CMS-1533-P-251 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. G. Richard Hastings** **Date & Time:** **06/11/2007**

Organization : **Saint Luke's Health System**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-251-Attach-1.DOC

#251

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; Proposed Rule (Vol. 72, No. 85), May 3, 2007

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the proposed rule cited above (CMS-1533-P). I submit these comments on behalf of Saint Luke's Health System (SLHS) in the Kansas City Metropolitan Region. SLHS consists of eleven hospitals, several physician groups, and other medical services organizations in both Missouri and Kansas. Saint Luke's Hospital of Kansas City, our largest facility with 629 beds, is a tertiary referral center, and the largest teaching facility for the University of Missouri – Kansas City School of Medicine. This same facility was the recipient of the Malcolm Baldrige National Quality Award in 2003. As a system, we also received the 2006 Missouri Quality Award, based on the Malcolm Baldrige principles of quality.

While we concur with the comments and recommendations submitted by Rick Pollack, Executive Vice President of the American Hospital Association, and Marc Smith, President of the Missouri Hospital Association, we feel it is important to address some of the proposed changes that will specifically impact SLHS. Specifically, we would like to comment on the changes regarding the Behavioral Offset in the DRG Reform, the Capital IPPS, the Wage Index, and Replaced Implantable Devices.

BEHAVIORAL OFFSET

CMS has proposed a 2.4 percent cut in both FYs 2008 and 2009 to eliminate what it claims will be the effect of coding or classification changes that do not reflect real changes in case-mix. This 2.4 percent "behavioral offset" or cut is based on an extrapolation of actual claims experience from Maryland hospitals.

This is extremely problematic for a variety of reasons. First, health systems such as ours have had to rely heavily on coding accuracy to receive proper payment for 23 years. Only recently has this been a priority for facilities in the State of Maryland. Further, the system in place in Maryland is the APR-DRG system which is certainly different than the MS-DRG system CMS is proposing. At SLHS, we have been applying the APR-DRG criteria for years and feel

strongly that had CMS used claims experience from facilities such as ours, there would have been little or no behavioral variance. To justify a $24 billion dollar cut by using facility specific data from a state that has been excluded from the PPS program since its inception is, in our opinion, completely illogical and without merit, and unfairly punishes systems such as ours that are subject to the system and have been using it appropriately for many years.

Second, CMS already has safeguards in place to ensure the accuracy of hospital coding and payments. If there are errors or omissions, these safeguards are designed to catch and correct them as well as review for accuracy. If any "behaviors" are inconsistent with CMS requirements, they will be addressed through those processes. Therefore, this "behavioral offset" seems redundant to the processes that are already in place to ensure proper payment. Further this cut implies that any errors, omissions or behavioral changes will only result in increased payments to hospitals, which is certainly not the case. And, does this "behavioral offset" take into account changes to the behavior of CMS contractors that typically comes with the implementation of a new system, such as increased denials and suspended claims?

Lastly, this behavioral offset seems eerily similar to the 5.7 % behavioral reduction CMS proposed at the inception of the Outpatient PPS. Congress was very clear in their rejection of this proposal, and clearly expressed that budget neutral did not include a fabricated reduction based on guesses instead of reasonable documentation. Therefore, we recommend that either the behavioral offset, or the policies that resulted in the behavioral offset, should be abandoned.

CAPITAL IPPS

For Fiscal Year 2008, CMS has proposed eliminating the capital update for all urban hospitals and the large urban hospital add-on. In addition, CMS is considering discontinuing the Indirect Medical Education (IME) and Disproportionate Share Hospital (DSH) adjustments to capital payment systems. These cuts are unprecedented, and would result in a decrease in capital payments to urban hospitals that cannot sustain themselves in an already under-funded system. For Saint Luke's Hospital of Kansas City, our requests for capital outnumber the funded purchases by nearly five to one. The items not being purchased due to lack of funding are not frivolous machines, but are instead medical equipment that could further increase the quality of care we deliver. If the proposed cuts are implemented, the impact to this one facility, a Malcolm Baldrige National Quality Award winning facility, would be equivalent to our entire 2007 capital expenditures budget for major medical equipment of $1.7 million. (See Exhibit One attached)

In addition, these cuts are extremely short sighted as it relates to technology which has been our single largest capital expenditure for years outside of new construction. During 2007, SLHS approved $12 million of the $22 million in technology capital requests. While technology investment is essential to be competitive and increase efficiency, much of it is as a result of complex payment systems such as this rule and regulatory compliance such as HIPPA, all imposed by the federal government. We as providers have accepted these unfunded mandates as a necessary consequence of the industry. However, how can CMS justify the mandate of capital spending for providers while at the same time restricting provider's ability to pay for it?

Furthermore, it is our opinion that the notion of the Medicare operating and capital margins can be viewed independently of each other is flawed. A facility can be experiencing significant operating losses, yet have positive capital margins for a variety of reasons. For example, the capital cycle is not annual, but can extend over several years, because the dollars required to purchase major medical equipment can take an extended period of time to accumulate. If the capital margin is viewed only on an annual basis, an accurate picture is not presented. CMS absolutely has to realize that providers draw no distinction between Medicare operating and capital payments or margins for the purposes of deciding capital expenditures. The cuts in this rule, both operating and capital will further reduce our capital investment which is already less than 50% of the necessary expenditures requested. The potential implications for technological advances and the quality of healthcare are in serious danger if the proposed changes are implemented, and we strongly encourage you to reconsider all of the proposed cuts to Capital.

WAGE INDEX

We concur with the AHA and their position regarding the proposed changes to the Wage Index, and are also concerned with MedPACs recommendation to utilize data from the Bureau of Labor Statistics (BLS) rather than hospital-reported data currently collected by CMS on Medicare cost reports. One specific concern expressed by AHA and the work group they convened is that fiscal intermediaries are inconsistent in their interpretations of wage index data. However, this issue is inadvertently being addressed by CMS through the F.I. consolidation process currently underway. In addition, the work group stated that another problem with the current system is the possibility for hospitals to be penalized for erroneous date submitted by other hospitals in the same geographic area. We propose instituting a system of checks and balances to insure hospitals are submitting accurate data instead of disregarding the entire cost report data system as proposed. We also propose that CMS reconsider the current exclusion of contracted labor not related to direct patient care when figuring the average hourly wage (AHW). Hospitals that contract for services like dietary and housekeeping still incur the cost of these services, but the costs are not figured in to the AHW calculation as they are for hospitals that employ staff for these services. Since these services generally have a lower AHW, the result is an artificial inflation in the statistics for an individual facility that chooses to contract for such services. CMS should adopt a policy to include these contracted services in the AHW calculation, or it should exclude the salaries and hours for the hospitals that do not contract for these services. Because CMS is required by law to consider changes to the wage index in Fiscal Year 2009, we encourage CMS to carefully examine the options available, and work with the AHA and the hospital community to make meaningful changes that support an accurate payment system that does not punish providers unnecessarily.

REPLACED EQUIPMENT

By definition, inpatient hospital DRG weights have been derived from average historical costs and charges from hospital specific data. This historical data includes hospital data where the implantable devices were provided at no cost with either a nominal or zero charge made to the program. These instances are not limited to replacement devices. There are also procedures where FDA approved Category B devices used in clinical trials are covered by Medicare. In

these clinical trials where the vendor provides the device at no cost there is no corresponding charge generated by the provider. There is no doubt instances such as these have found their way into the costing data used by CMS to develop DRG weights. This historical data also includes previous claims involving manufacturer-recalled devices. As the proposed rule suggests, 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 and were not already figured in to the DRG payments, or these types of cases are now occurring at a rate dramatically higher than at the time when the DRG weights were developed. There does not appear to be data detailing a significant increase in the number of recalled devices which could support the reduction in payments for such cases. If CMS decides to follow through with this proposal, we believe it is crucial to recalibrate the DRG weights by excluding claims with nominal charges such as those mentioned above, and then follow through with the reduction policy.

Again, we thank you for the opportunity to comment on CMS-1533-P. We strongly encourage you to reconsider the arbitrary and unwarranted cuts proposed by this rule. These cuts will serve to further exacerbate an already challenged healthcare system in this country, and will further strain the resources available to provide quality healthcare.

Should you have any questions, please feel free to contact me, or Scott Pester, Saint Luke's Health System Reimbursement Coordinator, at 816-932-5734.

