretion to adjust hospital payments, we urge restraint be used to avoid further damaging hospitals' financial conditions.

We recognize the difficulty CMS has in estimating the changes in case-mix that could occur under MS-DRGs due to improved documentation and coding by hospitals. However, hospitals have been documenting and coding secondary diagnoses since the implementation of DRGs in the early 1980s. To assume any significant increase in the coding of secondary diagnoses under MS-DRGs is, we believe, unwarranted.

CMS is proposing dramatic reductions in the standardized amount of 2.4% per year for the next two years to reflect the possible increase in case-mix under MS-DRGs due to improved documentation and coding. CMS bases this proposal on an analysis of the changes in case-mix experienced by Maryland hospitals after implementing APR DRGs.

We are concerned with the magnitude of the proposed adjustment, based on the hypothetical assumption that implementation of MS-DRGs nationwide will mirror the implementation of APR DRGs in Maryland. We believe the differences between the two systems are significant enough that it is improper to conclude the case-mix changes will be similar under the two systems. In particular, CMS notes that APR DRGs are an all-payer system, applying to all third party payers, and that Maryland hospitals were provided with training and extensive feedback during the implementation of APR DRGs.

As hospitals have known for several years that CMS has been evaluating severity-adjusted DRGs, we believe some increase in coding is already built into the MS-DRG weights CMS proposes. The short timeframe between publication of a final rule in August 2007 and implementation on October 1, 2007, leaves little time for any additional improvement in coding within the next year.

CMS will be able to evaluate the first few months' data under MS-DRGs to determine the need for adjustment to FY2009 standardized amounts in next year's proposed rule. Such an adjustment could be based on actual data, rather than speculating on the need for such a dramatic adjustment for FY2008.

If after evaluating public comments this year, CMS determines an adjustment to the standardized amount is warranted, we recommend CMS reevaluate the approach used to determine the 4.8% adjustment proposed over the next two years. CMS has noted a dramatic case-mix increase of 9.6% for two teaching hospitals in Maryland, compared to a modest case-mix increase of only 3.2% for the rest of Maryland. CMS blends these two increases together based on 25% weighting for the teaching hospitals and 75% for other hospitals to arrive at the final 4.8% adjustment proposed.

If there is in fact such a dramatic difference between the improved documentation (and case-mix) experienced by teaching hospitals compared to nonteaching hospitals, CMS should develop separate factors for adjusting payments to each category of hospitals, rather than penalizing nonteaching hospitals. To maintain a single set of standardized amounts, CMS could remove the penalty on nonteaching hospitals either through a separate payment add-on for nonteaching hospitals, or through negative adjustment to MS-DRG weights for those MS-DRGs expected to be experienced disproportionately by teaching hospitals.

Smaller, nonteaching hospitals, and rural hospitals in general, will suffer particularly from the proposed FY 2008 changes. We believe that many of our patients do not have the additional complications to code, thus we will not participate in the anticipated coding creep. CMS' proposal will result in us being penalized first by the basic implementation of the MS-DRGs, and penalized again by the across the board 4.8% reduction in the standardized amount. We will be penalized for anticipated coding creep to which we will not contribute. Thus, we believe we should be protected from any adjustment to standardized amounts for anticipated documentation or coding improvements. This could be accomplished, at least for the rural hospitals, by a rural add on as is now present in other prospective payment systems.

Because of these various concerns with the MS-DRG proposal, we support the recommendation of the American Hospital Association for the adoption of a four-year transition period for these changes, to ensure that rural hospitals are adequately prepared for these significant changes.

One additional aspect of the documentation and coding adjustment is the impact on the hospital-specific rate update for sole community and Medicare-dependent hospitals. CMS does not formally state a budget neutrality factor for the hospital-specific rate and omitted it from the October 11, 2006 Final IPPS Rule. As a general comment for future years, we request CMS formally state this factor in the IPPS proposed and final rules.

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Finally, CMS proposes an outlier fixed-loss cost threshold of \$22,940, compared to the current threshold of \$24,485. This reduction is due to the expected increased accuracy under the MS-DRG system. CMS reduces the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases, which CMS has estimated to be 5.1% for the last several years. As MS-DRGs should result in a significant improvement in payment accuracy, there should be a significant reduction in the number of outlier cases. We are concerned that CMS has not reduced the threshold enough. As actual payments have now been

less than the 5.1% estimate for several years, we request CMS revise its approach and further reduce the fixed-loss cost threshold for fiscal 2008.

### **DRGs: Relative Weight Calculations**

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Thus, we ask CMS to proceed cautiously with any cost report changes to avoid unintended consequences for CAHs or other hospitals for which cost reports still determine a significant portion of current reimbursement.

### **Replaced Devices**

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While we see the value of reporting quality data, we are also concerned that hospitals should not be overwhelmed with continual expansion of the number and types of elements to be reported. As previously mentioned, hospitals are suffering from increasingly negative margins serving Medicare patients, and do not have the financial resources to comply with ever-increasing reporting requirements. Thus, we urge CMS to use restraint by not proposing any additional expansion to the quality reporting requirements in 2009.

We appreciate this opportunity to comment on these important proposals. If you have any questions concerning our comments or require further information, please contact me at 573-348-8388.

Sincerely,



Dan Probstfield  
Senior Vice President/Chief Financial Officer

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JUN 12 2007

**NewYork-Presbyterian**  
The University Hospital of Columbia and Cornell

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President and  
Chief Executive Officer

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525 East 68<sup>th</sup> Street  
New York, NY 10021

June 11, 2007

Leslie V. Norwalk, Esq.  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1533-P  
Mail Stop C4-26-05,  
7500 Security Boulevard  
Baltimore, MD 21244-1850

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

Dear Ms. Norwalk:

As President and CEO of NewYork-Presbyterian Hospital (NYPH), I appreciate the opportunity to comment on the proposed changes to the Medicare Inpatient Prospective Payment System (PPS) published in the Federal Register on May 3, 2007.

**DRG Reclassifications (2.4% reduction):**

The proposed rule includes a reduction to the Inpatient PPS standardized amounts and Capital Federal rate by 2.4 percent each year for FY 2008 and FY 2009. An additional comment states that the Center for Medicare & Medicaid Services (CMS) is also considering proposing a 4.8 percent adjustment for FY 2008, and seeks comment on whether the proposed adjustment should be in a single year, over 2 years or in different increments than one-half of the adjustment each year.

The basis for this action is the presumption of "behavioral change" on the part of the coding and/or physician documentation practices, based on evidence from the Maryland experience with APR-DRGs. We challenge this foundation of Maryland experience for several reasons, the first of which has to do with profound uncertainty surrounding the newly revised Complications and Co-Morbidities (CC) list. CMS specifically informs us in the proposed rule that the percentage of patients "with no CCs" will increase dramatically under MS-DRGs, from 22% to 60%. With such a drastic increase in the proportion of patients without even a single CC, there clearly exists no prior experience for CMS to point to what would justify the "behavioral change" penalty CMS has proposed. Furthermore, the case mix increases observed in Maryland resulted in large measure, we believe, from increased coding of conditions which CMS *no longer* includes on the newly revised "cc-list". To substantiate this point, we reviewed four years of data from 2003 through 2006 for two of Maryland's major teaching hospitals, focusing on high-volume secondary diagnoses from the current CC list which are not CCs on the revised CC list. Our analysis found increases in selected high-volume secondary diagnosis coding as follows:

- 10% for Congestive Heart Failure (428.0)
- 26% for Mitral and Aortic Valve Disorders (424.0, 424.1)
- 13% for Atrial Fibrillation (427.31)
- 44% for Chronic Obstructive Asthma (493.20)
- 9% for Other Convulsions (780.39)

We acknowledge that these increases in coded secondary diagnoses contributed to “case mix creep” as observed in Maryland. However, these diagnoses will no longer be CCs under the proposed rule, and it is therefore unclear how CMS can continue to justify using the “Maryland experience” as the foundation for the “behavioral change” adjustment.

The concept of “behavioral changes,” while a real possibility for some facilities, does not justify applying the reduction to all hospitals in all states, especially prior to the availability of any substantial evidence for a larger sample population.

We point to New York State as an example where it is highly unlikely that such a “behavioral change” would occur, especially in contrast to Maryland. New York has utilized for non-Medicare payors, the AP-DRG methodology since 1988. Not long thereafter, a severity split, which incorporated CC’s and Major CC’s, was implemented. The New York State methodology is clearly analogous to the MS-DRG methodology currently proposed. For those hospitals in New York State, MS-DRGs appears to be a close copy of AP-DRGs in terms of methodology.

CMS has stated that their Major CC definitions were formed as the intersection of Major CC’s from the AP-DRG (New York State) grouper and certain severity levels from the APR-DRG grouper. This means that there are no “new” Major CC diagnoses for any hospital in New York State, and, in fact, that the population of potential Major CC diagnoses is actually lessened.

Since New York State hospitals have already been using a multi-tier methodology, and since there are no “new” diagnoses to capture in order to qualify as Major CC DRG under MS-DRGs, it logically follows that there will be no “behavioral change” for hospitals in New York State, because nothing has really changed.

It is also vitally important to remember that New York State is one of the top three states in terms of Medicare population (evidenced by the CMS RAC program’s focus on California, Florida, and New York). Therefore, it is especially important to consider the level of state and national impact if the assumption of CMI creep for New York State and other AP-DRG states is invalid. 3M has informed us that Indiana, Maine, Massachusetts, New Jersey, North Carolina, Virginia, Washington State and Washington, DC also use some form of AP-DRGs. The same logic used for New York State would apply to these states.

Equally, many non-Maryland hospitals have been using the APR-DRG grouper, even though it may not have had any direct impact in terms of reimbursement. The APR-DRG grouper is an excellent tool for measurement of Severity of Illness and Risk of Mortality. The APR-DRG grouper provides hospitals, which are strongly focused on Quality and Outcomes, with a powerful source of data for knowledge and improvement. Again, since the proposed MS-DRG grouper methodology incorporates an element of the APR-DRG SOI levels in determining which diagnoses will qualify as “Major CC’s, there is virtually zero likelihood of “behavioral

change” for hospitals currently using the APR-DRG grouper; there is nothing “new” to implement, either in terms of coding or documentation.

Finally, we contest the Maryland experience as a valid predictor of case mix change because it does not account for the migration of the least complex patients from inpatient to ambulatory settings. It is well known to MEDPAC and other experts that improvements in treatments and technologies, especially minimally invasive procedures, are driving this migration. In addition, third-party payors (and CMS intermediaries) are increasingly contesting payment for the inpatient setting. While we understand and support this trend for patients that can be safely treated as outpatients, it is nevertheless worth noting that this dynamic upsets the balance explicitly intended for the original DRG system, whereby hospitals would “win” financially on some patients in a given DRG and “lose” on others. It does this by removing the financial “winners” from the equation. For policy-makers who routinely seek to understand and manage incentives, we respectfully suggest it be carefully considered whether Maryland’s conversion to APR-DRGs could have altered incentives in regard to inpatient versus outpatient designation. We maintain that by differentiating for severity, and assigning lower cost weights to the least complex patients, any theoretical incentives to maintain these as inpatient cases would be sharply diminished. We also point out that case mix migration as suggested above would be more likely with the Maryland “early adoption” teaching hospitals, due to their presumably advanced adoption of new technology, and this phenomenon likely explains some portion of the excessive case mix increase seen among that group.

For the above reasons, we strongly recommend that the planned FY 2008 2.4 percent reduction be eliminated, or at least postponed, until there is large scale, empirical data available to support such a cut.

#### **Capital IPPS:**

Since the inception of the Capital Prospective Payment System in FY 1992, CMS has provided a 3 percent add-on to the Capital federal rate for hospitals that are located in “large urban” areas, and also has provided for Indirect Medical Education (IME) and Disproportionate Share (DSH) capital adjustments. In addition, an update factor has been applied annually to the Capital federal rate, which in this proposed rule, CMS plans to eliminate for urban areas. This proposed rule also eliminates the “large urban” add-on as well as the IME and DSH capital adjustments. These capital cuts are devastating to NYPH, since the PPS for inpatient capital costs uses DRGs in its payment formula, and the 2.4 percent cut referenced above, will already reduce capital payments to NYPH. **Therefore, CMS is proposing that NYPH will face a 2.4 percent cut to the base Capital rate, no urban update factor, elimination of the large urban add-on, elimination of the IME capital adjustment and elimination of the DSH capital adjustment.**

The basis for CMS’s proposals to eliminate the urban update, large urban add-on, and the IME and DSH adjustments was that CMS observed that large urban, teaching, and DSH hospitals had higher-than-average capital PPS margins from 1996–2004, which led to a concern that perhaps these payment adjustments were in excess. Large urban, teaching, and high-DSH hospitals have been in a lower-spending phase of their capital cycle than other hospitals. This is possible, since the capital cycle is roughly 20 years, far longer than the 8-year study period. To the extent that this is the case, cutting the payment adjustments would violate the promise of the capital PPS, which was that hospitals could accumulate surpluses during their low-spending phases to supplement merely average payments when they re-entered the high-spending phase.

These proposed cuts to capital payments would make it more difficult to purchase the advanced technology, equipment and clinical information systems that are critical to delivering the highest level of patient care, and could have the effect of slowing clinical innovation. Capital cuts of this magnitude will also disrupt the ability of the hospital to meet existing long-term financing obligations. NYPH has committed to capital improvements under the expectation that Medicare's PPS for capital-related costs would remain a stable source of income. Reducing capital payments creates significant financial difficulties for an innovative and cutting edge hospital such as NYPH and we hereby strongly recommend that these proposals be reconsidered.

**IME Adjustment:**

Time spent by residents on vacation and sick leave has always been included in the calculation of an FTE for both IME and direct GME purposes. In the May 3, 2007 proposed rule, CMS has proposed that vacation and sick leave should not be included in the determination of what constitutes an FTE resident (or would be removed from both the numerator and denominator of the FTE count) for both IME and GME payment purposes effective with cost report periods beginning on or after October 1, 2007. While this proposal seems to have a very small effect on individual resident FTE counts for reimbursement purposes, the work that will be needed to calculate appropriate FTE counts will be monumental.

For the recently filed 2006 Medicare cost report (cost report year January 1, 2006 through December 31, 2006), NYPH reported resident rotation time for 2,362 different residents. This proposal would require NYPH to maintain a vacation database for all 2,362 residents, and would require that the vacation history of residents be communicated to and from a rotating hospital so that both hospitals had the same definition of what defined an FTE. Failure to transfer this vacation history properly could lead to inaccurate FTE counts between two hospitals rotating the same resident.

Further analysis of the proposal reveals that inequities could occur as to sponsoring hospitals that typically pay for vacation time, and the benefit that accrues from this proposal for rotating hospitals that receive residents from the sponsoring hospital. Consider the following example for a sponsoring department at Hospital A with 12 residents that rotates a different resident to rotation Hospital B each month. At all times Hospital B has one resident from the sponsoring Hospital A assigned to its facility, therefore under the current regulations at year end, Hospital B's FTE count is 1.00 FTE. This is a common rotation cycle that ensures coverage for Hospital B. Hospital A as the sponsoring institution is paying for the resident's vacation time and is therefore claiming all of the remaining time. Under the current regulations, Hospital A would claim the remaining 11 FTEs.

Following the new methodology in the proposed rule, since a resident is always at Hospital B, the FTE count for the year for Hospital B would be 1.083 FTEs since there were 365 days covered at Hospital B yet the FTE denominator would only be 337 days (365 days less 28 vacation days). The FTE count at Hospital A would decrease for each resident since 28 vacation days would need to be removed from the numerator and denominator of Hospital A's FTE count. As such Hospital A's FTEs would be calculated as follows:

$$[(11 \text{ Residents} * 365 \text{ days}) \text{ less } (12 \text{ Residents} * 28 \text{ Vacation Days})] / (\text{FTE denominator of } 337 \text{ days}) = 10.917 \text{ FTEs}$$

While Medicare policy has been that the resident's salary payment should not be the criteria for determining GME reimbursement, the above example clearly demonstrates that the hospital that has absorbed the vacation

Leslie V. Norwalk, Esq.  
June 11, 2007  
Page 5

payment will be hurt by the proposed rule, thereby not matching third party reimbursement to the cost incurred. The policy of matching costs to reimbursement is an inherent principle of third party reimbursement and should have been considered when CMS proposed this change.

The time recording effort due to the proposed rule is further complicated because NYPH's cost report is filed on a calendar year basis, while the resident year typically runs from July 1 through June 30 each year. For example, a resident starting his residency on July 1, 2008 could take all four weeks (28 days) of his vacation time between July 1 and December 31, 2008, and therefore his FTE count for the 2008 cost report would be 0.462 FTEs (184 days less 28 vacation days divided by 366 days less 28 vacation days). Continuing this residency into the next cost report year 2009, the residents would have no vacation days left for the period of January 1, 2009 through June 30, 2009 and could decide not to take any vacation during the first part of his second residency year from July 1, 2009 through December 31, 2009. As such this resident would need to be calculated as 1.083 FTE for the 2009 cost report since the resident worked all 365 days in the year 2009, yet the FTE definition would be 337 days (365 days less the 28 day vacation allotment). Medicare's policy of not counting any resident for more than 1 FTE in a year will need to be altered for situations such as this if the proposed rule were to become final.

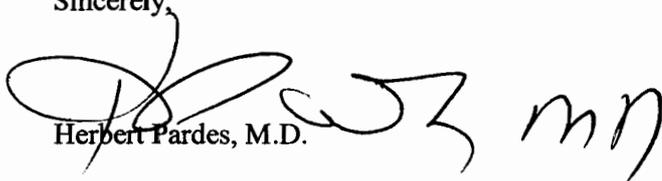
Lastly, a comment on the impact to the Medicare Intern and Resident Information System (IRIS) is warranted. While the official CMS position is that IRIS is not a sufficient mechanism for hospitals to meet their obligation to furnish information to support the FTE resident counts, in practice and reality, IRIS is the tool used by most hospitals. Since the proposed rule would require that the vacation and sick time would need to be eliminated from both the numerator and the denominator, updates will be needed to the IRIS software programs used by hospitals to develop the appropriate FTE counts. Current IRIS software uses a full 365 day year to calculate an FTE. The proposed rule will require that the software allow for the flexibility to define an appropriate FTE net of vacation and sick time.

Examples such as those above demonstrate that the proposal to remove vacation and sick time from the numerator and the denominator of the FTE count is not sound and should not be made as part of the final rule. In addition, the proposal creates additional non-productive work and costs that could alternatively be spent on providing direct patient care and not more paperwork.

Again, I very appreciate the opportunity to comment and look forward to further dialogue on these crucial issues.

All the best.

Sincerely,



Herbert Pardes, M.D.



112  
JUN 12 2007

*Taking your health personally*

June 11, 2007

Leslie V. Norwalk, Esquire  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS – 1533 – P  
Mailstop: C4 – 26 – 05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: CMS Proposed Inpatient Prospective Payment System Rule

Dear Ms. Norwalk:

As members of the Sun Health Board of Directors and, more importantly, as citizens of the communities served by this non-profit healthcare organization, we are extremely concerned about the impact on our two community hospitals – Sun Health Boswell Hospital and Sun Health Del E. Webb Hospital – of the proposed funding reductions in the Centers for Medicare & Medicaid Services (CMS) FY 2008 Medicare Inpatient PPS Proposed Rule released on April 13.

As proposed, the joint “behavioral offset” and reductions to capital payments would result in a combined loss for both hospitals of \$3,436,247 in FY 2008 alone. These cuts would have the effect of almost *quadrupling* the bottom-line loss of \$1.3 million Sun Health recorded on its healthcare operations in 2006! This rule change would cause immediate financial hardship for the organization as it strives to serve the needs of one of the largest concentrations of Medicare beneficiaries in the nation – needs that are requiring the expansions of both facilities just to keep pace with current demand.

What is of even greater concern is that these reductions become permanent and compound in subsequent years. The cumulative impact for FYs 2008-2012 becomes devastating: a combined loss for Sun Health’s hospitals of \$30,730,006. (Specifics of these losses for each hospital are included in the attached document.) These reductions are both unwarranted and unreasonable; they threaten the very ability not only of Sun Health’s hospitals to care for tens of thousands of elder citizens but also hospitals across the United States to care for millions of other Americans.

We urgently ask you to withdraw this proposed rule from consideration. For too long, our hospitals have been forced to shoulder cuts in appropriations needed to provide the quality of service deserved by the American people. This rule would be yet another example of that hardship. It must not be implemented.

For the Sun Health Board of Directors,

Sandra L. Foell  
Chairman of the Board

Leland W. Peterson, FACHE  
President/CEO

Attach: FY2008 Medicare Inpatient PPS Proposed Rule  
(shows impact on Sun Health Boswell Hospital and Sun Health Del E. Webb Hospital)

FY 2008 Medicare Inpatient PPS Proposed Rule  
 One Year and Five Year Impact of Selected Provisions  
 (2.4% behavioral offset, freeze in capital payments for all urban hospitals and elimination of large urban capital add-on)

Provider Number	Hospital Name	City	CD	FY 2008 Impact			FY 2008-12 Impact		
				Behavioral Reduction to Offset	Capital	Combined Loss	Behavioral Reduction to Offset	Capital	Combined Loss
30061	SUN HEALTH BOSWELL HOSPITAL	SUN CITY	AZ02	-1,850,303	-410,568	-2,260,871	-17,267,009	-2,947,258	-20,214,267
30083	SUN HEALTH DELE WEBB HOSPITAL	SUN CITY WEST	AZ02	-985,086	-210,291	-1,175,376	-9,006,169	-1,508,570	-10,515,739
Sun Health Corporation Total				-2,815,389	-620,858	-3,436,247	-26,273,178	-4,456,828	-30,730,006

Source: AHA analysis of FY 2008 proposed inpatient PPS rule and payment impact file. Capital column includes capital impact of behavioral offset.



**Dartmouth-Hitchcock Medical Center**  
Mary Hitchcock Memorial Hospital

Fiscal Services  
One Medical Center Drive  
Lebanon, New Hampshire 03756  
603-653-1155

June 5, 2007

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1533-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: DRG: Relative Weight Calculations

The purpose of this letter is to comment on the CMS proposed rule concerning the Hospital Inpatient Prospective Payment System as published in the Federal Register of Thursday, May 3, 2007.

By way of background, the Dartmouth-Hitchcock Medical Center (DHMC) is comprised of Mary Hitchcock Memorial Hospital, a 337 bed teaching hospital, the Dartmouth-Hitchcock Clinic, a large academic group practice, Dartmouth Medical School, and the Veterans Administration Hospital. Mary Hitchcock is the only academic tertiary care hospital in the state of New Hampshire, and is one of only a few major rural teaching hospitals in the country.

We would like to take this opportunity to express our concerns with how the current relative weights are being calculated. While we are in agreement with the CMS proposal to expand the number of cost center groupings, we are very concerned about how CMS would accomplish this with the current structure of the cost report. The cost to charge ratios, calculated on the cost report, do not account for the differences in mark-ups for high cost versus low cost services & supplies. Both the Severity Based DRG system and the Outpatient Prospective Payment System require a more detailed level of cost information. We recommend that CMS assign a task force to overhaul the cost report. The task force should include participants from the hospital community as well as the fiscal intermediary.

Thank you for consideration of these comments.

Sincerely,



Robin F. Mackey  
Director of Corporate Accounting & Reimbursement



June 11, 2007

JJA

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Mail Stop: C4-26-05  
Baltimore, MD 21244-1850

Via: UPS Delivery and  
<http://www.cms.hhs.gov/eRulemaking>

**Edward T. Karlovich**  
Chief Financial Officer  
Academic and Community  
Hospitals

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[karlovichet@upmc.edu](mailto:karlovichet@upmc.edu)

ATTENTION: CMS-1533-P

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 Sir or Madam:

On behalf of the University of the Pittsburgh Medical Center (UPMC) we are submitting one original and two copies of our comments regarding the Center for Medicare and Medicaid Services (CMS) proposed rule (Federal Register / Vol. 72, No. 85 / May 3, 2007 pages 24680 - 25135) "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule". We also are submitting these comments electronically to <http://www.cms.hhs.gov/eRulemaking>.

The following is a brief summary of the UPMC position and concerns regarding the major provisions of the FY2008 proposed rules, with more detailed responses in subsequent pages.

1. MS-DRG's Medicare Severity Diagnosis Related Groups (FR Page 24689)

While UPMC supports the continued efforts of CMS in the development of a severity adjusted DRG payment system, we are concerned that implementation and training costs associated with an interim system (MS-DRGs) would be detrimental to hospitals. UPMC suggests that it would be more beneficial to delay implementation until the study being conducted by Rand Corporation with an expected completion date of September 2007 is reviewed and an Inpatient Prospective Payment System is selected by CMS. When the system selection is finalized by CMS we recommend a four-year implementation period.

## 2. Case Mix Budget Neutrality Adjustment (FR Page 24710)

UPMC does not support the proposed “behavioral” case mix budget neutrality adjustment of 2.4% to FY2008 and FY 2009. This change is grounded on the belief that with the implementation of MS-DRGs hospitals would change coding practices resulting in higher payments. Not even in the initial years of the IPPS was coding change found to be of the magnitude of CMS’s proposed FY08 and FY09 cuts. There is no relevant data or experience to support a prospective 2.4 percent cut for anticipated behavioral changes in each of the next two years. MS-DRGs are simply a refinement of a classification system that hospitals have been using for 23 years. Hospitals already are coding as carefully and accurately as possible and have little ability to change their classification and coding practices. The rationale for the reduction is based on the recent transition of Maryland hospitals, which are excluded from Medicare’s IPPS, to a completely new type of classification and coding system known as All Patient Refined DRGs (APR-DRGs). MS-DRGs and APR-DRGs are two completely different systems for classifying patients and generalizing from one to the other is inappropriate.

## 3. MS-DRG Implications to the Inpatient Psychiatric PPS (FR Page 24976)

UPMC urges CMS to carefully consider the implication of its proposed MS-DRG changes on the inpatient psychiatric facility PPS; specifically, the DRGs for alcohol/drug use and the changes to the Complication and Comorbidity (CC) list (i.e. diabetic, renal and cardiac CCs). Note: We have also proposed CC reinstatements in issue 15.

## 4. Wage Index for Multicampus Hospital (FR Page 24783)

UPMC does not object to the proposed use of campus FTEs for the allocation of wages and hours for multicampus hospitals, but we would urge CMS to give providers the option of using the FTE allocation split or actual wage and hour data splits if available.

## 5. Capital Adjustment for Case Mix Index (CMI) change from the Proposed MS-DRGs and “Behavior Offset” (FR Page 24846)

UPMC does not support the proposed rule to reduce the capital Federal payment rate by the same case mix budget neutrality adjustment of 2.4% as proposed to the Federal Operating rate. For years the Medicare program has paid for its share of capital related costs of inpatient hospital services. This historical practice has allowed hospitals to purchase advanced technology and equipment which consumers have the right to expect. This adjustment would reduce the capital rate jeopardizing the hospital’s ability to continue to care for patients.

## 6. Establish Two separate Capital Federal Rates, one for Urban Capital and another for Rural Capital (FR Page 24846)

UPMC strongly urges CMS to remove the proposal of two separate capital Federal rates for FY2008. The proposed separation of urban and rural Federal rates and the elimination of a capital update for urban hospitals in FY2008 and FY2009 go against long standing principles and practices that Medicare adopted when implementing capital prospective payments in FY1992. The proposed rule would freeze capital payments for all hospitals in urban areas. These proposed changes would make it more difficult to purchase advance technology and equipment, and could have the effect of slowing clinical innovation. UPMC has made long term commitments to capital acquisitions and capital reductions of this magnitude will disrupt the ability of some of our hospitals to meet their existing long- term financing obligations. We have committed to these improvements under the expectation that Medicare's IPPS for capital related costs would remain a stable source of income. Reducing capital payments will create significant financial difficulties for our hospitals and we ask that it be removed from the proposed rule.

7. Elimination of Large Urban Capital Add-on of 3 Percent (FR Page 24822)

UPMC does not support the elimination of the large urban capital add-on of three percent. The elimination of this add on adjustment would disrupt the ability of large urban teaching hospitals to meet their long-term financial obligations. Hospitals cannot sustain-additional cuts in an already under-funded system. According to the Medicare Payment Advisory Commission overall Medicare margins will reach a ten-year low of a negative 5.4 percent in 2007. Therefore, we urge CMS to not eliminate the 3% capital add-on for large urban hospitals.

8. Proposal to Eliminate Capital Teaching and Capital Disproportionate Share Add-ons in the Near Future (FR 24822)

UPMC strongly opposes CMS's proposal that capital payments for teaching and disproportionate share hospitals are excessive and need to be reduced or eliminated. UPMC's innovative and cutting edge teaching hospitals need to make significant capital investments in order to update facilities, purchase high tech equipment, and update information systems required to provide the environment necessary to administer and maintain medical education programs, provide free and subsidized care for an increasing number of uninsured patients, as well as, to better care for an aging population. Medicare margins are projected by MedPAC to fall to a negative 5.4% in 2007 and will plummet further if the proposed cuts for 2008 are implemented.

9. CAHs Reverting Back to IPPS Hospitals and Raising the Rural Floor (FR Page 24786)

UPMC agrees with the Secretary that it would be appropriate for CMS to develop a policy that discourages Critical Access Hospitals (CAHs) hospitals from converting to IPPS, if they continue to meet the CAHs certification requirements. Since CAH

payments are generally greater than cost (approximately 101 percent) and are generally greater than the resulting IPPS payment these providers would receive no additional direct benefit to convert to IPPS. The only benefit would be to other state providers who might benefit from a higher rural floor rate. This would occur at the expense of every other IPPS hospital in the Nation because of budget neutrality requirements.

10. Time Spent by Residents on Vacation or Sick Leave and in Orientation (FR Page 24812)

UPMC strongly feels that vacation and sick time should be given the same consideration as time spent in orientation and remain in the resident FTE counts. Vacation and sick leave are allowable fringe benefits for the Medicare program; therefore time spent in these activities should be included when counting FTEs. The additional record keeping required to account for vacation and sick leave for each teaching hospital would be complicated and cumbersome. This proposed rule would also make it necessary to have CMS change the IRIS software program FTE calculation. We urge CMS to withdraw this proposal as the minimal count consistency refinements do not justify the provider cost and paperwork burdens required to implement.

11. Proposed Selection of Hospital-Acquired Conditions for FY 2009 (FR Page 24718)

While UPMC supports the CMS efforts to identify hospital acquired conditions that lead to higher DRG costs, we believe that only three of the six conditions representing serious preventable events identified by CMS – object left in during surgery, air embolism and blood incompatibility – are appropriate conditions to include for FY 2009. These three conditions are identified by discrete ICD-9 codes, and can be coded by hospitals. However the remaining conditions pose significant challenges to be correctly identified and rely on accurate “present-on-admission” coding by physicians, who have been properly trained in recognizing the need to carefully identify and record this data. We believe physician training and systems upgrade will take no less than 24 months to implement. As such we urge CMS to delay the implementation of these additional conditions until after appropriate identification and training processes can be developed and implemented.

12. Proposed New Quality Measures for FY 2009 and Beyond (FR Page 24805)

While UPMC agrees that all quality measures proposed should be adopted by the Hospital Quality Alliance (HQA), we also believe that all measures should also be endorsed by the National Quality Forum (NQF) and should undergo field tests for operational issues before they are adopted as a quality reporting measure by CMS. We believe that field tests are necessary to observe the actual operational issues and to assess the degree to which the measures can be implemented successfully by

hospitals and data vendors. Quality measures that do not meet these three conditions should not be chosen by CMS.

### 13. Physician Ownership Rules (FR Page 24816)

UPMC supports implementation of a physician-ownership disclosure requirement. Specific recommendations include: ownership disclosure requirements be incorporated into provider agreements; 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); that exceptions not be based on the size of investment; that patient disclosure be made at the time of scheduling, pre-admission, and registration; and that the list of physician investors be provided to patients at the time the request is made.

### 14. Replaced Devices (FR Page 24742)

UPMC believes this proposed rule 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.

### 15. CC Exclusion List (FR Page 24738 - CMS Table 6H)

UPMC believes that some of the conditions currently proposed for removal from the CC exclusion list should be reinstated, including several condition categories that affect the psychiatric PPS payment system.

### WAGE INDEX

In FY2009, CMS is required by law to consider changes to the area wage index. UPMC agrees that the wage index is not functioning and alternatives should be considered. We would like to take this opportunity to describe some of our fundamental concerns:

- Volatility of wage index year to year.

- Self-perpetuating - hospitals with low wages indices are unable to increase wages to become competitive in the labor market.
- Unrealistic geographic boundaries.
- Geographic boundaries create “cliffs” where adjacent areas have very different indices.
- Inaccurate measure of actual labor costs.
- Fiscal intermediaries are inconsistent in their interpretations.
- Hospitals can be penalized for erroneous data submitted by other hospitals in the same geographic area.
- Exclusion of some personnel from the wage index calculation – outsourcing of low-wage workers raises an area’s wage index.
- There are hospitals uniquely positioned in rural areas where the normal reclassification rules enable select hospitals to reclassify to a different CBSA area thereby providing a benefit to the rest of their state by raising the rural floor through budget neutrality to the detriment of other CBSA areas. Potentially, this problem can be further compounded by CAH providers choosing to convert back to IPPS, even though they still qualify as a CAH provider, to raise the rural floor even higher to the advantage of the state as a whole, but to the detriment of all remaining CBSA areas nationwide.

*Below please find more detailed explanations and comments on our positions as highlighted above. We appreciate your review and consideration of our comments prior to the completion of the final guidelines.*

### **Section “DRG Reform and Proposed MS-DRGs”**

1. “MS-DRGs: Medicare-Severity Diagnosis-Related Groups” (FR page 24689)

*Proposed FY 2008 Rule:* CMS is proposing significant changes to the current DRG payment system by requesting the adoption of the Medicare-Severity DRG (MS-DRG) classification system for the FY 2008 Inpatient Prospective Payment System (IPPS). Medicare indicates this proposed MS-DRG system will provide significant improvement in the recognition of severity of illness and resource usage in the DRG system. These changes would be reflected in the FY 2008 GROUPER, Version 25.0 and would be effective for discharges occurring on or after October 1, 2007. CMS notes this is an interim step in their ongoing refinement of the DRG process towards a severity adjusted system and is not necessarily the final chosen severity system.

*Response:* While UPMC supports the continued efforts of CMS in the development of a severity adjusted DRG payment system we are concerned that CMS may be moving too quickly in trying to achieve this goal. Some of the problems that seem apparent are:

- MS-DRG Implementation and Training Costs: While the proposed temporary FY 2008 MS-DRG severity payment system is less complex than the Consolidated Severity DRG System CMS proposed in FY 2007, it will require implementation and training costs at the provider hospital level. The costs incurred would be an unnecessary financial burden to providers since the CMS payment system may change again next year, requiring re-training and new implementation costs on a different payment system.
- Evaluations of Five Alternative Severity-Adjusted DRG Systems - Study by RAND Corporation (Phase I) – Although CMS has received a preliminary report from RAND Corporation on their initial findings regarding five Severity Adjusted DRG Models, the final report and recommendations will not be available for evaluation before the publication of the final IPPS rule for FY 2008. – CMS will require additional time to evaluate that report.
- Phase-Two of the RAND Corporation Analysis of Other Alternative Severity Adjusted DRG Models – The MS-DRG model currently proposed by CMS for FY 2008 is not one of the severity models under evaluation by RAND Corporation. CMS has indicated that RAND Corporation will evaluate this payment model in comparison to the other models evaluated. CMS also plans on having RAND Corporation analyze the Hospital Specific Relative Values (HSRVs) cost-weighting methodology. (Apparently this study will occur over the next fiscal year.)
- Comparison of the Proposed MS-DRG System to the Current CMS-DRG System – A comparison of the proposed temporary MS-DRG system to the current CMS-DRG system indicates the current 538 DRG's will be replaced by 745 Medicare Severity-adjusted DRG's (MS-DRG's). The MS-DRG numbers range from 1 to 989. The new MS-DRG's will subdivide based on three levels of complications or comorbidity (CCs), Major CCs, CCs and non-CCs. The old CMS-DRG's subdivided on two levels; with CCs and with-out CCs for selected base DRG's. As a result only 108 of the old DRGs match the same service description as the new MS-DRGs, but will have totally new DRG numbers. The remaining 647 MS-DRG's are totally new and different from the old CMS-DRG's. This will be a major re-learning effort for hospital staff, for a potential temporary one year conversion.

**Recommendation:** If CMS pursues the use of MS-DRG's before it completes all its other evaluations, then it should adopt these changes for several years and provide for a four-year transition period. We suggest the following transition:

- In FY 2008, CMS should emphasize preparation for and testing of the new classification system so that: (1) CMS has adequate time to finalize data, introduce and test software for case classification and payment and train its fiscal agents (2) Hospitals have adequate time to implement and test the new system and adjust operations and staffing for predicted revenues.
- In FY 2009, DRG weights should be computed as a blend derived 1/3 from the MS-DRG's and 2/3 from traditional CMS-DRG's.
- In FY 2010, DRG weights should be computed as a blend derived 2/3 from MS-DRG's and 1/3 from traditional CMS-DRG's.
- In FY 2011, DRG weights should be derived using only the MS-DRG's.

Should CMS reject the four-year transition approach and time table recommended above, then we believe that the MS-DRG model currently proposed should not be adopted for October 1, 2007 as there is not enough time for providers to train, implement and test this system. We suggest a minimum of one year implementation time for providers. We also believe the proposed one year adoption of the MS-DRG model as a potential temporary system places undue resource burdens on hospitals since potential duplicative re-training expenses would occur, and that a more prudent approach is required. UPMC suggests that it would be more beneficial to delay any implementation until the study by Rand Corporation is completed and an Inpatient Prospective Payment System is selected by CMS that will be used for several years.

2. Case-Mix Index (CMI) Change from the Proposed MS-DRGs and "Behavior Offset" – Operating (FR Page 24710)

*Proposed FY 2008 Rule:* CMS is proposing to use the Secretary's authority under section 1886(d)(3)(A)(vi) of the Act to decrease the full market basket update of 3.3 percent for anticipated hospital "behavioral" effects of (2.4) percent. This behavioral adjustment results from anticipated hospital improved coding and discharge documentation beyond anticipated annual "real growth" case-mix index (CMI) changes. This CMI increase would occur after the implementation of the proposed MS-DRG's system on October 1, 2007. This Inpatient Prospective Payment System (IPPS) standardized Federal rate reduction of a (2.4) percent would be applied to both FY 2008 and FY 2009. CMS may adjust the standardized amounts further to account for the difference between the projections and actual data in FY 2010 and FY 2011. CMS is basing this proposed case-mix index (CMI) behavioral adjustment on an actuary's analysis of coding and documentation improvement in the State of Maryland during a three year conversion from CMS-DRG's to APR-DRG's. In that study, the actuary estimated the case mix index (CMI) rose at a rate higher than the expected CMI by 4.8 percent.

*Response:* We do not support this proposed "behavioral" case-mix budget neutrality adjustment of (2.4%) to FY 2008 and FY 2009 Federal rates since it was based on actuarial studies of conversion issues for Maryland State hospitals which we do not believe will accurately forecast CMI conversion issues under the MS-DRG system, as currently proposed by Medicare. Several conversion differences include:

- The Maryland model was a conversion from a CMS-DRG system to an All Payer Related-DRG system (APR-DRG) not the Medicare Severity DRG system (MS-DRG) proposed in this rule
- Several of the largest teaching hospitals in the Maryland conversion model were given three years of advanced transition training regarding this new system coding which will not occur under this proposed rule and greatly overstates the coding increases anticipated by CMS
- Maryland hospitals had greater incentives for more complete medical records and accurate coding since this conversion was applied to all-payers in Maryland, not just Medicare. This will not be the case under this proposed rule, so coding changes and intensity of the magnitude CMS proposes seem highly unlikely
- Since Maryland is an IPPS waiver state their hospitals were paid under a state rate setting system with less coding significance than the subsequently adopted (and much more complicated) APR-DRG system – Since IPPS hospitals are not in waiver states they currently code under CMS-DRG's. Since Medicare has indicated that MS-DRG's are just a refinement of the CMS-DRG's and not an entirely new process (as occurred in Maryland) the CMI change should mirror the CMS to MS-DRG modeling determined by CMS without need for a behavior adjustment.