Sincerely,

G. Richard Hastings
President & CEO
Saint Luke's Health System
(816) 932-2101

Exhibit One

Major Medical (TEAM) 2007 Budget – Preliminary List

	Description	Quan	Cost	Comments
Contingency			150,000	
1	Rad -- Mini C-arm		70,000	
2	NNICU -- Ultrasound Machine		148,078	Requested for '06, not funded
3	Rad -- Replacement CT Table		40,000	
4	Rad -- MRI software upgrade		75,000	
5	Rad -- Replacement Rad Room for Trauma		340,000	includes 15K construction estimate
6	Rad -- Repalcement Interventional Radiographic Unit		2,020,000	includes 125K construction estimate
7	Resp -- Replacement Bronch Cart		50,000	
8	Resp -- Ventilator Upgrades (2 requests)		218,497	
9	Surg -- 4th Arm for DaVinci Robotis Surgical System	1	210,500	
10	Surg -- Electrosurgical Units	17	251,350	
11	Surg -- Eye Vitrectomy Machine	1	68,324	
12	Surg -- Fracture Table	1	148,499	
13	Surg --GYNURO Instrumentation Replacement	1	244,550	
14	Surg -- Laparoscopic Rooms (2)	2	625,000	
15	Surg -- Video Endoscopic System	1	70,000	
16	Surg -- Endoscopic Ultrasound	1	270,000	
17	ASC -- Arthroscopic Video Tower	1	42,060	
18	PACU -- Patient Physiological Monitors	21	429,654	
19	ANES -- Replacement Anesthesia Machines	20	1,182,245	
20	ANES -- Patient Physiological Monitors	20	785,288	
	Preliminary Total		7,439,045	
	Approved funding level		1,650,000	
	Variance		(5,789,045)	

CMS-1533-P-252 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Marilyn Litka-Klein** **Date & Time:** **06/11/2007**

Organization : **Michigan Health & Hospital Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see our attached comment letter.

CMS-1533-P-252-Attach-1.DOC

CMS-1533-P-252-Attach-2.DOC

#252

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

June 8, 2007

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

Re: FY 2008 Medicare Inpatient Prospective Payment System Proposed Rule CMS-1533-P

Dear Ms. Norwalk:

On behalf of its 145 member hospitals, the Michigan Health & Hospital Association (MHA) welcomes this opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule to update the Inpatient Prospective Payment System for Fiscal Year (FY) 2008. While the rule, which was published in the May 3, 2007, *Federal Register*, provides a 3.3 percent market basket increase for hospitals that submit data for the CMS quality measures, **we strongly oppose the CMS' 2.4 percent "behavioral offset" for anticipated changes in hospital coding.** We are also concerned about other significant policy changes included in the proposed rule that would negatively impact Michigan hospital Medicare reimbursement and undermine some fundamental payment principles.

The adequacy of Medicare payments to cover the cost of services provided is crucial for ensuring the future viability of Michigan's nonprofit hospitals. Based on the latest data available, approximately **50 percent** of Michigan hospitals experienced a negative margin on all Medicare services. This is very concerning particularly since Michigan's population is aging and the number of Medicare beneficiaries is projected to increase significantly over the next decade. By 2020, the number of Michigan residents who are 65 and older is expected to comprise 16.6 percent of the state's population.

When all payors are aggregated, Michigan hospitals experienced a negative 1.8 percent patient margin, with **88 hospitals**, or **60 percent,** losing money on patient care services. The proposed changes will further threaten the future viability of hospitals and access to healthcare services for Medicare beneficiaries and other residents of the state of Michigan.

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The MHA believes it is important for the CMS to recognize that the proposed payment changes alone will be financially devastating for many hospitals and includes operational modifications that hospitals could not adapt in the two months prior to Oct. 1. While hospitals support meaningful improvements to Medicare's inpatient PPS system, the CMS has exceeded its authority by recommending arbitrary and unnecessary cuts in this proposed rule. The MHA believes that these unprecedented budget cuts will further deplete scare resources, ultimately making hospitals' mission of caring for patients even more challenging. One of the fundamental values of a prospective payments system is the ability of providers to reasonably estimate payments in advance to impact their budgeting, marketing, staffing and other key management decisions. Given the extensive change and impact, two months is inadequate for hospitals to operationalize a $2 million payment reduction particularly when the latest margin data indicate the hospital lost $1.8 million providing patient care.

Our key concerns include:

2.4 Percent "Behavioral Offset"

(Federal Register Pages 24708-24711*)*

A provision in the Benefits Improvement and Protection Act (BIPA) of 2000, provides the CMS authority 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 MHA is strongly opposed to the proposed adjustment based on the assumption that the case mix index of hospitals will automatically increase. The MS-DRG system is an expansion of the current classification system rather than a replacement system such as the APR-DRG system that Maryland implemented. The CMS does not have any actual evidence that medical record coders will change their practice to "locate" complications to maximize reimbursement. Hospitals currently are coding complications, if they are documented in the patient record, in order to obtain the proper payment for the patient served. **The MHA recommends that the CMS eliminate this reduction and provide hospitals with the full 3.3 percent market basket increase. Until the MS-DRGs are fully implemented and the CMS can document and demonstrate that any increase in case mix results from changes in coding practices rather than actual changes in patient severity, there should be no behavioral offset. Until the MS-DRGs are fully implemented, and the 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". At that time, the CMS can evaluate whether payments have increased due to coding rather than the severity of patients and determine if an adjustment is necessary. The CMS is not required to make an adjustment at this time, and should not do so without evidence that coding changes have occurred.**

Medicare Severity (MS) DRGs

(Federal Register pages 24691 – 24712)

For FY 2008, the CMS is proposing to adopt Medicare Severity (MS) DRGs, which are the result of modifications to the current CMS DRGs to better account for patient severity. While the CMS proposes to implement the MS-DRGs on Oct 1, 2007, they believe that the MS-DRGs should be evaluated by RAND and have instructed RAND to evaluate the proposed MS-DRGs using the same criteria that it is applying to the other DRG systems.

The proposed MS-DRGs would increase the number of DRGs from 538 to 745. While the current CMS DRGs include 115 DRGs that are split based upon the presence or absence of a complication or comorbidity (CC), the MS-DRGs include 152 DRGs that subdivide into three tiers: major CC, CC and non-CC and another 106 DRGs that subdivide into two severity levels. While hospitals appreciate the CMS' recognition of the issues raised last year regarding its proposal to use Consolidated Severity (CS) adjusted DRGs, we believe it is crucial that a system change of this magnitude have a transition period of four years. The change to MS DRGs is projected to result in reimbursement decreases of 10 percent for some Michigan hospitals and an 8 percent increase for others, with hospitals unable to adapt to changes of this magnitude in two months after release of the final rule. As a result, the MHA recommends that in FY 2008, the emphasis be on preparation and testing of the new DRG classification system so that the CMS has adequate time to finalize data, introduce and test software for patient classification and payment and train its fiscal intermediaries. In addition, this will allow the CMS time for further analysis by hospital type to ensure the projected changes are consistent with the policy objectives the CMS desires to achieve. This would also give hospitals more time to implement and test the new system and adjust operations and staffing based on projected changes in Medicare revenues. **The MHA recommends a 4-year transition as follows:**

- In FY 2008, continue current DRG classification system with an emphasis on preparation for and testing of the new classification system. This provides the CMS with adequate time to finalize data and a CC list, introduce and test software for classification and payment, and train its fiscal agents. It would also provide hospitals additional time to implement and test the new system and adjust operations and staffing for predicted revenues. In addition, it would also 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 1/3 from the MS-DRGs and 2/3 from traditional DRGs.

- In FY 2010, DRG weights should be computed as a blend derived 2/3 from MS-DRGs and 1/3 from traditional DRGs

- In FY 2011, DRG weights should be derived using 100 percent of the MS-DRGs

Recalibration of DRG Weights

For FY 2008, the 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.

They identified 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.

In addition, the use of hospital-specific charges and a national cost/charge ratio will result in a distortion of the DRG weights. This has the potential of shifting Medicare payments among hospitals not based on resource utilization but rather on a mathematical calculation.

- The MHA recommends that the CMS review the impact of using hospital specific charges and costs to determine whether the national cost-to-charge ratio has created inaccurate DRG weights.
- In addition, the ability for hospitals to track replacement devices at no cost vs. those at full cost is difficult. Capturing this information for the patient bill may require manual tracking of the part through several departments at a hospital, just to obtain information for one patient bill, resulting in lost productivity for several CMS is concerned about

double payments for these devices. We believe there are other devices where CMS doe not provide adequate reimbursement which may offset those potential overpayments.

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.