Due to the dissimilarities of the proposed rule and the Maryland model referenced by CMS we cannot support the proposed rule of applying a behavioral modification adjustment of (4.8) percent split over two years (-2.4% per year), or 1 year (-4.8%) or over 3 years as considered by CMS for anticipated coding behavioral increases. Instead, we urge CMS to drop this estimated proposed budget neutrality adjustment since the circumstances between the system conversions of Maryland (an IPPS waiver state) and APR-DRG's are not similar to the proposed IPPS conversions from CMS-DRG's to MS-DRG's.

### 3. MS-DRG Implications to the Inpatient Psychiatric PPS (FR Page 24976)

*Proposed FY 2008 Rule:* CMS is proposing significant changes to the current DRG payment system by requesting the adoption of the Medicare-Severity DRG (MS-DRG) classification system for the FY 2008 Inpatient Prospective Payment System (IPPS). These proposed DRG changes do affect the psychiatric and alcohol/drug DRG services.

*Response:* We urge CMS to carefully consider the implication 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. (See issue 15 for recommendations to CC Exclusion list).

### Section "Multicampus Hospital"

4. “Wage Index for Multicampus Hospital” (FR Page 24783)

*Proposed FY 2008 Rule:* CMS is proposing changes in determining the wage index for multicampus hospitals. While there are only three multicampus hospitals with different geographical areas (currently in the country) CMS is proposing to apportion wages and hours for each campus of a multicampus hospital based on FTE staff. This data will be added to worksheet S-2 of the cost report. CMS had also considered using beds and discharges for allocation purposes.

*Response:* While we do not object to the proposed use of campus FTEs for allocation of wages and hours, for multicampus hospitals, we would urge CMS to give providers the additional option of applying actual multicampus details if data it is readily available. This would be a more exact option for determination of wage index and occupational mix for multicampus providers wishing to do so. As such we urge CMS to modify its proposed rule to allow providers the annual option of using the FTE allocation split or actual wage and hour data splits if available.

**Section “Capital IPPS” (FR page 24818)**

Overview of CMS Proposed Capital Payment Reductions – CMS has proposed four major capital payment reductions for “Large Urban”, “Teaching” and “Disproportionate Share” hospitals in FY 2008 and beyond. These proposed capital adjustments are discussed in further detail below.

Overview of UPMC Response on Proposed Capital Payment Reductions – UPMC strongly opposes CMS’s proposal that capital payments for teaching, disproportionate share and large urban hospitals are excessive and need to be reduced or eliminated. UPMC is an innovative and cutting edge health system that needs to make significant capital investments in order to update facilities, purchase high-tech equipment, and update information systems required to provide the environment necessary to administer and maintain medical education programs, as well as, to better care for an increasingly aging population. These reductions will affect all patients nationwide. The need for hospital care for seniors and the disabled covered by Medicare is increasing at a time when Medicare payments remain well below the cost of providing the care. Large urban teaching hospitals that also receive disproportionate share payments have an added burden of providing free and subsidized care for an increasing number of uninsured patients. In addition, large urban teaching hospitals are expected to be at the forefront of preparing for disasters such as pandemic and terrorist threats, and providing leadership in patient safety and infection control programs. Medicare needs to shore up these programs that provide for Medicare patients, not jeopardize them further. Medicare margins are projected by MedPAC to fall to a negative 5.4% in 2007 and will plummet further if the proposed cuts for 2008 are implemented. This trend is unsustainable over the long term. CMS’s proposed cuts in funding will disrupt the ability of large urban teaching hospitals to meet existing long-term financing obligations. UPMC has committed to these high-cost improvements expecting that Medicare funding provides a continuing stable source of

income. UPMC urges CMS to refrain from any reductions to capital payments for teaching, disproportionate share and large urban hospitals.

See additional details and comments on each of these proposed capital payment reductions in the pages below:

5. Capital Adjustment for Case-Mix Index (CMI) Change from the Proposed MS-DRGs and "Behavior Offset" (FR Page 24846)

*Proposed FY 2008 Rule:* CMS has proposed to reduce the capital Federal payment rate by the same case-mix budget neutrality adjustment of (2.4) percent as it proposed to the Federal Operating rate noted above.

*Response:* We do not support the proposed Federal payment rate reductions for Capital or Operating costs of (2.4) percent and urge CMS to drop these proposed case-mix budget neutrality adjustments. As explained in our detailed response to the "DRG Reform and Proposed MS-DRG" section noted above, we believe the State of Maryland situation is not comparable to the MS-DRG model proposed and the estimated proposed adjustment should not be adopted.

6. Establish Two Separate Capital Federal Rates, One for Urban Capital and another for Rural Capital (FR Page 24846)

*Proposed FY 2008 Rule:* This year CMS is proposing two separate capital Federal rates for FY 2008: A rural capital Federal rate based on an update of 0.8 percent and an urban capital federal rate based on a zero 0.0 percent update. CMS indicates they believe urban hospitals have sustained continuous large profit margins under capital PPS. CMS is also proposing a zero 0.0 percent update for urban hospitals in FY 2009.

*Response:* We do not support the proposed separation of capital into two separate urban and rural Federal rates, nor do we support the proposed elimination of a capital update for urban hospitals in FY 2008 and FY 2009. This goes against several long standing principles and practices that Medicare adopted when implementing capital Prospective payments, in FY 1992. They include:

- Per Discharge Average Pricing - That a uniform per discharge average pricing system be adopted as the most equitable way of providing incentives to control capital expenditures
- Payment Process be Consistent with Other PPS Approaches - That the Capital payment process be consistent with the Prospective payment system (PPS) approach implemented in the other payment areas
- Anticipate That Capital Payment Redistributions will Result – Due to the wide variation in capital costs we (CMS) realize that payment redistribution will result but that this is not inappropriate and that providers should adjust their capital spending plans to adapt by the end of the ten year phase-in period

Several CMS responses to comments in the FY 1992 PPS Capital Final Rule (56 Federal Register 43358, August 30, 1991 – Section IV.) document these adopted positions:

*CMS Response 8-30-91:* "Section 1886(g)(1) of the Act requires the Secretary to establish a prospective payment system for the inpatient capital-related costs of prospective payment hospitals for cost reporting periods beginning in FY 1992. We believe that a capital prospective payment system is necessary to create appropriate incentives for efficient capital spending. We acknowledge that, in moving to an average pricing system to pay for capital expenditures for hospital inpatient services, our payment will be independent of an individual hospital's capital cost experience and that payment redistributions will result. However, we do not agree that this effect is necessarily inappropriate. The wide variation in capital costs per case suggests that some redistribution of capital resources is appropriate." ...

"We do not believe that the current system is as equitable as a prospective payment system because discounting payments to efficient hospitals as well as inefficient ones penalizes efficient hospitals and subsidizes inefficient hospitals. Further, we believe that the financial difficulties created by moving to an average pricing system will be largely alleviated by the 10-year transition period, the protection for old and obligated capital costs, and the exceptions policies we are establishing in this final rule. We believe that most hospitals with substantially higher capital costs per discharge than the Federal rate will have adequate time under the transition period to adjust their capital spending plans and financing arrangements to meet the relatively lower payment levels by the time they reach capital payment based only on the Federal rate."...

" We continue to believe that a per discharge average pricing system remains the most equitable and feasible means to provide incentives to control capital expenditures, and is consistent with the methodology being considered for other Medicare payment areas. Thus, independent of the statutory mandate to implement capital prospective payments effective October 1, 1991, in our view this change is necessary and appropriate."

Also as recently as FY 2005 Congress required CMS to implement provisions to replace two separate National Urban and Rural Standardized "operating payment amounts" with one National standardized operating rate. We believe the current proposal by CMS to split the one "capital standard federal rate" into two separate urban and rural capital rates for FY 2008 does not follow this Congressional trend. As such, we believe CMS should not abandon their current historic capital payment practices and propose to adopt two separate capital rates, while maintaining one National operating cost rate.

In regards to the CMS proposal to penalize "select providers" for sustained positive margins, by eliminating their capital market basket update, we again urge CMS not to adopt this approach as it goes against the historic PPS practice of establishing standard average payments that an average efficient provider would require to supply the service. Since Medicare's national Federal capital rate was set at only 90 percent of the aggregate inpatient Medicare capital cost it is difficult to understand why Medicare now believes these payments are too high and that provider's who have

survived and adapted to these PPS capital rates must now be penalized with no capital increase. This proposed adjustment also ignores the cyclical nature of major capital expenditures such as building replacement which ranges from 25 to 100 years, and would not be reflective in a 10 year trend analysis. Based on these historic PPS capital practices, payment rates at less than 90 percent of aggregate capital cost, the cyclical nature of building replacement, and the need for positive margins to fund and accumulate depreciation reserve funds for asset replacement, for all these reasons we cannot support this proposed capital adjustment. We again urge CMS to maintain its previous capital practice of utilizing one Federal capital rate, and applying the full capital market basket update for all providers without penalizing select providers who have had a positive capital margin for a 10 year period.

7. Elimination of Large Urban Capital Add-on of 3 Percent (FR Page 24822)

*Proposed FY 2008 Rule:* CMS proposed the permanent elimination of the three percent capital add-on for large urban hospitals, due to larger positive profit margins that exceed those of rural providers. CMS has also indicated they will not increase the standard capital rate for the estimated funds saved by the elimination of this three percent “large urban capital add-on” adjustment. CMS indicates the Medicare program should realize this savings and not make the adjustment in a budget neutral manner, even though the base capital rate at PPS capital inception was reduced by the estimated expenditures attributed to this “large urban” capital add-on adjustment.

*Response:* We do not support the elimination of the large urban capital add-on of three percent, as proposed by CMS and urge the withdrawal of this proposal. This proposed elimination of large urban capital add-on by CMS should not be adopted for several reasons:

First, it is a major departure from the capital policies adopted by Medicare at the inception of capital PPS in FY 1992. At that time Medicare recognized through regression analysis, that large urban hospitals would be underpaid and rural hospitals would be overpaid relative to their actual capital costs per case without a payment differential between urban and rural. See CMS response from (56 Federal Register 43358, August 30, 1991 – Section IV.)

*“CMS Response 8-30-91: We are setting the large urban add-on at 3.0 percent in this final rule. The total cost regression equations using the pooled data from cost reporting periods beginning in FY 1988 and FY 1989 indicate that large urban and other urban hospitals have higher total costs, with regression coefficients of 0.1808 and 0.1277 respectively. These results imply that the Federal payment rate should be approximately 18.1 percent higher for large urban hospitals, and 12.8 percent higher for other urban hospitals, compared to the payment to rural hospitals.” ...*

*“Making this comparison, we found that we would underpay rural hospitals relative to other hospitals if we were to adopt the differentials indicated by the regression equations. Moreover, we believe payment differentials of the magnitude suggested by the total cost regression equation would be contrary to the direction taken by Congress*

in section 4002 of Public Law 101-508 to phase out by fiscal year 1995 the separate standardized amounts for rural and other urban hospitals under the prospective payment system for operating costs.”...

“When we simulated a payment system with no payment differential for hospitals in a large urban location, we determined that these hospitals would be underpaid relative to other urban and rural hospitals. When we simulated a payment system with a 1.6 percent payment differential, equivalent to the differential in the proposed rule, we found that large urban hospitals would still be relatively underpaid. When we simulated a payment system with a payment differential of 5.3 percent, equivalent to the difference between the large urban and other urban regression coefficients, we determined that we would underpay hospitals in other urban areas relative to other hospitals. We then simulated a payment differential of 3.0 percent for hospitals located in a large urban area, and concluded that this adjustment provided the most appropriate balance between payments to hospitals in the three different geographic locations in that the percentage change from total cost per case for large urban and other urban hospitals is more comparable than in the other simulations.”

Second, while CMS has currently expressed its concern over the lower profit margins of the rural providers in relation to the higher profit margins of large urban and teaching providers, they provided no performance factors, occupancy rates, length-of-stay, or cost per case tends to prove that the higher profit margin providers did not outperform the less profitable rural providers. In fact, the March 2007 MedPAC report indicates on page 64 that high margin hospitals (18% of hospitals) had a standardized 2005 cost per case of \$4,527 while low margin providers (18% of hospitals) had a standardized cost of \$6,203. The MedPAC report also indicated the low Medicare margin hospitals had smaller declines in length of stay, had higher growth costs and higher overall inpatient cost increases than those providers with consistently high margins. As a result providers with more consistent profit margins did work harder and were under more financial pressure to keep costs down to realize and maintain a profit. The stated intent of the Prospective Payment System (PPS) was to provide financial incentives to providers to provide a quality service to Medicare beneficiaries at a known fixed IPPS rate. Efficient providers would be rewarded with the cost savings and inefficient providers would lose money. If CMS adopts this capital proposal and eliminates the large urban three percent add-on, efficient providers will become discouraged to find cost savings when this was clearly not the intent of PPS and capital PPS.

We do not support the capital payment cuts proposed for large urban hospitals nor the capital update freeze proposed for these providers. The elimination of the large urban capital add-on adjustment, the capital update freeze and the proposed teaching and disproportionate share add-on capital payments eliminations can disrupt the ability of large urban teaching hospitals to meet their existing long-term financial obligations. These hospitals have committed to various long-term capital improvements, clinical information systems, or other high-tech advances under the expectation that Medicare’s PPS capital-related cost formulas and rates would remain a stable source of income. Reducing these capital payments creates significant financial difficulties for our Nations largest and most innovative hospitals. We urge CMS not to make

these capital rate reductions, especially when hospital margins are expected to reach a ten-year low in 2007 of negative 5.4 percent. (Per March 2007 MedPAC report).

In regards to the CMS proposal that all savings generated by the elimination of the three percent large urban add-on should be kept by the Medicare Program and not be rolled back into the federal capital standard base rate, or that it roll into a new separate rural capital base rate, we disagree. While we do not support the elimination of the large urban add-on adjustment as previously explained, we also cannot support your proposal that this payment reduction (if finalized by CMS) be retained by Medicare as a savings. We believe that any capital payment reductions made to large urban, teaching, or disproportionate share providers should be rolled back into the "federal standard capital base rate" from which it was taken at the time these payment provisions were originally adopted. Since the original payment methodology adjustment was made in a budget-neutral manner, so should your revision (if adopted). In addition, we also contend that the CMS proposal to keep additional capital cost savings beyond the 90 percent level already taken when PPS capital base rates were established in FY 1992 appears to be a conflict to section 4001(b) of Public Law 101-508, section 1886(g)(1)(A) of the Act. Medicare was required to make capital payment reductions not to exceed 10 percent of the capital payments on a reasonable cost basis, and these saving were to be based on the best available data at the time. Since PPS Capital rates were established at levels equal to 90 percent of the aggregate Medicare capital cost under the reasonable cost basis, the proposal to keep additional capital savings (i.e. 3 percent of large-urban capital add-on) would mean that CMS would exceed the required 10 percent capital cost savings. This proposal would appear to contradict that provision. We again urge Medicare to drop these proposals.

In regards to the optional proposal discussed by CMS that these capital rate reductions could be place into a separate rural capital PPS rate we do not believe this should be adopted. This approach does not follow the previous intent of Congress which mandated the elimination of separate rural and urban operating payment rates, and since the original base capital rate was reduced for all providers.

8. Proposal to Eliminate Capital Teaching and Capital Disproportionate Share Add-ons in the Near Future (FR Page 24822)

*FY 2008 Request for Comment and Probable FY 2009 Adjustment:* This year (FY 2008) CMS has requested comments on the possibility of eliminating capital teaching and capital disproportionate share add-on payments for teaching and disproportionate share hospitals in the near future (probably FY 2009) and beyond. CMS indicates that these "capital add-on adjustments" are not mandated by the Social Security Act (but were mandated for Operating IPPS) but were granted under the broad authority of the Secretary and that the high profit margins for these teaching and disproportionate share providers indicates that payment adjustments under the capital IPPS is warranted at this time. CMS indicates the following positive margins: Teaching hospitals (11.6 percent for the FY 1998 through 2004), urban hospitals (8.3 percent),

and disproportionate share hospitals (8.4 percent) positive margins. Hospitals with lower margins: rural hospitals (0.2 percent for FYs 1998 through FY 2004) and non-teaching hospitals (1.3 percent). CMS suggests that these high positive margins indicate excessive payment levels for these three hospital classifications. As such, CMS has requested comments on a proposal to reduce or terminate these payment adjustments in the near future. CMS is also requesting comments on their proposal for Medicare to keep these payment savings and not roll these savings back into the standard capital rate.

*Response:* We do not support the elimination of capital indirect medical education (IME) payments or capital disproportionate share (DSH) payments and urge CMS to drop the proposals to eliminate these two capital payments and not keep the potential savings in question. We do not support either of these proposals for the following reasons:

First, while the Social Security Act does not specifically require IME payments or DSH payments in its required capital PPS it did give the Secretary substantial latitude in implementing the capital prospective payment system.

The SSA Requirements for Capital PPS (sections 1886(g)(1)) that the Secretary had to meet were:

*Implement a PPS capital payment system for cost reporting periods on or after 10-1-1991*

- Aggregate PPS capital payments from 1992 through 1995 shall be equal to a 10 percent reduction in the payment of capital-related cost that would have been made each year under the reasonable cost method.
- Provides for capital prospective payments on a per discharge basis appropriately weighted for the classification of the discharge. It also gives the Secretary discretion to provide for adjustments to capital prospective payments for relative cost variations in construction by building type or area, for appropriate exceptions (including those to reflect capital obligations), and for adjustments to reflect hospital occupancy rate.

The Secretary chose to model final Capital PPS adjustments after “Operating PPS” adjustments with some modifications based on regression analysis and payment simulations. (Several of the Modifications have been listed below):

- Establish a standard Federal rate for inpatient capital-related costs on a discharge basis
- Adjust payment for DRG weights
- Adjust payment for geographical location
- Provide for a disproportionate share payment adjustment for urban hospitals with 100 or more beds
- Adjust standard capital payment for adjustments in a budget neutral manner and to conform to 10 percent reduction requirements noted above

- Base all capital payment adjustments on total costs regression equations and payment simulations (The final capital rule as published in the FR 8-30-1991 shows the adoption of the following adjustments based on total cost analysis):
  - a. We will increase a hospital's payments under the Federal rate by approximately 6.8 percent for every 10 percent increase in the hospital's wage index value.
  - b. We will make a 3 percent add-on payment to large urban hospitals.
  - c. We will increase a hospital's payments by approximately 2.0 percentage points for every .10 increase in its disproportionate share patient ratio.
  - d. We will increase a hospital's payment by approximately 2.8 percentage points for every .10 increase in its ratio of residents to average daily inpatient census.
  - e. We will make a cost of living adjustment in the payment to hospitals located in Alaska and Hawaii based on the current adjustment provided under the operating system.

Second, since these capital IME and DSH payment adjustments were founded based on “total cost” regression equations, payment simulations and modeled with some minor modifications after mandated operating PPS adjustments, we believe these historic capital add-ons should not be eliminated. CMS provided nothing in the current proposal to dispute the “total cost” regression computation and analysis from 1991. In addition these capital add-ons have been in effect since 10-1-1991 and were based on actual provider cost data which clearly indicated that these larger teaching and DSH hospitals had costs greater than non-teaching providers...

See CMS response from (56 Federal Register 43358, August 30, 1991 – Section IV.)

“Notwithstanding this improvement in the capital cost data base, we have decided to establish the payment adjustments in this final rule using regression analysis of total costs per case (that is, combined operating and capital costs but not including direct medical education and other excluded costs) rather than using regression results applicable only to capital costs per case. We are persuaded by the argument advanced by some commenter's, including ProPAC, that in the long run the same adjustments should be applied to capital and operating payments and that the level of the adjustments should be determined by examining combined operating and capital costs. ProPAC recommended that the unified adjustments be calculated within two years. However, we believe that it would be most appropriate to implement these adjustments with respect to the capital prospective payment systems from the outset. While the payment adjustments for the operating prospective payment system are determined by the Act (and therefore cannot be modified by the rulemaking process), we have the latitude to develop adjustments based on combined costs for the capital prospective payment system.”

*Third, Capital Costs Related to Indirect Medical Education (IME) are Excluded from Operating IME Rates* - The CMS response in the final Capital PPS rules confirms that the capital IME costs are not included in the operating IME and that the capital cost and IME rates were established based on “total cost regression analysis”, and does not duplicate any other Medicare payment. CMS Capital Comment 8-30-1991:

*8-30-1991 Response:*” We disagree with the commenter's with respect to the indirect costs of medical education. The indirect teaching adjustment under the operating prospective payment system is designed to represent the additional operating costs associated with teaching activity. It does not include any factor for higher capital costs since, prior to cost reporting periods beginning October 1, 1991, the capital costs have been payable on a reasonable cost basis. While the indirect teaching adjustment for capital costs that we are establishing in this final rule is based on the total cost regression analysis, adjusting capital payments by this factor will pay only the capital prospective payment system share of the indirect costs of medical education. Capital-related costs directly attributable to graduate medical education are classified as direct graduate medical education costs and included in the per resident amounts. These costs are not included in the capital-related costs used to establish the Federal rate or the payment adjustments. Further, the direct graduate medical education costs are removed from the costs used in the total cost regression equation. That is, the total cost regression equation includes only inpatient operating and capital costs and does not include the costs of graduate medical education.”

*Fourth, Patients Expect the Latest Cutting Edge Technology* - These proposed capital cuts (and others) would make it more difficult to purchase the advanced technology, equipment and clinical information systems that consumers have come to expect from large urban and teaching providers, and could have the effect of slowing clinical innovation. 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. CMS should not make such changes without assessing the broader ramifications to the health care teaching environment.

Again we urge CMS not to pursue the elimination of the capital IME and capital disproportionate share payments for the reasons cited above and for the capital overview responses given earlier in our comments.

#### **Section “Rural Floor” (FR Page 24786)**

##### **9. CAHs Reverting Back to IPPS Hospitals and Raising the Rural Floor (FR Page 24786)**

*Proposed FY 2008 Rule:* CMS has requested comments on the adoption of possible rules changes to discourage qualifying Critical Access Hospitals (CAHs) hospitals from converting to IPPS to take advantage of the rural floor provisions for other IPPS hospitals in their State. This is occurring for two specific CAH providers, but with no direct benefit to them, since they still qualify for CAH and receive payments at approximately 101 percent of cost.

*Response:* UPMC agrees with the Secretary that it would be appropriate for CMS to develop a policy that discourages CAH hospitals from converting to IPPS, if they continue to meet the CAHs certification requirements, in order to take advantage of

the rural floor provisions. Since CAH payments are generally greater than cost (approximately 101 percent) and are generally greater than the resulting IPPS payment these providers would receive, there would be no direct benefit for these CAH providers to convert to IPPS. The only benefit would be to other state providers who might benefit from a higher rural floor rate. This would occur at the expense of every other IPPS hospital in the Nation.

UPMC would also recommend that CMS removes the compounding affect of applying the budget neutrality adjustment for the rural floor to the standardized amount annually since 1998. We believe it was an unintended error to repeatedly apply the rural floor budget-neutrality adjustment without first reversing the prior year's adjustment as is done with the outlier calculation each year. We also suggest that CMS remove the effects of the adjustments made from 1999 to 2006 by increasing the positive budget neutrality adjustment proposed to the standardized amount intended to just reverse the 2007 adjustment.

### **Section "IME Adjustment" (FR Page 24812)**

#### **10. Time Spent by Residents on Vacation or Sick Leave and in Orientation (FR Page 24813)**

*Proposed FY 2008 Rule:* CMS has proposed that effective for cost reporting periods beginning on or after October 1, 2007 vacation and sick leave (that do not prolong the total time a resident is participating in the approved program beyond the normal duration of the program) is not included in the determination of full time equivalency (Note: CMS proposes to allow orientation time).

*Response:* The proposed removal of time spent on vacation and sick leave from the total time considered to constitute an FTE resident for purposes of IME and Direct GME payments would add a significant burden to the hospitals in the counting of an FTE. The removal of vacation and sick days from both the numerator and the denominator of the FTE count is the catalyst. This proposal initiates many questions and issues that must be considered and determined by CMS before the proposed rule is put into practice or the consistency and purpose of this proposed rule will only be subject to interpretation and therefore be inconsistent among the providers. Even the CMS IRIS program for reporting the IME and GME FTE counts is based on a set denominator of 365 days and would have to be changed to accommodate this proposal. The amount of additional record keeping that would be necessary for each facility would be extremely complicated and cumbersome.

Some issues that would make this an administrative burden are : the numerator and now the denominator would have to be completed for each resident and intern; some providers have varying vacation and sick policies for each residency program and these would have to be applied; when dealing with residents and interns that rotate to other facilities, not all providers have the same vacation and sick policies, therefore each provider on the rotation schedule would have to maintain records on the other

provider's sick and vacation policies and be knowledgeable of all vacation and sick days taken by each resident to determine their proper portion of an FTE; not all residents use their vacation and sick time, which is paid to them at the end of the year and if a provider uses payroll records to determine their FTE count this would be an issue; Medicare regulations allow fringe benefit expenses for all employees, and residents should be no exception.

We urge CMS to withdraw this proposed rule as it creates a major administrative burden on all providers, sites and programs involved in the resident rotations with very minor changes in FTE counts, depending on when vacation and or sick time is actually taken. It also creates major posting and software problems in the IRIS filings which CMS must consider. We request that this proposed rule not be adopted since it only creates additional problems and paperwork for providers and CMS auditors and does not warrant the resource burden involved. Since vacation and sick leave are allowable fringe benefits, we urge CMS to make these two categories of time an exception to the 2007 definitions and let them remain in the total allowable and non-allowable FTE counts as was historically allowed by CMS.

### **Section "DRGS: Hospital-Acquired Conditions"**

#### **11. Proposed Selection of Hospital Acquired Conditions for FY 2009 (FR Page 24718)**

*Proposed FY 2009 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 identifies 13 conditions that it is considering, but 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.

*Response:* We believe this policy should be implemented starting with a very small number of conditions because of the significant challenges to correctly identify the appropriate cases.

Conditions to include for FY 2009. We believe 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.

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. While CMS postponed these present-on-admission coding requirements from October 1, 2007 to January 1, 2008 for technical difficulties, we believe this is still not enough time. 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. Physicians must be 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 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. Therefore we urge CMS to delay implementation of payment classification changes for these cases, for at least 24 months and that CMS implement training sessions for physicians on these issues.

**Section “Hospital Quality Data” (FR Page 24802)**

12. Proposed New Quality Measures for FY 2009 and Beyond (FR Page 24805)

*Proposed FY 2009 Rule:* CMS has proposed adding only new quality measures that have been adopted by the Hospital Quality Alliance (HQA) for public reporting in FY 2009.

*Response:* While we agree that all measures proposed should be adopted by the HQA, we also believe that all measures should also be endorsed by the National Quality Forum (NQF) and should undergo field tests for operational issues before they are adopted as a quality reporting measure by CMS. We believe that field tests are necessary to observe the actual operational issues and to assess the degree to which the measures can be implemented successfully by hospitals and data vendors. Quality measures that do not meet these three conditions should not be chosen by CMS.

**Section “Physician Ownership in Hospitals” (FR Page 24816)**

13. Physician Ownership Rules

*Proposed FY 2009 Rule:* The proposed rule would require 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.

*Response:* UPMC supports implementation of a physician-ownership disclosure requirement and suggests the following:

**Location 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.

## **Section “Replaced Devices” (FR Page 24742)**

### **14. Replaced Devices (FR Page 24742)**

*Proposed FY 2009 Rule:* 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."

*Response:* Although UPMC 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.

**Section "CC Exclusion List"**

15. CC Exclusion List (FR Page 24738 - CMS Table 6H)

*Proposed FY 2008 Rule:* As part of the annual IPPS update, CMS published additions (CMS Table 6 G) and deletions to its CC exclusion list (CMS Table 6H).

*Response:* UPMC believes that some of the condition codes currently proposed for removal from the CC exclusion list should be reinstated, including several condition categories that affect the psychiatric PPS payment system. The reasoning for these reinstatements has been documented at length in the AHA comment letter, and has not been duplicated in our response. Please refer to "Exhibit A" for this list of recommended CC reinstatements.

Conclusion

We appreciate the opportunity to submit these comments on your proposed changes on the "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule" and hope they are considered before any final rules are published.

If you have any questions regarding our comments please telephone Paul Stimmel at (412) 623-6719.

Sincerely,



Edward Karlovich  
Chief Financial Officer  
Academic and Community Hospitals

CC: Concordia, Elizabeth  
Farner, David M.  
Huber, George  
Kennedy, Robert A.  
Lewandowski, Christine  
Stimmel, Paul  
System CFO's  
Zerega, Dennis

## Exhibit A

### AHA Listing of Complication and Comorbidity (CC) Codes that Should be Reinstated to the CC Exclusion List

*Proposed FY 2008 Rule:* As part of the annual IPPS update, CMS published additions and deletion to its CC exclusion list.

*Response:* The following list represents conditions currently proposed for removal from the CC exclusion list that the AHA has recommended be reinstated. We support the AHA's position and believe that these **conditions should be reinstated as CCs**. Several of these CC categories also affect the Psychiatric PPS payment system and should not be removed.

Category 250.xx Diabetic manifestations  
Code 276.6, Fluid overload  
Code 276.51, Dehydration  
Code 276.52, Hypovolemia  
Code 276.9, Electrolyte and fluid disorders  
Code 282.69, Other sickle-cell disease with crisis  
Code 284.8, Aplastic anemias, NEC  
Code 285.1, Acute posthemorrhagic anemia  
Codes 287.30, 287.39, 287.4, 287.5, Thrombocytopenia  
303.00-303.02, Acute alcohol intoxication  
Codes 402.xx, Hypertensive heart disease  
Codes 403.90 and 403.91  
Code 413.9, Angina pectoris  
Code 426, Conduction disorders  
Code 427.31, Atrial fibrillation  
Code 428.0, Congestive heart failure, unspecified  
Category 451, Thrombophlebitis  
459.0, Hemorrhage, unspecified  
Category 630-677, Complications of pregnancy, childbirth and puerperium  
Category 765.0, Extreme immaturity  
V45.1, Renal dialysis status  
Diagnoses associated with patient mortality

- 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.

Note: Refer to AHA comment letter of June 4, 2007 for complete detailed comments on why these CC codes should not be removed from the CC Exclusion list

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**Greater New York Hospital Association**

555 West 57<sup>th</sup> Street / New York, N.Y. 10019 / (212) 246-7100 / (212) 262-6350

Kenneth E. Raske, President

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June  
Eight  
2007

Leslie V. Norwalk, Esq.  
Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 443-G  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Subject: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates; Proposed Rule, *Federal Register* 72, no. 85 (May 3, 2007): 24679-25135. [CMS-1533-P]

Dear Ms. Norwalk:

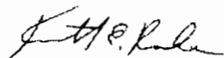
On behalf of the more than 150 hospitals that make up the membership of the Greater New York Hospital Association (GNYHA), I appreciate this opportunity to comment upon the Centers for Medicare & Medicaid Services' (CMS's) proposed rule for the Federal fiscal year (FY) 2008 inpatient prospective payment system (IPPS). This year's rule includes many significant proposed changes to the IPPS. We have chosen to focus on the following six topics:

- **Recalibration of DRG weights.** We support implementation of the short-term recommendations made in the RTI report on charge compression, and we encourage CMS to implement the intermediate- and long-term recommendations as well.
- **DRG reclassifications.** We endorse implementation of the revised Complication/Comorbidity (CC) list and the new Medicare Severity diagnosis-related groups (MS-DRGs). However, we urge an attenuated transition in order to minimize the amount of case-mix creep-related overpayments and, therefore, the size of the recoupment. We also recommend that the overpayment amount be computed retrospectively. We think it is absolutely essential to minimize the recoupment *if it must be made across-the-board* because the overpayments will not be made across-the-board.

- **Capital IPPS.** We vehemently oppose (1) the proposed elimination of the urban hospital update and the 3% large urban add-on in FY 2008; and (2) reduction or elimination of the indirect medical education (IME) and disproportionate share hospital (DSH) adjustments. We do not believe it is appropriate to base capital IPPS policy on a review of margins because the promise of the capital IPPS was that hospitals could accrue surpluses during the low-spending phase of their capital cycle to supplement the receipt of merely average payments when they re-entered the high-spending phase of their capital cycle. Moreover, these proposals were not empirically based and our research shows they are unfounded.
- **DRGs: hospital-acquired conditions.** We support CMS's adoption of the three serious preventable events in its CC suppression policy, but oppose inclusion of the three infection conditions. Based on our research and the expertise of our Infection Control Workgroup, we do not believe that the infections are reasonably avoidable for high-risk patients, and CMS did not propose excluding these patients. Therefore, instead of adopting these conditions in the CC suppression policy, we recommend that CMS add risk-adjusted infection rates to *Hospital Compare* and possibly to its value-based purchasing (VBP) plan.
- **Wage index.** During the next year, CMS must develop at least one proposed modification of the hospital wage index and must take into consideration recommendations made by the Medicare Payment Advisory Commission (MedPAC) in its forthcoming *Report to Congress*. We urge CMS to focus on the aspect of MedPAC's report that centers on blending wage indices between and within core-based statistical areas (CBSAs), and to eschew MedPAC's recommendation to switch the wage index data source from the cost reports to Bureau of Labor Statistics (BLS) data. We believe the BLS data are corruptible and insufficient, and would unnecessarily limit CMS's flexibility in defining or refining labor markets.
- **Value-based purchasing plan.** We appreciate CMS's decision to model the VBP on the Reporting of Hospital Quality Data for the Annual Payment Update (RHQDAPU) program, and we provide several technical suggestions. Our most important recommendation is that CMS should set the thresholds for both regular and topped-out measures at the lower of 60% or the national median, and that CMS should set the benchmarks for both types of measures at the lower of 90% or the average score of hospitals performing at or above the 90<sup>th</sup> percentile. We also strongly favor the implementation option that would phase in the share of the withhold amount that would be based on performance.

Attached is a more detailed discussion of our analysis and recommendations. If you or your staff have any questions or would like to discuss our comments further, please contact Karen S. Heller, Senior Vice President and Executive Director of The Health Economics and Outcomes Research Institute (THEORI), who can be reached at (212) 506-5408 or at [heller@gnyha.org](mailto:heller@gnyha.org).

Sincerely,



Kenneth E. Raske, President

## **Greater New York Hospital Association Analysis of the Medicare Inpatient Prospective Payment System Fiscal Year 2008 Proposed Policies and Rates and Recommendations for the Final Rule**

*(Recommendations are presented in bold and italics.)*

### **RECALIBRATION OF DRG WEIGHTS**

Last year, we spent considerable time analyzing the challenges associated with changing the basis for the diagnosis-related group (DRG) weights from charges to cost. The most significant problem we identified was that there are large and widespread discrepancies between how hospitals report charges by cost center in the Medicare cost reports and how their charges are sorted into revenue centers on the *Medicare Provider Analysis and Review* (MedPAR) file. We also noted mismatched costs and charges within the cost report for a significant number of hospitals.

We urged the appointment of a workgroup to develop recommendations for resolving these problems so that correct cost-to-charge ratios (CCRs) in the cost reports could appropriately be applied to charges in the MedPAR file to estimate cost. We are very grateful that the American Hospital Association, the Association of American Medical Colleges, and the Federal of American Hospitals collaborated to sponsor such a workgroup of which we were a member. The principal recommendations for short-term remediation of the problems were: that hospitals ensure that costs and charges for particular items and services are reported in the same cost centers on the cost reports; that hospitals change the cost centers in which they report items and services to match the automatic assignment of charges to revenue centers in MedPAR; and that hospitals utilize standard cost centers whenever feasible. *We now urge the Centers for Medicare and Medicaid Services (CMS) to instruct the fiscal intermediaries to allow changes made for this purpose in the service of payment accuracy.*

While in the near term, we agree that hospitals should change their reporting to conform to MedPAR, as a longer-term project, we believe that the assignment of revenue codes and charges to revenue centers in MedPAR should be reviewed and changed, as necessary, to better reflect hospital accounting practices. That way, the cost report could be a resource for hospitals and researchers as well as a document for reimbursement. *We, thus, hope that the national associations will continue their cost report workgroup and that CMS will allow joint meetings and collaboration with its internal cost report workgroup.*

Another problem that was brought to light last year—and has been noted repeatedly in the past—was that the combination of certain items and services in the same cost and revenue centers inappropriately dilute the estimated cost of the higher-cost items. This has the effect of compressing the range of the DRGs weights and, thus, of over-correcting for the problem that charge-based weights seemed to overpay high-technology surgical DRGs and underpay medical DRGs. We much appreciated that CMS contracted with RTI, Inc., to investigate options for disaggregating high- and low-cost items and services, and were also grateful for the opportunity to participate on the Technical Expert Panel.

We have carefully reviewed the RTI report and think it provided an excellent presentation of the issues, that it reflected sound and comprehensive research, and that its recommendations were appropriate. *We thus urge CMS to implement the report's short-term, medium-term, and long-term recommendations.* The report's short-term recommendations were as follows:

- Expand the cost report edits to identify and reject those with extreme CCR values.
- Encourage providers to review and correct the assignment of costs and charges before filing their cost reports.
- Revise the cost report instructions to reduce cost and charge mismatching and program charge misalignment.
- Separate Emergency Room from "Other Services" and compute a 14<sup>th</sup> national CCR for the DRG cost computations.
- Consider separating Blood and Blood Products from "Other Services" and computing a 15<sup>th</sup> national CCR for the DRG cost computations.
- Use regression-based estimates to disaggregate national average CCRs for Medical Supplies, Drugs, and Radiology.
- Routinely collect a limited number of Inpatient Standard Analytical File (SAF) variables for use in computing statistically-adjusted CCRs.

#### **DRG RECLASSIFICATIONS**

CMS is proposing to refine the CMS-DRGs by implementing Medicare Severity DRGs (MS-DRGs). Both systems start with 335 base DRGs and then subdivide them based on patient severity of illness. The base DRG splits in the CMS-DRG system result in 538 final DRGs, while the base DRG splits in the MS-DRG system result in 745 final DRGs. Thus, the MS-DRG system is much more refined. It is also a logical, transparent, and non-proprietary system, which well suits the needs of the health care community. We greatly appreciate CMS's responsiveness to issues that were raised in last year's discussion of refined DRGs and approve of CMS's proposal to implement the MS-DRGs.

In developing the MS-DRGs, CMS found that it had to overhaul the Complication/Comorbidity (CC) list, mostly by adding *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) codes utilized by other refined groupers, including New York State's All-Patient DRGs (AP-DRGs) and 3M's All Patient Refined DRGs (APR-DRGs). In addition, for the first time since the CC list was developed, CMS evaluated the existing codes and removed some based on several criteria. We compared the old and revised CC lists and found that the revision added 2,002 codes and dropped 425 codes, for a net increase of 1,577 codes. Even though the number of added codes far exceeds the number of dropped codes, in the last three MedPAR files, the dropped codes were used an average of 40,864 times, while the added codes were used an average of only 887 times.

Many of the dropped codes pertain to unspecified conditions for which more specific codes are available and included on the revised CC list. The most dramatic example is ICD-9-CM code 428.0, Congestive heart failure, unspecified, which was applied to an average of 2.3 million Medicare fee-for-service cases a year during the past three years. This was the most widely used

secondary diagnosis code, despite the fact that 12 more specific codes were added in FY 2003. As shown in Table 1, the new codes were used far less frequently.

Table 1. Incidence of Secondary Diagnosis Coding for Heart Failure, FY 2004–FY 2006

ICD-9- CM Code	Description	New in FY 2003	Average Annual Number of Cases With the Code, from FY 2004–FY 2006
428.0	Congestive heart failure, unspecified		2,342,901
428.1	Left heart failure		4,298
428.20	Systolic heart failure; unspecified	✓	19,276
428.21	Systolic heart failure; acute	✓	3,490
428.22	Systolic heart failure; chronic	✓	7,152
428.23	Systolic heart failure; acute on chronic	✓	4,377
428.30	Diastolic heart failure; unspecified	✓	85,703
428.31	Diastolic heart failure; acute	✓	6,511
428.32	Diastolic heart failure; chronic	✓	13,573
428.33	Diastolic heart failure; acute on chronic	✓	6,579
428.40	Combined systolic and diastolic heart failure; unspecified	✓	4,949
428.41	Combined systolic and diastolic heart failure; acute	✓	874
428.42	Combined systolic and diastolic heart failure; chronic	✓	1,470
428.43	Combined systolic and diastolic heart failure; acute on chronic	✓	1,529
428.9	Heart failure, unspecified		6,490

If the revised CC list were implemented before hospitals had a chance to improve their coding to accommodate the revisions, then case-mix creep and inpatient prospective payment system (IPPS) overpayments would ensue. This is because, if CMS computed DRG weights based on current coding practices, then it would effectively assume that roughly 1.6 million cases, or 12% of all cases, would be down-weighted.

In reviewing the data, we found that most of the cases that would be regrouped into a lower-weighted DRG have charges that are lower than the charges of the remaining cases in the higher-weighted DRG but higher than the charges of the cases in the lower-weighted DRG. Regrouping the mid-range cases would, therefore, have the effect of increasing the weights of all the DRGs. The national case mix index would remain the same, however, because there would be a higher proportion of cases in the lower-weighted DRGs. However, if hospitals substituted included CCs for dropped CCs in the payment year, then the mix of lower-weighted and higher-weighted cases would not change as much as expected and the national CMI would increase, leading to unwarranted, higher IPPS payments.

Since hospitals vary greatly in the specificity of their coding practices and in their proportionate of cases with split DRGs, the overpayments would not be distributed across-the-board, but rather to the hospitals that had the most opportunity for coding correction and coding refinement. The hospitals that already use the more specific codes and those with a low proportion of cases in

split DRGs would receive fewer, if any, overpayments because their case mix indices would not increase as much, or at all.

New York hospitals, in particular, would have less opportunity for coding improvement than other hospitals because the union of the Medicare CC list and the New York State CC list has 279 more codes than the Medicare CC list alone. Thus, moving from the union CC list to the revised CC list would add only 1,298 codes, 279 fewer codes than in the rest of the country. Furthermore, New York hospitals are well-practiced in using specific codes because the New York State AP-DRG grouper differentiates between CCs and major CCs, as the MS-DRG grouper would do.

Since overpayments would not be distributed proportionately to each hospital, it would be unfair to recoup the overpayments through an across-the-board cut. Unfortunately, however, CMS may not have the option to recoup overpayments on a hospital-specific basis, as is done in New York. The statute authorizing CMS to avoid or recoup creep-related overpayments, Section 301(e) of the Benefits Improvement and Protection Act of 2000 (BIPA), seems to require that CMS do so by reducing the operating and capital standardized amounts:

Insofar as the Secretary determines that the adjustments under paragraph (4)(C)(i) for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year that are a result of changes in the coding or classification of discharges that do not reflect real changes in case mix, the Secretary may adjust the average standardized amounts computed under this paragraph for subsequent fiscal years so as to eliminate the effect of such coding or classification changes. §1886(d)(3)(A)(vi) of the Social Security Act (42 U.S.C. 1395ww(d)(3)(A)(vi))

Therefore, CMS proposed to avoid creep-related overpayments by reducing the standardized amounts by 2.4% in FY 2008 and by 4.8% in FY 2009. The CMS actuary estimated these “behavioral offsets” based on a study conducted by 3M of the experience of Maryland hospitals when that state’s all-payer reimbursement system adopted APR-DRGs.

We have two problems with the proposed behavioral offsets. First, we suspect they are too high because hospitals in other states—particularly New York—have more experience with secondary diagnosis coding than the Maryland hospitals had before their change to APR-DRGs. Therefore, hospitals in other states probably have less room for improvement and would likely generate less creep. Second, even though the BIPA requires creep avoidance or recoupment by cutting the standardized amounts, doing so as CMS proposed would greatly harm hospitals that have put the time and effort into accurate coding, as well as hospitals with a low proportion of cases in split DRGs. For those hospitals, the rate reductions would not offset higher case mix indices, yielding no effect on payments; rather, they would result in significant payment losses.

To resolve these problems, we recommend the following:

1. *CMS should retrospectively determine the national rate reduction to offset case-mix creep, even though the reduction would be made to future rates.* Retrospective determination is specifically authorized in Section 301(e) of the BIP1 and that is the only way to ensure that the level of the reduction is accurate.
2. *CMS should phase in the revised CC list and MS-DRGs to reduce the amount of creep-related overpayments that would be made in the first place. We recommend a five-year phase in during which the blend of the old CC list/CMS-DRG weights and the new CC list/MS-DRG weights would be 80%/20% in FY 2008, 60%/40% in FY 2009, 40%/60% in FY 2010, 20%/80% in FY 2011, and 0%/100% in FY 2012.*
3. *CMS should release the MS-DRG grouper software as soon as possible and should also encourage vendors to release products as soon as possible that ensure that both old and new CCs are listed among the first eight secondary diagnoses, as these are the only ones that can be used for payment purposes.*
4. *CMS should revise its systems so that all secondary diagnoses can be used for payment purposes in the future.*

With respect to the phase in, we believe it is prudent to begin to use the new CC list/MS-DRGs in FY 2008 so that hospitals are compelled as soon as possible (1) to improve their coding, and (2) to educate their physicians about complete documentation. *However, we would not want the new DRG weights to represent a majority of the blend until they can be based on the first year of corrected data.* The FY 2010 weights would be based on the FY 2008 cases, so they would reflect the first year's coding corrections and would presumably be more accurate. Since it can take several years for hospitals and physicians to adjust to new documentation and coding requirements, continuing blended payments in FY 2011 would be important to minimize creep-related overpayments.

Again, the goal is to minimize the aggregate level of creep-related overpayments so that hospitals not generating creep are not unfairly penalized by an across-the-board reduction. If overpayments could be recouped on a hospital-specific basis, an attenuated phase-in would not be necessary, but this may not be an option. We realize that our recommended phase in would be cumbersome because each case would have to be grouped twice to determine the DRG assignment under the CMS- and MS-DRG groupers. However, we believe this is the lesser of two evils, since the alternative for good-coding hospitals and those with relatively few patients in split DRGs would be to effectively eliminate the IPPS update for two years.

#### **CAPITAL IPPS**

What is most interesting about the capital PPS is that it is not actually a capital PPS. It would more correctly be described as an empirically-derived PPS for total inpatient acute care costs, with the standardized amount truncated to 7.8% of the total standardized amount. In 1991, after exhaustive research, CMS concluded that the appropriate way to reimburse capital costs under

the PPS was to add them to the operating PPS and then revise the regression model to develop empirical adjustments based on total cost rather than operating costs alone.<sup>1</sup> This is how capital costs have been incorporated into all the other prospective payment systems.

The reason why CMS did not combine the operating and capital PPS systems after the 10-year capital transition period was that it did not have authority to change the operating IME and DSH adjustments, since they are set in statute. The Agency did not want to apply the statutory IME and DSH adjustments to capital costs because they include “policy” adjustments, which are payments above the empirical level.

Nevertheless, the large urban, labor share, IME, and DSH adjustments in the capital PPS reflect empirical adjustments from a total cost model, as well as CMS’s updated thinking regarding variable specification.

### **Proposed Cuts are Excessive and Not Empirically Based**

While CMS still does not have the authority to change the operating PPS adjustments, it retains its authority to update the total cost model used for the capital PPS. For FY 2008, CMS has proposed to make two major changes to the capital PPS: it would eliminate the inflation update for urban hospitals for two years and eliminate the 3% large urban add-on altogether. CMS also requested comments on reducing or eliminating the IME and DSH adjustments. The savings generated from these proposals would not be reinvested in the federal rate, but taken as Medicare program savings.

Unfortunately, these changes are not empirically-based. Based on our own empirical analysis conducted during this brief comment period,<sup>2</sup> *we believe that the cuts that CMS is proposing to urban and large urban hospitals, and the cuts that CMS may be contemplating for teaching and DSH hospitals are grossly excessive and we strongly oppose them.*

We believe that if CMS wishes to update the capital PPS, then it should do so by revising its total cost regression model. If the Agency did that, we predict it would find that the large urban, teaching, and DSH variable coefficients are all still substantial and statistically significant. While the IME coefficient is lower than it was in 1991, the DSH coefficient is higher and the labor share is much higher, in the area of 85%.

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<sup>1</sup> Prospective Payment System for Inpatient Hospital Capital-Related Costs; Final Rule, *Federal Register* 56, no. 169 (August 30, 1991). [BPD-681-F]

<sup>2</sup> We are not describing our models and presenting results with these comments because our research was necessarily limited and was conducted solely to determine whether the large urban, teaching, and DSH adjustments were still warranted. Our data sources were the 2004 cost reports, the FY 2004 MedPAR file for which we derived cost per case for last year’s comment letter, and the FY 2007 final rule Impact file. We used the same dependent and independent variables as the 1991 capital PPS regression model, and the same functional form of both the model and the variables.

## Margin Analysis was Too Limited

The impetus for CMS's proposals to eliminate the urban update and the large urban add-on, and to request comments on the IME and DSH adjustments, was that the Agency observed that large urban, teaching, and DSH hospitals had higher-than-average capital PPS margins from 1996–2004, which led to a concern that perhaps the payment adjustments were too generous. We also replicated CMS's margin analysis and determined that it was too limited to form the basis for the Agency's conclusions and proposals.

While we observed the same 8-year margin trend in the capital PPS, we also examined the trend in the combined operating and capital PPS margin—both with and without the operating PPS policy adjustments<sup>3</sup>—the trend in the total (all payer) margin, and the trends in unit price and cost growth. We present these results in Tables 3 and 4.

Table 3. Comparative Medicare and Total Margins, 2004

	Medicare Inpatient Acute Care Margins			Total Margins (All Payers)	
	Capital	Operating and Capital, <u>with</u> Policy Adjustments	Operating and Capital, <u>without</u> Policy Adjustments	<u>With</u> Medicare Policy Adjustments	<u>Without</u> Medicare Policy Adjustments
All Hospitals	5%	0%	-10%	5%	3%
Large Urban	8%	2%	-10%	4%	2%
Not Large Urban	3%	-2%	-11%	6%	4%
High DSH	7%	4%	-10%	4%	2%
Other DSH	1%	-8%	-11%	6%	5%
Teaching	11%	4%	-8%	4%	2%
Non-Teaching	-3%	-6%	-14%	5%	4%
Large Urban, High DSH, and Teaching	12%	9%	-8%	3%	0%
Not Large Urban, High DSH, or Teaching	-9%	-11%	-13%	6%	5%

<sup>3</sup> Our data source was the HCRIS file, so our IME payments include payments made on behalf of Medicare Advantage enrollees. The proper way to identify the empirical IME and DSH amounts would have been to apply the capital PPS IME and DSH adjustments to the operating and capital PPS base payment amounts. Then the policy-related IME and DSH amounts would be the difference between the total payments and the empirical amounts. We did not have time to assemble the database we would have needed to properly derive empirical IME and DSH amounts, since the capital IME and DSH adjustments were not available on the cost reports for all hospitals during the capital PPS transition period and we do not have Impact files dating from FY 1998 (corresponding with 1996 cost report data). Therefore, we defined policy-related DSH payments as all operating DSH payments and policy-related IME payments as the amount of operating IME payments represented by the declining constant on the IME formula. Our shortcut both understates and overstates the policy amounts.

Table 4. Compound Annual Growth in Unit Price and Unit Cost, 1996–2004

	Medicare Capital		Medicare Operating and Capital <u>With</u> Policy Adjustments		Medicare Operating and Capital <u>Without</u> Policy Adjustments	
	Price	Cost	Price	Cost	Price	Cost
All Hospitals	0.1%	2.1%	2.1%	4.4%	2.1%	4.4%
Large Urban	-0.4%	1.4%	1.4%	3.9%	1.5%	3.9%
Not Large Urban	0.5%	2.7%	2.7%	4.7%	2.5%	4.7%
High DSH	0.0%	1.8%	1.9%	4.3%	2.0%	4.3%
Other DSH	0.0%	2.4%	1.9%	4.4%	2.0%	4.4%
Teaching	-0.4%	1.0%	1.3%	3.6%	1.5%	3.6%
Non-Teaching	-0.1%	2.8%	2.3%	4.7%	2.0%	4.7%
Large Urban, High DSH, and Teaching	-0.5%	0.8%	0.8%	3.5%	1.4%	3.5%
Not Large Urban, High DSH, or Teaching	0.8%	4.4%	2.8%	5.2%	2.7%	5.2%

We believe that it is not appropriate to examine capital PPS margins alone to ascertain whether the capital PPS adjustments are excessive because the adjustments were derived from a total cost regression model. That is why we looked at the combined operating and capital PPS margins.

What we observed was the following:

- ***The combined operating and capital PPS margin was zero in 2004. Therefore, if CMS revises its capital PPS adjustments, they should be budget neutral.***
- When removing the IME and DSH policy payments, the combined operating and capital PPS margin was significantly negative for all classes of hospitals, including large urban, teaching, and high-DSH hospitals, which we defined as hospitals having a disproportionate patient percentage of at least 17.5%. Therefore, the cuts enacted in the Balanced Budget Act of 1997 (BBA) were excessive. Furthermore, hospitals receiving IME and DSH policy payments are now having to divert some of those payments to cover their Medicare inpatient losses rather than using all of them to help finance their social missions.
- Even with the Medicare IME and DSH policy payments, the total margins of large urban, teaching, and high-DSH hospitals were lower than the margins of other hospitals. Without the policy payments, hospitals with all three characteristics would have had a zero total margin compared with a 5% total margin for hospitals with none of these characteristics. Therefore, targeting large urban, teaching, and DSH hospitals for cuts, as CMS proposed and is otherwise considering, is not only wrong because the cuts are not empirically justified, but also wrong because they could lead to access problems for Medicare beneficiaries.
- Large urban, teaching, and high-DSH hospitals have all experienced slower capital unit cost growth than other hospitals over the 8-year study period. This may be because these hospitals have been in a lower-spending phase of their capital cycle than other hospitals. This is

possible, since the capital cycle is roughly 20 years, far longer than the 8-year study period. To the extent that this is the case, cutting the payment adjustments would violate the promise of the capital PPS, which was that hospitals could accumulate surpluses during their low-spending phases to supplement merely average payments when they re-entered the high-spending phase.

We know for a fact that our member hospitals, which are virtually all large urban, teaching, and DSH hospitals, are in the low-spending phase of their capital cycle because they underwent major modernizations at the same time in the early 1990s. They were put on the same capital cycle by the New York State Department of Health (DOH), when DOH imposed a moratorium on major modernizations in the 1980s. When the moratorium was lifted, the backlogged projects were all initiated at the same time.

Another possible explanation for the lower capital unit cost growth of large urban, teaching, and high-DSH hospitals could be that since Medicare capital payments are no longer tied to Medicare capital costs, these hospitals have the flexibility to spend their scarce resources on their most pressing needs, which might overwhelm the need for continued growth in capital investment.

We know that our member hospitals are not investing in information technology and funding their depreciation at the rate of other hospitals, since those needs must compete with unfunded priorities, including: complying with new state laws on charity care and services to patients with limited English proficiency; reducing outcome disparities between majority and minority communities; complying with quality improvement and quality-related data reporting requirements; maintaining primary care, standby capacity for emergency and trauma care, and other money-losing services; subsidizing losses from private payers who inappropriately deny payment for medically necessary services; and paying the enormous and ever-growing cost of medical liability insurance.

Given these burdens, it is absolutely essential that CMS not target arbitrary cuts at large urban, teaching, and DSH hospitals. *Furthermore, when or if CMS does update its total cost regression model, then we believe that the Agency should publish its results for public comment before proposing changes in the payment system.*

#### **DRGs: HOSPITAL-ACQUIRED CONDITIONS**

Section 5001(c) of the Deficit Reduction Act of 2005 (DRA) required the following:

1. By October 1, 2007:
  - a. Hospitals must identify whether secondary diagnoses were present on admission (POA), and
  - b. The Secretary must select at least two conditions that: (1) if developed in the hospital, could reasonably have been prevented through the application of evidence-based guidelines; (2) cause patients to be grouped into a DRG with a CC; and (3) have a high cost, a high volume, or both.

2. In FY 2009, CMS must ignore the identified conditions for DRG grouping purposes if they were not POA. This would be accomplished by suppressing the pertinent ICD-9-CM secondary diagnosis codes in the DRG grouping process. Therefore, we refer to this provision as the *CC suppression policy*.

In the proposed rule, CMS provided its condition selection criteria and recommended that six be subject to the new policy. All six are represented by a unique ICD-9-CM code, except that decubitus ulcers can be identified by one of nine codes, some of which identify the location of the ulcer on the patient's body. The affected ICD-9-CM codes are shown in Table 4.

Table 4. Proposed ICD-9-CM Codes to be Suppressed if Hospital-Acquired Conditions

Proposed Condition	ICD-9-CM Code	Description	Average Annual Cases with Code, FY 2004–FY 2006
1.	996.64	Infection and inflammatory reaction; due to indwelling urinary catheter	12,844
2a.	707.00	Decubitus ulcer; unspecified site	14,159
2b.	707.01	Decubitus ulcer; elbow	2,261
2c.	707.02	Decubitus ulcer; upper back	4,033
2d.	707.03	Decubitus ulcer; lower back	111,738
2e.	707.04	Decubitus ulcer; hip	19,395
2f.	707.05	Decubitus ulcer; buttock	38,898
2g.	707.06	Decubitus ulcer; ankle	10,308
2h.	707.07	Decubitus ulcer; heel	66,054
2i.	707.09	Decubitus ulcer; other site	44,866
3.	998.4	Foreign body accidentally left during a procedure	861
4.	999.1	Complication of medical care; air embolism	47
5.	999.6	Complication of medical care; ABO incompatibility reaction	57
6.	038.11	Staphylococcus aureus septicemia	36,601

*After reviewing the selection criteria and proposed conditions, and conferring with our Infection Control Workgroup and our Quality Improvement Organization (IPRO), we have determined that we can support the inclusion of the three serious preventable events in the new policy:*

1. Foreign body accidentally left during a procedure (998.4);
2. Air embolism (999.1); and
3. ABO incompatibility reaction (999.6).

We believe these conditions are appropriate for the new policy because it is easy to determine whether they developed in the hospital or prior to admission, they are definitely preventable, and,

although they occur infrequently, they are serious and expensive events. Thus, they meet the selection criteria set forth in the DRA.

*We do not believe that the other proposed conditions (catheter-associated urinary tract infections, decubitus ulcers, and Staphylococcus aureus septicemia) are appropriate for the new policy because they are not always reasonably preventable and, with only one exception, CMS did not propose criteria for excluding patients in whom those conditions would probably not be preventable.* It would be inappropriate to withhold funding without examining the clinical conditions in which complications occur and making allowances for unavoidable complications.

On the other hand, we appreciate the desire by Congress and CMS to associate financial penalties with avoidable complications. Therefore, we recommend that CMS develop risk-adjusted models for infection rates that could be incorporated into *Hospital Compare* and possibly into CMS's value-based purchasing plan. Like the mortality models, infection models would control for the patient characteristics and diagnoses that would otherwise serve as exclusion criteria under the CC suppression policy. Furthermore, if important risk factors were missing from the claims database, they could be added by assigning new ICD-9-CM codes.

Approaching infection control through the quality program rather than through the reimbursement system—although the quality program is about to have financial repercussions—would benefit patients as well as providers. By comparing actual and expected complication rates, CMS could identify hospitals with statistically significant infection control and other problems and work with them individually. In addition, the national average complication rates would improve steadily as hospitals strove to obtain more VBP points.

Below, we comment briefly on the problems associated with including the proposed infections in the CC suppression policy.

### **Catheter-associated Urinary Tract Infections (UTIs)**

According to the Centers for Disease Control (CDC) prevention guidelines, using a closed drainage system is the key to preventing catheter-associated UTIs because none of the other recommended prevention steps have been shown to be as effective. Using a closed method for drainage substantially reduces the risk compared with using an open drainage system. However, even if this guideline were followed faithfully, CDC estimates that 20% of catheterized patients would still be expected to develop a UTI. Moreover, some risk factors—e.g., admission with a catheter, advanced age, debilitation, and being postpartum—predispose patients for catheter-associated UTIs.

Because such a high percentage of patients are expected to develop catheter-associated UTIs, even when the hospital adheres to best practices, and because patients with a high risk of developing these infections would not be excluded from the CC suppression policy, we believe this condition does not meet the selection criterion of being reasonably preventable.

Furthermore, our Infection Control Workgroup was concerned about the ability to identify patients with a UTI present on admission. They advised that the only way to be sure whether a

UTI was POA would be to screen all patients likely to have a urinary catheter during their hospital stay, which would be an unfortunate diversion of scarce resources. Even then, pre-admission UTIs would not be detected for nursing home residents admitted with a catheter in place and who were on or recently completed antibiotic therapy for treatment of a UTI, since their urine cultures would be negative for bacterial growth.

### **Decubitus Ulcers**

The guidelines for avoiding pressure ulcers are clear and there are good diagnostic scales for identifying high-risk patients to whom the protocol should be applied. However, there is insufficient evidence that pressure ulcers can reasonably be prevented in high-risk patients, despite good compliance with the prevention protocol. Therefore, to include this condition in the CC suppression policy, CMS would have to identify criteria for excluding certain patients, which the Agency did not propose.

*Again, we believe that the better route to reducing pressure ulcers would be for CMS to develop a risk-adjusted model for evaluating hospital ulcer rates. If CMS followed that course, then we would also recommend the development of ICD-9-CM codes that would capture each patient's level of risk for developing a pressure ulcer.* This would be similar to the body mass index and other V-code scales that have been introduced in recent years. Simply adjusting for this risk factor would motivate all hospitals to improve their patient assessment, which, in turn, would help them better identify patients who should receive the prevention protocol.

### ***Staphylococcus aureus* Septicemia**

*S. aureus* septicemia is the most problematic of the conditions proposed for the CC suppression policy because there are so many co-occurring conditions that place patients at high risk, all of which would significantly reduce the ability to avoid the condition, even with careful application of the prevention protocols. CMS appropriately proposed to exclude patients admitted to the hospital with *S. aureus* pneumonia. However, many other patients are at high risk of developing *S. aureus* septicemia, including—but not limited to—patients admitted with portals for infection such as cellulitis or abscesses, and patients admitted with suppressed immune systems such as patients with HIV/AIDS or patients receiving chemotherapy or corticosteroids.

### **WAGE INDEX: MEDPAC STUDY AND CMS PROPOSALS FOR FY 2009**

The Tax Relief and Health Care Act of 2006 (TRA) required the Medicare Payment Advisory Commission (MedPAC) to submit a report to Congress that addresses several issues of concern pertaining to the hospital wage index. MedPAC's report will be published by the end of this month, June 2007. In addition, in the FY 2009 proposed rule, CMS must propose at least one revision to the hospital wage index and must consider MedPAC's report in developing its proposal(s).

Rather than merely studying the issues of concern to Congress, MedPAC will propose a major overhaul of the hospital wage index in its June 2007 report. We have had the opportunity to thoroughly review this proposal—although we have not yet modeled its financial impact—and

would like to share our views about its strengths and weaknesses. In particular, there is a feature of the proposal that we like and another that we dislike immensely.

### **Customizing Labor Markets**

*The feature that we like is that MedPAC would sculpt the current labor markets, which are plains and mesas, into hills and valleys, both between and within Core-Based Statistical Areas (CBSAs).* By limiting the difference between wage indices of contiguous counties in different CBSAs, MedPAC would reduce unfair payment differences that have given rise to the proliferation of formula-driven and political reclassifications. And by adjusting for wage level differences within CBSAs, MedPAC would address the problem that some CBSAs combine dissimilar labor markets, which has harmed the higher-wage areas.

While we like this feature conceptually, we do not favor the technical approach that MedPAC suggests. The Agency proposes an arbitrary—and expensive—10% limit on the difference between the wage indices of contiguous counties, and proposes to use outdated decennial census data to disaggregate wage levels within CBSAs.

We much prefer an empirical approach, an example of which is the out-migration adjustment provided by Section 505 of the Medicare Modernization Act of 2003 (MMA). The “505” adjustment blends the wage indices of contiguous CBSAs for counties in which a high proportion of hospital employees reside in a different CBSA. The commutation data are provided by BLS in the form of a table that provides the number of workers who live and work in every combination of counties.

During the next few months, we will model different approaches to implementing a similar methodology both across and within CBSAs and share our results with CMS. The first option we are interested in exploring would be to compute county-level wage indices from the cost report data for counties with a minimum population and/or number of hospitals. Then, based on the BLS commutation data, we would compute a blended wage index for each county in which a hospital is located based upon the residential distribution of the county’s workforce among different counties or CBSAs. We would not restrict ourselves to contiguous counties.

If the cost reports had a worksheet in which hospitals provided the number of FTEs living in each county, we could customize a wage index for each hospital, which might be ideal. That was the spirit behind CMS’s nearest neighbor proposal in 1994; however, those wage indices had a far weaker empirical basis.

### **Using BLS Data to Derive the Wage Indices**

MedPAC will strongly recommend that CMS change the data source for the wage indices from hospital cost report data to BLS data. We vigorously oppose this recommendation.

Our greatest concern about the use of BLS data is that using them for a purpose other than statistical comparisons might invite a corruption of the data. The BLS survey data are “pure” because they are only used for statistical reporting. If the data were used for Medicare

reimbursement and if any organization could obtain and submit a survey, then providers in any CBSA could collude to bias the results. This would render the data useless for the entire U.S. economy.

Regardless of any safeguards that might exist today, an entire infrastructure of auditors would need to be built around the BLS survey process to protect its integrity. This would be redundant to the cost report auditors and, therefore, wasteful of government resources. On the other hand, if BLS specifically restricted its data collection to a sample of employers, then its choice of employers would be vulnerable to criticism. In the end, the cost report data—while admittedly imperfect—are still the most reliable for Medicare wage index construction.

Other limitations of the BLS data include the following:

- The BLS data contain no fringe benefits, which must be included to fully reflect regional differences in compensation levels. To accommodate this problem, MedPAC imputed a fringe benefit adjustment for each CBSA from the cost report data. This is problematic because the fringe benefit adjustment reflects skill mix while the BLS data do not. Since the benefit share of total compensation declines as salaries increase, the fringe benefit adjustment is too low for tertiary hospitals, which have a more expensive mix of personnel. Therefore, MedPAC's approach underestimates the wage levels of areas with high concentrations of tertiary hospitals. In addition, when hospitals were missing benefits on Worksheet A or when the benefits were outliers, MedPAC used Worksheet S-3, Part II data. This is problematic because those data would not be available if the wage index survey were discontinued—another feature of MedPAC's proposal. If hospitals had to continue to fill out the wage index survey to meet this need, then there would be no reduction in reporting burden, and no benefit whatsoever to using BLS data.
- MedPAC excluded Part A physicians, which causes an understatement of wage levels in inner-city communities. While most Part A physicians are teaching physicians and, therefore, excluded from the wage index, many hospitals employ physicians to staff outpatient clinics. This tends to occur in inner-city communities where hospital clinics serve as the family doctor. Patients generally do not have access to private physician offices because physician reimbursement is inadequate from the State Medicaid programs. MedPAC excluded physicians from the BLS data because they would have been over-represented in the occupational mix compared with their representation in the hospital cost report data. However, this decision underestimates the wage levels of inner-city communities.
- MedPAC was forced to weight the occupational data based on each occupation's share of wages instead of hours or even employees. This also leads to error.
- Using BLS data restricts CMS's flexibility to revise or customize labor markets.

***In preparing its proposals for FY 2009, we implore CMS not to switch the wage index data source to BLS data and to continue to use the hospital cost report survey. Despite its problems, we believe it is the best and most reliable data source.***

## VALUE-BASED PURCHASING PLAN

Section 5001(b) of the DRA required CMS to develop a VBP plan. While further legislation would be needed to implement the plan, the prior Congress aimed for implementation to begin in FY 2009. During the past year, CMS has developed a plan and shared it in the context of an evolving options paper and in listening sessions with the public. We have followed that development and have also analyzed and modeled the plan as outlined in the version of the options paper issued April 12, 2007.

At the outset, we want to commend CMS for the basic structure of the plan. It is modeled on the RHQDAPU program in that it would withhold a certain percentage of funding from each hospital, which the hospital could earn back by meeting certain performance goals. Since the performance goals are always based on a prior year's data, theoretically at least, any hospital could earn back its entire withhold. This contrasts with the Premier demonstration project under which all the rewards were distributed to hospitals performing in the top two deciles. It is appropriate that the structure of the VBP and Premier plans is different because the financing of the incentive payments under the two plans is different: the Premier plan was financed with new money, while the VBP plan is financed by withholds.

***Because we believe that the opportunity must be available for all hospitals to earn back their full without amount, we strongly recommend that CMS preserve its policy to base the performance goals on a prior year's data.***

Essentially the VBP plan works as follows (italicized words are VBP terms of art):

- CMS would compute an *overall score* for each hospital by dividing the number of points the hospital earned by the maximum number of points it was possible for the hospital to earn. Then the overall score would be converted into an earned share of the withhold amount through an *exchange function*.
- The overall score would be based on points earned for each measure in the VBP portfolio. The conditions currently evaluated by CMS—i.e., heart attack, heart failure, pneumonia, and surgical infection prevention—would not be weighted equally; rather they would be weighted indirectly by the number of measures included for each condition.
- Points for each measure would be the higher of *attainment* or *improvement* points, with each type conferring between zero and 10 points. For each type, one point would be conferred for achieving a *threshold* score and 10 points would be conferred for achieving a *benchmark* score. All thresholds and benchmarks would be computed from the prior year's data.
- For any given measure, the attainment range would be the same for all hospitals. Its threshold would be the median score (1 point) and its benchmark would be the average score for hospitals at or above the 90<sup>th</sup> percentile (10 points). The exception to this would be that for *topped-out measures*, the threshold for all measures would always be a score of 60% and the benchmark for all measures would always be a score of 90%.

- The improvement range would be hospital-specific. Its threshold would be the hospital's prior year score, while its benchmark would be the attainment benchmark.

After modeling how the plan would work, we developed several recommendations, which center on hospital and data exclusions, point scoring, identifying topped-out measures and setting their attainment range, the exchange function, the use of unearned withholds, and the timing of implementation.

The data source we used to analyze the VBP plan was the *Hospital Compare* database, and the releases we used were the March 2007 file for the "current" year and the March 2006 file for the "prior" year. The March 2007 file included data from the fourth quarter of 2005 through the third quarter of 2006, and the March 2006 file included data from the fourth quarter of 2004 through the third quarter of 2005. Again, data from the prior year are used to compute the national attainment range for each measure and the hospital-specific improvement range for each measure.

### **Hospital and Data Exclusions**

According to the options paper, a hospital would be excluded from VBP if it did not have at least 50 cases among measures with at least 10 cases. In addition, a hospital that is otherwise included would be excluded from any particular measure for which it had fewer than 10 cases. *We recommend that whenever a hospital is excluded from performance evaluation, its data also be excluded from computation of the threshold and benchmark scores.* Since these scores are based on percentiles, including hospital data that are not good predictors of performance would be inappropriate and would bias the results.

### **Point Scoring**

The options paper says that a hospital would receive 10 points on any measure if its performance was greater than or equal to the benchmark. However, to receive lower point values, the hospital's performance would have to be greater than the threshold and interim scores, which would include even a slight fraction above those values but not the values themselves. This inconsistency is aesthetically disrupting and makes virtually no difference in the outcome. *Thus, we would appreciate it if CMS would confer points for hospital performance that is greater than or equal to the threshold and interim scores, as well as the benchmark.*

### **Identifying Topped-Out Measures and Setting their Attainment Range**

The options paper established a fixed attainment range for topped-out measures based on compliance scores of 60% to 90%, meaning that the threshold would be 60%, at which hospitals would receive one point, and the benchmark would be 90%, at which hospitals would receive 10 points. Furthermore, the options paper said that topped-out measures would be identified as those in which the 75<sup>th</sup> percentile score was statistically indistinguishable from the 90<sup>th</sup> percentile score, and it indicated which of the candidate VBP measures were topped out.

Because the options paper did not provide the formula it used to measure the statistical significance of the difference between the 75<sup>th</sup> and 90<sup>th</sup> percentile scores, we tried to replicate the paper's identification of topped-out measures using several different formulas, but were unable to do so. Part of our problem was surely that we used different databases, but we are nevertheless concerned that the options paper did not designate certain measures as topped out which we believe would meet the criteria.

Below we provide graphs of all the *Hospital Compare* process measures, which show where the regular and topped-out attainment ranges would be for each measure. We derived these ranges from both the March 2006 and March 2007 releases of the *Hospital Compare* database to observe the stability of the results, and show the ranges for both timeframes. Simply based on visual inspection, we would identify only three measures from the March 2006 database and only one measure from the March 2007 database that is not topped out (AMI-7 Thrombolytic within 30 minutes).

*Since the thresholds and benchmarks differ greatly for regular and topped-out measures while their actual scores are not very dissimilar, we believe that CMS should eliminate the distinction between regular and topped-out measures and simply set 60% and 90% as threshold and benchmark caps, respectively. That is, the thresholds for all measures would be the lower of 60% or the measure-specific median, and the benchmarks for all measures would be the lower of 90% or the measure-specific average scores of hospitals at or above the 90<sup>th</sup> percentile.*

### **The Exchange Function**

The options paper presented two alternative exchange functions for converting overall scores into earned shares of the withhold amount:

- A linear exchange that would provide a positive share for any score above zero, and would provide 100% of the withhold amount for any score at or above 85%; and
- An exponential exchange that would provide a positive share for any score above 10%, and would provide 100% of the withhold amount for any score at or above 90%. The exponential function would provide higher shares for lower scores than the linear function.

*We believe that the exchange function should accommodate the distribution of the overall scores.* If the thresholds are set at the lower of 60% or the median, then hospitals will accrue relatively high scores and the linear function could be appropriate. However, if the thresholds are set higher so that hospitals accrue relatively low scores, then the exponential function would be more appropriate.

*Regardless, we urge CMS to release a public use file with the hospital-specific data it used to prepare the options paper (with encrypted provider numbers and no names or state identifications), along with the formula it used to identify topped-out measures, and the threshold and benchmark scores it computed.* We would like to study how different scoring methodologies and exchange functions affect the earned withhold shares so we can provide more specific recommendations to CMS.

## **Use of Unearned Withholds**

The options paper presented alternative ways to spend the unearned withhold amounts in any given year, including: (1) using them to reward the best performing hospitals—e.g., the 10% of hospitals with the best performance; or (2) distributing them in proportion to each hospital's earned withhold amount. *Of those two options, we would favor the latter because it would distribute funding to more communities.* Since not all patients can go to only 10% of the nation's hospitals, concentrating the unearned withhold amounts in those communities would be inequitable.

*For the same reason—i.e., concern about community services—we would like CMS to consider the possibility of spending at least a portion of the unearned withholds on strategies to improve quality in poor performing hospitals, especially if those hospitals are the only provider in their communities.*

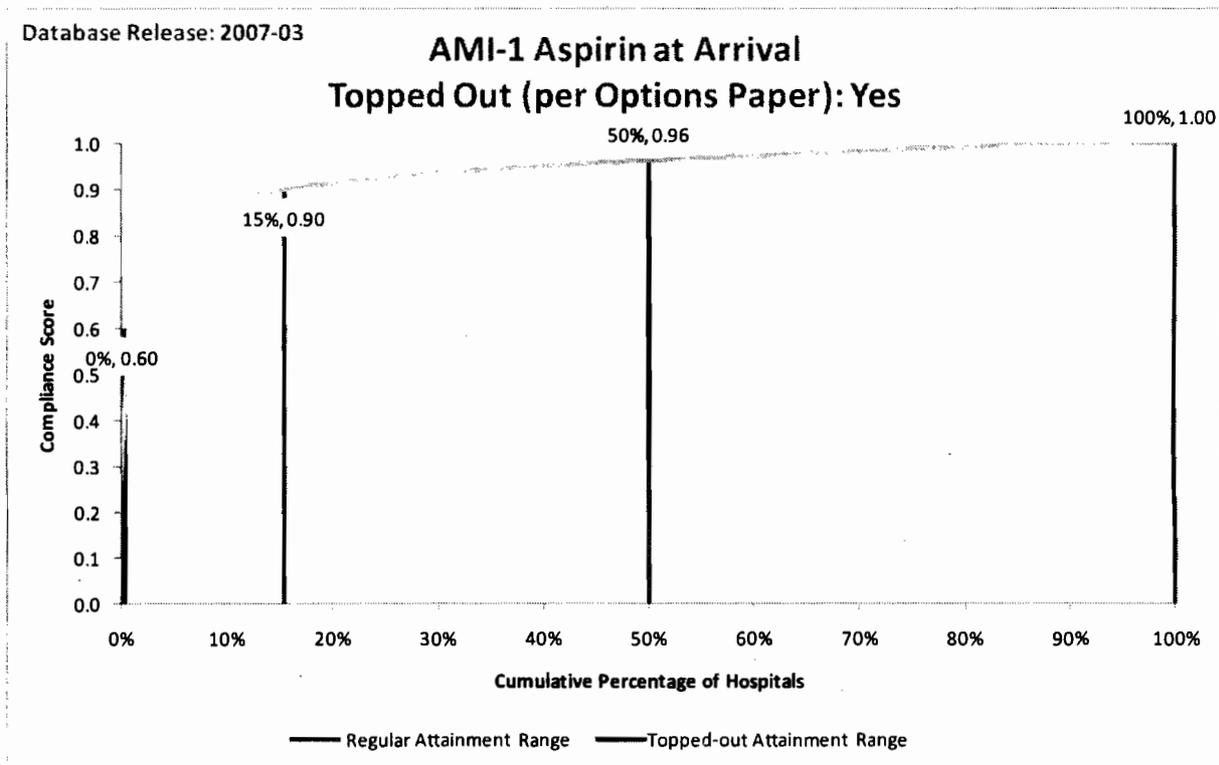
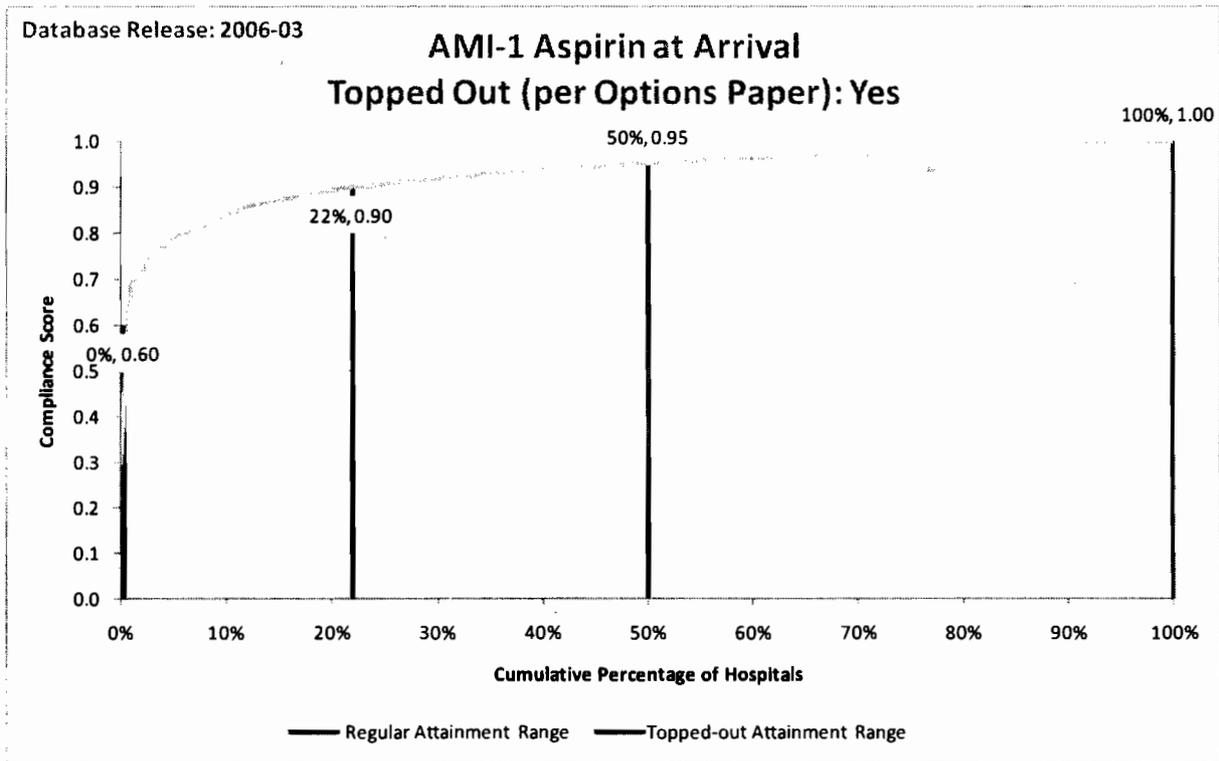
## **Timing of Implementation**

The options paper presented two alternatives for implementation:

1. The first alternative was a phase in. In FY 2009, earning 100% of the withhold amount would continue to be based upon the RHQDAPU criteria. In FY 2010, earning 50% of the withhold amount would be based on the RHQDAPU criteria and 50% would be based on performance. In that year, 2007 data would be used to set the thresholds and benchmarks for the attainment and improvement ranges, and 2008 data would be used to compute the current year's performance. In FY 2011, earning 100% of the withhold amount would be based on performance. In that year, 2008 data would represent the prior year and 2009 data would represent the current year.
2. The second alternative was no phase in. In FY 2009, earning 100% of the withhold amount would be based on performance. In that case, 2006 data would be used to set the thresholds and benchmarks for the attainment and improvement ranges, while 2007 data would represent the current year's performance.