IPPS Capital Payments

(*Federal Register* pages 24818 – 24823)

Reimbursement for capital-related costs was implemented in FY 1992. Over a ten-year period, payments for capital were transitioned from a reasonable cost-based methodology to a prospective methodology. Beginning in FY 2002, all hospitals were paid based on 100 percent of the capital Federal rate, which is updated based on changes in a capital input price index (CIPI) and several other policy adjustment factors. Since inception of the capital IPPS, urban and rural hospitals have received the same update to the capital Federal rate. For 2008, the CMS is proposing to give rural hospitals the full 0.8 percent update but no update for urban hospitals based on "observed adequate capital margins." The MHA opposes the CMS proposal to freeze urban capital rates and the CMS application of the 2.4 percent "behavioral offset" to capital rates. Hospitals have already committed funds toward various capital projects with the expectation that Medicare funding would be available to reimburse a portion of the cost. **The MHA recommends that the CMS eliminate the 2.4 percent "behavioral offset" and provide all hospitals with the full 0.8 percent capital update.**

Capital Large Urban Add-On

(*Federal Register* pages 24818 – 24823)

Since implementation of the capital IPPS in FY 1992, the CMS has provided a 3.0 percent add-on to the Federal capital rate for hospitals that are located in large urban areas. These additional funds allow hospitals to install new technology to better serve Medicare and other patients. For 2008, the CMS proposes to discontinue the 3.0 percent additional payment that has been provided to hospitals in large urban areas. **The MHA opposes the elimination of these additional capital payments and urges the CMS to continue providing these payments to hospitals in large urban areas. Hospitals have installed equipment or completed renovations with the expectation that Medicare would reimburse a portion. To eliminate this funding after the fact is irresponsible. We are opposed to these unnecessary cuts, which ignore how vital capital payments are to the ongoing maintenance and improvement of hospital facilities and technologies and believe the CMS should not make any cuts or other adjustments to the capital PPS.**

In addition, the 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 limit the ability of hospitals to invest in the advanced technology and equipment that patients expect slow 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 curtailing the investment in health information technology.

Capital IME and DSH Adjustments – Potential Elimination

(*Federal Register* pages 24818 – 24823)

Under current law, the CMS has *"broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs."* In the proposed rule, the CMS considers and seeks comment on eliminating the special payment adjustments provided under the capital IPPS.

Based on the CMS' analysis of capital IPPS margins, the CMS is considering further reductions to certain classes of hospitals that have sustained positive capital margins. These reductions would be focused on the payment adjustments received by teaching hospitals and disproportionate share hospitals. Because these adjustments are not required by law, the CMS is considering proposals that would reduce or eliminate the IME and DSH capital adjustments. The CMS is also evaluating whether these potential changes to the capital IPPS should be made in a budget neutral manner, or should instead result in savings to the Medicare program. The hospitals receiving these adjustments are providing teaching opportunities for future physicians and provide services to a significant number of patients that are indigent. **The MHA opposes the elimination of these indirect medical education and disproportionate share capital payments, which equate to approximately $37 million annually for Michigan hospitals, and urges the CMS to continue these adjustments.** The 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 for the CMS to consider such changes without a clear understanding of the broader ramifications.

IME ADJUSTMENT

(*The Federal Register* Pages 24812-24813)

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

orientation time. Orientation time would continue to be included as part of the full-time equivalent (FTE) count, as it always has.

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

The MHA appreciates the 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.

Devices Replaced at No Cost or With Credit to Hospital

(*Federal Register* pages 24742 – 24746)

In the FY 2007 IPPS final rule, the CMS addressed the topic of payment for devices that are replaced at no cost or where credit for a replaced device is furnished to the hospital. The CMS believes that Medicare should not pay the hospital for the full cost of the replacement if the hospital is receiving a partial or full credit, due either to a recall or to service during the warranty period. In this case, this CMS states that the cost of the device was incurred at the time of initial implantation, and Medicare should receive the credit that is being provided to the hospital. In the FY 2008 IPPS proposed rule, the CMS proposes to reduce the amount of the Medicare IPPS payment when a full or partial credit towards a replacement device is made of the device is replaced without cost to the hospital or with full credit for the removed device. For a device provided to the hospital without cost, the fiscal intermediary would subtract the cost of the device from the DRG payment. For a device for which the hospital received a full or partial credit, the FI would subtract the amount credited from the DRG payment.

The MHA is concerned with this concept in that the CMS is not taking into account the impact of transitioning to a cost-based methodology for determining DRG weights. Under the old charge-based method of determining DRG weights the CMS is correct in their assumption that the facility could be paid more than once for a device that they paid for only once. However, under the new cost-based methodology the cost for the replacement device will not be in the facility's base cost since there was no payment to the manufacturer for the replacement device. As a result, a further reduction of payment would not be needed and would, in fact, result in a negative impact to the facility.

Cost Outliers

(*Federal Register* pages 24836 – 24838)

The CMS provides payments for outlier cases involving extraordinarily high costs when compared to average cases in the same DRG. To qualify as a cost outlier, a hospital's cost for the case must exceed the payment rate for the DRG plus a specified amount called the fixed-loss threshold. The outlier payment is equal to 80 percent of the difference between the hospital's cost for the stay and the threshold amount. The threshold is adjusted every year based on CMS' projections of total outlier payments to make outlier reimbursement equal 5.1 percent of total payments.

The CMS is proposing to decrease the fixed-loss cost outlier threshold from the current $24,485 to $22,940, which represents a 6 percent decrease. Although a 5.1 percent pool is set aside each year for outlier payments, the CMS estimates that it spent 4.1 percent for outliers in FY 2005, 4.7 percent in FY 2006 and that only 4.9 percent will be spent in FY 2007.

We believe the CMS under spent the funds set aside for outliers by an estimated $3 billion over FYs 2004, 2005 and 2006. **This represents payment reductions that hospitals have not recouped through increases in the standardized rates.** While we appreciate the CMS' recognition of the need to reduce the outlier threshold, **we believe the CMS should consider a further reduction in the outlier threshold for FY 2008 to ensure that the entire 5.1 percent is paid to hospitals and the $3 billion unpaid is added to the standardized rate for FY 2008.**

Revision of the Wage Index Adjustment – FY 2009 Proposed Rule

(*Federal Register* page 24802)

Section 106(b)(1)of the Tax Relief and Health Care Act of 2006 requires MedPAC to review the current Medicare wage index classification system and recommend alternatives to the method of computing the wage index. MedPAC is required to submit a report to Congress on their findings by June 30, 2007.

In addition, the law requires the CMS, taking into account MedPAC's recommendations, to include one or more proposals to revise the wage index adjustment applied to the IPPS in the FY 2009 IPPS proposed rule. The law requires the proposal (or proposals) to consider the following:

- problems associated with the definition of labor markets for the wage index adjustment;
- the modification or elimination of geographic reclassifications and other adjustments;
- the use of Bureau of Labor of Statistics data or other data or methodologies to calculate relative wages for each geographic area;
- minimizing variations in wage index adjustments between and within MSAs and statewide rural areas;

- the feasibility of applying all components of CMS' proposal to other settings;
- methods to minimize the volatility of wage index adjustments while maintaining the principle of budget neutrality;
- the effect that the implementation of the proposal would have on health care providers on each region of the country;
- methods for implementing the proposal(s) including methods to phase in such implementations; and
- issues relating to occupational mix such as staffing practices and any evidence on quality of care and patient safety including any recommendation for alternative calculations to the occupational mix.

To date, MedPAC has presented its preliminary findings regarding this issue which include replacing the current system with the information from the Bureau of Labor Statistics. **The MHA opposes the CMS' use of the (BLS) data as a basis for future wage index calculations, particularly since the BLS fails to include fringe benefits, which are generally higher for hospitals compared to other industries. We believe the CMS should continue to collect hospital-specific data and evaluate other alternatives to minimize variation and volatility in the wage index.**

A review of the wage index changes indicates an approximate $500 million (or 0.5%) reduction to hospital payments including approximately $60 million for section 508 that would be budgeted. The CMS table 1 on page 25118 of the federal register indicates the reduction is 0.1 percent but does not quantify the dollar impact of the change. **We believe the CMS should provide dollars in addition to percentages in order for independent verification of these change. In addition, we are unable to identify a commensurate increase to the standardized rate for these reductions.**

Additional Payments for New Technology

(*Federal Register* pages 24771 – 24776)

The CMS provides additional add-on payments for approved new technologies. To be approved for payment as a new technology, an item must be considered new, be inadequately paid otherwise and represent a substantial clinical improvement over previously available technologies. The cost threshold for new technologies to qualify for add-on payments is the lower of the following:

- 75 percent of the standardized amount (increased to reflect the difference between costs and charges)
- 75 percent of one standard deviation for the DRG involved

In FY 2008, the CMS proposes to discontinue reimbursement for the three technologies that

are currently eligible for new technology payments. In addition, one technology is under review and may be approved for new technology payments in FY 2008. The CMS continues to review approval for: Wingspan® Stent System with Gateway™ PTA Balloon Catheter. **The MHA urges the CMS to approve and provide new technology payments for this new stent system in FY 2008.**

Possible Quality Measures and Measure Sets for FY 2009 RHQDAPU Program

Federal Register pages 24802-24809

Hospital Quality Data

(*Federal Register* pages 24802 – 24809)

The Medicare Modernization Act (MMA) required hospitals to submit data on quality measures to the CMS. Participating hospitals were required to submit data on a set of ten quality measures and for their data to meet certain validation requirements. Hospitals that withdrew from the program or failed to submit valid data received the market basket increase minus 0.4 percent for FFYs 2005 and 2006.

The DRA extended and expanded this program, giving CMS greater authority. In the FFY 2007 IPPS final rule, the penalty for withdrawal from the program or failure to comply with its requirements was increased to 2.0 percent; and the set of quality measures was expanded to a total of twenty-one. For FY 2009, the CMS is proposing to add 1 outcome measure and 4 process measures to the existing 27 measure set to establish a new set of 32 quality measures to be used for the FY 2009 annual payment determination. **While the MHA is supportive of measuring and improving quality of care, we recommend that the CMS evaluate whether the measures currently utilized are capturing improvements in quality and ensure that additional measures will result in meaningful quality improvements rather than merely increased administrative burden by hospitals without measurable improvement in patient care or results.**

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, the CMS puts forward five new measures – four process measures and one outcome measure – to be included for the FY 2009 annual payment determination. To receive a full market basket update, hospitals would have to pledge to submit data on these and all measures currently included in the Hospital Quality Alliance's (HQA) public reporting initiative for patients discharged on or after January 1, 2008. In addition, hospitals would have to pass data validation tests for data submitted in the first three calendar quarters of 2007.

New quality measures. We are pleased that the 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, the CMS and others – are engaged in and agree with the adoption of a new measure, and the 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.

While we agree with the CMS' consideration of the ICU measures for FY 2009 and subsequent years, we strongly disagree with the following measures:

- Readmission Measures – this represents a burdensome data collection for hospitals. Data must be derived from medical records as there is not an effective mechanism from identifying readmissions using administrative data.
- Nursing Sensitive Condition Set – these measures require chart abstraction to verify and are far from ready for implementation.
- Inpatient Cancer Measures – inpatient cancer treatment is low volume and would result in small numbers of reported cases. This leads to low statistical value.
- Leapfrog measures – hospitals have been reporting these measures for sometime, yet they have limited value in assessing quality.

Development of Value-based Purchasing

(*Federal Register* pages 24809 - 24810)

The DRA required the CMS to develop a plan to implement hospital value-based purchasing (pay-for-performance) beginning in FY 2009. The plan must consider the following issues:

- measure development — the ongoing development, selection and modification process for measures of quality and efficiency in hospital inpatient settings
- data infrastructure and refinement — reporting, collecting and validating of quality data
- incentives — the structure of payment adjustments, including the determination of thresholds for improvements in quality that would substantiate a payment adjustment, the size of such payments and the sources of funding for the payments
- public reporting — disclosure of information on hospital performance

To date, the CMS has created an internal hospital pay-for-performance workgroup that is charged with preparing a set of design options, narrowing the set of design options to prepare a draft plan, and preparing the final plan for implementing VBP that will be provided to Congress. The workgroup is organized into four subgroups to address each of the required planning issues: measures, data collection and validation, incentive structure and public reporting. In addition, the CMS has hosted two "Listening Sessions" to solicit input from relevant affected parties on

outstanding questions associated with development of the final plan. The CMS states in the proposed rule that, although the DRA authorized development of a VBP program, additional legislation will be required to establish and implement the VBP program. **The MHA encourages the CMS to continue its efforts in collaborating with a workgroup comprised of industry representatives, including physicians, to develop pay-for-performance measures are meaningful, represent improvements to patient care and are not overly burdensome for hospitals.**

Hospital-Acquired Conditions

(*Federal Register* Page 24716 - 24726)

Complications such as infections acquired in the hospital can trigger higher payments in the form of outlier payments and/or higher DRG payments due to the presence of a complication or comorbidity (CC). The DRA requires the CMS to identify, by October 1, 2007 (FY 2008), at least two CC secondary diagnoses that:

- are high cost, 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
- could reasonably have been prevented through the application of evidence-based guidelines.

For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases where one of the selected conditions was not present on admission, meaning the case would be paid as though the secondary diagnosis was not present. The law states that the CMS can revise the list from time to time, as long as the list contains at least two conditions. Additionally, the DRA requires hospitals to report the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007.

The CMS selected 13 conditions as possible candidates to satisfy the DRA provision for hospital-acquired conditions. According to the CMS' selection method, the conditions at the top of the following list best meet the statutory selection criteria, while the conditions lower on the list may meet the selection criteria but could present a particular challenge (that is, they may be preventable only in some circumstances, but not in others) and therefore, the first conditions listed should receive the highest consideration of selection among the initial group of hospital-acquired conditions.

Six conditions proposed for consideration for FY 2009

The CMS requests 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 the CMS in its effort to identify appropriate conditions that should not occur in hospitals. However, we believe the challenge is two-fold -- meeting criteria defined by Congress while ensuring accuracy in the billing data that enable the appropriate identification of cases. The implementation of the MS-DRG system requiring implementation of "present on admission" (POA) codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

For FY 2009, we **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 since these conditions:

- Have been identified and supported by NQF;
- Are identifiable by discrete ICD-9 codes,
- Can be coded for by hospitals without dependence on POA codes

These are events that can cause great harm to patients and for which there are known methods of prevention. Hospitals are committed to reducing the risk of such occurrences.

However, we **do not support numbers 1, 2 and 6** Catheter-associated urinary tract infections, pressure ulcers and *Staphylococcus aureus* septicemia for general and specific reasons for FY 2009. We believe these three indicators are potential candidates for the future, but each condition depends strongly upon the ability to properly identify them (definitional issues) as well as accurate use of POA codes. As noted earlier, the CMS proposes to rely on POA coding, a requirement that has now been delayed to January 1, 2008, due to technical difficulties. The CMS is aware of the experiences reported by AHRQ and that of two states already using POA codes, whose efforts determined that implementation requires a minimum of 2 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 the CMS to provide educational support to hospitals. Until the CMS is satisfied that POA coding is fairly accurate, we do believe it is inappropriate for the CMS to require POA codes in order to determine whether or not the condition is hospital-acquired.

In addition to the POA coding, we do not believe that each of these conditions is always reasonably preventable. Even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. Definitions are critical in order to detect and apply appropriate interventions. Some of the definitions are currently under review and require updating before they can be implemented successfully in a hospital reporting program.

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

The CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after several days of catheter placement due to colonization of catheters during that time period. 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 CC. Further, we remain concerned about the inclusion of "inflammatory reaction from the indwelling catheter." UTI prevention guidelines remain under review and although the *preventive* interventions are focused on removal of appropriately placed urinary catheter as soon as possible, there will be patients who genuinely need the catheter who still may suffer the complication of catheter-associated inflammation.

Unintended consequences: As POA coding becomes more reliable, there may also be unintended consequences. As attention is paid to carefully identify catheter-associated UTI that are present on admission, there may be excessive urinalysis/culturing of patients entering the hospital which could further lead to unnecessary antimicrobial use.

#2 Pressure ulcers – (ICD-9-CM Codes 707.00 through 707.09)
We have a number of additional concerns that should be addressed by the CMS once the POA code issue is reliably implemented. However, the condition is not limited to hospitals, and given the large volume of transfers between hospitals and other institutions, long-term care facilities for example, a critical examination for existing pressure ulcers on admission is of prime importance. Although non-CDC guidelines exist and this condition is less complicated in terms of exclusion codes, all the remarks made earlier regarding POA codes remain crucial.

- 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. Even detection of stage I pressure ulcers on admission is difficult as the skin is not yet broken, even though the tissue is damaged.
- The POA coding of pressure ulcers 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.
- If the 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 wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

Unintended consequences The necessity to complete diagnostic tests before a patient is admitted to confirm POA admission status could lead to delayed admissions and a delay in care for some patients and disrupt efficient hospital flow.

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

The 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 diagnosing *Staphylococcus aureus* septicemia on admission is a major challenge. Patients may be admitted to the hospital with a *Staphylococcus aureus* infection secondary to infection at another location, such as pneumonia or skin/soft tissue infection. Subsequent development of *Staphylococcus aureus* septicemia may be detected later as the result of the localized infection and not as a hospital-acquired condition. Additionally, the recent proliferation of changes in coding guidelines for sepsis complicates efforts of coding personnel to accurately capture POA status. The prevention guidelines for *Staphylococcus aureus* septicemia primarily relate to device-associated infections for which there is no specific code.

The category of *Staphylococcus aureus* septicemia is simply too large and varied to determine that the infections were reasonably preventable. Once the POA coding has been established with reliability we believe this category is feasible only if the codes are identified and applied to patients 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.