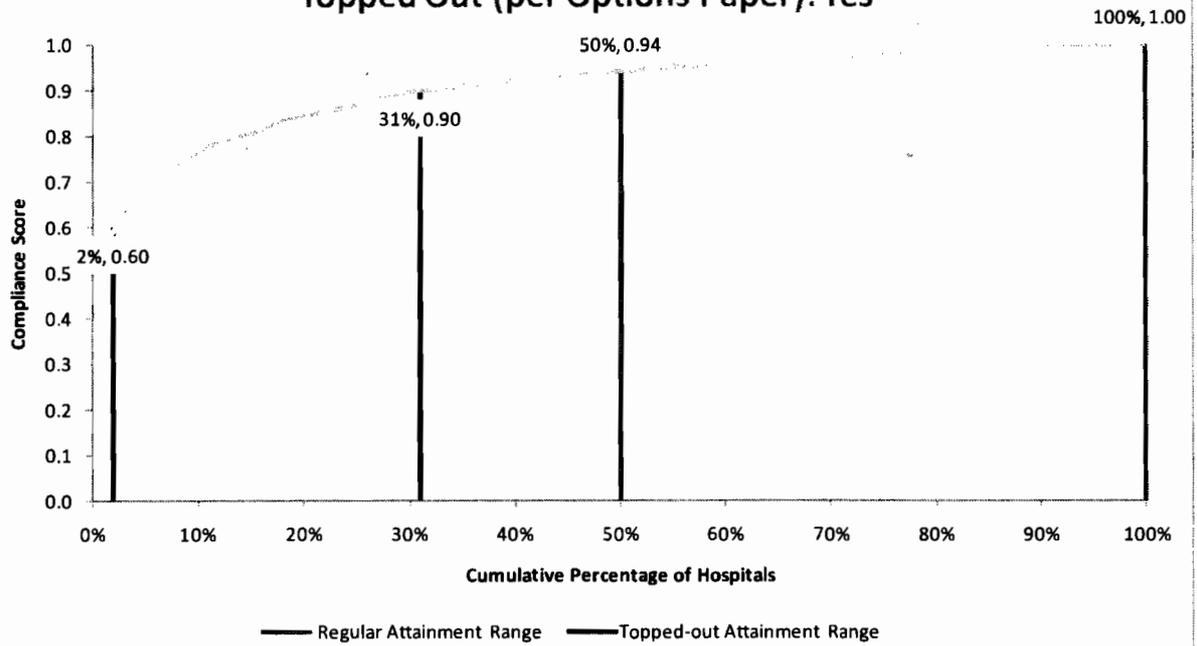
*Given that we are almost half-way through 2007, we think it would be unfair to base the FY 2009 withhold on 2007 data. Hospitals should be given notice about VBP implementation before the first "current" year begins. Therefore, we strongly favor option 1.*

## Value-Based Purchasing Plan Regular and Topped-Out Attainment Ranges



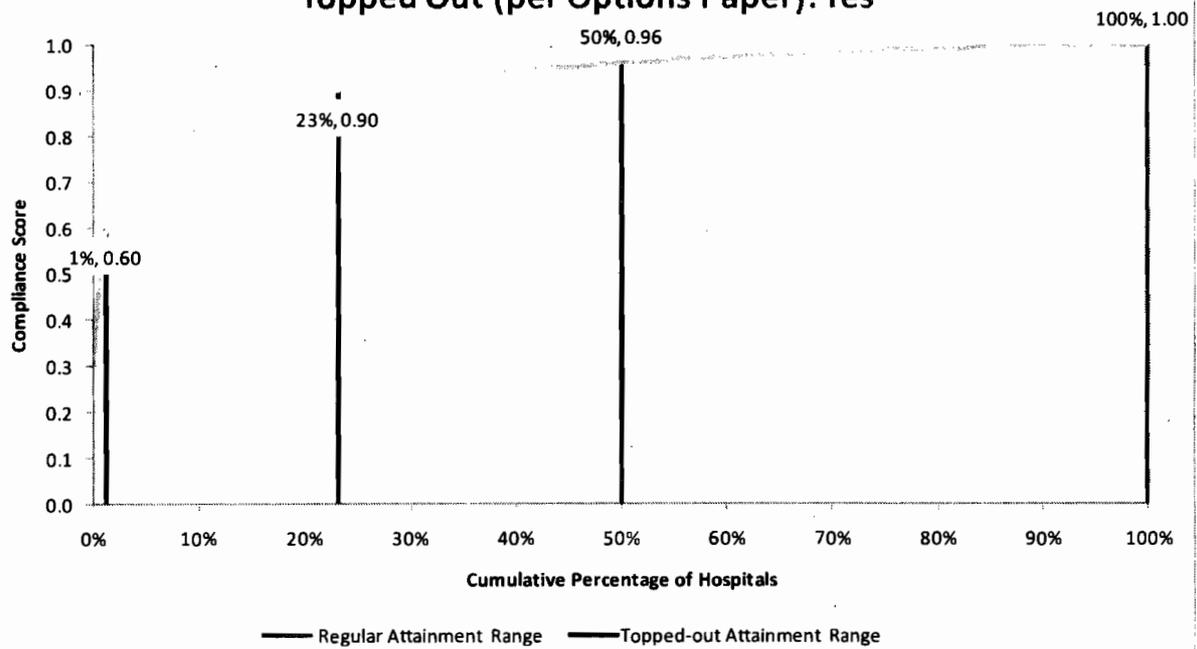
Database Release: 2006-03

### AMI-2 Aspirin at Discharge Topped Out (per Options Paper): Yes



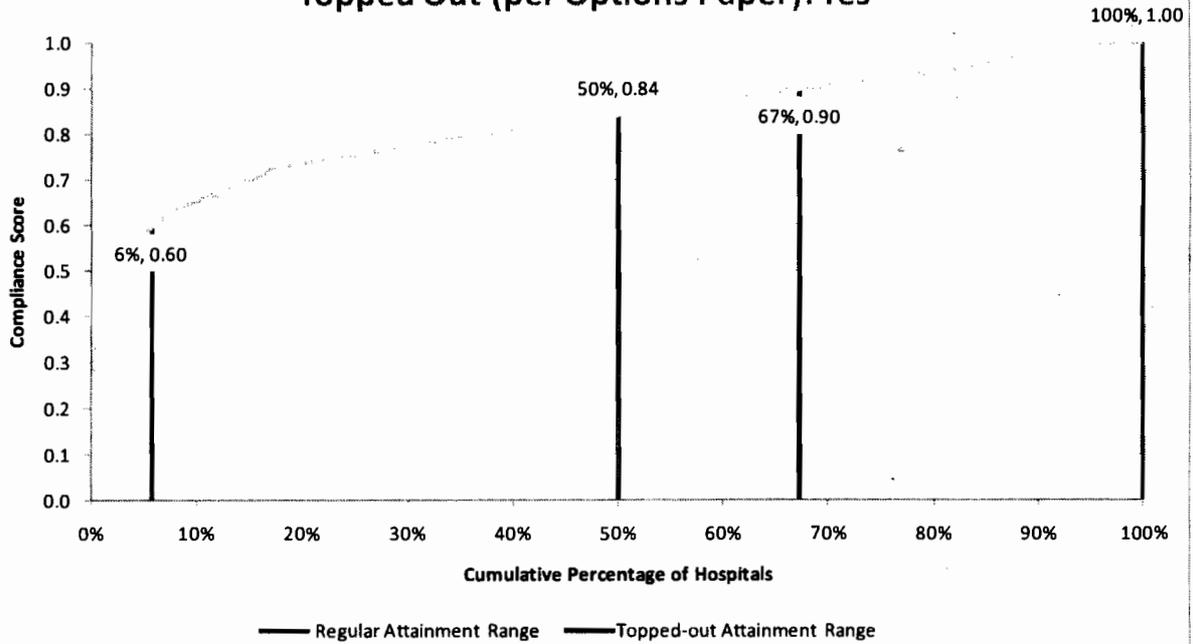
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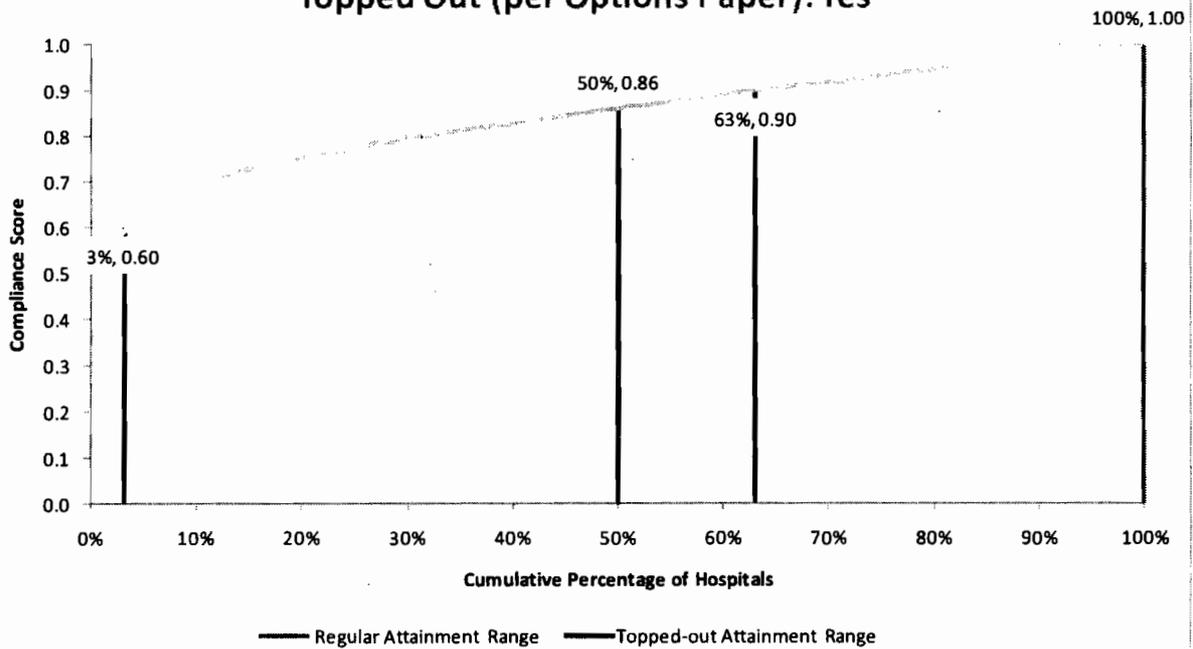
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### AMI-3 ACEI or ARB for LVSD Topped Out (per Options Paper): Yes



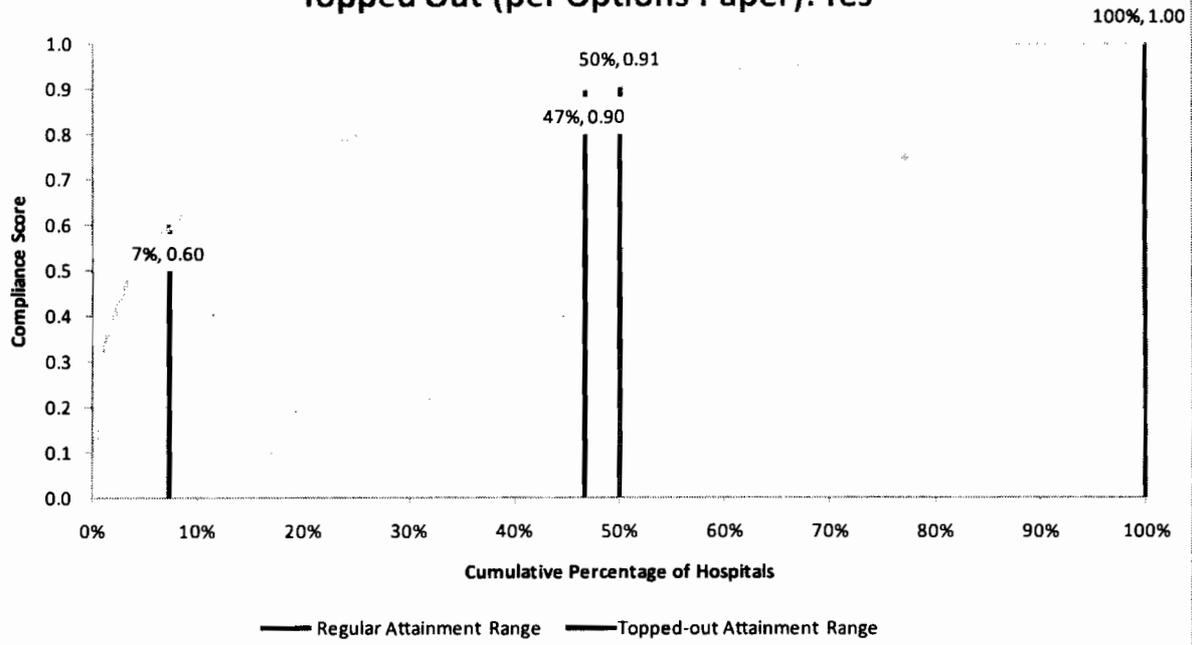
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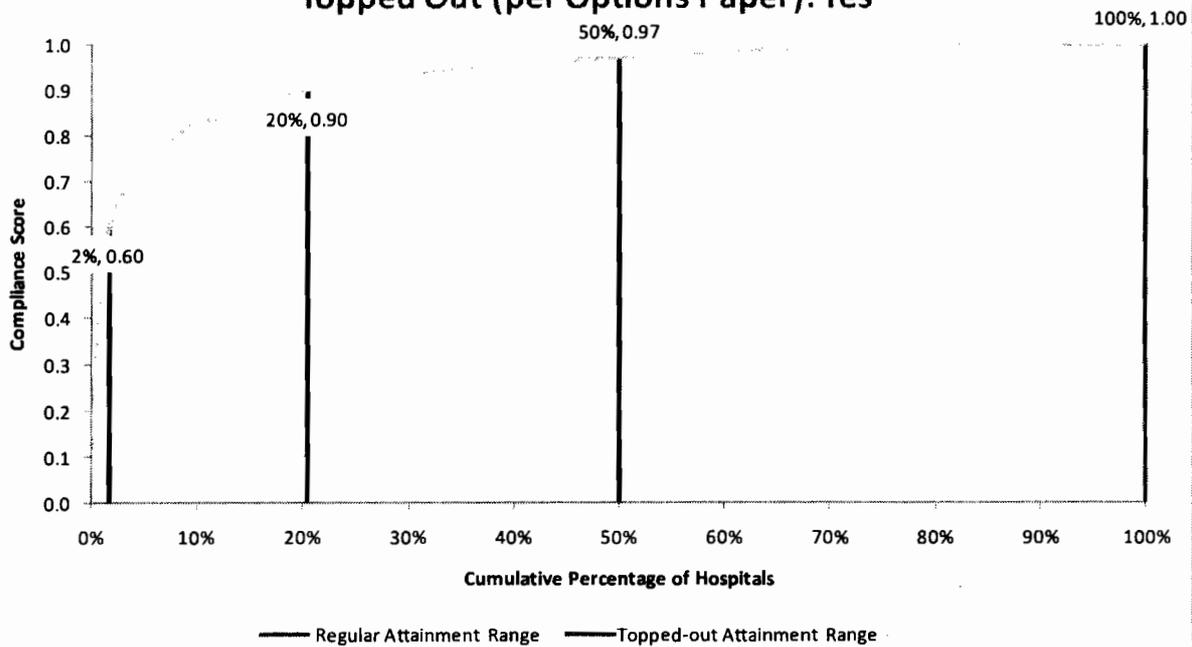
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### AMI-4 Smoking Cessation Topped Out (per Options Paper): Yes



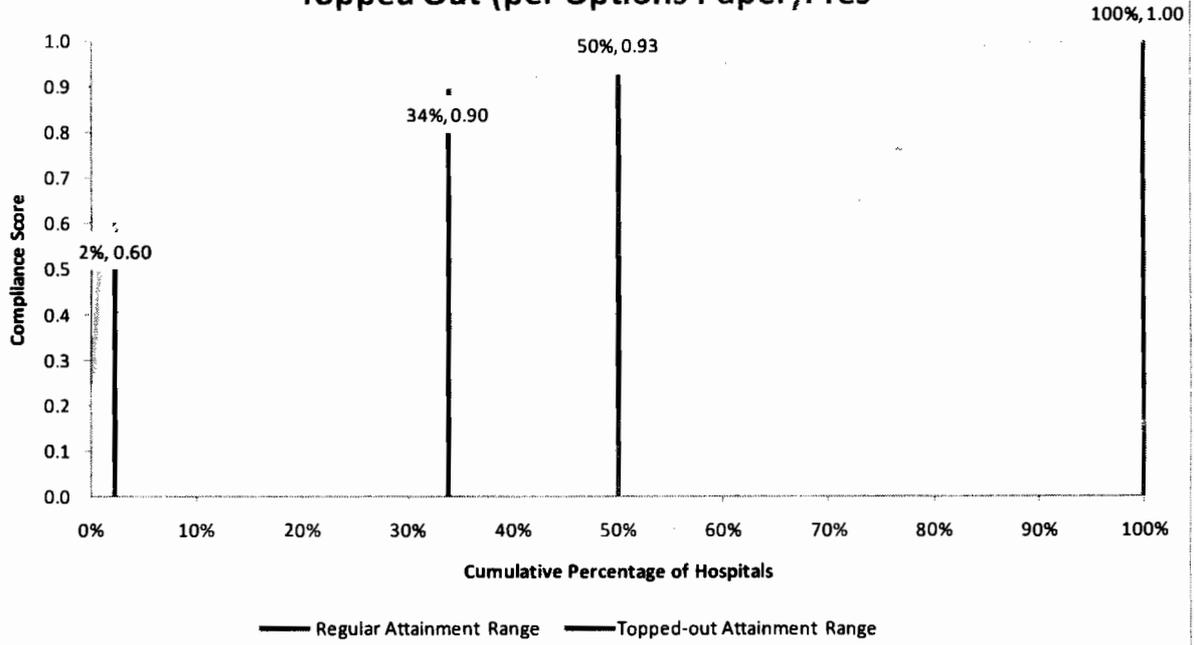
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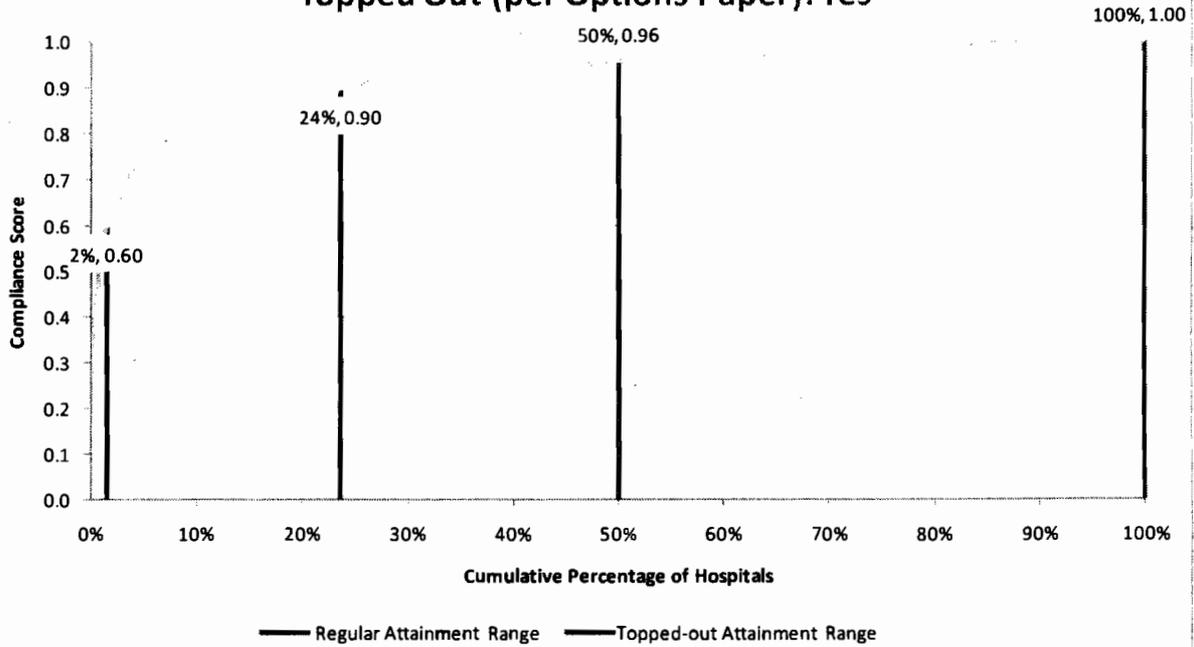
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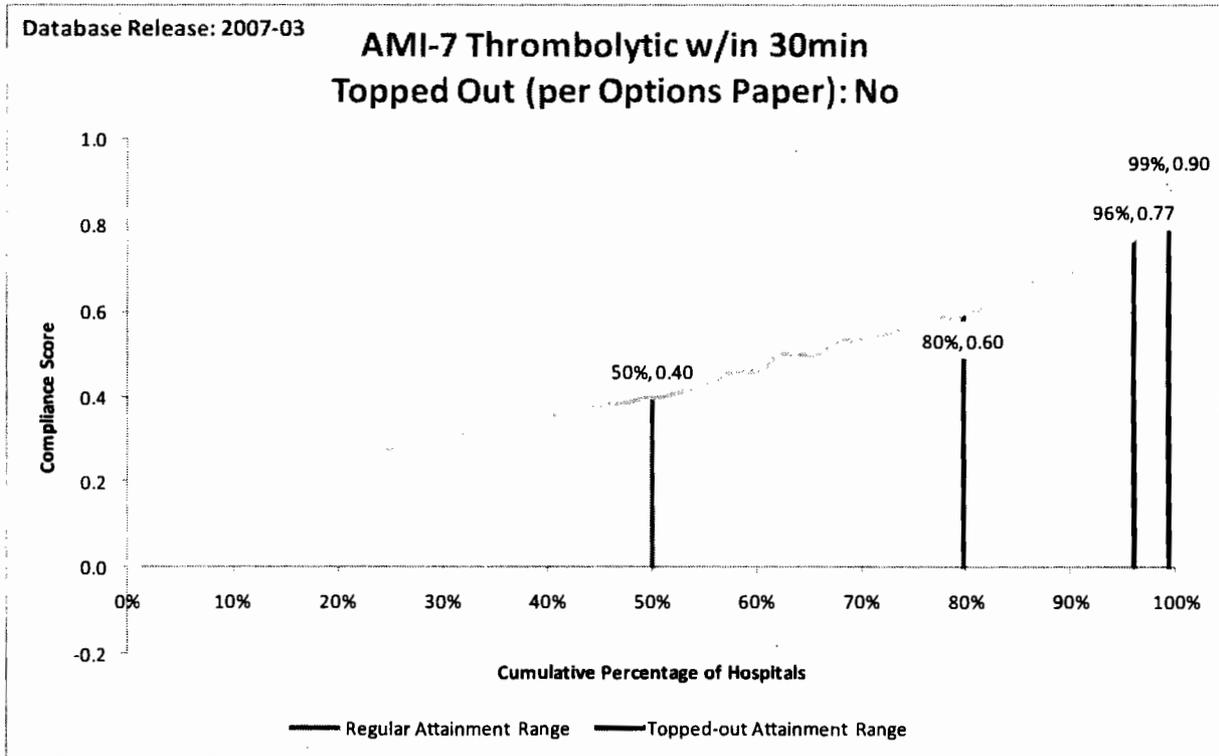
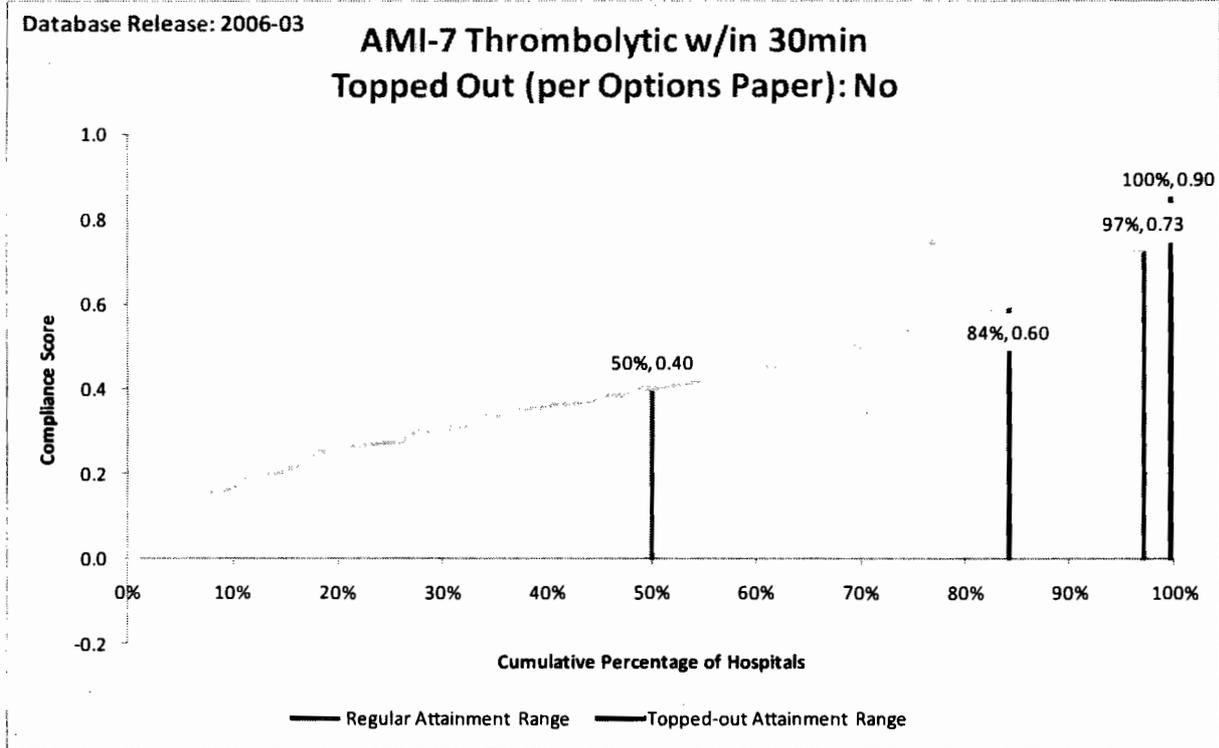
### AMI-5 Beta Blocker at Discharge Topped Out (per Options Paper): Yes



Database Release: 2007-03

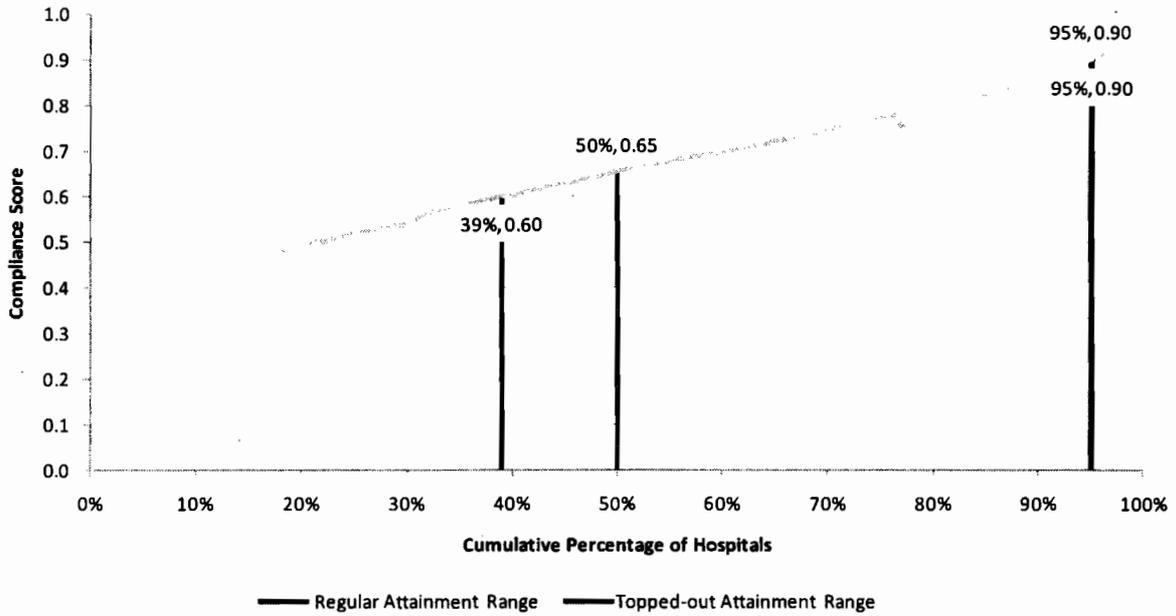
### AMI-5 Beta Blocker at Discharge Topped Out (per Options Paper): Yes





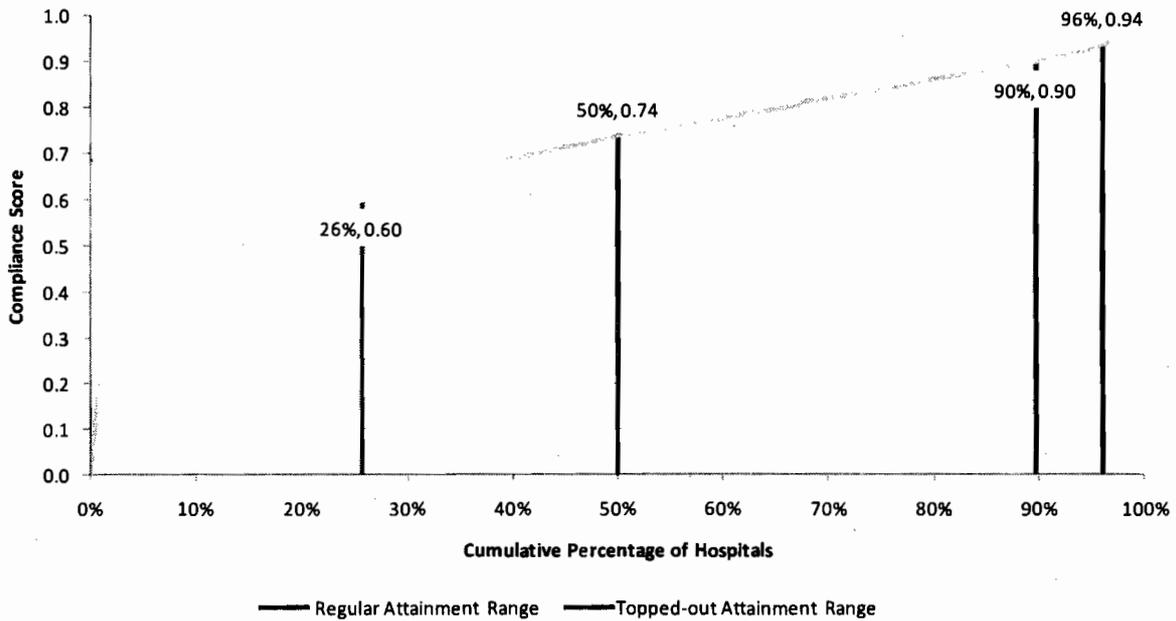
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### AMI-8 PCI w/in 120min Topped Out (per Options Paper): No



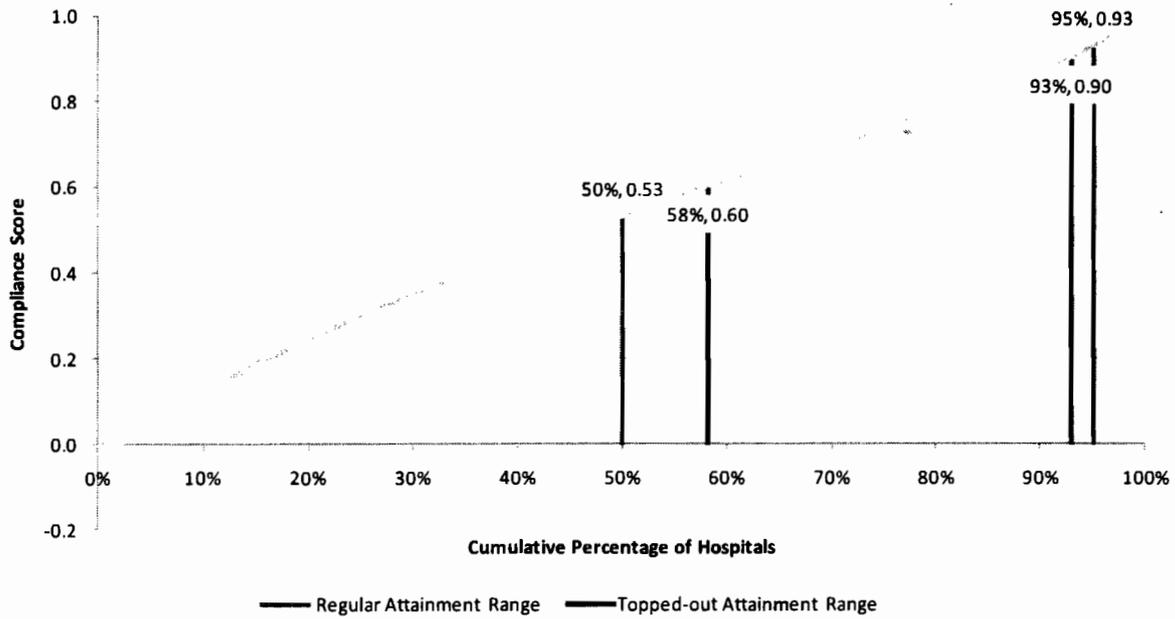
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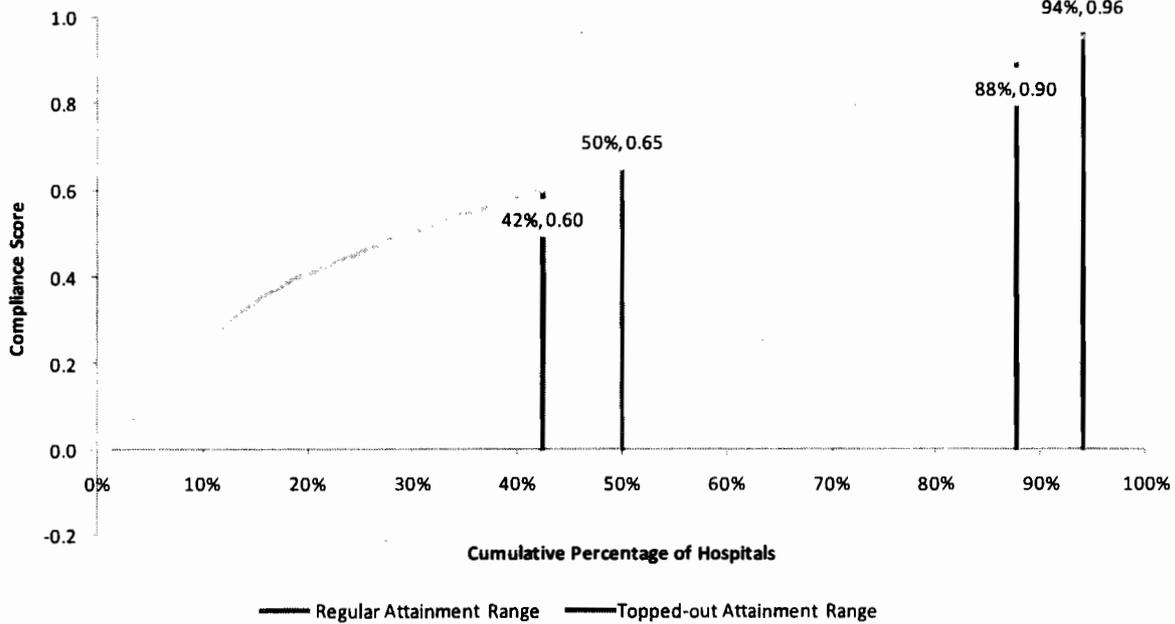
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### HF-1 Discharge Instructions Topped Out (per Options Paper): No



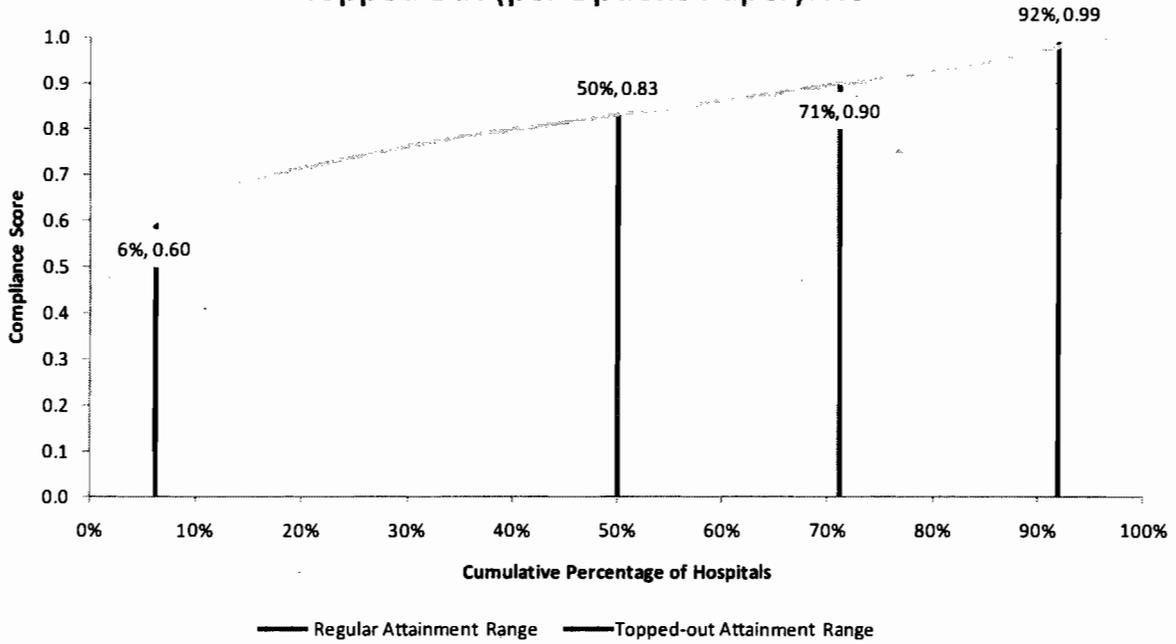
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### HF-1 Discharge Instructions Topped Out (per Options Paper): No