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

The CMS has clearly identified the problems with each of these indicators based on lack of unique codes, complication codes or guidelines addressing reasonable preventability. However, we recommend that the CMS continue to address the coding challenges for ventilator-associated pneumonia, vascular catheter-associated infections and surgical site infections and determine if

these conditions warrant inclusion in the hospital-acquired conditions policy in the future since they are important causes of healthcare-associated mortality and morbidity. These require not only reliable use of POA codes but other unique definitional and coding issues. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic.

Potential FY 2009 recommendations

Of the possible conditions for which the CMS requested comments, we do suggest and **support** two approaches that do ***not*** depend on POA codes, though would require coding and cross referencing. We recommend these be considered for FY 2009 until POA coding is proven to be reliable for other 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).

The CMS states: "This code includes infections associated with all vascular devices, implants, and grafts. It does not uniquely identify vascular catheter associated infection. 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 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***.

It is possible to:

a) Screen for bloodstream infection codes (996.62)
b) Exempt or exclude all vascular surgery and other implantable device codes
c) Examine the record for CPT codes for CVC placement occurring on the same admission. 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)

The 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."

1) Although we agree this approach is unworkable, we would suggest selecting 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.

2) Further, the CMS might consider post-operative sepsis, using a specific procedure code such as CABG (with or without valve) and/or total knee or hip replacement-excluding trauma.

3) Finally, the CMS could consider a similar logic as noted above using postoperative sepsis following 'CABG without valve' with mediastinitis:

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

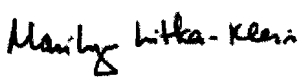
Finally, we would like clarification from the CMS regarding how hospitals may appeal a CMS decision if an error in coding occurs, and a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment.

The MHA and its member hospitals embarked on a joint project with Johns Hopkins, funded by a $1 million grant from the U.S. Agency for Healthcare Research and Quality (AHRQ) to reduce ICU infections through the MHA Keystone Center. Over two years, 77 hospitals and 127 hospital ICUs voluntarily participated in this project to reduce infections in the ICU. After 18 months, the predictive model suggests that teams saved 1,574 lives, over 84,000 ICU days and over $175 million dollars. Infections from central IV catheters plummeted. **The median CR-BSI rate in participating ICUs has now been at zero for almost a year.** Ventilator associated pneumonia rates in the ICUs have been cut by 40%. **Forty six ICUs have gone for over six months with no ventilator associated pneumonias. Fifty seven ICUs have gone for over six months with no blood stream infections from IV catheters.** The MHA believes proactive projects such as these will result in better patient safety and quality. However, hospitals need the training and funding in order to implement these changes.

The MHA believes the CMS proposal that complications are solely the result of hospital actions is fundamentally flawed. To reduce hospital payments for a condition present upon admission, but not documented, is too punitive. In addition, 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. Rather, the MHA recommends that the CMS provide funding and expand demonstration projects such as the MHA Keystone Center. The results and process improvements could be shared with all hospitals nationally to improve quality and patient safety. Imposing a punitive payment vs. providing the tools to improve would not produce the positive results the CMS desires.

Again, the MHA appreciates this opportunity to provide comments to the CMS regarding this proposed inpatient rule and urge you to please take them into consideration. We believe our suggested modifications will result in positive changes for hospitals and the Medicare beneficiaries they serve. If you have questions on this comment letter, please contact me at (517) 703-8603 or mklein@mha.org.

Sincerely,



Marilyn Litka-Klein
Senior Director, Health Policy

#252-2

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

June 8, 2007

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

Re: FY 2008 Medicare Inpatient Prospective Payment System Proposed Rule CMS-1533-P

Dear Ms. Norwalk:

On behalf of its 145 member hospitals, the Michigan Health & Hospital Association (MHA) welcomes this opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule to update the Inpatient Prospective Payment System for Fiscal Year (FY) 2008. While the rule, which was published in the May 3, 2007, *Federal Register*, provides a 3.3 percent market basket increase for hospitals that submit data for the CMS quality measures, **we strongly oppose the CMS' 2.4 percent "behavioral offset" for anticipated changes in hospital coding.** We are also concerned about other significant policy changes included in the proposed rule that would negatively impact Michigan hospital Medicare reimbursement and undermine some fundamental payment principles.

The adequacy of Medicare payments to cover the cost of services provided is crucial for ensuring the future viability of Michigan's nonprofit hospitals. Based on the latest data available, approximately **50 percent** of Michigan hospitals experienced a negative margin on all Medicare services. This is very concerning particularly since Michigan's population is aging and the number of Medicare beneficiaries is projected to increase significantly over the next decade. By 2020, the number of Michigan residents who are 65 and older is expected to comprise 16.6 percent of the state's population.

When all payors are aggregated, Michigan hospitals experienced a negative 1.8 percent patient margin, with **88 hospitals**, or **60 percent,** losing money on patient care services. The proposed changes will further threaten the future viability of hospitals and access to healthcare services for Medicare beneficiaries and other residents of the state of Michigan.

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The MHA believes it is important for the CMS to recognize that the proposed payment changes alone will be financially devastating for many hospitals and includes operational modifications that hospitals could not adapt in the two months prior to Oct. 1. While hospitals support meaningful improvements to Medicare's inpatient PPS system, the CMS has exceeded its authority by recommending arbitrary and unnecessary cuts in this proposed rule. The MHA believes that these unprecedented budget cuts will further deplete scare resources, ultimately making hospitals' mission of caring for patients even more challenging. One of the fundamental values of a prospective payments system is the ability of providers to reasonably estimate payments in advance to impact their budgeting, marketing, staffing and other key management decisions. Given the extensive change and impact, two months is inadequate for hospitals to operationalize a $2 million payment reduction particularly when the latest margin data indicate the hospital lost $1.8 million providing patient care.

Our key concerns include:

2.4 Percent "Behavioral Offset"

(Federal Register Pages 24708-24711*)*

A provision in the Benefits Improvement and Protection Act (BIPA) of 2000, provides the CMS authority 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 MHA is strongly opposed to the proposed adjustment based on the assumption that the case mix index of hospitals will automatically increase. The MS-DRG system is an expansion of the current classification system rather than a replacement system such as the APR-DRG system that Maryland implemented. The CMS does not have any actual evidence that medical record coders will change their practice to "locate" complications to maximize reimbursement. Hospitals currently are coding complications, if they are documented in the patient record, in order to obtain the proper payment for the patient served. **The MHA recommends that the CMS eliminate this reduction and provide hospitals with the full 3.3 percent market basket increase. Until the MS-DRGs are fully implemented and the CMS can document and demonstrate that any increase in case mix results from changes in coding practices rather than actual changes in patient severity, there should be no behavioral offset. Until the MS-DRGs are fully implemented, and the 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". At that time, the CMS can evaluate whether payments have increased due to coding rather than the severity of patients and determine if an adjustment is necessary. The CMS is not required to make an adjustment at this time, and should not do so without evidence that coding changes have occurred.**

Medicare Severity (MS) DRGs

(Federal Register pages 24691 – 24712)

For FY 2008, the CMS is proposing to adopt Medicare Severity (MS) DRGs, which are the result of modifications to the current CMS DRGs to better account for patient severity. While the CMS proposes to implement the MS-DRGs on Oct 1, 2007, they believe that the MS-DRGs should be evaluated by RAND and have instructed RAND to evaluate the proposed MS-DRGs using the same criteria that it is applying to the other DRG systems.

The proposed MS-DRGs would increase the number of DRGs from 538 to 745. While the current CMS DRGs include 115 DRGs that are split based upon the presence or absence of a complication or comorbidity (CC), the MS-DRGs include 152 DRGs that subdivide into three tiers: major CC, CC and non-CC and another 106 DRGs that subdivide into two severity levels. While hospitals appreciate the CMS' recognition of the issues raised last year regarding its proposal to use Consolidated Severity (CS) adjusted DRGs, we believe it is crucial that a system change of this magnitude have a transition period of four years. The change to MS DRGs is projected to result in reimbursement decreases of 10 percent for some Michigan hospitals and an 8 percent increase for others, with hospitals unable to adapt to changes of this magnitude in two months after release of the final rule. As a result, the MHA recommends that in FY 2008, the emphasis be on preparation and testing of the new DRG classification system so that the CMS has adequate time to finalize data, introduce and test software for patient classification and payment and train its fiscal intermediaries. In addition, this will allow the CMS time for further analysis by hospital type to ensure the projected changes are consistent with the policy objectives the CMS desires to achieve. This would also give hospitals more time to implement and test the new system and adjust operations and staffing based on projected changes in Medicare revenues. **The MHA recommends a 4-year transition as follows:**

- In FY 2008, continue current DRG classification system with an emphasis on preparation for and testing of the new classification system. This provides the CMS with adequate time to finalize data and a CC list, introduce and test software for classification and payment, and train its fiscal agents. It would also provide hospitals additional time to implement and test the new system and adjust operations and staffing for predicted revenues. In addition, it would also 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 1/3 from the MS-DRGs and 2/3 from traditional DRGs.

- In FY 2010, DRG weights should be computed as a blend derived 2/3 from MS-DRGs and 1/3 from traditional DRGs

- In FY 2011, DRG weights should be derived using 100 percent of the MS-DRGs

Recalibration of DRG Weights

For FY 2008, the 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.

They identified 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.

In addition, the use of <u>hospital-specific charges</u> and a <u>national cost/charge</u> ratio will result in a distortion of the DRG weights. This has the potential of shifting Medicare payments among hospitals <u>not</u> based on resource utilization but rather on a mathematical calculation.

- The MHA recommends that the CMS review the impact of using hospital specific charges and costs to determine whether the national cost-to-charge ratio has created inaccurate DRG weights.
- In addition, the ability for hospitals to track replacement devices at no cost vs. those at full cost is difficult. Capturing this information for the patient bill may require manual tracking of the part through several departments at a hospital, just to obtain information for one patient bill, resulting in lost productivity for several CMS is concerned about

double payments for these devices. We believe there are other devices where CMS doe not provide adequate reimbursement which may offset those potential overpayments.

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.

IPPS Capital Payments

(*Federal Register* pages 24818 – 24823)

Reimbursement for capital-related costs was implemented in FY 1992. Over a ten-year period, payments for capital were transitioned from a reasonable cost-based methodology to a prospective methodology. Beginning in FY 2002, all hospitals were paid based on 100 percent of the capital Federal rate, which is updated based on changes in a capital input price index (CIPI) and several other policy adjustment factors. Since inception of the capital IPPS, urban and rural hospitals have received the same update to the capital Federal rate. For 2008, the CMS is proposing to give rural hospitals the full 0.8 percent update but no update for urban hospitals based on "observed adequate capital margins." The MHA opposes the CMS proposal to freeze urban capital rates and the CMS application of the 2.4 percent "behavioral offset" to capital rates. Hospitals have already committed funds toward various capital projects with the expectation that Medicare funding would be available to reimburse a portion of the cost. **The MHA recommends that the CMS eliminate the 2.4 percent "behavioral offset" and provide all hospitals with the full 0.8 percent capital update.**

Capital Large Urban Add-On

(*Federal Register* pages 24818 – 24823)

Since implementation of the capital IPPS in FY 1992, the CMS has provided a 3.0 percent add-on to the Federal capital rate for hospitals that are located in large urban areas. These additional funds allow hospitals to install new technology to better serve Medicare and other patients. For 2008, the CMS proposes to discontinue the 3.0 percent additional payment that has been provided to hospitals in large urban areas. **The MHA opposes the elimination of these additional capital payments and urges the CMS to continue providing these payments to hospitals in large urban areas. Hospitals have installed equipment or completed renovations with the expectation that Medicare would reimburse a portion. To eliminate this funding after the fact is irresponsible. We are opposed to these unnecessary cuts, which ignore how vital capital payments are to the ongoing maintenance and improvement of hospital facilities and technologies and believe the CMS should not make any cuts or other adjustments to the capital PPS.**

In addition, the 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 limit the ability of hospitals to invest in the advanced technology and equipment that patients expect slow 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 curtailing the investment in health information technology.

Capital IME and DSH Adjustments – Potential Elimination

(Federal Register pages 24818 – 24823)

Under current law, the CMS has *"broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs."* In the proposed rule, the CMS considers and seeks comment on eliminating the special payment adjustments provided under the capital IPPS.

Based on the CMS' analysis of capital IPPS margins, the CMS is considering further reductions to certain classes of hospitals that have sustained positive capital margins. These reductions would be focused on the payment adjustments received by teaching hospitals and disproportionate share hospitals. Because these adjustments are not required by law, the CMS is considering proposals that would reduce or eliminate the IME and DSH capital adjustments. The CMS is also evaluating whether these potential changes to the capital IPPS should be made in a budget neutral manner, or should instead result in savings to the Medicare program. The hospitals receiving these adjustments are providing teaching opportunities for future physicians and provide services to a significant number of patients that are indigent. **The MHA opposes the elimination of these indirect medical education and disproportionate share capital payments, which equate to approximately $37 million annually for Michigan hospitals, and urges the CMS to continue these adjustments.** The 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 for the CMS to consider such changes without a clear understanding of the broader ramifications.

IME ADJUSTMENT

(The Federal Register Pages 24812-24813)

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

orientation time. Orientation time would continue to be included as part of the full-time equivalent (FTE) count, as it always has.

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

The MHA appreciates the 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.

Devices Replaced at No Cost or With Credit to Hospital

(*Federal Register* pages 24742 – 24746)

In the FY 2007 IPPS final rule, the CMS addressed the topic of payment for devices that are replaced at no cost or where credit for a replaced device is furnished to the hospital. The CMS believes that Medicare should not pay the hospital for the full cost of the replacement if the hospital is receiving a partial or full credit, due either to a recall or to service during the warranty period. In this case, this CMS states that the cost of the device was incurred at the time of initial implantation, and Medicare should receive the credit that is being provided to the hospital. In the FY 2008 IPPS proposed rule, the CMS proposes to reduce the amount of the Medicare IPPS payment when a full or partial credit towards a replacement device is made of the device is replaced without cost to the hospital or with full credit for the removed device. For a device provided to the hospital without cost, the fiscal intermediary would subtract the cost of the device from the DRG payment. For a device for which the hospital received a full or partial credit, the FI would subtract the amount credited from the DRG payment.

The MHA is concerned with this concept in that the CMS is not taking into account the impact of transitioning to a cost-based methodology for determining DRG weights. Under the old charge-based method of determining DRG weights the CMS is correct in their assumption that the facility could be paid more than once for a device that they paid for only once. However, under the new cost-based methodology the cost for the replacement device will not be in the facility's base cost since there was no payment to the manufacturer for the replacement device. As a result, a further reduction of payment would not be needed and would, in fact, result in a negative impact to the facility.

Cost Outliers

(*Federal Register* pages 24836 – 24838)

The CMS provides payments for outlier cases involving extraordinarily high costs when compared to average cases in the same DRG. To qualify as a cost outlier, a hospital's cost for the case must exceed the payment rate for the DRG plus a specified amount called the fixed-loss threshold. The outlier payment is equal to 80 percent of the difference between the hospital's cost for the stay and the threshold amount. The threshold is adjusted every year based on CMS' projections of total outlier payments to make outlier reimbursement equal 5.1 percent of total payments.

The CMS is proposing to decrease the fixed-loss cost outlier threshold from the current $24,485 to $22,940, which represents a 6 percent decrease. Although a 5.1 percent pool is set aside each year for outlier payments, the CMS estimates that it spent 4.1 percent for outliers in FY 2005, 4.7 percent in FY 2006 and that only 4.9 percent will be spent in FY 2007.

We believe the CMS under spent the funds set aside for outliers by an estimated $3 billion over FYs 2004, 2005 and 2006. **This represents payment reductions that hospitals have not recouped through increases in the standardized rates.** While we appreciate the CMS' recognition of the need to reduce the outlier threshold, **we believe the CMS should consider a further reduction in the outlier threshold for FY 2008 to ensure that the entire 5.1 percent is paid to hospitals and the $3 billion unpaid is added to the standardized rate for FY 2008.**

Revision of the Wage Index Adjustment – FY 2009 Proposed Rule

(*Federal Register* page 24802)

Section 106(b)(1)of the Tax Relief and Health Care Act of 2006 requires MedPAC to review the current Medicare wage index classification system and recommend alternatives to the method of computing the wage index. MedPAC is required to submit a report to Congress on their findings by June 30, 2007.

In addition, the law requires the CMS, taking into account MedPAC's recommendations, to include one or more proposals to revise the wage index adjustment applied to the IPPS in the FY 2009 IPPS proposed rule. The law requires the proposal (or proposals) to consider the following:

- problems associated with the definition of labor markets for the wage index adjustment;
- the modification or elimination of geographic reclassifications and other adjustments;
- the use of Bureau of Labor of Statistics data or other data or methodologies to calculate relative wages for each geographic area;
- minimizing variations in wage index adjustments between and within MSAs and statewide rural areas;

- the feasibility of applying all components of CMS' proposal to other settings;
- methods to minimize the volatility of wage index adjustments while maintaining the principle of budget neutrality;
- the effect that the implementation of the proposal would have on health care providers on each region of the country;
- methods for implementing the proposal(s) including methods to phase in such implementations; and
- issues relating to occupational mix such as staffing practices and any evidence on quality of care and patient safety including any recommendation for alternative calculations to the occupational mix.