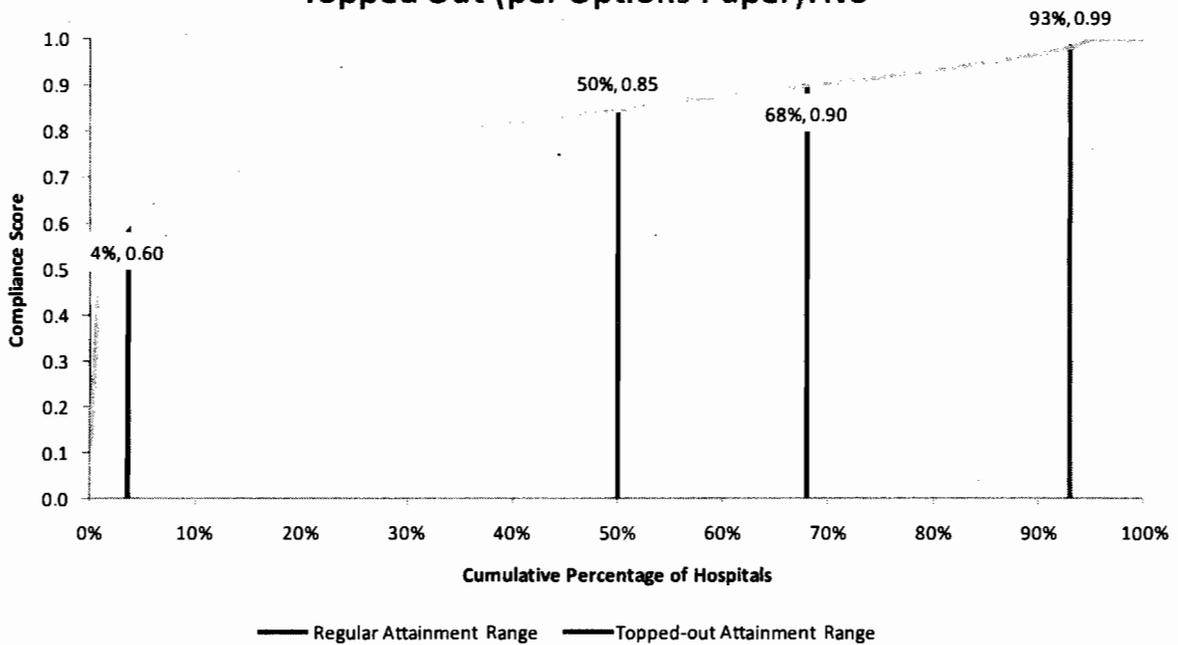
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### HF-3 ACEI or ARB for LVSD Topped Out (per Options Paper): No



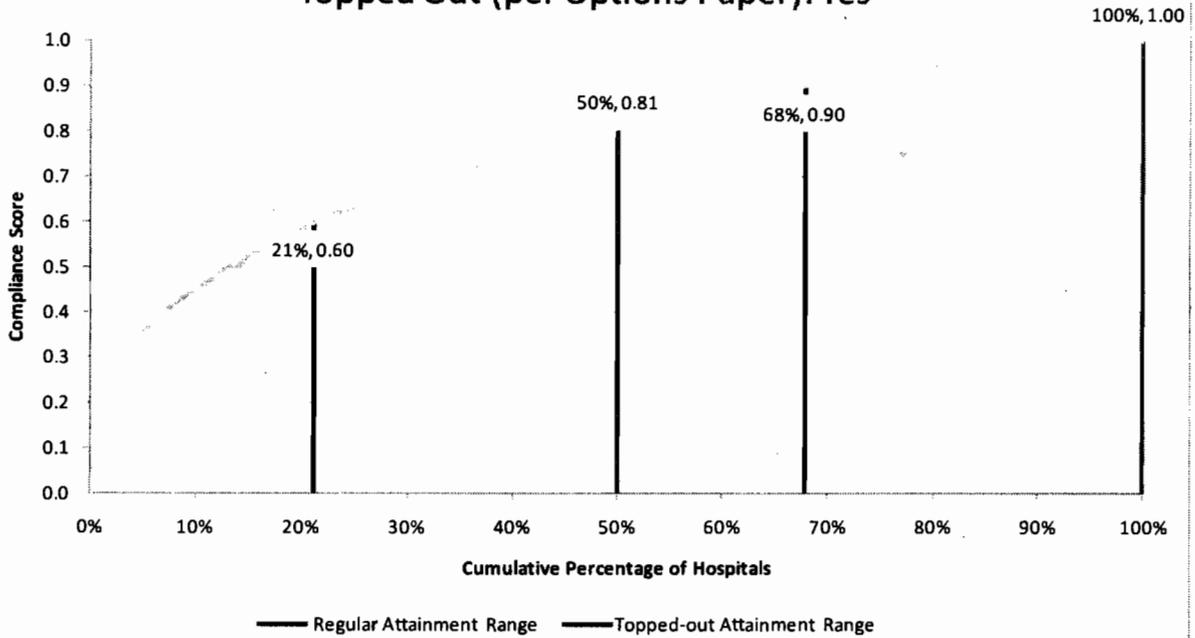
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### HF-3 ACEI or ARB for LVSD Topped Out (per Options Paper): No



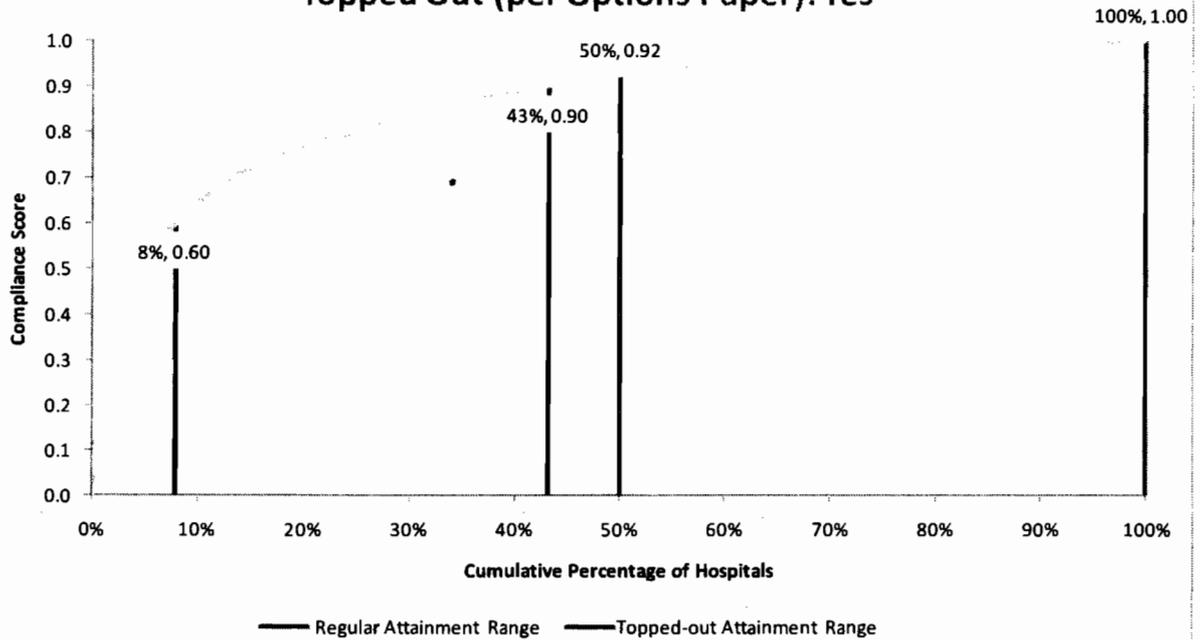
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### HF-4 Smoking Cessation Topped Out (per Options Paper): Yes



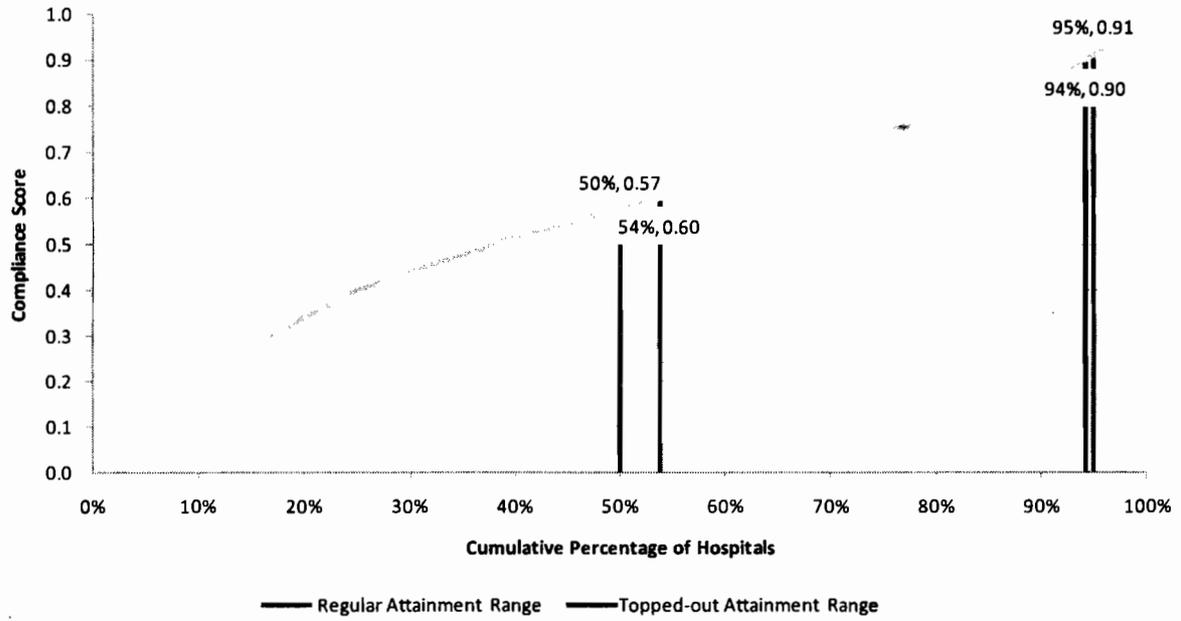
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### HF-4 Smoking Cessation Topped Out (per Options Paper): Yes



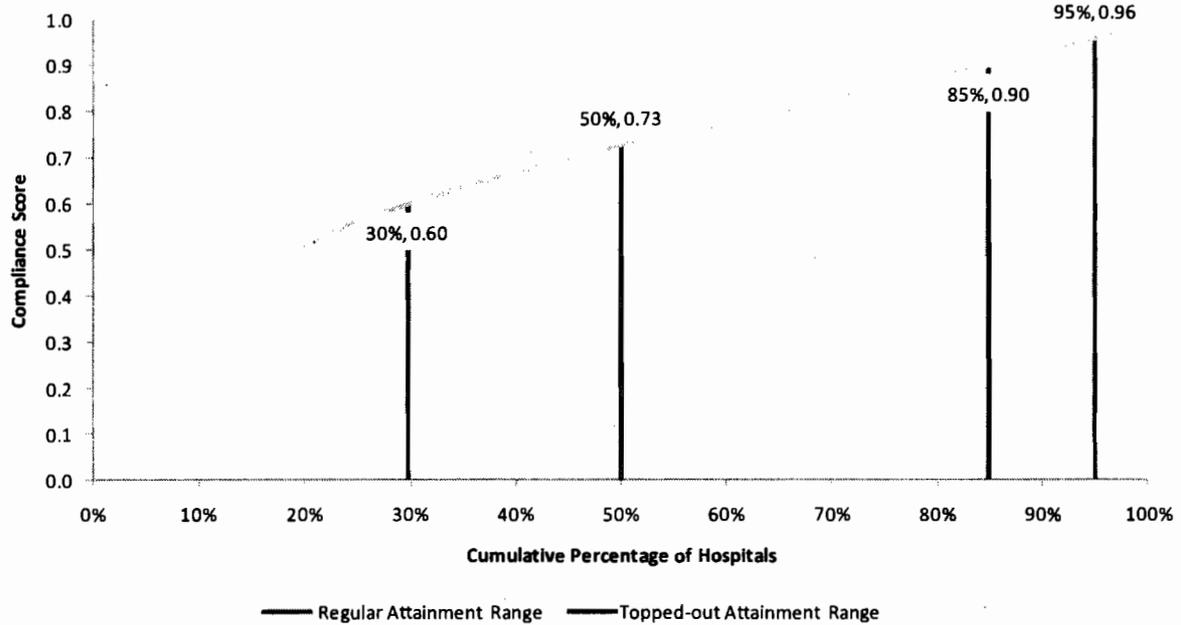
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### PN-2 Pneumococcal Vaccination Topped Out (per Options Paper): No



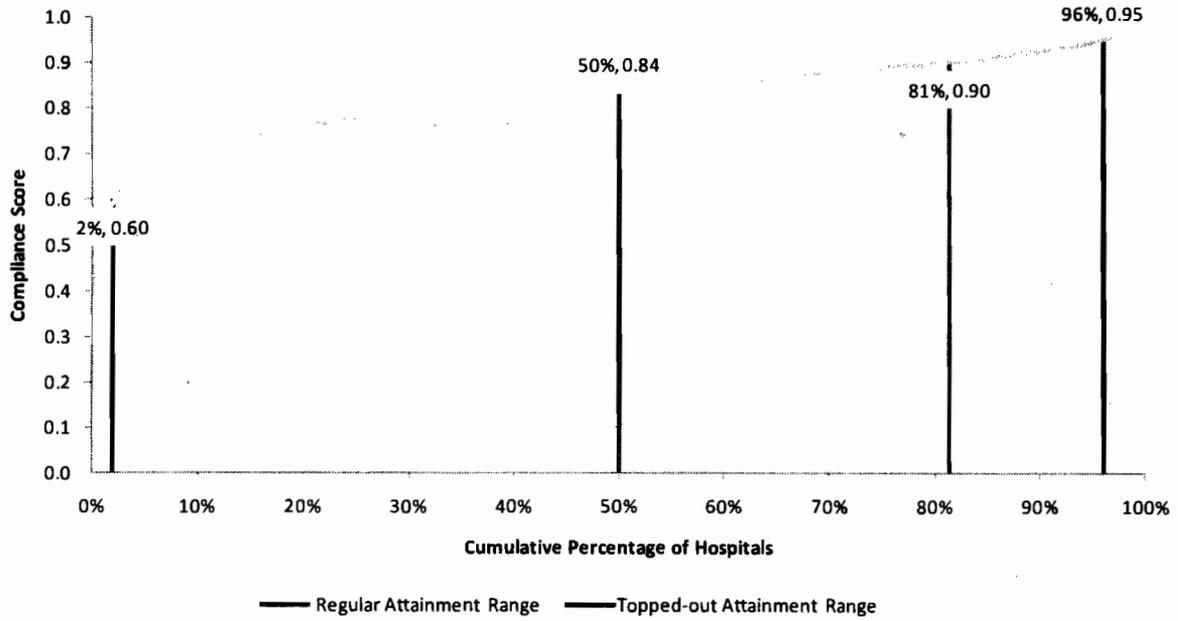
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### PN-2 Pneumococcal Vaccination Topped Out (per Options Paper): No



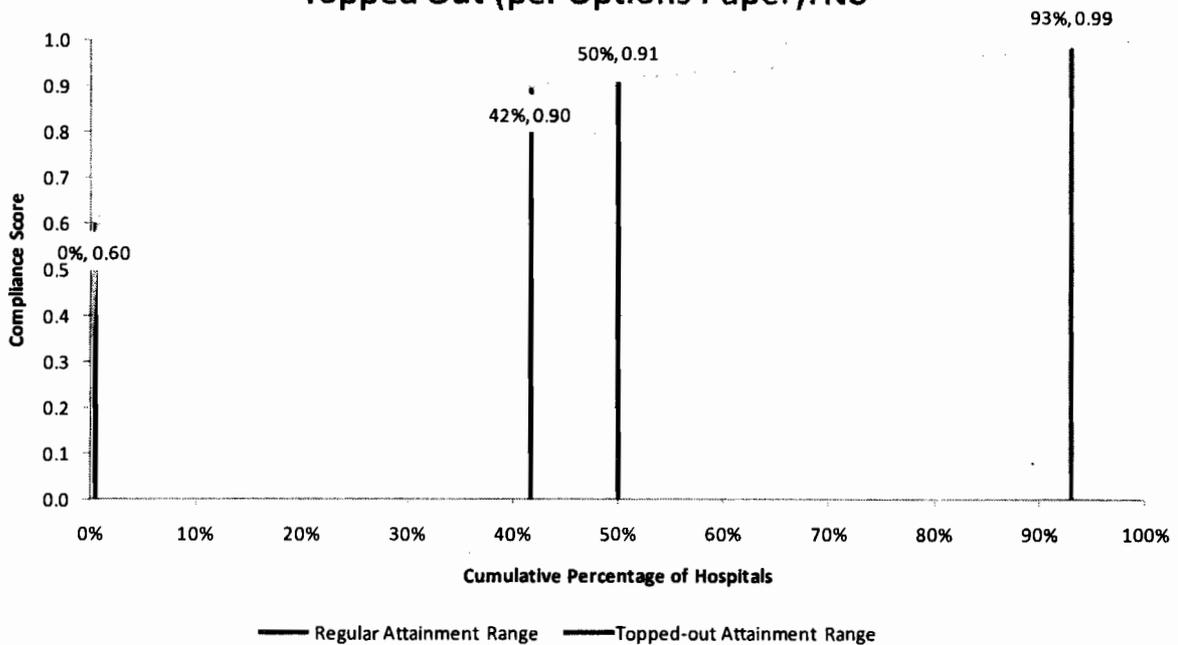
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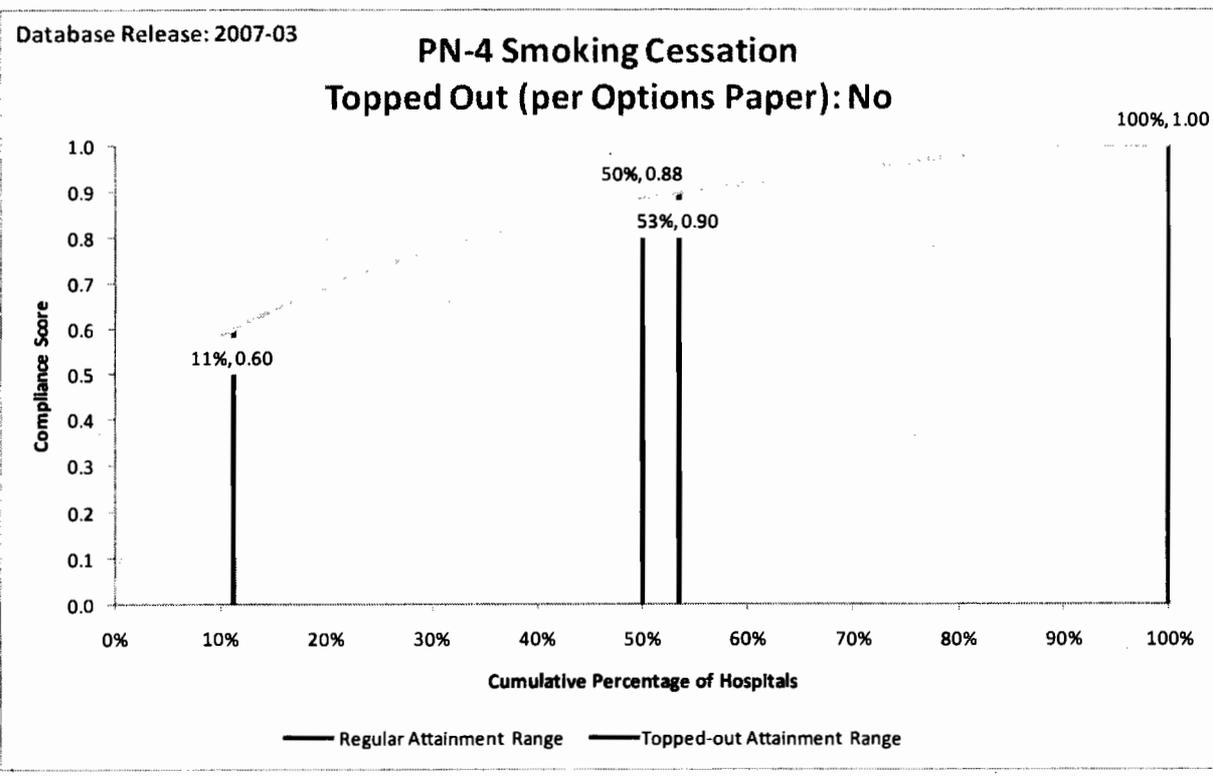
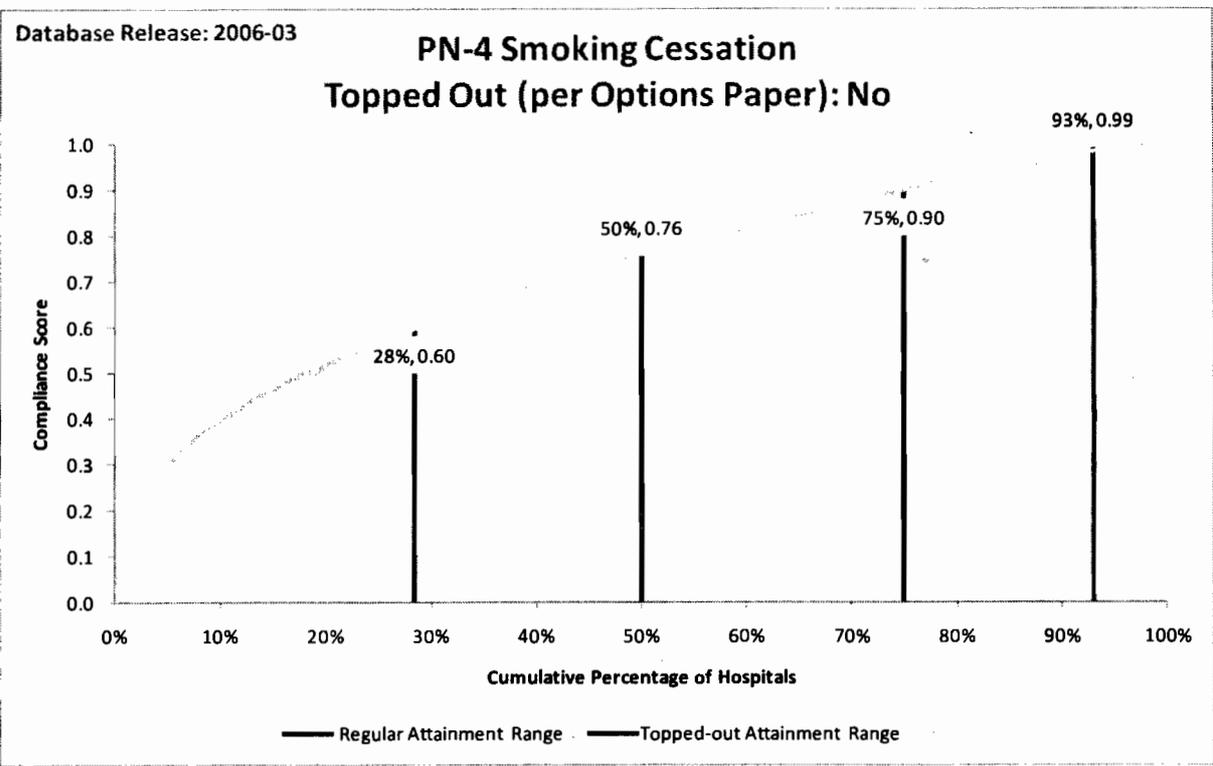
### PN-3 Blood Culture before Antibiotic Topped Out (per Options Paper): No



Database Release: 2007-03

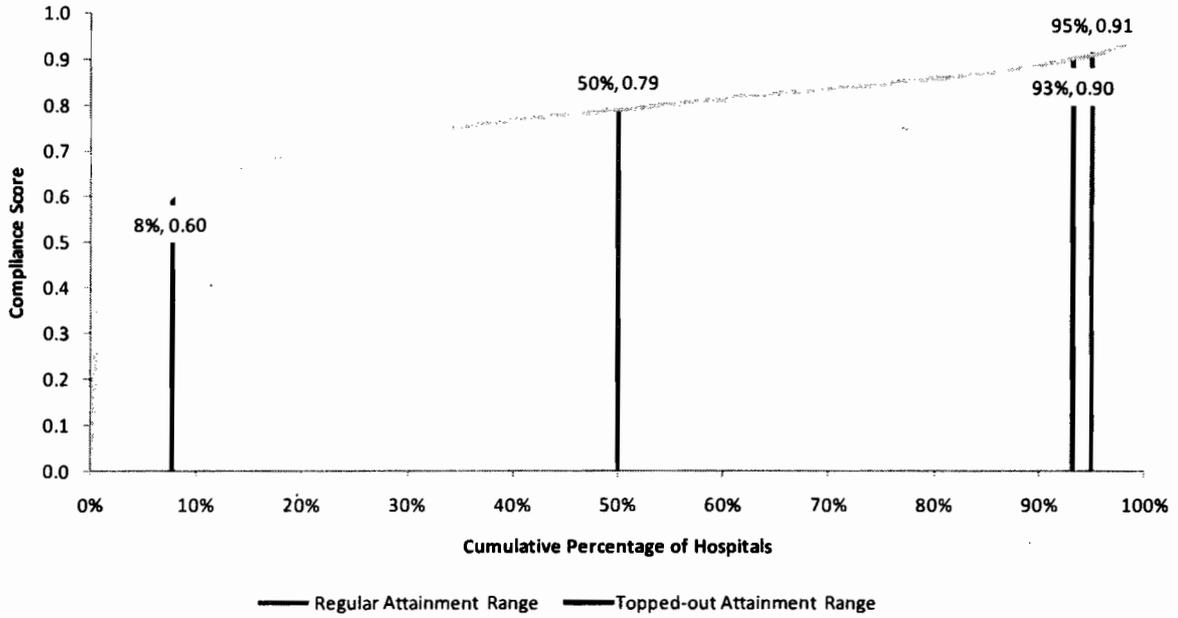
### PN-3 Blood Culture before Antibiotic Topped Out (per Options Paper): No





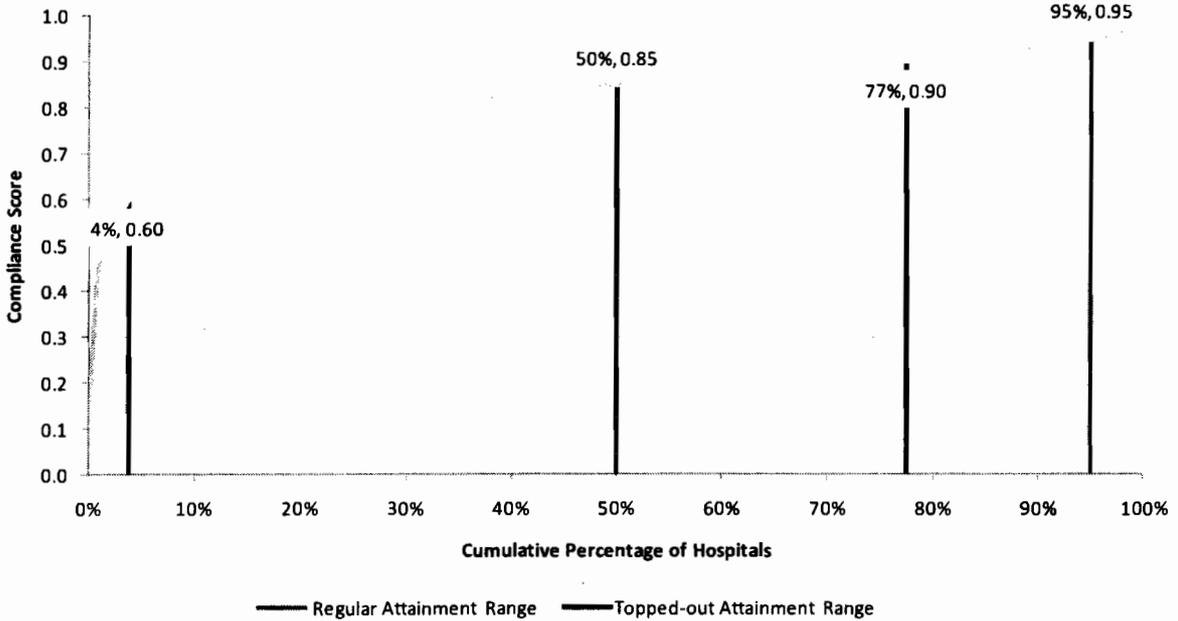
Database Release: 2006-03

### PN-6 Appropriate Antibiotic Topped Out (per Options Paper): No



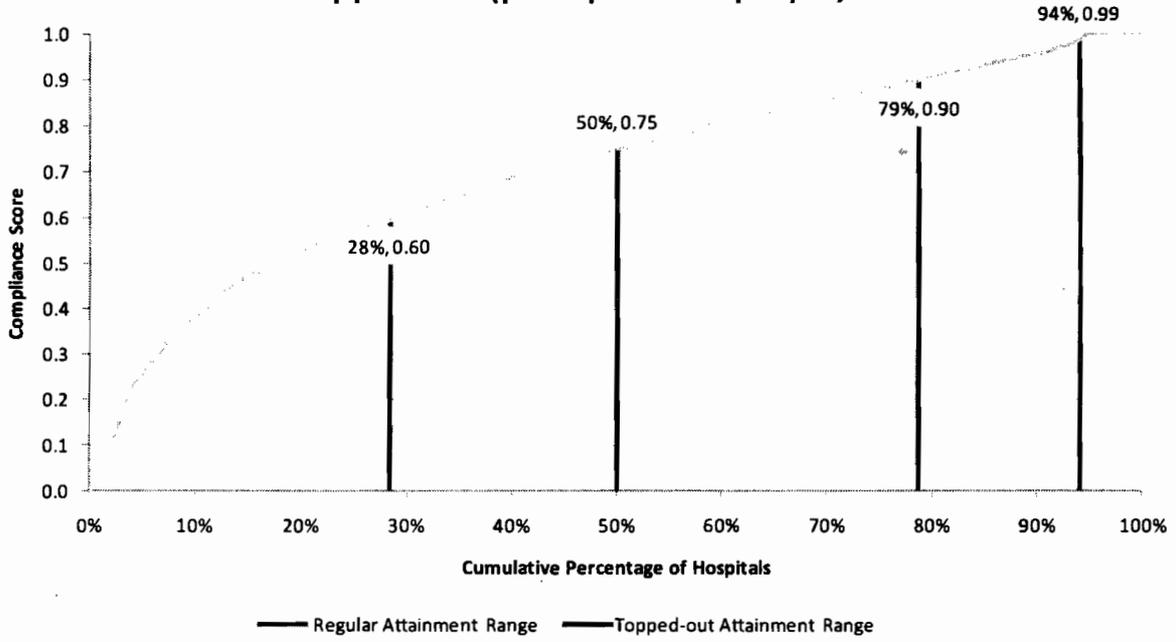
Database Release: 2007-03

### PN-6 Appropriate Antibiotic Topped Out (per Options Paper): No



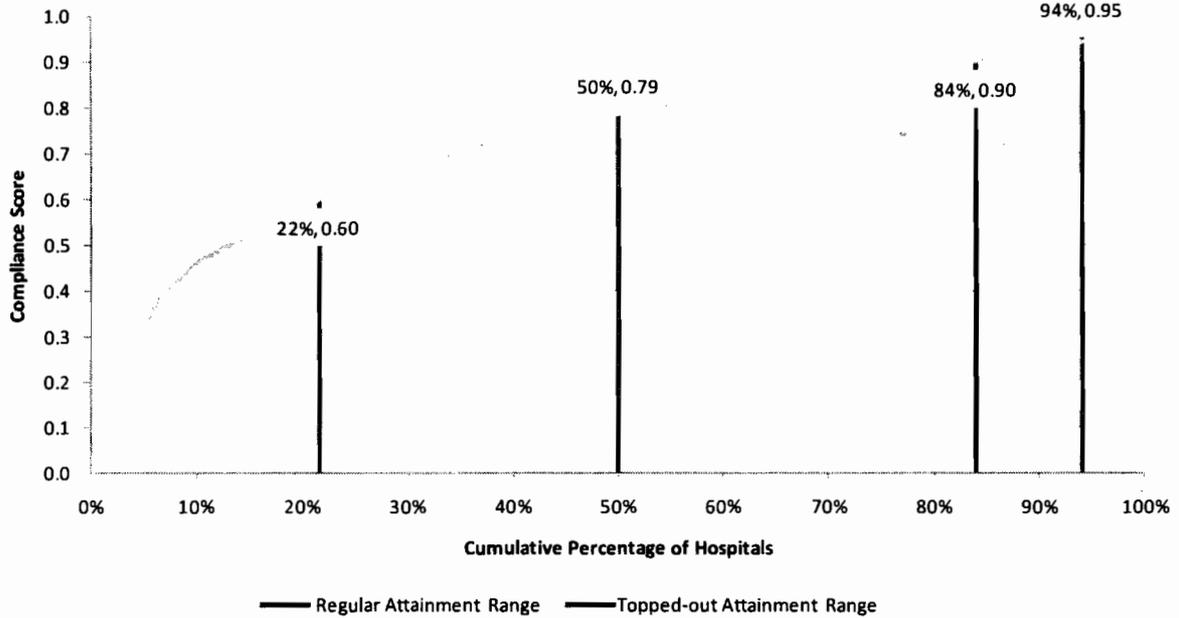
Database Release: 2007-03

### PN-(New) Influenza Vaccination Topped Out (per Options Paper): n/a



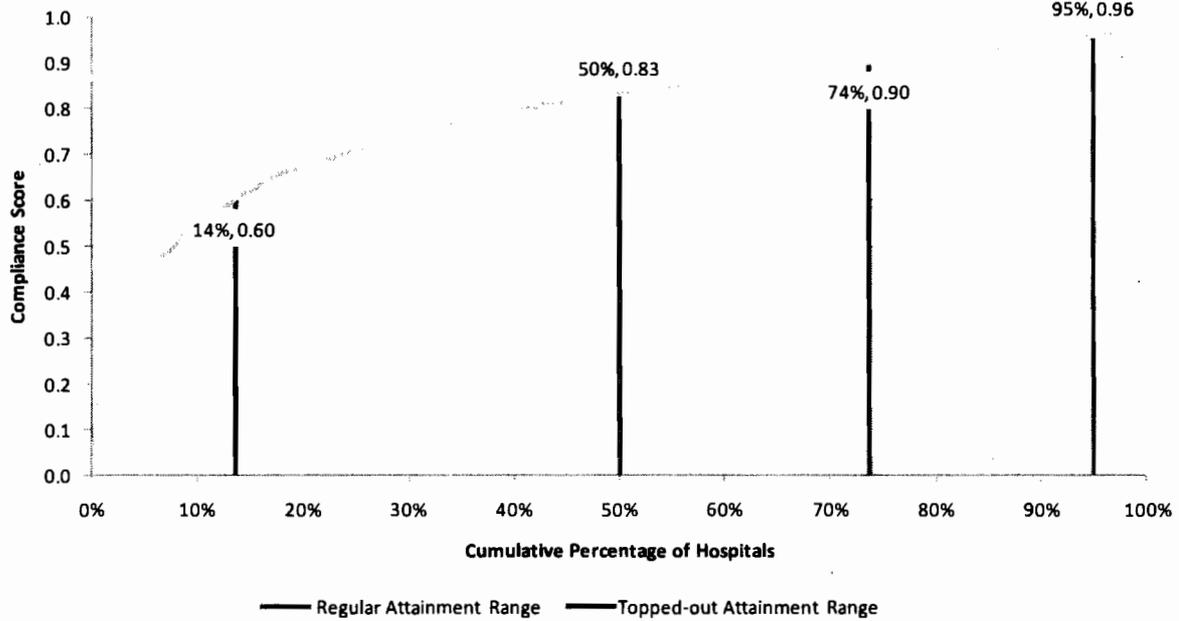
Database Release: 2006-03

### INF-1 Antibiotic 1h Pre-Surgery Topped Out (per Options Paper): No



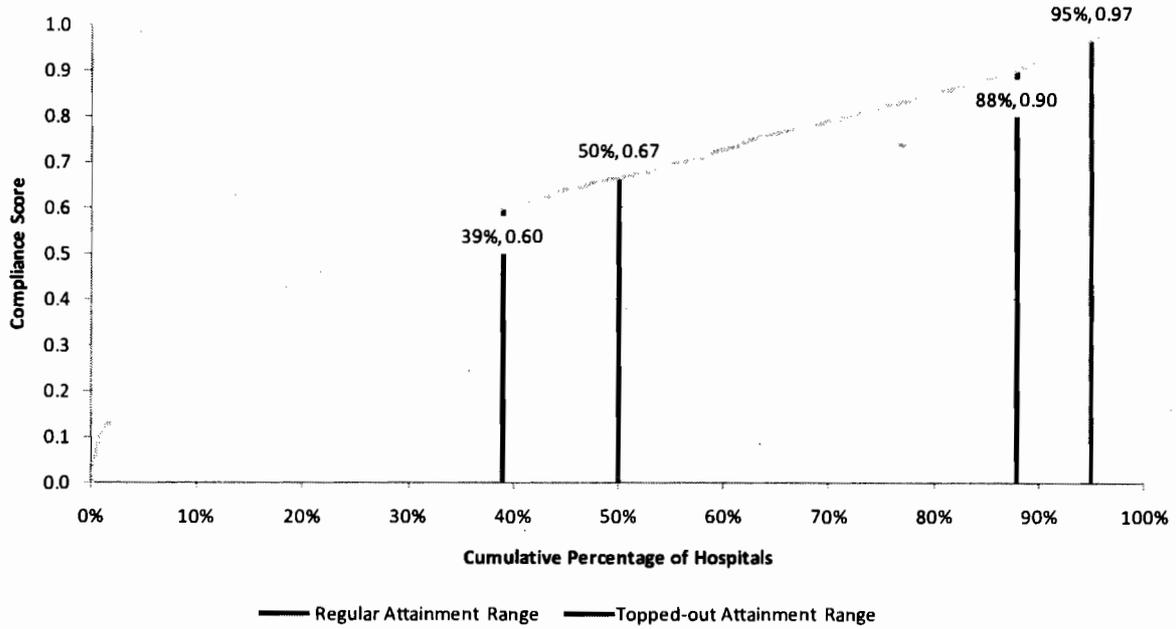
Database Release: 2007-03

### INF-1 Antibiotic 1h Pre-Surgery Topped Out (per Options Paper): No



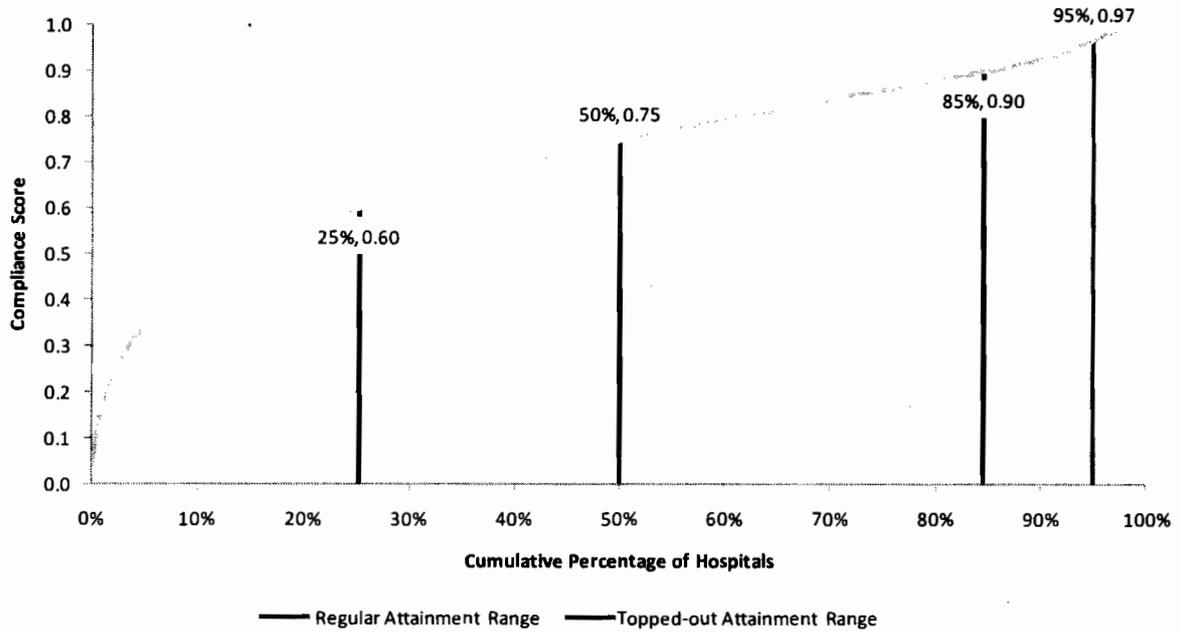
Database Release: 2006-03

### INF-3 Stop Antib. 24h Post-Surgery Topped Out (per Options Paper): No



Database Release: 2007-03

### INF-3 Stop Antib. 24h Post-Surgery Topped Out (per Options Paper): No



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June 11, 2007

Ms. Leslie Norwalk, Acting Administrator  
Center for Medicare & Medicaid  
Department of Health & Human Services  
Attn: CMS-1533-P  
7500 Security Blvd., Mailstop C4-26-05  
Baltimore, MD 21244-1850

Dear Ms. Norwalk:

Health Management Associates, Inc. is the premier operator of acute care hospitals primarily in the southeast and southwest areas of non-urban America. On behalf of our 61 hospitals containing over 8,500 beds and more than 30,000 employees and physicians we appreciate the opportunity to comment on the Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates.

We applaud CMS for continuing to review and refine the DRG system however we are particularly concerned with the proposed expansion of the number of DRG's with the implementation of the MS-DRG's and the proposed 2.4% reduction in the case-mix budget neutrality adjustment. It is our belief that implementation of the proposed MS-DRG's will have a significant negative impact on rural hospitals and should be delayed while CMS and perhaps RAND or others continue to analyze the impact such a change would have on beneficiaries and providers in rural areas. Changes to the system of such magnitude should be shared with providers at least a year or more in advance in order to give rural hospitals, their physicians and staff, ample time to learn and understand the proposed changes. Rural hospitals must provide quality healthcare services to Medicare beneficiaries the same as urban providers, however, unlike their urban counterparts, rural providers do not have the large support staffs that urban hospitals have to educate, train and assist with such significant system changes. Rural hospitals must make do with the staff they have and often times rely more on outside consulting help to help them migrate and implement such significant changes. Quite simply the staffs at rural hospitals have not had the resources to thoroughly analyze the changes. CMS must be cognizant of the impact proposed changes of this magnitude will have on rural providers and beneficiaries served by rural providers. Given that there are fewer resources available in rural areas and beneficiaries treated by rural providers deserve the same standard of care as beneficiaries in urban areas CMS should make every effort possible to adequately provide for rural hospitals with training and education, extra time and consideration for major system revisions and more than adequate reimbursement rates for rural providers. CMS proposal will have the inequitable effect of channeling

reimbursement away from rural providers to urban providers and further compounding the plight of rural providers and their beneficiaries. CMS would be well advised to hold off on implementing the proposed MS-DRG system and take another year to thoroughly analyze the impact it would have on rural hospitals and the beneficiaries they serve and at the same time providing more information on the proposed system to the provider community, particularly the rural providers. A delay of one year or more would be beneficial while the effects, both anticipated and unanticipated, of the proposed system change are reviewed.

With regard to the proposed changes to the care-mix index and anticipated behavioral changes we believe the logic is flawed and urge CMS to remove the 2.4% reduction. Indeed, hospitalized patients are sicker today than they were 4 or 5 years ago. That's to be anticipated as more patients are treated on an outpatient basis or in physicians office for services that previously were performed on an inpatient basis. Physicians and nurses all agree that inpatients today are sicker than they use to be due in part to the migration toward outpatient services. In it's explanation, CMS sites this increase in case-mix as one of the reasons they believe the new system will lead to case-mix growth. We believe the changes to the DRG relative weights will account for such changes in severity of illness. We believe the 2.4% reduction would unduly harm hospitals and is unnecessary. We thought CMS wanted providers to improve coding and documentation not penalize them.. Over the years hospitals have made considerable efforts to properly chart and document patient's conditions in the medical record. There is no proof that with the implementation of the MS-DRG's that physician's behavior will suddenly change and they will suddenly start putting more information in the medical record than they previously did. For the most part, physicians will continue to document patient's condition for the medical record the same way they always have. Implementation of the new system will not cause physicians behavior to change. Physicians will not suddenly start to document more than they previously did. If the physician does not document for the medical record it will not be possible for coders to code what is not present in the record. The majority of physicians are still independent practitioners. They are not going to do anything that would jeopardize the medical record or their ability to practice medicine. Coders are not going to code what does not exist in the medical record. They have nothing to gain and everything to lose doing so. Four or five years ago many coders were intentionally under coding, many of them petrified of the OIG's enforcement efforts they were reading about. Coder's behavior is not going to change just because a DRG refinement is implemented. The behavior of the physicians, coders and billers will not change just because there's a new DRG system. Physicians will continue to document, coders will continue to code and billers will continue to bill the same way they always have. There is no incentive for them to do otherwise. There is no empirical data to prove otherwise. In its explanation, CMS sites the rate of growth from the implementation of the IPPS from 1981 to 1984. Such statistics are not relevant today in light of the continual improvements in documentation and coding over the past 25 years. It's not relevant going from a cost reimbursed system in 1981 in which DRG's did not determine reimbursement amounts to the first of the IPPS in which DRG's were used to determine reimbursement and attempting to apply that variance factor to a system refinement 25 years later. It is expected that the variance would be larger during the initial implementation phase and illogical to assume that the same variance would apply 25 years later. Further, CMS sites experience with the State of Maryland adoption of the APR DRG system. The State of Maryland is not representative of the rest of the country. As CMS notes, Maryland is a highly regulated state, its hospitals subject to the all-payer rate setting commission governing hospitals. The experience of Maryland does not represent the rest of the country and should not be used. It's like comparing apples to oranges. The 2.4% reduction is an arbitrary number that can not be supported. It is illogical to assume that every hospital in the country will somehow be able to enhance their documentation and coding to achieve a 2.4% increase. It won't happen! In light of



the difficulty CMS has had in predicting outlier's, CMS should not implement an arbitrary reduction for anticipated behavioral change that is illogical and can not be supported. CMS should only consider such an adjustment on a retrospective basis.

We appreciate the opportunity to comment on the proposed rule. Thank you for your consideration.

Sincerely,



Robert Farnham  
Senior Vice President  
Chief Financial Officer



Kenneth M. Koopman  
Senior Vice President of Reimbursement

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**AdvaMed**

Advanced Medical Technology Association

**Via Electronic and U.S. Mail**

June 12, 2007  
Ms. Leslie Norwalk  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Room 443-G  
Hubert H. Humphrey Building  
200 Independence Ave, S.W.  
Washington, DC 20201

**File Code CMS-1533-P: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Dear Ms. Norwalk:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide this comment letter on the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2008 rates (CMS-1533-P), (hereinafter referred to as "Proposed Rule" or "NPRM"). AdvaMed is the largest medical technology trade association in the world. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed shares CMS's goal of assuring beneficiary access to medical services and technologies, and believes that improving the payment system will help achieve this goal. AdvaMed supports movement toward improved accuracy in reimbursement under the inpatient prospective payment system (IPPS) and appreciates that CMS has devoted significant resources to examining proposed changes that would better reflect patient

severity. CMS is to be commended for its careful consideration of the comments from a broad array of stakeholders, as expressed in response to last year's proposed IPPS rule.

The FY 2008 Proposed Rule includes several modifications to the inpatient prospective payment system. AdvaMed's comments are provided in greater detail in later sections of this letter. A brief summary is provided below:

**AdvaMed supports the implementation of the proposed Medicare Severity Diagnosis-Related Group (MS-DRG) patient classification system as soon as practicable. AdvaMed agrees that the MS-DRG system is an effective method for incorporating greater refinements to reflect variations in patient severity. We encourage CMS to implement refinements to the MS-DRGs to reflect the complexity of devices and other advanced medical technologies used to detect, diagnose, and treat diseases and conditions among the elderly and disabled populations.**

**AdvaMed supports a phase-in period for MS-DRGs of two to three years to allow hospitals and physicians to adapt to the new changes and requirements before full implementation and to reduce, minimize, or eliminate the need for prospective or retrospective adjustments for changes in coding practices.**

**AdvaMed supports the adoption of a regression-based methodology to remove the systematic bias caused by "charge compression" in the calculation of the relative payment weights. Under contract with CMS, the Research Triangle Institute (RTI) evaluated and validated the regression-based methodology, finding that it could be used as a short-term adjustment or as a more permanent adjustment if other methods seem impractical. The RTI report confirmed a number of previous analyses that have identified charge compression as a significant issue for items in the medical supplies cost center. AdvaMed strongly recommends implementation of an adjustment to this cost center in FY 2008. AdvaMed further strongly believes that the application of this methodology to diagnostic radiology services would be premature as the application of such an adjustment to these capital-intensive procedures has not been fully validated and would benefit from additional analysis.**

**AdvaMed recommends that CMS reconsider the proposed minus 2.4% across-the-board reduction (for two years) applied to both operating and capital Medicare payments as an adjustment for changes in hospital coding practices that are anticipated under the new classification system. As proposed, the capital portion of the FY 2008 payment rates would be below the FY 2007 capital portion of the payment rates due to a zero update applied to urban hospitals and a 0.8 update applied to rural hospitals, and the application of the 2.4 percent reduction. The proposed reductions, for operating and capital**

**payments are estimated to reduce hospital payments by approximately \$24 billion over five years. A reduction of this magnitude could reduce the ability of hospitals to provide Medicare beneficiaries medical technologies, equipment, and diagnostic and clinical information systems that are necessary to maintain high quality health care and improve patient outcomes.**

AdvaMed provides comments on several additional areas that should be addressed in the Final Rule. These key issues are summarized below:

### **MEDICARE SEVERITY DRGs (MS-DRGs)** **(“DRG Reclassifications”)**

The most significant proposed modification is to adopt a new Medicare Severity Diagnosis-Related Group (“MS-DRG”) patient classification system in FY 2008. The MS-DRG system reflects considerable analysis and evaluation of the existing classification system to create an improved version. AdvaMed supports implementation of the MS-DRGs as soon as practicable. MS-DRGs reflect variations in the level of patient acuity while retaining the general structure of the DRG patient classification system and refinements and improvements that have been made in recent years through notice and comment rulemaking. The MS-DRG are significantly superior to the classification system proposed last year (CS-DRGs) which would have added more complexity while disregarding important DRG refinements made in recent years, particularly in the areas of certain cardiovascular DRGs, drug eluting stents and joint replacements. We applaud CMS for addressing many concerns expressed regarding CS-DRGs.

AdvaMed urges CMS to continue its work on recognizing that complexity and resource intensity should be key factors in determining DRG assignment. We encourage CMS to make individual consideration for cases where resources are an important factor in assigning MCC or CC categories, even if the patient does not exhibit the designated secondary diagnoses that trigger assignment to the higher-paying DRG under the proposed MS-DRGs.

We are also in agreement that CMS should not adopt a proprietary DRG system that would limit public access. The proposed MS-DRGs would apparently be publicly available on the same terms as the current CMS DRGs, a feature that AdvaMed supports. The transparency of the current system has been a critical aspect of its success over the years, and this will be even more important to ensure the successful adoption of the new severity-adjusted system.

AdvaMed continues to be supportive of CMS’s efforts to implement a new classification system that accounts for patient severity of illness, complexity of devices and medical technologies and other features that benefit Medicare beneficiaries. While the MS-DRGs

do not include complexity and patient benefit factors today, we will seek opportunities to work with CMS to address these issues as the MS-DRG system is implemented and refined. We appreciate the significant analysis of clinical and resources utilization data to produce the proposed MS-DRGs refinement categories—major complications and complications and co-morbidities (MCC), complications and co-morbidities (CC), and no complications and co-morbidities (non-CC). **In examining the MS-DRGs in detail, there are a few specific modifications that we suggest to improve the proposed classification system. These recommendations are summarized in Attachment A**

To facilitate the transition from the current system to MS-DRGs, AdvaMed recommends a phase-in period of two to three years. This will ease the redistributive impacts across hospitals and allow them time to adapt to the new system. Apart from running two DRG systems simultaneously, which would be overly burdensome, such a transition could be accomplished by prospectively calculating a single weight for each MS-DRG.

In conjunction with developing the proposed MS-DRGs based on severity defined by the CC list, CMS proposes a revised list of CCs and identifies MCCs based on secondary diagnoses requiring the highest resource usage. CMS conducted analysis of the resources associated with treating each secondary diagnosis to assess whether each was appropriately classified as a no-CC, CC, or MCC. Table I on page 24704 of the Proposed Rule provides an example of the results of this analysis for six codes. We would request that CMS provide the complete results of this analysis for all codes in conjunction with the Final Rule.

AdvaMed supports the implementation of MS-DRGs and recognizes that significant resources are required to implement a new system. We are not in favor of CMS adopting one severity system for FY 2008, and switching to another severity system in FY 2009. AdvaMed notes that there are significant foreseeable and potentially many unforeseeable implementation costs if CMS adopts the MS-DRGs in FY 2008 and an alternative system in FY 2009. We encourage CMS to implement the MS-DRGs, phased in over two to three years and to use the RAND analysis of alternative classification systems in considering future refinements of the MS-DRGs. We would not wish to see CMS switch to a completely different severity-based DRG system in FY 2009 or phase in a different system in subsequent years.

## **CHARGE COMPRESSION ADJUSTMENT** *("DRGs: Relative Weight Calculations")*

AdvaMed supports a statistical regression-based adjustment for charge compression to remove a bias in the calculation of estimated costs that exists today under the Medicare inpatient hospital payment system. The adjustment would improve the accuracy of the calculations under the system today and under any of the payment weight methodologies

under consideration for 2008 or 2009. Since the adjustment is applied by CMS to the data used in the calculation, it places no implementation burden on the hospitals.

AdvaMed and its member companies identified the charge compression problem in 2000. MedPAC and other researchers have also noted this problem. Since the "supplies" category, in particular, is so broad it includes a variety of low cost supplies—that generally have higher mark-ups as well as highly complex medical devices—that generally have much lower mark-ups. By using the same category in the estimates, there is a systematic bias in the calculation such that the 'estimate costs' are inaccurate for both types of products.

Last year, AdvaMed recommended that CMS implement a regression-based adjustment. This methodology was further evaluated and subsequently validated by RTI in a CMS-commissioned report to examine this adjustment and other methods to improve the accuracy of Medicare data. The RTI experts agreed that a regression-based statistical adjustment was appropriate and could be implemented quickly. An adjustment for charge compression would remove the bias in the calculation of "estimated costs" used under any of the payment weight methodologies under consideration by CMS. AdvaMed recommends that CMS implement the regression-based adjustment in FY 2008.

RTI recommended applying the regression approach to disaggregate national average CCRs for medical supplies, drugs, and radiology. AdvaMed notes that the vast majority of analyses on charge compression have focused on the medical supplies cost center, particularly regarding implantable devices, and CMS stated in the Proposed Rule that: "Of all the adjusted CCRs, the largest impact on weights came from accounting for charge compression in medical supplies for devices and implants."<sup>1</sup> Thus, the strongest case can be made, and full justification exists, to implement the charge compression adjustment for the medical supplies cost center in FY 2008.

AdvaMed further recommends that CMS refrain from applying any regression-based adjustments when calculating estimated costs for radiology services, as this would be premature. An analysis by Direct Research, LLC found that the majority of hospitals do not allocate the capital cost of MRI and CT machines to radiology cost centers. The analysis suggests that the differential cost-to-charge ratios found for MRI and CT reflect the way hospitals allocate capital costs for these services rather than actual differential markups. The RTI findings for radiology services assume a detailed capital allocation for these specific services that is not found in the data. The radiology issue is distinct from the issue of charge decompression for supplies. For supplies, the costs are operating costs, and routinely allocated to the supply cost center. No such capital allocation is required for the charge decompression estimate for supplies.

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<sup>1</sup> "A Study of Charge Compression in Calculating DRG Relative Weights." ResearchTriangle Institute Report prepared for CMS (January 2007).

## **HOSPITAL SPECIFIC RELATIVE VALUE METHODOLOGY** *("DRGs: Relative Weight Calculations")*

In the Proposed Rule, it is suggested that the implementation of a charge compression adjustment could be considered for implementation with the Hospital Specific Relative Value Cost Center (or HSRVcc) methodology for calculating relative weights. These two changes should not be linked. The charge compression adjustment would correct for a widely-acknowledged and measurable bias in the estimation of costs. By contrast, the HSRVcc methodology would introduce a new bias in the calculation of relative weights.

AdvaMed worked with an external expert to perform micro-simulation modeling of the HSRVcc methodology. The results demonstrated that the method would provide accurate relative weights only under three highly unlikely scenarios:

- 1) all hospitals have identical mix of patients and identical cost structures;
- 2) all hospitals have identical costs across all cost centers; or
- 3) all hospitals have the same case-mix and the costs differ by a factor that is constant across all DRGs and all cost centers.

Otherwise, the HSRVcc methodology results in biased weights. Further, the methodology would not incorporate legitimate differences in costs and case-mix among hospitals including differences in input prices not picked up in the current adjustments, such as providing a trauma unit or a burn unit, and differences in utility costs. The methodology also destroys legitimate cost information while it exacerbates inaccuracies that may arise because of the mix of patients treated at a particular hospital. The implementation of HSRVcc is contrary to the movement, supported by both CMS and AdvaMed, toward improved accuracy in reimbursement under (IPPS). HSRVcc is a methodology that offers no tangible benefit or increase in payment accuracy, but rather introduces additional biases into the IPPS, and AdvaMed does not support the use of this methodology in FY2008 or in the future.

## **CALCULATION OF PROPOSED STANDARDIZED AMOUNT— ADJUSTMENTS TO THE AVERAGE STANDARDIZED AMOUNT** *("Other Adjustments to the Average Standardized Amount")*

Citing the Secretary's authority under section 1886(d)(3)(A)(vi) of the Act to adjust the standardized amount to eliminate the effect of changes in coding or classification of discharges that do not reflect real changes in case-mix, the Proposed Rule includes a provision to reduce the IPPS standardized amounts by -2.4 percent each year for FY 2008 and FY 2009. The rule further cites section 1886(d)(3)(A)(vi) as authority to revisit adjustments to the standardized amounts for changes in coding or classification of

discharges that were based on estimates in a future year. CMS proposes to compare the actual increase in case-mix due to documentation and coding to CMS's 2.4 percent projection once the agency has actual data for FY 2008 and FY 2009 and the Proposed Rule notes that further adjustments to reflect the difference between projected and actual changes would be included in the FY 2010 and FY 2011 IPPS rules.

AdvaMed notes that a behavioral offset of the magnitude proposed (minus 2.4 percent for 2 years) is unprecedented and exceeds the coding-related increase expected in the initial years of the conversion to an inpatient prospective payment system in the mid-1980s-- estimated by RAND to be approximately 2 percent per year. Given the magnitude of that change, we are perplexed by a proposed adjustment that is greater now, where the current proposal is building off the existing classification system, than it was with the conversion of the entire hospital payment system to PPS. Moreover, the experience with the Maryland system that is cited by CMS in the Proposed Rule raises several key issues:

- First, Maryland hospitals are excluded from the PPS system, so the use of this a unique system that is not paid under PPS as a model for what will happen within a PPS system is less persuasive.
- Second, Maryland hospitals moved from DRGs to an entirely different system (APR-DRGs). By contrast, the proposed change from the current classification system to MS-DRGs is less disruptive as it builds off the existing DRG classification system. Although CMS has said it believes the incentives to properly code as completely as possible are the same under both the MS-DRGs and the APR-DRGs, we disagree. We note that CMS acknowledges-- when discussing RAND's analysis elsewhere in the Proposed Rule that different severity DRG systems may create different changes in coding behavior. The APR-DRGs are more complex than MS-DRGs and include four, rather than three, severity levels. Therefore, it is unlikely that any change in case mix when MS-DRGs are implemented would be as large as the change when implementing APR-DRGs.
- Third, CMS analysis, as reflected in Table Q in the Proposed Rule, estimates the national average case mix change using both the MS-DRGs and the current DRGs, throws-out the low and high estimates, then combines the different estimates. We recommend, at a minimum, CMS include all the data in its estimate of national average case mix change. A better estimate, however, would be to use the national estimate based on the MS-DRGs, because they are able to measure within-DRG change.

AdvaMed also notes that acute care hospitals have been coding under the current DRG system since 1983. While there is always a possibility that certain hospitals will improve their coding, hospitals are increasingly participating in quality reporting activities and

impacted by risk adjustment mechanisms, which both require and provide incentives for careful and accurate coding. Moreover, Medicare claims data from 2001 to 2005 indicate that hospitals have been coding complications and co-morbidities (CC) at very high rates, with more than 70 percent of claims containing CCs, and many Medicare claims contain up to nine CCs, the maximum capacity currently collected under Medicare's grouping program. With the large number of CCs already in use, and the majority of hospitals already coding at high levels with CCs, we suggest that CMS consider these factors and conduct further exploration of the estimated offset in the Proposed Rule.

Given the concerns regarding the adjustment for improved coding of minus 2.4 percent per year in FY 2008 and FY 2009, we recommend that CMS drop consideration of the prospective adjustment in the Final Rule. If a retrospective analysis finds that a quantifiable adjustment is warranted, we recommend that it be applied over several years.<sup>2</sup>

## **PROPOSED CHANGES FOR INPATIENT IPPS CAPITAL-RELATED COSTS** *("Capital IPPS")*

The Proposed Rule includes a provision to reduce capital prospective payments by eliminating the update factor for urban hospitals for FYs 2008 and 2009. For at least those two fiscal years, CMS would update the capital standard Federal rate only for rural hospitals, which would get the 0.8 percent update indicated by the capital update framework for FY 2008. CMS also would apply the 2.4% hospital coding offset to the

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<sup>2</sup> At a minimum, the 4.8 percent off-set be should be reconsidered. To control for changes in the observed case-mix increase in Maryland that was not attributable to implementing APR-DRGs but was instead attributable to an actual increase in year-to-year case mix, the Actuary estimated the national increase in average case mix from FY 2004 to FY 2006. This is determined by combining estimates of case mix increase using both the current DRGs and the MS-DRGs. However, the Actuary proposes not to use the highest estimate of national average case mix change (2.65 percent from FY 2005 to FY 2006 using MS-DRGs) or the lowest estimate (-0.04 percent from FY 2004 to FY 2005 using the current DRGs), stating they "appear atypical to national trends (page 24710)." The resulting estimate of national average case mix from FY 2004 to FY 2006 is 1.68 percent. This is then subtracted from the observed case mix increase in Maryland to arrive at the 4.8 percent estimate. The decision to eliminate the highest and lowest estimate of national average case mix change removes half the available data from CMS' analysis. If these data were included, it would increase the national average case mix increase from 1.68 percent to 2.61 percent, with the net effect of reducing the estimate of the effect of changes in coding behavior by over .9 percent (when the national average case mix increase is subtracted from the average increase in Maryland). This equates to an impact on hospital payments nationally of approximately \$900 million. Moreover, since the goal of the offset estimate is to anticipate the increase in the national average case mix due to changes in coding practices as a result of implementing the MS-DRGs, the MS-DRG system should be used to estimate the increase in the national average case mix. It is to be expected that a more refined patient classification system would generate a more precise estimate of case mix, including estimating real case mix increase. This change would reduce the estimated case mix increase in Maryland from 4.8 percent to 3.4 percent.

capital standardized amounts for both urban and rural hospitals. The reduction in aggregate hospital payments is estimated to be \$1.4 billion over the next five years.

AdvaMed is particularly concerned that these significant reductions in capital payments are unwarranted and could have a highly negative impact upon the adoption and dissemination of newer technologies, health information systems, electronic health records, imaging, and scanning devices that are a critical part of health care services provided to seniors and disabled Americans and enhance patient safety and quality of care. The proposed reductions could slow or reduce innovation. AdvaMed previously in this letter noted our concerns about the -2.4 percent offset in FY2008 and FY2009 proposed for possible coding-related increases. We also believe the proposal to eliminate the update for urban hospitals is inconsistent with the structure of the capital prospective payment system as enunciated in the August 30, 1991 final rule implementing the capital PPS. To justify the cut, CMS cites what it considers to be large inpatient capital margins over the period FY 1996-2004. The existence of positive margins is not justification to eliminate payment updates for several reasons:

- Capital investments occur in cycles and the development of the payment system envisioned that payments would exceed costs in some time periods. Hospitals were expected to establish funds in anticipation of future capital needs. These funds would permit future capital investment to be funded in part with equity financing rather than borrowing.<sup>3</sup>

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<sup>3</sup> In the 1991 rulemaking to create the capital PPS, many commenters urged that Medicare's payment amount for capital should recognize the effect of age and financing variables on capital costs, but HCFA (the predecessor agency to CMS) stated in the August 30, 1991 final rule that it did "not believe that it is appropriate to recognize the effect of age and financing variables on capital costs in the long run. We believe that the Federal capital payment should be independent of the timing and financing of capital acquisitions. Two hospitals that are identical, except that one recently purchased a new piece of equipment, while the other hospital is accumulating funds to purchase the same equipment, should not be paid differently for treating the same case. Further, two identical hospitals, one of which purchased a piece of equipment with funded depreciation, and the other of which financed the same equipment, should not receive different payments. By severing the link between Medicare payment and capital spending, we will provide neutral incentives with respect to the timing and financing of new capital acquisitions." Other comments on the Proposed Rule suggested that Medicare permit hospitals to elect keeping the excess of capital prospective payments above inpatient capital costs on deposit with HCFA in interest bearing Medicare capital accounts. HCFA responded that deposits could be established with banking institutions, but that such actions by HCFA could be construed as involvement in hospital management practices. Again, the Proposed Rule recognized a capital cycle and noted that hospitals would establish funds for future capital investment. The goal of the capital PPS to sever the link between hospitals' capital costs and their Medicare payment is further indicated in this statement from the August 30, 1991 final rule, "Under a cost-based payment system, hospitals have limited incentive to delay or forego a capital project because Medicare payments increase as capital costs increase and excess capacity is subsidized. Further, the current system favors debt financing over equity financing and capital investment over operating expenditures. By making Medicare's payment independent of a hospital's decisions with respect to the timing and financing of capital projects and by aligning the

- The capital prospective payment system is not, and was not designed to be, a separate payment system. Its structure and payment adjustments are based on regression analyses of *total* inpatient costs, not capital alone. HCFA (the predecessor agency to CMS) followed the 1991 recommendation of the Prospective Payment Assessment Commission (ProPAC) that hospitals should receive a single, combined payment for the capital and operating portion of their costs. Thus, while there are specific computation parameters for capital costs and operating costs, just as there are for labor and non-labor costs, hospitals receive a single, combined payment. Moreover, the capital adjustments for factors such as wages, indirect teaching and disproportionate share were estimated using regression analyses of *total* costs, not capital costs alone.

AdvaMed recommends that in the Final Rule, CMS consider MedPAC's findings of overall Medicare margins reaching a ten-year low of negative 5.4% in 2007, rather than the isolated capital prospective payment system which focus on total payments and total costs. In this regard, the proposal to reduce the capital portion of the total payment stands to further reduce the total operating margins.

For these reasons, AdvaMed opposes the proposed capital reductions. The structure of the capital PPS is sound and has served the Medicare program well. Since its inception, annual updates to the capital rate have been modest, but they have been based on a rigorous update framework developed by the CMS actuaries. This framework should continue to be used as the basis for updates for all hospitals.

## **NEW TECHNOLOGY ADD-ON PAYMENTS** *("New Technology")*

AdvaMed applauds CMS for holding a Town Hall Meeting and Workshop on February 22, 2007 to discuss the issue of new technology payments. At that February 22 meeting, AdvaMed noted that the number of applicants for inpatient hospital new technology add-on payments has declined over the last three years as presented in the table below.

<b>Year</b>	<b>Initial Applicants</b>	<b>Approved</b>
2005	10	2
2006	8	2
2007	3	1

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*incentives of the capital payment system with those of the operating prospective payment system, we expect that hospitals will make efficient capital decisions."*

AdvaMed continues to believe that it is critical that CMS maintain and improve incentives for the advancement of, and access to, innovative technologies. The new technology add-on payments, the assignment of new technologies to analogous, appropriate MS-DRGs, and the recognition of complexity within any new or revised inpatient hospital payment system proposed by CMS are key to maintaining and improving access to innovative technologies. AdvaMed and other organizations strongly support increasing the add-on payment levels from 50 to 80 percent of the difference between the standard DRG payment and the cost of the procedure with the new technology. Increasing the payment percentage would ensure that the Medicare patient population continues to benefit from the latest medical technology that improves care and provide increased stability and consistency for hospitals providing Medicare patients access to new technologies.

AdvaMed continues to support modifications to better reflect the lags in the data used for determining payment weights. Currently, CMS regulations provide at section 412.87(b)(2):

"medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new medical service or technology (depending on when a new code is assigned and data on the new medical service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion for this section."

However, CMS begins the 2-year to 3-year period of newness for a technology or medical service upon the date of FDA approval, and not when the assignment of an ICD-9 code allows specific identification of the new technology in MedPAR data (unless there is a documented delay in bringing the product onto the market after FDA approval). AdvaMed encourages CMS to reconsider this policy, and make the assignment of an ICD-9 code or FDA approval, whichever is later--the controlling date for starting the eligibility window for a new technology payment. This could be done in a way that eliminates any concern that preexisting technologies get new ICD-9 codes by establishing a criterion that the assignment of the ICD-9 code must be within 18 months of approval of the technology by FDA.

Finally, AdvaMed believes that producing quarterly updates to the MedPAR data would enhance the ability to demonstrate that new technologies satisfy the CMS criteria. In addition, allowing the use of unbiased and valid external data for determining new technology payments would further improve the process.

## **REPLACED DEVICES** *("Replaced Devices")*

The device industry supports the goal of accurate payment for services provided and supports the concept of a payment offset for devices that are replaced without cost or where a credit is furnished to the hospital for a replaced device. However, the administrative process proposed by CMS may cause an undue administrative burden on hospitals.

CMS proposes to reduce the amount of Medicare IPPS payments when a full or partial credit towards a replacement device is made or the device is replaced without cost to the hospital. However, in recognition of the fact that, in many cases, the cost of the device is a relatively modest part of the IPPS payment, CMS is proposing to apply the policy only to those DRGs under IPPS where the implantation of the device determines the base DRG assignment (22 DRGs) and situations where the hospital receives a credit equal to 20% or more of the cost of the device. CMS believes that a credit that is equal to or greater than the proposed 20% threshold is "substantial" and that Medicare should share in the savings.

CMS proposes to use Condition Codes 49 (Product Replacement within Product Lifecycle) and 50 (Product Replacement for Known Recall of a Product) to reduce payment when the hospital uses a device for which full or partial credit is given. When the condition code is received by the fiscal intermediary (FI) or the Medicare Administrative Contractor (MAC) and the discharge is assigned to a DRG that is subject to this policy, CMS proposes to suspend the claim so that it does not automatically process and the FI (or MAC) makes a manual payment determination. CMS is proposing to require the hospital to provide invoices or other information indicating the "normal" cost of the device and the amount of credit it received.

The process proposed by CMS will require that claims be suspended or held by the hospital until credit information is received from the manufacturer. While this does not typically present a problem in the case of a known recall (Condition Code 50), the determination of warranty status (Condition Code 49) may require six weeks or more following return of the device to the manufacturer, as most devices will require laboratory analysis. Thus, claims may be suspended or held by the hospital for more than 45 days, which will create administrative and financial burdens for hospitals. In addition, many of the devices returned to the manufacturer for analysis will not qualify for warranty credit. This will mean that only a fraction of the suspended or held claims will ultimately be subject to the payment offset.

We recommend that CMS consider the following changes to address the issues identified above:

- Allow hospitals the option to either submit Condition Code 49 claims for device replacement without the condition code or hold the claims until the warranty credit is determined. The option of submitting claims up front, without the condition code, achieves timely payment. The offset can then be handled through claim adjustment when the hospital has received a credit that exceeds the threshold.
- CMS should work with hospital associations to determine if a higher credit threshold (above 20%) is appropriate given the administrative burden to all parties associated with the identification, reporting and processing of these claims.
- To drive consistency for reporting device credits, CMS should standardize the data needed for hospitals to accurately report the credit while ensuring that an undo administrative burden is not placed on the hospitals or the FIM/MAC. CMS should limit their data requirements to the minimum necessary. That is, the amount of the credit when the credit exceeds the threshold. This information can be submitted by the hospital through a standardized process without need for submission of an invoice.

## **HOSPITAL-ACQUIRED CONDITIONS, INCLUDING INFECTIONS** *("DRGs: Hospital-Acquired Conditions")*

The Deficit Reduction Act of 2005 (DRA) requires the Secretary to improve the quality of care in hospitals by eliminating payment increases when certain complications occur in the hospital. AdvaMed has long supported the view that cost improvements cannot come at the expense of quality. Rather, we believe that high quality and efficiency in healthcare must work hand-in-hand, and the conditions/infections provision, properly implemented, has the potential to effectively accomplish this end. AdvaMed commends CMS on its effort to research and evaluate the various conditions identified for possible inclusion under this provision.

**AdvaMed supports the inclusion of the six conditions as proposed by CMS, and agrees with CMS that the literature and Medicare claims data show that these conditions meet the criteria for inclusion.**

AdvaMed applauds CMS for recognizing the prevalence of pressure ulcers in the inpatient hospital setting and for the advancement of evidence-based practices for wound care. Although they are not infections, pressure ulcers can be associated with infections, and affect a significant number of Medicare patients each year. AdvaMed agrees that selecting this condition will provide hospitals with appropriate incentives to carefully examine the skin of patients upon admission to identify existing pressure ulcers and to take appropriate measures to treat the problem and avoid additional occurrences during their stay.

We do, however, have concerns regarding the use of the ICD-9-CM code set to track pressure ulcer incidence and serve as a basis for a severity-adjusted DRG payment. ICD-9-CM codes are not precise enough to delineate differences in wound depth, which is a key factor in determining pressure ulcer severity. For example, the resources required to treat a Stage IV ulcer (full thickness tissue loss with exposed bone, tendon or muscle) are considerably greater than the resources required to treat a Stage II ulcer (partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough).<sup>4</sup> ICD-9-CM codes for pressure ulcers would not differentiate between these two wound types and would yield the same for payment for both. We recommend the use of a coding modifier or other mechanism to supplement the proposed ICD-9-CM codes for pressure ulcers to delineate differences in wound depth and severity.

We agree that "serious preventable events" should never occur during an inpatient stay and hospitals should not receive extra payment should they occur. We are encouraged that these events--object left in surgery, air embolism, and blood incompatibility--are extremely rare.

AdvaMed strongly supports the inclusion of Staphylococcus Aureus Bloodstream Infection/Septicemia as a condition under this provision. This will provide incentives for hospitals to identify patients with "staph" infections early in the disease process in order to avoid having those patients convert to sepsis. We also note the existence of developed technologies that allow physicians to rapidly determine whether patients enter the hospital with a community acquired staph infection or not.

**AdvaMed Supports Reconsideration of Additional Conditions--**CMS identified several additional conditions, including numerous infections, which it is not proposing to include at this time. However, we urge the agency to reconsider three conditions: ventilator associated pneumonia; vascular catheter associated infections; and methicillin-resistant staphylococcus arueus. We recommend that CMS track the incidence of these conditions, using temporary codes if necessary, during FY 2008 in order to lay the groundwork for their inclusion in the list of conditions not triggering higher payment when acquired during a hospital stay in FY 2009.

Given the significant volume of Ventilator Associated Pneumonia (VAP) and Other Types of Pneumonia cases reported by the Centers for Disease Control and Prevention (CDC), the high associated costs reported in the literature, and the existence of prevention guidelines, we urge CMS to include VAPs in its initial implementation of this DRA provision. While we acknowledge that a specific code is not currently available that definitively describes VAP, CMS could establish a temporary code to track this

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<sup>4</sup> National Pressure Ulcer Advisory Panel (NPUAP) Pressure Ulcer Staging System, revised February 2007, <http://www.npuap.org/pr2.htm>.

condition in Medicare claims in FY 2008 to enable its inclusion in the list of conditions not triggering higher payment when acquired during a hospital stay in FY 2009.

AdvaMed also recognizes the lack of a unique code to identify Vascular Catheter-Associated Infections. Given that a unique code may be available in time for the implementation of the FY 2008 IPPS, and that, per change request 5499 dated May 11, 2007, the present on admission (POA) indicator will not be used by claims processing systems until January 1, 2008, we urge the agency to provisionally include this condition, pending final approval of the new ICD-9-CM code that will specifically describe it. The public health issues represented by this condition warrant its inclusion as the coding issue is expected to be resolved in time for actual implementation.

While CMS notes that cases with Methicillin-Resistant Staphylococcus Aureus (MRSA) as a secondary diagnosis do not generate a CC or MCC under the new MS-DRGs, MRSA cases were both high volume (more than 95,000 cases in 2006) and high cost (more than \$31,000 in average Medicare charges per case and more than \$3.1 billion in total charges in 2006.) Both the CDC and the Society for Healthcare Epidemiology of America (SHEA) have clear prevention guidelines. We urge CMS to track the frequency of MRSA infections acquired in the hospital during FY 2008 in order to prepare for inclusion of this condition in the list of conditions not triggering higher payment when acquired during a hospital stay in FY 2009.

## **OTHER DECISIONS AND PROPOSED CHANGES TO IPPS FOR OPERATING COSTS**

("Hospital Quality Data)

AdvaMed continues to support efforts to increase the quality of care provided in Medicare, and to require that measures be endorsed by the National Quality Forum. The five measures that CMS proposes to adopt for FY 2009 include an important outcome measure--pneumonia 30-day mortality for Medicare patients--and important measures to assess surgical processes. We support inclusion of these measures.

AdvaMed is encouraged that CMS is considering adding measures regarding hospital-acquired infections in FY 2009 or beyond. As payments to hospitals will no longer increase for some infections acquired in the hospital, (through implementation of the DRA provision on hospital-acquired infections/condition) CMS will be able to monitor the frequency of such infections through claims data. Basing hospital payments on these measures will add no additional administrative costs for hospitals, and these measures could easily be included in CMS reports on hospital performance. We encourage CMS to include these measures in the Reporting Hospital Quality Data for Annual Payment Update, or "RHQDAPU" Program.

**ATTACHMENT A**

**MEDICARE SEVERITY DRGs (MS-DRGs)**

*("DRG Reclassifications")*

AdvaMed recommends the following specific modifications to improve the new MS-DRG classification system:

**MS-DRG 490**

AdvaMed appreciates CMS's recognition of emerging spine technologies and the analytic efforts that have resulted in the proposal to move cases with procedure codes 84.58, 84.59 and 84.65 into proposed MS-DRG 490 (Revised title: "Back and Neck Procedures Except Spinal Fusion with CC or MCC or Disc Devices"). We believe that these changes are a positive step in appropriately recognizing resource utilization and clinical complexity. We remain concerned that appropriate resource utilization is not yet properly reflected in the claims data for MS-DRG 490 given the early stage of some of these technologies. We ask that CMS continue to give consideration to further DRG refinements for these technologies in the future.



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June 12, 2007

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Submitted electronically at <http://www.cms.hhs.gov/eRulemaking>

**Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008**

Dear Ms. Norwalk:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the proposed rule relating to Medicare's hospital inpatient prospective payment system (IPPS) for fiscal year 2008. Our comments focus on possible revisions in the cost-to-charge ratio for radiology services.