To date, MedPAC has presented its preliminary findings regarding this issue which include replacing the current system with the information from the Bureau of Labor Statistics. **The MHA opposes the CMS' use of the (BLS) data as a basis for future wage index calculations, particularly since the BLS fails to include fringe benefits, which are generally higher for hospitals compared to other industries. We believe the CMS should continue to collect hospital-specific data and evaluate other alternatives to minimize variation and volatility in the wage index.**

A review of the wage index changes indicates an approximate $500 million (or 0.5%) reduction to hospital payments including approximately $60 million for section 508 that would be budgeted. The CMS table 1 on page 25118 of the federal register indicates the reduction is 0.1 percent but does not quantify the dollar impact of the change. **We believe the CMS should provide dollars in addition to percentages in order for independent verification of these change. In addition, we are unable to identify a commensurate increase to the standardized rate for these reductions.**

Additional Payments for New Technology

(*Federal Register* pages 24771 – 24776)

The CMS provides additional add-on payments for approved new technologies. To be approved for payment as a new technology, an item must be considered new, be inadequately paid otherwise and represent a substantial clinical improvement over previously available technologies. The cost threshold for new technologies to qualify for add-on payments is the lower of the following:

- 75 percent of the standardized amount (increased to reflect the difference between costs and charges)
- 75 percent of one standard deviation for the DRG involved

In FY 2008, the CMS proposes to discontinue reimbursement for the three technologies that

are currently eligible for new technology payments. In addition, one technology is under review and may be approved for new technology payments in FY 2008. The CMS continues to review approval for: Wingspan® Stent System with Gateway™ PTA Balloon Catheter. **The MHA urges the CMS to approve and provide new technology payments for this new stent system in FY 2008.**

Possible Quality Measures and Measure Sets for FY 2009 RHQDAPU Program

Federal Register pages 24802-24809

Hospital Quality Data

(*Federal Register* pages 24802 – 24809)

The Medicare Modernization Act (MMA) required hospitals to submit data on quality measures to the CMS. Participating hospitals were required to submit data on a set of ten quality measures and for their data to meet certain validation requirements. Hospitals that withdrew from the program or failed to submit valid data received the market basket increase minus 0.4 percent for FFYs 2005 and 2006.

The DRA extended and expanded this program, giving CMS greater authority. In the FFY 2007 IPPS final rule, the penalty for withdrawal from the program or failure to comply with its requirements was increased to 2.0 percent; and the set of quality measures was expanded to a total of twenty-one. For FY 2009, the CMS is proposing to add 1 outcome measure and 4 process measures to the existing 27 measure set to establish a new set of 32 quality measures to be used for the FY 2009 annual payment determination. **While the MHA is supportive of measuring and improving quality of care, we recommend that the CMS evaluate whether the measures currently utilized are capturing improvements in quality and ensure that additional measures will result in meaningful quality improvements rather than merely increased administrative burden by hospitals without measurable improvement in patient care or results.**

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, the CMS puts forward five new measures – four process measures and one outcome measure – to be included for the FY 2009 annual payment determination. To receive a full market basket update, hospitals would have to pledge to submit data on these and all measures currently included in the Hospital Quality Alliance's (HQA) public reporting initiative for patients discharged on or after January 1, 2008. In addition, hospitals would have to pass data validation tests for data submitted in the first three calendar quarters of 2007.

New quality measures. We are pleased that the 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, the CMS and others – are engaged in and agree with the adoption of a new measure, and the 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.

While we agree with the CMS' consideration of the ICU measures for FY 2009 and subsequent years, we strongly disagree with the following measures:

- Readmission Measures – this represents a burdensome data collection for hospitals. Data must be derived from medical records as there is not an effective mechanism from identifying readmissions using administrative data.
- Nursing Sensitive Condition Set – these measures require chart abstraction to verify and are far from ready for implementation.
- Inpatient Cancer Measures – inpatient cancer treatment is low volume and would result in small numbers of reported cases. This leads to low statistical value.
- Leapfrog measures – hospitals have been reporting these measures for sometime, yet they have limited value in assessing quality.

Development of Value-based Purchasing

(*Federal Register* pages 24809 - 24810)

The DRA required the CMS to develop a plan to implement hospital value-based purchasing (pay-for-performance) beginning in FY 2009. The plan must consider the following issues:

- measure development — the ongoing development, selection and modification process for measures of quality and efficiency in hospital inpatient settings
- data infrastructure and refinement — reporting, collecting and validating of quality data
- incentives — the structure of payment adjustments, including the determination of thresholds for improvements in quality that would substantiate a payment adjustment, the size of such payments and the sources of funding for the payments
- public reporting — disclosure of information on hospital performance

To date, the CMS has created an internal hospital pay-for-performance workgroup that is charged with preparing a set of design options, narrowing the set of design options to prepare a draft plan, and preparing the final plan for implementing VBP that will be provided to Congress. The workgroup is organized into four subgroups to address each of the required planning issues: measures, data collection and validation, incentive structure and public reporting. In addition, the CMS has hosted two "Listening Sessions" to solicit input from relevant affected parties on

outstanding questions associated with development of the final plan. The CMS states in the proposed rule that, although the DRA authorized development of a VBP program, additional legislation will be required to establish and implement the VBP program. **The MHA encourages the CMS to continue its efforts in collaborating with a workgroup comprised of industry representatives, including physicians, to develop pay-for-performance measures are meaningful, represent improvements to patient care and are not overly burdensome for hospitals.**

Hospital-Acquired Conditions

(*Federal Register* Page 24716 - 24726)

Complications such as infections acquired in the hospital can trigger higher payments in the form of outlier payments and/or higher DRG payments due to the presence of a complication or comorbidity (CC). The DRA requires the CMS to identify, by October 1, 2007 (FY 2008), at least two CC secondary diagnoses that:

- are high cost, 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
- could reasonably have been prevented through the application of evidence-based guidelines.

For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases where one of the selected conditions was not present on admission, meaning the case would be paid as though the secondary diagnosis was not present. The law states that the CMS can revise the list from time to time, as long as the list contains at least two conditions. Additionally, the DRA requires hospitals to report the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007.

The CMS selected 13 conditions as possible candidates to satisfy the DRA provision for hospital-acquired conditions. According to the CMS' selection method, the conditions at the top of the following list best meet the statutory selection criteria, while the conditions lower on the list may meet the selection criteria but could present a particular challenge (that is, they may be preventable only in some circumstances, but not in others) and therefore, the first conditions listed should receive the highest consideration of selection among the initial group of hospital-acquired conditions.

Six conditions proposed for consideration for FY 2009

The CMS requests 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 the CMS in its effort to identify appropriate conditions that should not occur in hospitals. However, we believe the challenge is two-fold -- meeting criteria defined by Congress while ensuring accuracy in the billing data that enable the appropriate identification of cases. The implementation of the MS-DRG system requiring implementation of "present on admission" (POA) codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

For FY 2009, we **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 since these conditions:

- Have been identified and supported by NQF;
- Are identifiable by discrete ICD-9 codes,
- Can be coded for by hospitals without dependence on POA codes

These are events that can cause great harm to patients and for which there are known methods of prevention. Hospitals are committed to reducing the risk of such occurrences.

However, we **do not support numbers 1, 2 and 6** Catheter-associated urinary tract infections, pressure ulcers and *Staphylococcus aureus* septicemia for general and specific reasons for FY 2009. We believe these three indicators are potential candidates for the future, but each condition depends strongly upon the ability to properly identify them (definitional issues) as well as accurate use of POA codes. As noted earlier, the CMS proposes to rely on POA coding, a requirement that has now been delayed to January 1, 2008, due to technical difficulties. The CMS is aware of the experiences reported by AHRQ and that of two states already using POA codes, whose efforts determined that implementation requires a minimum of 2 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 the CMS to provide educational support to hospitals. Until the CMS is satisfied that POA coding is fairly accurate, we do believe it is inappropriate for the CMS to require POA codes in order to determine whether or not the condition is hospital-acquired.

In addition to the POA coding, we do not believe that each of these conditions is always reasonably preventable. Even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. Definitions are critical in order to detect and apply appropriate interventions. Some of the definitions are currently under review and require updating before they can be implemented successfully in a hospital reporting program.

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

The CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after several days of catheter placement due to colonization of catheters during that time period. 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 CC. Further, we remain concerned about the inclusion of "inflammatory reaction from the indwelling catheter." UTI prevention guidelines remain under review and although the *preventive* interventions are focused on removal of appropriately placed urinary catheter as soon as possible, there will be patients who genuinely need the catheter who still may suffer the complication of catheter-associated inflammation.

Unintended consequences: As POA coding becomes more reliable, there may also be unintended consequences. As attention is paid to carefully identify catheter-associated UTI that are present on admission, there may be excessive urinalysis/culturing of patients entering the hospital which could further lead to unnecessary antimicrobial use.