**DRGs: Relative Weight Calculations**

The proposed rule discusses the notion of disaggregating the single cost-to-charge ratio for radiology services into three separate cost-to-charge ratios, one for Computed Tomography (CT), one for Magnetic Resonance Imaging (MRI), and a third for all remaining radiology services. This is based on work done for Centers for Medicare & Medicaid Services (CMS) by RTI International. Although CMS did not formally propose making this change for FY 2008, the agency did invite public comments on the issue and also noted that any such change might also potentially apply to the Medicare outpatient prospective payment system (OPPS).

The ACR opposes the RTI-recommended change to the radiology cost-to-charge ratio and we urge CMS to carefully examine the validity of RTI's findings prior to proposing any such change for either the IPPS or the OPPS. We believe that RTI's finding that the cost-to-charge ratios for CT and MRI are lower than the cost-to-charge ratio for all other radiology procedures is an artifact of the way in which hospitals report their costs and charges for these services. As we have noted before, hospitals have relatively little firm guidance about how they should report this information, and different hospitals take different approaches. In the case of CT and MRI, services that are obviously very capital intensive, we believe that hospital costs, as determined by RTI, are significantly understated because of the way in which many hospitals choose to report their capital costs relating to CT and MRI. As we understand it, many hospitals do not assign these capital costs to their radiology department cost center.

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**2008 IPPS Proposed Rule**  
**The Joint Commission Comments**  
(Hospital-Acquired Conditions, Hospital Quality Data, Hospital Value-Based Purchasing, and  
Physician Ownership in Hospitals)

**DRG: Hospital-Acquired Conditions**

Section II-F: Hospital Acquired Conditions, Including Infections (pgs. 24716-24726)

As mandated by the *Deficit Reduction Act (DRA)*, CMS must select, by October 1, 2007, at least two healthcare associated conditions for a new Medicare payment scheme. For discharges on or after October 1, 2008, hospitals will receive no additional payment for cases in which one of the selected conditions was not present on admission. That is, the case will be paid as though the secondary diagnosis was not present. These healthcare associated conditions should be (a) high cost or high volume or both, (b) result in the assignment of a 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 the FY2008 IPPS Notice of Proposed Rulemaking (NPRM), CMS seeks input on a list of thirteen hospital acquired conditions derived from a collaborative exchange with the CDC and multiple stakeholders.<sup>1</sup> Although the *DRA* mandates that CMS select at least two measures, CMS is leaning towards the first six, and encourages debate on all thirteen. The following conditions are ranked in order of relative importance (as determined by CMS):

- 1) catheter-associated urinary tract infections
- 2) pressure ulcers
- 3) objects left in during surgery;
- 4) air embolism
- 5) blood incompatibility
- 6) staphylococcus aureus bloodstream infection/septicemia
- 7) ventilator associated pneumonia (VAP)
- 8) vascular catheter-associated infections
- 9) clostridium difficile-associated disease (CDAD)
- 10) methicilin-resistant staphylococcus aureus (MRSA)
- 11) surgical site infections
- 12) surgery on the wrong body part
- 13) falls

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<sup>1</sup> These conditions are detailed in Sections 6(a) through 6(m) (pgs. 24718-24725).

## Joint Commission Comments: Overall View of Proposed IPPS Payment Changes

- The Joint Commission supports the alignment of payment and quality incentives.
- The Joint Commission has a Payment and Quality Alignment Board Subcommittee that established principles for aligning quality and payment, and these principles are on our website – [www.jointcommission.org](http://www.jointcommission.org).
- Many believe that withholding Medicare payment for care associated with healthcare associated infections and medical errors, as well as the public dissemination of these healthcare associated conditions, could drive reporting “underground.”
- The Joint Commission recommends only three healthcare associated conditions for beginning the alignment of quality and payment by CMS. They are: object left in during surgery; surgery on wrong body part or patient; and blood incompatibility.
- If CMS chooses hospital acquired infections for the new payment program, it should pursue the implementation of a limited demonstration or pilot program to test the healthcare associated condition methodology, and watch for unintended consequences before going nationwide.

Hospital-acquired conditions affect thousands of Americans each year. For example, up to two million inpatients acquire nosocomial infections annually. Additionally, various types of serious, preventable hospital-based errors result in thousands of deaths per year. The origins of hospital-acquired conditions are extremely diverse and stem from multiple areas of the delivery system, which is why many in the healthcare community prefer the term “healthcare associated conditions.” The Joint Commission was one of the first organizations to implement a rigorous program to assess adverse healthcare associated conditions, referred to as “Sentinel Events.” A sentinel event is defined as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a person or persons, not related to the natural course of the patient's illness. The National Quality Forum (NQF) built upon this concept to form its own “Serious Reportable Events” nomenclature. According to the NQF, Serious Reportable Events are errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients. Examples of Serious Reportable Events include surgery on the wrong

body part, a foreign body left in a patient after surgery, a mismatched blood transfusion, or a major medication error. In assessing the origins of healthcare associated conditions or Serious Reportable Events, researchers assign responsibility to, among other things, the complexity of delivery systems, a lack of adequate leadership, the reluctance of providers to admit misjudgment and reimbursement systems that reward errors. The *DRA*-mandated IPPS payment scheme, that would be implemented through this proposed rule, attempts to address a portion of this “faulty” reimbursement system in the Medicare program, by withholding payment for certain preventable events.

The Joint Commission has been a proven leader in addressing adverse healthcare associated conditions, especially since the implementation of the Sentinel Event Program in 1996. The Joint Commission has never questioned the importance of addressing the healthcare (hospital) acquired conditions listed in this IPPS proposed rule. In fact, The Joint Commission has procedures in place to examine various aspects of most healthcare associated conditions, especially through a large body of infection standards. For example, through our National Patient Safety Goals, hospitals must be in compliance with the Centers for Disease Control and Prevention’s (CDC’s) hand-washing guidelines, and all unanticipated deaths associated with healthcare associated infections must be managed as Sentinel Events. The evidence of a serious healthcare associated condition, or Sentinel Event, can influence a hospital’s accreditation status with The Joint Commission.

The Joint Commission recognizes that hospital leaders need to focus more on quality and patient safety, and financial incentives are a proven way to modify behavior. Thus, it is understandable that many stakeholders might support a new Medicare payment scheme that financially penalizes an institution for the presence of healthcare associated conditions. However, the legislatively-mandated system that CMS plans to implement, also has the potential to stifle reporting. Many believe that withholding Medicare payment for care associated with healthcare associated infections and medical errors, as well as the public dissemination of these healthcare associated conditions, could drive reporting “underground.” Thus, The Joint Commission urges CMS to carefully implement this new payment scheme, and consider a system that rewards improvement with the reduction of healthcare associated conditions over time, only penalizing a provider when

they do not demonstrate a concerted effort to improve the quality and safety of care. The Joint Commission's experience with its Sentinel Event Program has shown that a confidential sharing of experiences, in a learning environment, can often bring about the most positive changes in quality.

Because of the incomplete knowledge and experience in the healthcare associated condition arena, The Joint Commission would urge that any CMS payment program be initially limited to only those healthcare associated conditions that would be more difficult to drive underground. Therefore we recommend limiting the initial payment changes to healthcare associated conditions: object left in during surgery; surgery on wrong body part or patient; and blood incompatibility. This would preclude starting with hospital-acquired infections. Additionally, CMS should pursue the implementation of a limited demonstration or pilot program to test each hospital-acquired infection methodology, and watch for unintended consequences before going nationwide. During this testing period, CMS should watch for changes in coding practices within hospitals over time. For example, some hospitals in the new plan might stop using certain codes and switch to others, and CMS might get the false sense that the incidence of certain adverse events has decreased. It would be important to follow-up with these hospitals to see if they actually instituted interventions to reduce the rates of these events, or they just changed coding practices.

Another concern of The Joint Commission involves how the origins of healthcare associated conditions, particularly infections, are determined. It is not always clear when or where the patient developed an infection. As detailed in the proposed rule (pg. 24718), the attribution that an event, such as septicemia, was acquired in the hospital can be difficult to make. The origins of an infection can have a "significant variety of clinical scenarios." To assist in this determination, a Present on Admission (POA) indicator would most likely be required to determine if a selected condition developed during a hospital stay. Unfortunately, CMS has not collected Medicare POA data and the historical prevalence of conditions that were POA is unknown. Thus, during any CMS healthcare associated condition monitoring or payment program, it would be appropriate to watch for significantly increasing trends in the use of POA measures, and to watch for changes in the sequence of codes.

Additionally, this proposed rule does not address patients admitted with subclinical infections that are recognized during hospitalization, relies too heavily on secondary diagnosis codes (which is an inaccurate method for identifying true healthcare acquired conditions), and ignores the identification of infections after discharge which may increase costs in the ambulatory arena. As evidenced above, because healthcare associated conditions will be so difficult to measure from existing Medicare coding data, CMS might consider delaying or limiting its initiative until it can develop a better tool to determine when these healthcare associated conditions have occurred.

Joint Commission Comments: Defining and Coding Healthcare Associated Conditions

The Joint Commission agrees with CMS that the definitions of healthcare acquired conditions lack national uniformity. Often, we find that inter-rater reliability in infection control surveillance is a substantial problem, made more problematic by the lack of standardized definitions. Nevertheless, The Joint Commission believes these healthcare associated condition definition differences are relatively minimal. For example, a common debate surrounds the time frame for hospitalization or device application before a healthcare associated infection may be diagnosed, with most experts arguing between 48 or 72 hours. Because this scientific debate may never be completely resolved, CMS should simply choose the more specific measurement over the more sensitive one. The lack of national standards should not stand in the way of choosing the most important healthcare associated conditions.

In regards to measuring hospital-acquired conditions, The Joint Commission sees no undue collection burden that might be experienced. The burden of data collection would be minimally increased at the point of initial submission of the codes, since providers are coding in order to bill. However, an increased burden will be placed on hospitals to challenge non-payment or reduced payment if the codes are inaccurately applied, or exclusion codes are not submitted correctly. The Joint Commission also supports the development of special GROUPER logic to exclude similar ICD-9-CM codes. Additionally, rather than continuing to retrofit ICD-9-CM codes for quality monitoring, CMS may get more value out of promoting quick uptake of electronic medical records (EMRs), which would enhance the richness of clinical data.

The Joint Commission feels that the serious preventable event – surgery on wrong body part, wrong patient, or wrong surgery (wrong site surgery or WSS) – should be ranked higher in CMS’ list of 13 healthcare associated conditions. Because CMS has one code that is not specific to all WSS – which can be the wrong site, the wrong patient, or the wrong procedure – there is an erroneous assumption made in the proposed rule that the occurrence of WSS is rare. In fact, there is ample evidence that the occurrence of WSS is quite prevalent. Within The Joint Commission’s Sentinel Event Program, WSS is the number one reported event. Since WSS became a reviewable Sentinel Event, The Joint Commission has assessed over 550 wrong site surgery issues. Furthermore, the true number of WSS is much higher because The Joint Commission believes that the Sentinel Event Program only captures around ten percent of the total number of WSS cases annually. This would equate to over 500 WSS cases per month nationwide. Finally, The Joint Commission disagrees with CMS’ belief that WSS could not be considered as a complication because it is a risk of being in a hospital. If CMS is trying to prevent adverse events with this healthcare associated condition payment scheme, WSS qualifies as one of the prime candidates because of the potential damage to the patient. CMS should develop specific codes for WSS (a code for wrong organ, wrong patient, etc.). Because it is likely that CMS/Medicare is paying for WSS through other codes, The Joint Commission believes that Congress would be very interested in having WSS as one of the selected healthcare associated conditions.

Finally, while there would be clear public health benefits to reducing the transmission of methicillin-resistant staphylococcus aureus (MRSA) and clostridium difficile, as mentioned on page 24718, the origins of these conditions would be particularly difficult to measure. Because these bacteria are now common in the community, active surveillance cultures (ASC) would probably be needed in order to rule out an infection being acquired within a healthcare facility. Although some healthcare organizations in the U.S. screen for these infections, requiring ASC would be a significant change in clinical practice for most.

**Hospital Quality Data** (pgs. 24802-24809)

Section IV/A: Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs: Reporting of Hospital Quality Data for Annual Hospital Payment Update

Section 5001(a) of the *Deficit Reduction Act of 2005 (DRA)*, set out new requirements for the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program.

Specifically, the section mandates that the payment update for FY2007, and each subsequent fiscal year, will be reduced by 2.0 percentage points for any “subsection (d) hospital” that does not submit certain quality data.

On page 24805 (Section 3a) - New Quality Measures and Program Requirements for FY 2009 and Subsequent Years: Proposed New Quality Measures for FY2009 and Subsequent Years - CMS proposes five new measures to the existing set of 27. These measures are:

- Pneumonia 30-Day Mortality;
- SCIP Infection 4/Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose;
- SCIP Infection 6/Surgery Patients with Appropriate Hair Removal;
- SCIP Infection 7/Colorectal Patients with Immediate Postoperative Normothermia;
- SCIP Cardiovascular 2/Surgery Patients on a Beta-Blocker Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period.

Joint Commission Comments

The Joint Commission approves of all five new measures detailed in the FY2008 IPPS proposed rule. In fact, aside from the AMI, HF and pneumonia 30-day mortality measures, CMS and The Joint Commission are aligned on all proposed measures through FY2009. Additionally, all of the data associated with these measures (five new proposed measures included) can be transmitted through The Joint Commission’s ORYX performance measurement systems.

**Hospital Quality Data** on page 24806 (Section 3a), CMS identifies other potential measures in the table: Possible Measures and Measure Sets for the RHQDAPU Program for FY2009 and Subsequent Years.

#### Joint Commission Comments

Out of the 18 measures and eight measure sets listed in the table on page 24806 of the proposed rule, The Joint Commission would approve of CMS adding several measures for FY2009 payment only if; they were measures put forth by the Hospital Quality Alliance (HQA) for inclusion in their public reporting, and were subject to National Quality Forum (NQF) endorsement. The Joint Commission would recommend that HQA determine the measures or measures sets to be included in FY2009, and develop an implementation schedule for subsequent years. In order for The Joint Commission to provide comments/recommendations on measure sets of potential interest within the table, more information would be needed than was available in the proposed rule (e.g., Nursing Sensitive Condition Set).

It is not clear from the proposed rule through which data transmission mechanism will data from other measure developers come from. The Joint Commission would encourage consideration of ORYX performance measurement systems as an existing, well established reporting infrastructure.

The Joint Commission would like to explicitly inquire about the patient safety measures 16, 17 and 18, or the “Leapfrog Leaps.” It is not clear from the minimal information provided in the proposed rule (table on page 24806 only), how these measures would be reported. Would they be reported on an annual basis? Furthermore, all measures currently reported for RHQDAPU are at the patient level, and these Leapfrog Leap measures address structural components and would require a different infrastructure to collect.

**Hospital Quality Data** on page 24806 (Section 3b) – Data Submission – CMS requests comment on the data submission process. CMS references the CMS/Joint Commission Specifications Manual for National Hospital Quality Measures as the source for technical specifications for the quality measure reporting requirements. For the additional SCIP measures, CMS proposes that the deadline for hospitals to submit the new first calendar quarter of 2008 quality measures, for FY2009 payment, would be August 15, 2008. The data then must be submitted for each subsequent quarter 4.5 months after the end of that quarter.

For the proposed Pneumonia 30-Day Mortality measure, CMS proposes to use claims data that are already being collected for index hospitalizations to calculate the mortality rates. More specifically, data from 3Q06 to 2Q07 would be used to calculate the Pneumonia 30-Day Mortality Rate FY2009 annual payment determination.

Joint Commission Comments

The Joint Commission would approve of these timelines because the measures are already included in the CMS/Joint Commission Specifications Manual (contingent on NQF endorsement). Additionally, all the measures in this section of the proposed rule have been programmed and verified for ORYX performance measurement systems.

**Hospital Quality Data on page 24807 (Section 4) – Retiring or Replacing RHQDAPU Program Quality Measures** – CMS explains that new measures will be added to reflect clinical and other program goals and measures that are no longer supported by clinical evidence will be removed. CMS seeks suggestions on how best to structure a mechanism to identify and retire/replace measures that in the RHQDAPU program.

Joint Commission Comments

For those measures aligned and common to both CMS and The Joint Commission, consideration for retirement and/or replacement should be mutually agreed upon, and the same date for retirement and/or replacement established. CMS should continually interact with The Joint Commission and other stakeholders to ensure that measures remain consistent with national and regional quality measurement efforts. New measure focus areas should be explicitly identified via a consensus process. Measures should be endorsed by NQF, and recommended by the HQA. The CMS/Joint Commission Measure Maintenance Workgroup should continue to be the designated mechanism for maintaining measure alignment/identity. Measures should have at least a 6-12 month pre-implementation or testing period to ensure that any technical problems are corrected before final VBP implementation.

CMS should continually track those measures endorsed by NQF, and any alterations to quality measures from that organization. Recently NQF endorsed a pneumonia antibiotic timing measure - initial antibiotic received within 6 hours of hospital arrival - which replaced the measure - initial antibiotic received within 4 hour of hospital arrival. However, because the 4 hour measure is part of the RHQDAPU program and these IPPS proposed rules are undergoing public comment, no immediate action can be taken to cease data collection for the 4 hour measure and discontinue public reporting until the final IPPS rules are published. Needless to say, a mechanism must be developed whereby CMS can be more nimble and take immediate action when a measure ceases to be NQF endorsed.

**Hospital Quality Data on page 24807 (Sections 5c(1) and (2)) – Chart Validation Requirements**  
– CMS seeks comment on its chart-audit validation criteria. For the FY2008 payment update, CMS is requiring a minimum of 80 percent reliability, based upon the chart-audit process. CMS, for the FY2008 update, will not require validation for three SCIP measures (Infection 2, VTE 1 and VTE 2).

Joint Commission Comments

The Joint Commission was under the impression that CMS was moving to using the reliability of category assignments rather than data elements. The Joint Commission would encourage CMS to move in this direction. The reason to move toward reliability of category assignments is because the category assignments determine what is publicly reported. If a data element is unreliable but does not influence the category assignment, then it really should not be influencing repayment. The category assignments determine what is reported; the data elements are only important if they influence the category assignment.

**Hospital Quality Data on page 24808 (Sections 5c(3)) – Data Validation and Attestation – CMS**  
seeks comment on internal and external edit checks to ensure the integrity of submitted data.

Joint Commission Comments

The Joint Commission vendors already provide data validation services to their hospital customers as required in the Joint Commission Performance Measurement System Requirements for ORYX Listing. Vendors, contracting with The Joint Commission, are contractually required to adhere to a new data audit methodology. It would be prudent for CMS to entertain a formal relationship with The Joint Commission to leverage the power of this auditing capability, rather than CMS being solely responsible for this enormous task of national data validation. The Joint Commission would be an ideal candidate to provide timely, effective third-party assessment. Additionally, the current process the Joint Commission uses to track the quality of data it receives from Performance Measurement Systems could be expanded to include those providers that are not Joint Commission accredited as well.

**Hospital Quality Data on page 24809 (Sections 5d) – Public Display** – CMS estimates the five to ten percent of hospitals reported on Hospital Compare share Medicare Provider Numbers (MPNs). For FY2008 and after, CMS is proposing to require all hospitals that share MPNs to be listed on Hospital Compare.

#### Joint Commission Comments

The Joint Commission approves of increased transparency and CMS' efforts to list all hospitals that share MPNs. The Joint Commission has a website similar to Hospital Compare, Quality Check. Currently, on this website, all hospitals that share MPNs are listed for only one measure, but The Joint Commission plans to expand this practice to all measures.

#### **Hospital Value-Based Purchasing (pg. 24809-24810)**

##### Section IV/B: Development of the Medicare Hospital Value-Based Purchasing Plan (VBP)

Section 5001(b) of the *DRA* mandates that CMS develop a VBP for payments beginning in FY2009.

#### Comments:

Receiving data directly from hospitals will require infrastructure and support challenges at CMS (e.g., help desk calls from hospitals). For this large undertaking, The Joint Commission would inquire about the data quality mechanisms that would be in place to ensure the accuracy and completeness of data received directly from hospitals.

## **Physician Ownership in Hospitals**

CMS has proposed changes to the provider agreement regulations to formally define “physician-owned hospital,” and to require that as part of their Medicare provider agreement, a physician-owned hospital must furnish notice to all patients at the beginning of their inpatient stay or outpatient visit that the hospital is a physician-owned hospital, that the disclosure should be reasonably understandable to all patients, and should indicate that the list of physician owners or investors is available upon request. Additionally, physicians are required, as a condition of continued medical staff membership, to agree to disclose in writing their ownership interest to all patients they refer to the hospital, and to make such disclosure at the time of the referral, and that a physician-owned hospital that fails to disclose (or fails to have procedures in place for making such disclosures) ownership interests will be denied a Medicare provider agreement if they are a prospective provider, or their existing provider agreement will be subject to termination.

### Joint Commission Comments

The Joint Commission recognizes that CMS is taking these actions to implement plans included in the Study and Report to Congress that CMS completed in response to the mandate in the *Deficit Reduction Act of 2005 (DRA)*. We understand the desire to improve transparency in disclosing these ownership details, but we note that the disclosure of ownership interest provides no useful information to the patient. The Joint Commission is unsure what the patient or potential patient can be expected to do with the information concerning physician ownership or the list of physician owners. Imposition of this requirement will serve no useful purpose unless it is accompanied by a comprehensive CMS outreach and educational initiative for Medicare beneficiaries and other patients. Such educational efforts would provide some guidance for using this ownership data in conjunction with other information that may be available about a particular facility, so the patient or potential patient can make an informed decision about whether or not to use a particular hospital. The Joint Commission believes that these requirements are more appropriately included in the provider agreement rules rather than in the conditions of participation (CoP) for hospitals. However, since the proposed rule calls for a specific requirement pertaining to medical staff membership, it seems the regulations for medical staff bylaws at 42CFR482.22(c) may require revision to reflect this requirement.

Under the subtopic of patient safety measures, CMS has proposed that any hospital (physician-owned or otherwise) must furnish all patients a written notice if a doctor of medicine or osteopathy is not present in the hospital 24 hours a day, seven days a week. The notice is to be provided at the beginning of an inpatient stay or outpatient visit and must indicate how the hospital will meet the emergency needs of any inpatient who develops an emergency medical condition at a time when there is no physician present in the hospital. CMS has proposed this rule as a provision of the provider agreement regulations, but is specifically seeking comment on whether it should remain such or whether it would be more appropriate to include this requirement in the CoPs.

#### Joint Commission Comments

If CMS proceeds with establishing this requirement, The Joint Commission believes that it is more appropriate to include it in the provider agreement rules rather than in the CoPs of hospitals. We would point out that this requirement, which occurs post-admission, fails to provide the patient with useful information that is timely or useful. Once again, we urge CMS to undertake a comprehensive consumer education initiative prior to imposing this requirement, so the patient can make an informed choice about any particular facility. It might also be argued that this requirement should be extended to cover the presence or absence of particular equipment, or the level of expertise of the faculty staff, including physicians, so the patient can understand what to expect depending on the nature of the emergency and the capabilities of the facility, and the likelihood of requiring a transfer to another hospital for any particular medical emergency.

CMS has also noted that it has come to their attention that hospitals, even hospitals with emergency departments, have called 911 when a patient has experienced an emergency and a physician was not on the premises, and onsite clinical personnel lacked the equipment and training to provide the assessment, treatment and referral required of all hospitals. Therefore, CMS is seeking input on whether requirements for emergency service capabilities should be strengthened in all hospitals, whether or not they have emergency departments. Specifically, CMS would like comments on whether the hospital (and critical access hospital) condition of participation for emergency services should be expanded to include: the clinical personnel that

must be present at all times in hospitals with and without emergency departments; the competencies such personnel must demonstrate, for example training in Advanced Cardiac Life Support or successful completion of specified professional training programs; the emergency response equipment that must be available and the manner in which it must be available (for example in the emergency department or in every inpatient unit); and whether emergency departments must be operated 24 hours a day, seven days a week.

The Joint Commission unreservedly agrees that the CoP for emergency services for hospitals and critical access hospitals should be strengthened. The Joint Commission believes that a hospital should be capable of handling any situation that they can reasonably be expected to be presented with. With respect to the precise regulatory provisions that should be included in a revision to emergency services CoP, The Joint Commission believes that CMS should bring together experts in the field who can best address the specific requirements needed to bolster and modernize the requirements. CMS could convene an expert panel or at a minimum, consult with the State agencies and recognized national accrediting bodies, as required by section 1863 of the Social Security Act.



June 12, 2007

Leslie Norwalk, Esq.  
Acting Administrator  
Centers for Medicare and Medicaid Services  
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 and Fiscal Year 2008 Rates; Proposed Rule

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the proposed rule (72 FR 24680-25135, May 3, 2007) for the Hospital Inpatient Prospective Payment System. The University of Pennsylvania Health System (UPHS) serves the Greater Philadelphia area through three teaching hospitals, offering a full range of acute and post-acute services. Combined, our hospitals admit over 15,000 Medicare Beneficiaries on an annual basis and provide training to over 1,000 interns and residents.

**1. DRG REFORM AND PROPOSED MS-DRGs (pp. 24691-24712)**

We commend CMS for its continued efforts to modify the existing DRG payment system to make payments for inpatient hospital services equitable and fair. While we may dispute some of the conclusions and resulting proposed actions, we do agree that the existing system needs to be refined.

**a. Evaluation of Alternative Severity-Adjusted DRG Systems**

We are supportive of the efforts of CMS to evaluate several alternatives to the existing DRG system. We appreciate that CMS has incorporated comments submitted by the provider community in setting the criteria for evaluating the

competing products. We look forward to reviewing the final recommendations when the RAND report is released in September.

**b. Development of Proposed Medicare Severity DRGs (MS-DRG)**

We are in agreement with the MedPAC recommendation of moving to a DRG system that more accurately reflects the variation of severity within a particular diagnosis group. We have reviewed the methodology utilized in creating the MS-DRGs and are in support of revising the CC (Comorbidities and Complications) list and the general method for assigning severity tiers to the MS-DRG.

However, we are concerned with the rapid implementation of such a far-reaching change in DRGs without the opportunity to fully model how the MS-DRGs will impact our individual hospitals. The only way to truly assess the impact would be to run current cases through the GROUPER that would be in effect under MS-DRGs. As this GROUPER was not made available to the public, we had to rely upon alternative, less accurate methods for determining what the impact would be. Without a true measure of the expected impact of the MS-DRG changes, hospitals cannot be expected to fully understand the scope and breadth of the proposed changes.

We are supportive of the MS-DRGs, but would appreciate a transition period to ensure that not only hospitals, but also fiscal intermediaries and third party software systems are fully prepared to implement (and reimburse on) the MS-DRGs. Historically, whenever CMS has changed from cost-based systems to Prospective Payment Systems (outpatient, Inpatient Rehabilitation, Inpatient Psychiatry) there has been some transition period. While this is not an entirely new payment system, it certainly represents a significant change that warrants some type of transition period.

**c. Impact of the Proposed MS-DRGs**

We strongly disagree with the 2.4 percent reduction for FY 2008 and FY 2009 in the federal base rate amounts (referred to as a "behavioral adjustment").

In developing the 2.4 percent reduction, CMS relied upon the historical experience of the state of Maryland when it transitioned from the Medicare DRG system to the APR-DRG (All-Patient Refined DRG) system. We believe that it would be inappropriate to rely upon the results witnessed in Maryland because there are significant differences between the APR-DRG system and the proposed MS-DRG system. Most notably, the APR-DRG system employs a far more extensive coding hierarchy in assigning cases and requires hospitals to report far more codes than both the MS-DRG and existing DRG systems. Additionally, the APR-DRGs rely upon the interactions between certain diagnoses and procedures, while the MS-DRG (and existing DRG) system does not. Lastly, we question the appropriateness of relying

upon the experience of one state (with less than 50 hospitals) in setting national policy that would affect more than 3,600 hospitals.

Since the proposed MS-DRG system relies upon existing base DRGs, it does not require the extensive coding logic that APR-DRGs requires, nor does it require the volume of codes to be assigned to each case under the APR-DRG system. The existing DRG GROUPER accepts a maximum of eight secondary diagnosis codes. A recent article in the April 2007 issue of *Healthcare Financial Management* (published by the Healthcare Financial Management Association) concluded that coding of cases was driven by coding guidelines, not by financial incentive. Thus, even under the existing restriction of eight secondary diagnosis codes, hospitals will likely not change their medical record coding practices.

Lastly, a review of all-payer health care claims databases by the American Hospital Association identified that less than 1% of claims (0.25%, to be exact) contained a secondary diagnosis code in the 10<sup>th</sup> through 25<sup>th</sup> coding positions that appears on the revised lists of CCs and MCCs. One can reasonably conclude that if CMS were to accept a full 25 secondary diagnosis codes, only a small percentage of existing Medicare cases could possibly be assigned a higher weighted MS-DRG.

We believe that CMS should not implement the 2.4% “behavioral adjustment” for the reasons mentioned above.

## **2. IME ADJUSTMENT (pp. 24812-24815)**

The University of Pennsylvania Health System has over 75 accredited residency and fellowship programs, with more than 1,000 residents in these programs. On average, about 70% of these trainees spend at least some part of their annual training at hospitals and locations outside of our Health System, enhancing their educational experience and providing much-needed services to the receiving facilities. As a premier Academic Medical Center, we also attract over 125 residents and fellows each academic year from about 16 different hospitals and health systems in the Metropolitan Philadelphia area. Given the size and scope of our training programs, we have an acute interest in any and all regulations that affect Medicare payments for residents.

### **a. Vacation and Sick Leave Time**

In the Proposed Rule, CMS is expanding on the policy to exclude residents’ time spent in non-patient care activities (set forth in the FY 2007 final rule). CMS notes that vacation and sick leave time does not fit into either the category of patient care or non-patient care. Therefore, the proposed rule sets forth a third category time that would exclude vacation and sick time from the determination of both the Direct (GME) and Indirect (IME) FTE calculation.

As written, the proposal calls for vacation and sick time to be removed from both the numerator and the denominator of the FTE calculation. Our comments are specific to vacation time since that time is usually planned and would generally be for several

days or weeks. Sick time, is unplanned and generally only amounts to one or two days a year. Extended periods of sick time that require the resident to extend their training beyond the expected end date have always been excluded from the numerator in the IME and GME counts (since the time is "made up" at a later date).

If the basis for one FTE was 2,080 hours and a resident took 40 hours of vacation, the new FTE basis (for that resident only) would be 2,040 hours. On the surface, this certainly seems reasonable and logical. The resident would calculate to one FTE regardless of how the vacation time was treated. However, the policy unfairly penalizes hospitals that send residents to multiple locations to enhance their medical training and experience.

When hospitals send residents to other locations, there is usually an agreement between the hospital and the receiving institution to compensate the hospital for the time the resident is at the receiving institution. Since the receiving institution usually is accepting the residents because of a desire to provide more medical staff coverage, they will not allow residents to take vacations when scheduled at their facility. Then, if the resident's vacation is excluded from the FTE calculation (as proposed), the receiving facility will be getting more of an FTE than they are paying for.

	<u>Home Hospital</u>	<u>Receiving Hospital</u>	<u>Total</u>
Existing Rules			
Rotation time (Weeks)	26	26	52
FTE	0.5000	0.5000	1.0000
Salary (\$1,000/week)	\$ 26,000	\$ 26,000	\$ 52,000
Proposed Rules (assume 1 week of vacation)			
Rotation time (Weeks)	25	26	51
FTE	<b>0.4902</b>	<b>0.5098</b>	1.0000
Salary (\$1,000/week)	\$ 26,000	\$ 26,000	\$ 52,000
FTE Change	<b>(0.0098)</b>	<b>0.0098</b>	-

While the FTE did not change in total, the redistributive effect of this proposed policy cannot be ignored. While the change may seem small, multiply that effect by 1,000 residents and you have a redistribution of 10 resident FTE's.

This redistribution of resident FTE's has serious ramifications when one notes that the resident FTE caps that were implemented in 1996 and modified by section 422 of the Medicare Modernization Act. Similarly, the 1985 base year for the Per Resident Amounts would be incorrect. Excluding the vacation time now, when it was not excluded in any base year is inconsistent with general Medicare payment principles. When Medicare transitioned from cost-based operating payments to Prospective Payments, there was increased scrutiny of hospitals capital policies to ensure that hospitals were not shifting costs that were considered operating in the PPS base year to capital in the subsequent years. Likewise, when the Per Resident Amounts were

established in 1985, there was an effort to make sure that hospitals weren't shifting costs that were borne by the community into the base year amounts. Implementing a policy that causes a redistribution of resident FTE's that is inconsistent with multiple base year policies is inherently flawed.

Even if CMS believes that the proposed change is not inherently flawed and contradictory to base year handling, the proposed change will be an administrative burden to not only hospitals, but CMS and its fiscal intermediaries as well. Currently, there is no industry standard for how much vacation time is allotted to residents and there is also not any consistency between individual programs.

With the policy as it is proposed, hospitals would have to notify any receiving hospital whether or not each resident they receive took vacation and how much vacation time they took. If the receiving hospital doesn't receive this information, their FTE count would then be understated because they would be using too large of a denominator. Upon audit, the fiscal intermediary will have to ascertain that the correct denominator was used for each resident, since the amount of vacation time taken will vary by resident.

We strongly urge CMS to reconsider its position on vacation and sick time. We believe that the administrative burden imposed by such a change, coupled with the redistributive effect and the lack of consistency to the base year methods for counting residents are compelling reasons to not implement this change.

**b. Interns and Resident Information System (IRIS) Implications**

Each year, hospitals are required to enter all of their residents into the IRIS program and submit this entered data with their filed Medicare cost report. An incorrect or missing IRIS submission is cause for the Intermediary to reject the submitted cost report. The fiscal intermediaries utilize IRIS to identify residents that have been claimed by more than one hospital for the same time period. If the duplicated records can't be resolved, the intermediaries will disallow the duplicated time period at all hospitals involved. As such, the IRIS is a critical component of the cost reporting process and one that is taken seriously by the provider community.

Currently, IRIS is a database-driven program that runs in the MS-DOS operating system. It is cumbersome and requires a significant amount of manual intervention to complete. Prior to UPHS implementing a costly resident tracking software suite, over 300 man-hours had to be devoted to entering over 1,000 residents into IRIS. While the IRIS is not designed to calculate FTE's, many hospitals and fiscal intermediaries extract the data to verify the FTE on the cost report. Without a significant revision to the IRIS software, the proposed vacation and sick policy will hinder the ability of providers and fiscal intermediaries to use IRIS for this purpose, thus adding another administrative burden to all parties.

We urge CMS (regardless of whether or not the vacation and sick proposal is adopted) to review the IRIS program and make recommendations for updating the software. The program has not changed significantly since 1999 when it was updated for Y2K. The current format and the operating system it runs on (MS-DOS) are no longer industry standards and should be updated to reflect current operating environments.

### **3. CAPITAL IPPS (pp. 24818-24823)**

#### **a. Capital Payment Update**

Citing an analysis that purports to show that urban hospitals have experienced positive capital margins at a rate far in excess of their rural counterparts, CMS is proposing to eliminate the 0.8 percent increase in capital payments for urban hospitals only. This cut is proposed by CMS without any congressional direction and is not supported by any data more current than FY 2004.

The trend analysis presented by CMS is deficient in that it only covers from 1996 to 2004 and most capital spending cycles run in 15 to 20 year increments. If the declines from 2002 to 2003 and again from 2003 to 2004 are trended forward to 2007, the capital margins would be negative.

At UPHS, hospital overall margins and cash positions during the same time frame (1996-2004) were generally weak, or negative. During times of such fiscal pressures, there is a tendency to not expend dwindling resources on large capital projects, thus our capital payments from Medicare would generally grow faster than our capital costs. During the most recent period of economic recovery (2002-2007), UPHS hospital overall margins and cash positions are improving, the cost of borrowing is coming down and there is far greater capital expansion than occurred in the previous 5 years (1996-2001). An ever-aging set of buildings (some are over 125 years old) and increasing costs of technology make the ability to fund capital expansion all the more critical to our hospitals.

As buildings are replaced and new technologies implemented, our Medicare capital costs will be much higher in years to come. If capital payments are reduced, we will certainly be witnessing negative capital margins in the future. Therefore, we believe that it would be improper to remove the 0.8 percent increase in capital payments.

#### **b. Large Urban Add-On**

Currently, hospitals located in Large Urban areas receive an adjustment that adds three percent to their Medicare Capital payment. This add-on was established when Congress mandated that Capital payments were transitioned from cost-based to Prospective Payment. Ostensibly, the three percent accounts for the fact that the cost of capital in large urban areas is higher than rural areas (higher labor cost, higher

building supply costs, etc.). CMS has proposed to eliminate this add-on beginning in FY 2008.

As in the case of the elimination of the 0.8 percent update, this proposed elimination is without congressional direction and seems to be in response to the perceived disparity in capital margins between rural and urban hospitals. We are opposed to this reduction for many of the same reasons outlined above.

c. **Capital IME and Capital DSH**

In addition to the base capital payment, the Capital PPS system also makes additional payments to hospitals that train residents (Capital IME) and hospitals that serve a disproportionate share of indigent patients (Capital DSH). In the proposed rule, CMS is not making any changes to these add-ons, but you are seeking comments on future reductions, or eliminations of these payments.

We oppose any and all reductions, or eliminations, of these amounts without a clear impact analysis supporting the logic and rationale behind such cuts.

**4. DRGS: HOSPITAL-ACQUIRED CONDITIONS (pp. 24716-24726)**

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. Along with the AHA, UPHS 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. UPHS 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. UPHS 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.

Thank you again for the opportunity to comment on this proposed rule. If you have questions regarding anything I have commented upon, please do not hesitate to contact me at 215-662-2203.

Sincerely,



Ralph W. Muller

Chief Executive Office, University of Pennsylvania Health System

cc: Herb Kuhn, Centers for Medicare & Medicaid Services  
Robert Dickler, Association of American Medical Colleges  
Robert Greenwood, Hospital Association of Pennsylvania



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*Re: Medicare Program; Proposed Changes to the Hospital  
Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates;  
Proposed Rule -- CMS-1533-P "DRGs: Hospital-Acquired  
Conditions"*

**Introduction**

The Society for Healthcare Epidemiology of America (SHEA) wishes to thank the Centers for Medicare & Medicaid Services for the opportunity to provide additional input to the CMS proposed IPPS changes.

SHEA was founded in 1980 to advance the application of the science of healthcare epidemiology. SHEA works to maintain the utmost quality of patient care and healthcare worker safety in all healthcare settings. It upholds its high success rate in infection control and prevention, while applying epidemiologic principles and prevention strategies to a wide range of quality-of-care issues. SHEA is a growing organization, strengthened by its membership in all branches of medicine, public health, and healthcare epidemiology.

As an organization with considerable expertise in the prevention, detection, and control [and treatment] of healthcare-associated infections (HAIs), we are responding to the current CMS proposals outlined in Section F: CMS-1533-P Hospital-Acquired Conditions, beginning on page 172. We appreciate the opportunity to comment on how many and which conditions should be selected for implementation in FY 2009. Further, we have worked collaboratively and are in essential agreement with our colleagues in key organizations representing infectious disease and infection control authorities in our nation's acute healthcare facilities,

namely: the Association for Professionals in Infection Control and Epidemiology (APIC) and the Infectious Diseases Society of America (IDSA).

We applaud the foresight of CMS in this arena, as we have a shared vision of preventing adverse events, including HAIs, in the patients we serve in our respective care settings. We have participated in discussions with the Centers for Disease Control and Prevention (CDC) and appreciate that the broader scope of the Deficit Reduction and Reconciliation Act (DRA) of 2005 is "Hospital-Acquired Conditions." However we will focus most of our comments on HAIs, where we believe we have the most expertise. We hope that these suggestions will help finalize decisions that must be made this year in order to implement the proposed rule scheduled for October 1, 2008 (FY 2009).

We understand the DRA requires that by October 1, 2007, CMS must identify "at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a 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." For discharges occurring on or after October 1, 2008, we understand hospitals will not receive additional payment for cases in which one of the selected conditions was not *present on admission* (POA). That is, the case will be paid as though the secondary diagnosis was not present. The DRA requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding conditions present on admission (POA) would be delayed to January 1, 2008 because of technical difficulties in the software program that accepts the new information.

In the proposed rule, CMS is seeking comments on how many and which conditions should be selected for implementation in FY 2009, along with justifications for these selections.

### **Six conditions proposed for consideration for FY 2009**

CMS asks for comments on six conditions that include three serious preventable events as defined by the National Quality Forum (NQF):

1. Catheter-associated urinary tract infections;
2. Pressure ulcers;
3. Object left in during surgery;
4. Air embolism;
5. Blood incompatibility; and
6. *Staphylococcus aureus* septicemia.

We support CMS in this effort to identify appropriate conditions that should not occur in our hospitals. The challenge is two-fold: meeting criteria defined by Congress while also ensuring accuracy in the billing data that enable the appropriate identification of cases. We emphasize our belief and our concern that transition to the MS-DRG system requiring implementation of POA codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

### **Recommendations for FY 2009**

## **Support**

Although our organization's focus is infection prevention, we do **support numbers 3, 4 and 5** that is, the three serious preventable events: object left in during surgery, air embolism and blood incompatibility, as appropriate conditions to include for FY 2009. These conditions have been identified and supported by the National Quality Forum (NQF) and are currently identifiable by discrete ICD-9 codes. For the most part, these conditions can also be coded by hospitals without dependence on POA codes. POA codes *will* be necessary for “object left during surgery” because recognition of this condition can occur months to years after the initial event and, according to a recent review, lead to readmission in 30% of cases.<sup>1</sup> These are events that can cause great harm to patients and for which there are known methods of prevention.. It will of course be essential to ensure that the definitions, surveillance methods, and coding of these events are consistently applied and that certain specific medical circumstances are noted as exceptions. For example when patients deliberately have objects left in place, as opposed to accidental retained foreign objects, in emergencies when patients deliberately receive unmatched blood, or when air embolism is technically unavoidable because of a specific surgical procedure.

## **No support for FY 2009**

**We do not support numbers 1, 2 and 6 for FY 2009; i.e.,** catheter-associated urinary tract infections, pressure ulcers, and *Staphylococcus aureus* septicemia as currently proposed. We strongly agree that every effort should be made to eliminate HAIs that are preventable by applying state-of-the-art and evidence-based science. We believe these three indicators are potential candidates for the future, but each condition poses challenges in three areas: the critical need for accurate POA codes (which do not currently exist), the ability to identify these outcomes properly and consistently (definition issues), and the fact that, in many cases, the referenced complications may not be reasonably or entirely preventable.

As noted earlier, CMS proposes to rely on POA coding, a requirement that has now been pushed back to January 1, 2008 due to technical difficulties. CMS is aware of the experiences reported by the Agency for Healthcare Research and Quality (AHRQ)<sup>2</sup> which concluded that: “The level of hospital and coder commitment to accurate collection depended on the support and involvement of regional health information management associations, the amount of education provided by the state, and the availability of clearly defined coding guidelines.” CMS is also aware of two states already using POA codes, whose experience demonstrated that implementation requires a minimum of two years to achieve reliability. The process requires intensive education of clinicians to identify and record the complication enabling proper and accurate coding to determine the proper DRG assignment. We look to CMS to provide educational support. Until CMS is satisfied that POA coding accuracy is reliable, we do not believe any of these conditions can be selected. Although “object left in during surgery” also poses POA challenges, this condition is relatively rare. Definitions become critical in order to identify and apply appropriate interventions. Some of the relevant definitions are currently under review and require updating before they can be implemented successfully in a hospital reporting program.

We do not believe that each of these three conditions is always reasonably preventable. In our previous letter to CMS<sup>3</sup>, we noted that even when reliable science and appropriate care processes

are applied in the treatment of patients, not all infections can be prevented. After POA codes are functioning reliably, each of the following conditions will need additional exclusion codes to minimize the risk of including nonpreventable infections.

We offer the following specific comments on each of these conditions

***#1 Catheter-associated urinary tract infection (ICD-9-CM Code 996.64 - Infection and inflammatory reaction due to indwelling catheter)***

CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after catheters have been in place for several days. The evidence based guideline referenced by CMS ([http://www.cdc.gov/ncidod/dhqp/gl\\_catheter\\_assoc.html](http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html)) was published in 1981 and is scheduled to be reviewed and updated by CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC). Although *preventive* interventions focus on timely removal of appropriately placed urinary catheters, there are patients who genuinely need long-term catheterization and who may suffer the complication of catheter-associated inflammation. Some host factors that appear to increase the risk of acquiring catheter-associated urinary tract infections including advanced age and debilitation may not be modifiable.

It is understood that this condition would require an initial cross check with POA codes, and only then, after excluding all the proposed codes, including chronic conditions, would a decision be made as to whether to classify as a concurrent condition (CC). In addition to the numerous exclusionary codes listed by CMS, we propose the code list exclude conditions such as immunosuppression (e.g., bone marrow transplant or burn patient), patients in whom a catheter is placed for therapeutic installation of antimicrobial and/or chemotherapeutic agents, patients who have sustained urinary tract trauma, or patients requiring permanent use of catheters such as patients with anatomic conditions who cannot have their catheter discontinued. Further, we would ask CMS to consider a new code for "inflammatory reaction from the indwelling catheter" distinct from catheter-associated UTI.

*Unintended consequences:* Even as POA coding is implemented and considered reliable, there may also be unintended consequences as suggested by anecdotal reports from Pennsylvania. In order to document that catheter-associated bacteriuria was present on admission, clinicians may feel obligated to order urine cultures at the time of hospital admission and then attempt – often unnecessarily – to sterilize the patient's urine. Authorities on the management of urinary tract infections and bacteriuria associated with an indwelling bladder catheter agree that such antibiotic therapy is usually not warranted when the patient has no symptoms of either a urinary tract or a systemic infection. Treatment under these circumstances is often associated with superinfection and selection of antibiotic-resistant pathogens such as Klebsiella or Candida species.

***#2 Pressure ulcers – (ICD-9-CM Codes 707.00 through 707.09)***

We believe this indicator could improve initial patient assessment for pressure ulcers, but there are a number of additional concerns that should be addressed by CMS beyond POA coding issues. This condition is not limited to hospitals; given the large number of transfers between hospitals and long-term care facilities a thorough examination and documentation of

existing pressure ulcers on admission is of prime importance. According to Medicare coding rules, POA coding of pressure ulcers must rely solely on physicians' notes and diagnoses and cannot make use of notes from nurses and other practitioners. Although non-CDC guidelines exist and this condition is less complicated in terms of exclusion codes, all the concerns expressed previously about POA codes remain relevant.

The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers<sup>4</sup> 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. Even detection of stage I pressure ulcers on admission is difficult as the skin, although damaged, is not yet broken. Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. 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 such as hemiplegia, quadriplegia, wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

**#6 *Staphylococcus aureus* Bloodstream Infection/Septicemia (ICD-9-CM Code 038.1)**

CMS states: The codes selected to identify septicemia are somewhat complex. The following ICD-9-CM codes may also be reported to identify septicemia: 995.91 (sepsis) and 995.92 (severe sepsis). These codes are reported as secondary codes and further define cases with septicemia; 998.59 (other postoperative infections). This code includes septicemia that develops postoperatively; 999.3 (other infection). This code includes but is not limited to "sepsis/septicemia resulting from infusion, injection, transfusion, vaccination (ventilator-associated pneumonia also included here)."

Accurately ascertaining for DRG purposes that *Staphylococcus aureus* septicemia was present on admission may be a major challenge, since there is no specific vascular catheter code. Patients may be admitted to the hospital with a localized *S. aureus* infection such as pneumonia or a skin/soft tissue infection. *S. aureus* septicemia may subsequently develop as a consequence of the localized infection, but distinguishing this septicemia as POA and not as a hospital-acquired condition may be difficult. Additionally, the recent proliferation of changes in coding guidelines for sepsis complicates efforts of coding personnel to accurately capture POA status. Even if POA coding can be reliably established, the category of *S. aureus* septicemia is simply too large and varied to determine that the infections were reasonably preventable. We believe this category is feasible only if a subset of patients can be identified for whom it is reasonably clear that the infection was acquired by the patient in the hospital and that it could have been reasonably prevented by evidence-based interventions. The prevention guidelines for *S. aureus* septicemia primarily relate to device-associated infections for which there is no specific code. As with CA-UTI, additional conditions should be added to CMS's current list of exclusions, such as patients with severe immunosuppression (e.g., leukemia, bone marrow transplant, or HIV/AIDS).

**Seven conditions mentioned but not recommended for consideration for FY 2009**

7. Ventilator associated pneumonias.
8. Vascular catheter associated infections
9. *Clostridium difficile*- associated disease (CDAD)
10. Methicillin-resistant *Staphylococcus aureus* (MRSA)
11. Surgical site infections
12. Serious preventable event-- Wrong surgery
13. Falls

CMS has clearly identified the problems with each of these indicators based on lack of unique codes, complication codes or guidelines addressing reasonable preventability. Five of these seven conditions relate to infectious diseases, all of which are important causes of healthcare-associated mortality and morbidity. Consequently, we recommend that CMS continue to address the coding challenges and determine if these conditions warrant inclusion in the hospital-acquired conditions policy in the future.<sup>5</sup> Identification of these conditions requires not only reliable use of POA codes but other unique definition and coding issues. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic. Although judicious antibiotic use and appropriate infection control measures can reduce the burden of CDAD, a significant percentage of CDAD is unavoidable. Distinguishing community-acquired from hospital-associated CDAD is challenging, thus making this condition the least attractive of the group.

#### **Potential FY 2009 recommendations**

Of the infection-related conditions for which CMS requested comment, we will specifically address two with the most potential in the near term. We suggest two approaches that do *not* depend on POA codes, though do require coding and cross referencing. We recommend these be considered for FY 2009 UNTIL after POA coding is implemented and proven to be reliable, permitting reconsideration of several of the initial six proposed conditions.

#### ***#8 Vascular-associated infections Coding--The code used to identify vascular catheter associated infections is ICD-9-CM code 996.62 (Infection due to other vascular device, implant, and graft).***

**CMS states:** "This code includes infections associated with all vascular devices, implants, and grafts. It does not uniquely identify vascular catheter associated infections. Therefore, there it is not a unique ICD-9-CM code for this infection. CDC and CMS staff requested that the ICD-9-CM Coordination and Maintenance Committee discuss the creation of a unique ICD-9-CM code for vascular catheter associated infections because the issue is important for public health. The proposal to create a new ICD-9-CM was discussed at the March 22-23, 2007 meeting of the ICD-9-CM Coordination and Maintenance Committee. A summary of this meeting can be found at: <http://www.cdc.gov/nchs/icd9.htm>. Coders would also assign an additional code for the infection such as septicemia. Therefore, a list of specific infection codes would have to be developed to go along with code 996.62. If the vascular catheter associated infection was

hospital-acquired, the DRG logic would have to be modified so that neither the code for the vascular catheter associated infection along with the specific infection code would count as a CC."

Although we acknowledge the comments above and agree that as stated this condition would be problematic, we would suggest another approach-- not dependent on POA or a special code for vascular catheters. We agree that at the moment there is no specific code for ***catheter-associated blood stream infection*** (CA-BSI) -- a reasonably preventable condition.

However--***there are specific codes for insertion of catheters***. There may be an alternative approach to circumvent the absence of a unique ICD-9-CM code for CA-BSI, using specific codes for insertion of catheters, although this approach may be cumbersome to implement.

It is possible to:

- a) Screen for bloodstream infection codes (996.62)
- b) Exempt or exclude all vascular surgery and other implantable device codes and other obvious sources of existing conditions causing BSI prior to catheter placement
- c) Examine the record for CPT codes for central venous catheter (CVC) placement occurring on the same admission in which the 996.62 code occurs after insertion. For example, one would include CPT code 36556 (insertion of non-tunneled centrally inserted central venous catheter-age 5 or older ) or 36569 (insertion of peripherally inserted non-tunneled catheter-age 5 or older)
- d) Risk of including catheters from *prior admission or placed at another institution* is reduced by ***excluding*** long term catheter insertions such as the tunneled central venous catheter using codes 36557 through 36566.
  - Code 36557 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, younger than 5
  - Code 36558 Insertion of tunneled centrally inserted central venous catheter without subcutaneous port or pump, 5 yrs or older
  - 36560 - Insertion of tunneled centrally inserted central venous catheter with a subcutaneous port , younger than 5
  - 36561 - Insertion of tunneled centrally inserted central venous catheter with a subcutaneous port 5 yrs or older
  - 36563- Insertion of tunneled centrally inserted central venous catheter with a subcutaneous pump, younger than 5
  - 36565 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; without subcutaneous port or pump (e.g., Tesio type catheter)
  - 36566 - Insertion of tunneled centrally inserted central venous access device requiring 2 catheters via 2 separate venous access sites; with subcutaneous port or pump

***#11 Surgical site infections are identified by ICD-9-CM code 998.59 (Other postoperative infection)***

CMS notes that "While there are prevention guidelines, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, we are not proposing

to select surgical site infections as one of our proposed hospital-acquired conditions at this time."

Although we agree with postponing consideration of surgical site infections at this time, we would suggest focusing efforts on a *single high volume surgical procedure* such as coronary artery bypass graft codes - e.g., "CABG without valve," for which there *is* a CC code for mediastinitis, and for which there are guidelines addressing preventability. Further, CMS might consider post-operative sepsis, using a specific procedure code such as CABG (with or without valve). CMS could also consider a similar logic as noted above using postoperative sepsis following 'CABG without valve' with mediastinitis and

- a) Screen for bloodstream infection codes (996.62)
- b) Screen for CC code for mediastinitis (519.2)
- c) Exempt or exclude all cardiovascular surgery and other implantable codes
- d) Examine the record for CABG codes 'without valve' occurring on the same admission

In addition to our comments regarding specific conditions, we would like clarification from CMS *on how hospitals may appeal a CMS decision if an error in coding occurs, and a particular patient incorrectly falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment.*

Our coalition continues to work with the Centers for Disease Control and Prevention to prevent these conditions and disseminate successful infection prevention practices. We are committed to improving the safety of healthcare and look forward to working with CMS toward this goal.

Sincerely,



Victoria J. Fraser, MD  
SHEA President

## References

<sup>1</sup> Lincourt AE, Harrell, A, Cristiano J et al. Retained Foreign Bodies after Surgery. J. Surgical Research 2007; 138:170-4.

<sup>2</sup> AHRQ POA The Case for the Present-on-Admission (POA) Indicator Report# 2006-01 Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality Access at [www.hcup-us.ahrq.gov/reports/methods.jsp](http://www.hcup-us.ahrq.gov/reports/methods.jsp)

<sup>3</sup> APIC-IDSA-SHEA letter to Mark McClellan dated June 12, 2006

<sup>4</sup> National Pressure Ulcer Guidelines accessed at [www.npuap.org/documents/PU\\_Definition\\_Stages.pdf](http://www.npuap.org/documents/PU_Definition_Stages.pdf)

<sup>5</sup> Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. Klevens M, Edwards JR, Richards, Jr. CL, Horan TC, Gaynes RP, Pollock DA, Cardo DM. Public Health Reports. March–April 2007; 122: 160-166.

# Covenant HEALTH

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June 12, 2007

Leslie Norwalk, Esq.  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
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:

Covenant Health and its affiliate hospitals (see attached listing) appreciate the opportunity to submit comments on the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2008 inpatient prospective payment system (PPS) proposed rule.

We appreciate CMS's recognition of the concerns raised last year about its proposal to use Consolidated Severity- adjusted DRGs and we believe that MS-DRGs provide a reasonable framework for patient classification for Medicare's Inpatient PPS, provided that MS-DRG's are used for several years. However, we believe a four year transition period should be used for implementation of MS-DRGs as follows:

1. In FY 2008, the emphasis should be on preparation for and testing of the new classification system. This would provide CMS adequate time to finalize data, introduce and test software for case classification and payment and train its fiscal agents. It would also allow hospitals time to implement and test the new system and adjust operations and staffing for predicted revenues.
2. In FY 2009, DRG weights should be computed as a blend derived 1/3 from the MS-DRGs and 2/3 from the traditional DRGs.
3. In FY 2010, DRG weights should be computed as a blend derived 2/3 from MS-DRGs and 1/3 from traditional DRGs.
4. In FY 2011, DRG weights should be derived using only MS-DRGs.

Additionally, 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.

Covenant Health appreciates the opportunity to submit these comments. If you have any questions about our remarks, please feel free to contact me or Nancy Beck at (865) 374-6494 or [nbeck@covhlth.com](mailto:nbeck@covhlth.com).

Sincerely,

COVENANT HEALTH

A handwritten signature in black ink, appearing to read "John T. Geppi". The signature is written in a cursive style with a large initial "J" and "G".

John T. Geppi  
Executive Vice President/CFO

**ATTACHMENT**

<u>Affiliate Hospitals</u>	<u>Provider Numbers</u>
Fort Sanders Regional Medical Center	440125
Parkwest Medical Center	440073
Loudoun Medical Center	440110
Methodist Medical Center	440034
Fort Sanders Sevier Medical Center	440081

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June 7, 2007

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1533-P  
PO Box 8011  
Baltimore, MD 21244-1850

RE: Comment on FY 2008 Proposed Changes to IPPS

## II. G. Proposed Changes to Specific DRG Classifications – Cochlear Implants

I am writing to submit public comments in response to the proposed re-classification of cochlear implants to MS-DRG 129. MED-EL Corporation, cochlear implant manufacturer, would first like to express gratitude to CMS for acknowledging the payment issues facing cochlear implants under the current CMS-DRG 49. Unfortunately, re-classification of cochlear implants to MS-DRG 129 represents a *very* small change in payment for FY 2008, further perpetuating a cycle of insufficient payment for these cases.

Past MED-PAR data analyses have shown charges for cochlear implantation to be more similar to higher weighted cases that involve surgical procedures on or inside the skull and implantation of complex, neural stimulation devices (DRG 543), rather than procedures within DRG 49 that treat diseases of the head and neck, but lack implantation of a complex medical device. Thus, CMS' re-assignment of cochlear implants to the highest severity level within CMS-DRG 49 (MS-DRG 129), is inappropriate for cochlear cases, as compared to non-cochlear cases.

### **Recommendation 1**

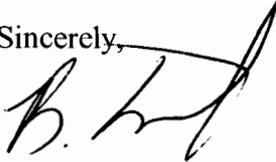
Re-assign cochlear implants to a separate or different DRG that involves implantation of a complex neural stimulation device. We contend that procedures within existing CMS-DRG 543 (proposed MS-DRGs 23 and 24, Craniotomy w/major device implant or acute complex CNS PDX with or without MCC) that involve implantation of an intracranial device, are more clinically coherent and resource similar than procedures within DRG 49. The cochlear device is similar to an intra-cranial type of stimulator in terms of general design. Creation of a separate, more appropriate DRG (MS-DRG) or re-assignment to an existing, comparable DRG (MS-DRG) will work to preserve the original intent of the DRG System.

**Recommendation 2**

Allow pre-MDC assignment for cochlear implantation based on complexity. Cases with cochlear implants involve high complexity and resource utilization. The MED-EL PULSAR CI<sup>100</sup> device is a highly sophisticated neural stimulator with 24 new and improved current sources that provide electrical stimulation to the auditory nerve, which occurs between 18,000-50,000 times per second, making the cochlear implant a real-time active implantable device that replaces a non-functional sensory organ. DRG assignments should reflect the resource intensity of complex, technologically advanced devices that increase costs as well as clinical coherence and severity of illness.

Unless an equitable payment solution is established, cochlear implants will continue to be severely underpaid under Medicare IPPS due to inappropriate DRG assignment. Hospitals that perform the cochlear implant procedure have experienced inadequate reimbursement for many years, which has had an adverse impact on access to this life-altering technology in the Medicare population. We ask that CMS consider the above recommendations to allow Medicare beneficiaries access to this technology when performance of the procedure in the inpatient setting is necessary for the patient's overall health condition.

Sincerely,



Barbara Carter  
MED-EL Corporation

June 11, 2007

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Leslie Norwalk, Esq.  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
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, May 3, 2007**

Dear Ms. Norwalk:

The Florida Hospital Association (FHA), on behalf of its member hospitals and health systems, 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 FHA supports meaningful improvements to the Medicare inpatient PPS, as well as many of the proposed rule's provisions, there are others that cause grave concern for our members – particularly the proposed “behavioral offset” cuts related to the move to severity-adjusted diagnosis-related groups (DRGs) and the cuts to capital payments.

The proposed rule includes numerous provisions and, as requested, comments are provided based upon the CMS-designated issue categories.

**Medicare Severity Diagnosis-Related Groups (MS-DRGs)**

The FHA supports the recommendation developed by the American Hospital Association, state association executives, the Association of American Medical Colleges, and the Federation of American Hospitals related to the MS-DRG component of the FY2008 Medicare inpatient PPS proposed rule. We appreciate CMS' recognition of the concerns raised last year about its proposal to use Consolidated Severity-adjusted DRGs, such as using a transparent, non-proprietary grouper and building on past DRG refinements. In addition, we appreciate that MS-DRGs provide a reasonable framework for patient classification for Medicare's inpatient PPS, provided that MS-DRGs are used for several years.

We believe that a four-year transition period should be used to implement MS-DRGs, however. The following transition schedule is suggested:

- In FY2008, the emphasis should be on preparation for and testing of the new classification system. This would provide CMS adequate time to finalize data, introduce and test software for case classification and payment and to train its contractors. It would also provide hospitals adequate time to implement and test the new system and adjust operations and staffing for predicted revenues. It would also allow time for vendors and

state agencies to incorporate the new system into their respective software and information systems.

- In FY2009, DRG weights should be computed as a blend derived 1/3 from the MS-DRGs and 2/3 from traditional DRGs.
- In FY2010, DRG weights should be computed as a blend derived 2/3 from MS-DRGs and 1/3 from traditional DRGs.
- In FY2011, DRG weights should be derived using only the MS-DRGs.

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 (see below).

### **Behavioral Offset**

The proposed rule calls for refinement of the existing DRGs, which will result in changes to Medicare payments. With these DRG changes, CMS believes that there will be significant changes to provider coding behavior, proposing a minimum 2.4 percent behavioral offset based on the belief that, with implementation of the MS-DRGs, the changes hospitals will make in coding practices will result in higher payments. CMS maintains that under a new system of DRGs, hospitals will change coding behavior. Yet, even during the initial years of the inpatient PPS, when hospitals moved from a cost-based system to a prospective DRG system, we did not see coding changes of the magnitude that CMS anticipates in attempting to justify this dramatic cut. MS-DRGs are based on the existing DRG system and are simply a refinement of a classification system that hospitals have been using for over 20 years.

CMS also cites as rationale for the behavioral offset the transition of hospitals in Maryland to a completely new system called All Patient Refined DRGs (APR-DRGs). This rationale is flawed as the classification system adopted by Maryland is much more complicated than what CMS has proposed and, in fact, completely changed the coding incentives for Maryland's hospitals. MS-DRGs and APR-DRGs are two completely different ways to classify patients and generalizing from one system to another cannot – or should not – be done.

There is no precedent in other payment systems for making a prospective adjustment of this magnitude without any evidence of actual and measurable changes in coding. While CMS has made adjustments for coding in the implementation of new payment systems, these changes have been based on actual experience, rather than making anticipatory adjustments. 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 – and if – there is evidence that such an offset is justified.

### **Cost-based Weights**

CMS has proposed refinements to the development of cost-based weights based on the recommendations of RTI International. These changes include 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. Rather than make these changes at this time, we urge CMS to work with the AHA and other groups to assure that the way hospitals report costs and charges, particularly for supplies and pharmaceuticals, is consistent with how MedPAR groups charges. Until reporting is consistent and accurate, changes will do little to address the issue of charge compression and its impact on the development of cost-based weights.

### **Wage Index Issues**

**Core-Based Statistical Areas for the Hospital Wage Index.** CMS has consistently referred to Metropolitan Statistical Areas (MSAs) as Core-Based Statistical Areas (CBSAs) since adopting the new metropolitan areas effective for FY2005. The term “Core-Based Statistical Area” actually includes both Metropolitan Statistical Areas and Micropolitan Statistical Areas. Micropolitan Statistical Areas are considered by CMS to be a part of “statewide rural areas.” It was an excellent idea at the time for CMS to differentiate the 2000 census data by using the term CBSAs from the terminology used for the 1990s of “MSAs.” However, to be more technically correct, CMS should now consider returning to the use of MSAs or Metropolitan Statistical Areas rather than using the looser term CBSAs.

**Worksheet S-3 Wage Data for the Proposed FY2008 Wage Index.** CMS is including indirect contract labor for the administration and general cost center, and housekeeping and dietary cost centers for inclusion in the FY2008 wage index data. Based on the formulas that are used, it is not clear if CMS has added these amounts from the applicable lines of worksheet S-3 into the underlying data (similar to Line 9 for Clinical Contract Labor). CMS should ascertain that the hours and amounts paid to these clinical contractors have been included in the base data used to compute the wage index.

### **Budget Neutrality/Rural Floor**

For the first time CMS is proposing a positive budget neutrality adjustment for the impact of the rural floor provisions on the wage index pursuant to Section 4410 of the Balanced Budget Act of 1997. This is an adjustment that has needed to be made for several years and we agree with the concept of making this adjustment for FY2008.

CMS proposes to make this adjustment as a part of the wage index calculation, rather than the traditional methodology of adjusting the standardized amount. However, as proposed in the rule, it appears that CMS has bifurcated this adjustment and would add back the effect of one or more the prior years’ rural floor adjustment in a standardized amount adjustment in the amount of 1.002214 (see pages 24839 of the May 3, 2007 *Federal Register*). It is not clear if this 1.002214 is a single year’s budget neutrality adjustment (for FY2007) or if this adjustment is to correct the cumulative adjustment of the prior year’s adjustments from FY1999 through FY2007. We ask

### **Hospital-Acquired Conditions**

Of the six conditions proposed by CMS for inclusion in the category of preventable complications subject (in FY2009) to payment adjustment as required under the Deficit Reduction Act, only object left in surgery, air embolism, and blood incompatibility should be considered for FY2009 payment adjustments. Each of these conditions is identified by a discrete ICD-9 code, is known to cause great harm to patients, and can be addressed through known methods of prevention.

The other proposed conditions – catheter-associated urinary tract infections, pressure ulcers, and staphylococcus aureus septicemia – should not be included in the FY2009 DRA adjustment. Providers will be required to indicate whether these conditions were present on admission (POA). POA guidelines are just being released to hospitals and CMS will not even be able to edit for their inclusion until January 2008. POA reporting requires both hospital and physician education and implementation of the DRA provision should be delayed for these conditions until providers are proficient at coding POA. Hospitals face significant challenges in detecting and diagnosing these conditions accurately on admission, particularly without increased ancillary testing – and the resultant increased cost of services.

### **Reduced-cost Devices**

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 fiscal intermediaries. The hospital would be required to provide paper invoices or other information to the 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.

Such a proposal is adverse to the whole concept of the Medicare prospective payment system – particularly one moving towards cost-based weights – and should be reconsidered. 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. Incidental device failure has occurred in the past and reduced or no cost device replacements were historically addressed in the costs reported by the hospitals in their cost report. Reducing payment for certain cases involving a re-implantation would ignore the average DRG weight for those cases that already implicitly includes this reduction.

that CMS quantify the computation of this adjustment by year for each year from FY1999 through FY2007 to allow for the testing of the reasonableness of the CMS calculations.

Additionally, on page 25123 of the proposed rule the effect of the FY2008 rural floor adjustment of 0.997084 - which CMS proposes to apply to the wage index - is included in the footnotes to Table I. In the calculations of the wage indexes, CMS has inflated the national average hourly wage in order to recompute wage indexes and apply the FY2008 portion of the budget neutrality adjustment (the negative portion of the adjustment) even though the prior year's positive adjustment is made to the standardized amount. As CMS noted in the proposed rule, this affects hospitals with a wage index of lower than 1.0000 differently than it affects hospitals that have a wage index of 1.0000 or more because the labor related share is only .62 for the lower wage indexes compared to .697 for the wage indexes of 1.0000 and higher.

Further, CMS provides no justification as to why CMS proposes to make only a portion of the budget neutrality adjustment in the wage index. This treatment creates a further complication of the already difficult computation of the wage index – and further reduces transparency. We ask CMS to report the amounts of the rural floor standardized amount adjustments from 1999 through 2007, as well as provide the amount of the adjustment applicable to FY2008. In the interest of promoting further transparency, these adjustments should be fully explained and the prior year adjustments should be enumerated for each year in making the cumulative adjustment that is needed to correct prior inequities.

### **Capital Reductions**

The FHA opposes the elimination of the capital payment update for all urban hospitals and the large urban hospital capital payment add-on. These capital payments are vital to the ongoing maintenance and improvement of hospitals' facilities and technology. We also oppose any reductions to, or elimination of, the indirect medical education and disproportionate share hospital adjustments under the capital system.

Capital PPS margins – if such a margin truly exists – have declined significantly from 1998 to 2004. You must also exclude the years during the transition to capital PPS from any analysis. The timeframe used in the CMS analysis of capital margins is not long enough to cover the full capital cycle, which is generally considered to be 15 to 20 years.

These proposed cuts to capital payments would make it more difficult to purchase the advanced technology, equipment and clinical information systems that consumers have come to expect and could have the effect of slowing clinical innovation. Capital cuts of this magnitude will disrupt the ability of urban hospitals to meet their existing long-term financing obligations. Hospitals have committed to these improvements under the expectation that Medicare's PPS for capital-related costs would remain a stable source of income.

With overall Medicare margins decreasing, some hospitals have been forced to subsidize operating losses with money that should otherwise be devoted to capital – leading to a shortage of funds for investment in information technology and other capital needs. As average age of

plant increases and hospitals continue to put off capital investments in order to maintain everyday operations, the need for adequate capital funding will increase, not decrease.

Again, the FHA appreciates the opportunity to comment on the proposed rule. If there are any questions on the comments provided, please do not hesitate to contact me at (407) 841-6230 or via email at [kathyr@fha.org](mailto:kathyr@fha.org).

Sincerely,

A handwritten signature in cursive script that reads "Kathy".

Kathy Reep

Vice President/Financial Services

June 11, 2007

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

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

Dear Ms. Norwalk:

On behalf of Jewish Hospital & St. Mary's HealthCare (JHSMH) we appreciate this opportunity to comment on the proposed regulations for the fiscal year 2008 Inpatient PPS system. While JHSMH supports many of the proposed rule's provisions including the move to severity adjusted DRGs, we oppose the proposed "behavioral offset" cuts related to the move to severity-adjusted diagnosis-related groups (DRGs), and the cuts to capital payments.

**DRG REFORM AND PROPOSED MS-DRGS**

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. They will also continue to 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.

**SEVERITY ADJUSTED DRGS**

CMS agreed last year to implement the recalibration of DRGs over three years partially to smooth the transition of both this proposal and the severity adjusted DRGs. **We agree with the implementation of the severity adjusted DRGs and believe that they should be implemented as soon as possible.** If CMS agrees to extend the implementation period we do not believe they should extend it more than two years. We believe offsets that will occur under the severity adjusted DRGs should coincide with the changes due to the recalibration of the DRG weights.

**DRGs: HIP AND KNEE REPLACEMENTS**

The American Association of Hip & Knee Surgeons (AAHKS) recommended that CMS make further refinements to the DRGs for knee and hip arthroplasty procedures. AAHKS conducted detailed analysis for over 6,000 cases. The analysis recommended that CMS examine Medicare claims data and consider the creation of separate DRGs for total hip and total knee arthroplasty procedures. Due to the creation of the severity adjusted DRGs CMS has created more DRGs; however, they do not create a distinction between hip and knee DRGs. JHSMH's average cost for

a total hip case is \$18,701 while the average cost of a total knee is \$14,788. We believe that the care involved, the cost of the implant and rehab necessary to treat a total hip is significantly different and should be acknowledged by CMS. Without distinguishing separate payment, hospitals could choose to only do those procedures where Medicare payment is adequate and restrict access to care for those patients needing Hip replacement or HIP Revision surgery thereby using the DRG system to their advantage. **We urge CMS to implement the AAHKS recommendation to create separate DRG payments for all Hip and Knee DRGs.**

## **RECALIBRATION OF DRG WEIGHTS**

CMS is proposing continuing the three year implementation of the cost based DRGs. We believe that the differences in cost report groupings currently allowed for hospitals distorts the reliability of the information obtained. We support CMS efforts and we urge CMS to move to **more standard cost report groupings in order to improve this methodology. We agree with the expanded groupings on the cost report and believe CMS should move quickly to implement standardization.** Although it will be a burden to administrative functions within hospitals it will more appropriately weight DRGs. The charge compression issue is a major concern to our organization as we do not believe the larger more complex procedures are getting an appropriate percentage of the costs.

## **BEHAVIORAL OFFSET**

JHSMH currently spends considerable time and expense to make sure our coding is as accurate and complete as possible. Hospitals have diligently coded all appropriate diagnosis codes so that the coding payment and external quality assessments are accurate. **We believe this recommendation is arbitrary in nature and should not be implemented. CMS should not implement such an offset without adequate data that supports the need for an adjustment.**

## **CAPITAL IPPS**

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. **JHSMH is opposed to these unnecessary cuts, which ignore how vital these capital payments are to the ongoing maintenance and improvement facilities and technology. JHSMH is committed to improving our facilities and information technology structure but we are finding it difficult under the current payment framework and will find it impossible given these cuts. While we appreciate CMS's continued support of rural hospitals it should not come at the expense of urban hospitals that are considered safety net hospitals. Also please keep in mind that all safety net hospitals do not receive the same luxuries that are afforded to government owned facilities.**

Hospitals are not creating positive margins on their capital payments and are more than likely replacing technology at a slower rate under the capital PPS structure.

## **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.

We appreciate CMS' efforts to clarify its policies, and its attempt not to 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. Vacation and sick time were included in the base period and should remain in the calculations. This will create an administrative burden on both the Medical schools and the hospitals.**

### **DRGS: HOSPITAL-ACQUIRED CONDITIONS**

JHSMH agrees with AHA comments regarding 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 as Hospital Acquired Conditions 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. We also agree with AHA's recommendation not to include the other three codes because there are not discrete codes to currently identify these conditions and would require the present on admissions coding which will not be implemented by October 1, 2007.

### **HOSPITAL QUALITY DATA**

JHSMH agrees with AHA's positions regarding data reporting and also would like to see an appeal process implemented regarding the validation process.

### **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.

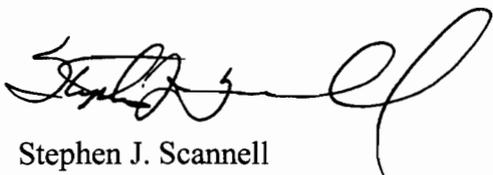
CMS also proposes to use new condition codes to report the use of such devices to trigger manual processing by the FIs. The hospital would be required to provide paper invoices or other information to the FI indicating the hospital's normal cost of the device and the amount of the credit received. In 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 we do 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, due to the administrative burden on both the hospitals and the regional FIs and the fact that the DRG system would already have incorporated the cost in the average payment, we ask CMS to reconsider implementing this proposal. 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.**

We appreciate your consideration of these comments.

If you have any questions, please do not hesitate to contact me at (502) 587-4883.

Sincerely,



Stephen J. Scannell  
Vice President Finance and Associate Chief Financial Officer

cc: Robert Shircliff, CEO, Jewish Hospital & St. Mary's HealthCare  
Mark Carter, Sr. Vice President, Jewish Hospital & St. Mary's HealthCare



June 11, 2007

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1533-P  
Post Office Box 8011  
Baltimore, Maryland 21244-1850

Dear CMS Policy Makers:

This communication is in response to the proposed modification/proposals for modification of the Hospital IPPS for fiscal 2008. We have reviewed the significant and sweeping changes proposed. Correspondence from CMS requested participant response to the proposed measures. It is respectfully requested that you give serious consideration to the following observations and recommendations.

**The initial recommendations/request is to defer the en bloc introduction of the changes proposed.** Elements among the proposed changes would corrupt existing utility of the system and negatively impact quality healthcare delivery. The proposed changes would have a marked negative impact on quality improvement efforts and the sustainable delivery of top quality healthcare. **Specifically noted is that the proposed 2.4% payments reduction is clearly not supported by the documentation/coding practices of North Memorial.**

#### **Primary problems with proposal/rule:**

- 1) **Elimination of legitimate and significant CCs** will lead to misrepresentation of care requirements (clinical and economic).
- 2) Completely new **reference system with no "crosswalk"** potential. This will severely disrupt/destroy numerous highly useful, data-history based ongoing clinical outcomes, utilization review and quality improvement efforts.
- 3) CMS's DRG system is the foundation for hospital reimbursement industry wide. The misdirected and **negative consequences will be magnified** by extension throughout the industry.
- 4) The net effect of these changes will serve to **obstruct the sustainable delivery of quality, value based healthcare.**
- 5) **No basis for 2.4% payment reduction** based on our coding practices.

**Discussion:**

Several individual elements of the sweeping proposed change are clearly problematic. The wholesale change in the DRG reference system and the radical changes in the acknowledged complications and co-morbidities (CCs) will result in a counterproductive influence on quality assessment/improvement and accurate reflection of the costs/requirements for the provision of effective patient care. Additionally, **the utility of the DRG system in quality improvement, cost reduction and outcomes assessment will be corrupted.** Multiplying this negative impact is the historically dominant leadership/practice influence that CMS policy has on the remainder of the insurance/HMO/general payer industry. **The exclusion of significant and common legitimate conditions as CCs corrupts the system's assessment of healthcare resource requirements and has multiple 'downstream' negative results on efforts to maximize quality and most efficiently deliver remarkable care.** It appears the system proposals will result in net lesser payment with the cost being corrupted accuracy of actual care requirements and value/quality assessment...this is not desirable for CMS, our patients or the future of healthcare.

Discussion of each of the individual alterations in the accepted CC diagnoses is beyond discussion in this correspondence. The overall impact would be profound and undesirable. It is strongly recommended that this area be reviewed in greater detail with the opportunity for utilization review and clinician input. **Many of the proposed exclusions are inappropriate and will result in inaccuracy and misrepresentation of care requirements, outcomes assessment and quality.**

The current DRG system serves as the framework upon which a number of our institution's service and quality improvement efforts are based. Ongoing highly effective systems of physician and facility performance tracking, clinical quality improvement initiatives and cost/value analysis utilize the DRG reference system. **The proposed changes eliminate the utility of the DRG system in continuing these effective large scale complex efforts directed at improving the quality and efficiency of healthcare at North Memorial and throughout the industry.** Specifically, the complete reordering of the DRG reference system and the dramatic alteration of acceptable CC diagnoses would result in loss of these historically effective and ongoing efforts. **Overall this would markedly compromise quality improvement efforts and profoundly compromise delivery of remarkable hospital-based patient care.**

The concept of severity adjustment for DRGs is reasonable and consistent with the historic objectives and uses of the resulting data. **Unfortunately elements of the current proposal would compromise primary desired goals and eliminate historically valuable data based utilities (e.g. quality and value improvement efforts).**

In response to these anticipated untoward outcomes **it is strongly recommended that the proposals suggested are deferred** and that step wise evaluation and possible introduction of the productive elements of the proposal be carried out over a much longer time frame. The merit and effort of CMS' efforts at improving the system are

acknowledged and appreciated; however, **the suggested proposals and time frame for introduction will significantly compromise both CMS and our hospital's shared objective ... remarkable healthcare quality of excellent value.**

Respectfully Submitted,

Handwritten signature of Thomas J. Combs MD/bat in black ink.

Thomas J. Combs, MD  
HIM/Physician documentation liaison  
North Memorial Medical Center  
[tjc4444@earthlink.net](mailto:tjc4444@earthlink.net) or 763-442-0291

TJC/bat

cc: Congressman Jim Ramstad  
The Honorable Keith Ellison