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

We have a number of additional concerns that should be addressed by the CMS once the POA code issue is reliably implemented. However, the condition is not limited to hospitals, and given the large volume of transfers between hospitals and other institutions, long-term care facilities for example, a critical examination for existing pressure ulcers on admission is of prime importance. Although non-CDC guidelines exist and this condition is less complicated in terms of exclusion codes, all the remarks made earlier regarding POA codes remain crucial.

- 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. Even detection of stage I pressure ulcers on admission is difficult as the skin is not yet broken, even though the tissue is damaged.
- The POA coding of pressure ulcers 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.
- If the 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 wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

Unintended consequences The necessity to complete diagnostic tests before a patient is admitted to confirm POA admission status could lead to delayed admissions and a delay in care for some patients and disrupt efficient hospital flow.

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

The 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 diagnosing *Staphylococcus aureus* septicemia on admission is a major challenge. Patients may be admitted to the hospital with a *Staphylococcus aureus* infection secondary to infection at another location, such as pneumonia or skin/soft tissue infection. Subsequent development of *Staphylococcus aureus* septicemia may be detected later as the result of the localized infection and not as a hospital-acquired condition. Additionally, the recent proliferation of changes in coding guidelines for sepsis complicates efforts of coding personnel to accurately capture POA status. The prevention guidelines for *Staphylococcus aureus* septicemia primarily relate to device-associated infections for which there is no specific code.

The category of *Staphylococcus aureus* septicemia is simply too large and varied to determine that the infections were reasonably preventable. Once the POA coding has been established with reliability we believe this category is feasible only if the codes are identified and applied to patients 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.

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

The CMS has clearly identified the problems with each of these indicators based on lack of unique codes, complication codes or guidelines addressing reasonable preventability. However, we recommend that the CMS continue to address the coding challenges for ventilator-associated pneumonia, vascular catheter-associated infections and surgical site infections and determine if

these conditions warrant inclusion in the hospital-acquired conditions policy in the future since they are important causes of healthcare-associated mortality and morbidity. These require not only reliable use of POA codes but other unique definitional and coding issues. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic.

Potential FY 2009 recommendations

Of the possible conditions for which the CMS requested comments, we do suggest and **support** two approaches that do ***not*** depend on POA codes, though would require coding and cross referencing. We recommend these be considered for FY 2009 until POA coding is proven to be reliable for other 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).

The CMS states: "This code includes infections associated with all vascular devices, implants, and grafts. It does not uniquely identify vascular catheter associated infection. 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 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***.

It is possible to:

a) Screen for bloodstream infection codes (996.62)
b) Exempt or exclude all vascular surgery and other implantable device codes
c) Examine the record for CPT codes for CVC placement occurring on the same admission. 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)

The 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."

1) Although we agree this approach is unworkable, we would suggest selecting 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.

2) Further, the CMS might consider post-operative sepsis, using a specific procedure code such as CABG (with or without valve) and/or total knee or hip replacement-excluding trauma.

3) Finally, the CMS could consider a similar logic as noted above using postoperative sepsis following 'CABG without valve' with mediastinitis:

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

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

The MHA and its member hospitals embarked on a joint project with Johns Hopkins, funded by a $1 million grant from the U.S. Agency for Healthcare Research and Quality (AHRQ) to reduce ICU infections through the MHA Keystone Center. Over two years, 77 hospitals and 127 hospital ICUs voluntarily participated in this project to reduce infections in the ICU. After 18 months, the predictive model suggests that teams saved 1,574 lives, over 84,000 ICU days and over $175 million dollars. Infections from central IV catheters plummeted. **The median CR-BSI rate in participating ICUs has now been at zero for almost a year.** Ventilator associated pneumonia rates in the ICUs have been cut by 40%. **Forty six ICUs have gone for over six months with no ventilator associated pneumonias. Fifty seven ICUs have gone for over six months with no blood stream infections from IV catheters.** The MHA believes proactive projects such as these will result in better patient safety and quality. However, hospitals need the training and funding in order to implement these changes.

The MHA believes the CMS proposal that complications are solely the result of hospital actions is fundamentally flawed. To reduce hospital payments for a condition present upon admission, but not documented, is too punitive. In addition, 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. Rather, the MHA recommends that the CMS provide funding and expand demonstration projects such as the MHA Keystone Center. The results and process improvements could be shared with all hospitals nationally to improve quality and patient safety. Imposing a punitive payment vs. providing the tools to improve would not produce the positive results the CMS desires.

Again, the MHA appreciates this opportunity to provide comments to the CMS regarding this proposed inpatient rule and urge you to please take them into consideration. We believe our suggested modifications will result in positive changes for hospitals and the Medicare beneficiaries they serve. If you have questions on this comment letter, please contact me at (517) 703-8603 or mklein@mha.org.

Sincerely,

Marilyn Litka-Klein
Senior Director, Health Policy

CMS-1533-P-253 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Wanda Strzemienski** **Date & Time:** **06/11/2007**

Organization : **Association of Professionals in Infection Control**

Category : **Nurse**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

As an Infection Prevention and Control Pracitioner of 15 years and health care consumer, I am very supportive of CMS's initiatives to identify preventable events, including infections, that should not occur as a result of providing health care. However, I do not support all that is being proposed. Implementation must be in a manner that lends to the event being identifiable through appropriate and consistent criteria, events that are truely preventable, are of high risk as a complication in cost in dollars and lives, and realistically able to be identified without causing extreme burden on the available resouces.

The MS-DRG system requiring implementation of □present on admission (POA)□ codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.

I DO NOT SUPPORT the following three events identified by CMS: number 1, catheter-associated urinary tract infections; (2) pressure ulcers and (6) Staphylococcus aureus septicemia,because things ARE NOT always reasonably preventable, even when reliable science and appropriate care processes are applied in the treatment of patients; not all infections can be prevented, and each of these conditions carry with them unintended, far- reaching consequences. because each condition depends on the ability to identify them properly as well as accurate use of POA codes. This would take enormous training but still may not result as true and accurate due to the significant number of factors that are related to being actually healthcare acquired.

I DO SUPPORT the following: number 3, object(s) left during surgery; (4) air embolism, and (5) blood incompatibility, whereas these conditions are identifiable by discrete ICD-9 codes and can be coded for by hospitals without dependence on POA codes.These extremely harmful events have known methods of prevention.

I do suggest CMS continue to address the coding challenges for ventilator-associated pneumonia, vascular catheter-associated infections, and surgical site infections in order to determine if these conditions warrant inclusion in the CMS□s hospital-acquired conditions policy in the future, since they are important causes of healthcare-associated mortality and morbidity. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under the current coding methods.

A more realistic and reliable approach would be to not depend on POA codes, but instead require coding and cross referencing for vascular- associated infections (which includes infections associated with all vascular devices, implants and grafts) and infections such as septicemia; both of which would necessitate the creation of a unique ICD-9-CM code.While there is no specific code for catheter-associated blood stream infections, there are specific codes for insertion of catheters.

There are prevention guidelines for surgical site infections, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, suggest select a single high volume, high risk surgical procedure, such as coronary artery bypass graft codes (without valve), for which there is a CC code for mediastinitis and for which there are guidelines addressing preventability.

There also needs to be clarification from CMS on how hospitals may appeal a CMS decision.

Thank you for consideration of my comments.

CMS-1533-P-253-Attach-1.DOC

#253

June 11, 2007

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: Comments regarding CMS–1533–P

As an Infection Prevention and Control Pracitioner of 15 years and health care consumer, I am very supportive of CMS's initiatives to identify preventable events, including infections, that should not occur as a result of providing health care. However, I do not support all that is being proposed. Implementation must be in a manner that lends to the event being identifiable through appropriate and consistent criteria, events that are truely preventable, are of high risk as a complication in cost in dollars and lives, and realistically able to be identified without causing extreme burden on the available resources. The MS-DRG system requiring implementation of "present on admission" (POA) codes will demand enormous resources in a very short time period for training and education of clinical and coding staff and still not result as true and accurate due to the significant number of factors that ar related to determination of being actually a healthcare acquired infection.

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There also needs to be clarification from CMS on how hospitals may appeal a CMS decision.

Thank you for consideration of my comments.

Sincerely,
Wanda Strzemienski, RN, CIC

CMS-1533-P-254 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Edward Karlovich** **Date & Time:** **06/11/2007**

Organization : **UPMC**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attached letter for all comments proposed by UPMC

CMS-1533-P-254-Attach-1.DOC

CMS-1533-P-254-Attach-2.DOC

#254

June 11, 2007

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

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

#254-2

June 11, 2007

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

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

CMS-1533-P-255 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Patti S Grant** **Date & Time:** **06/11/2007**

Organization : **Ms. Patti S Grant**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-255-Attach-1.DOC

#255

06/11/07

Leslie V. Norwalk, Esq.
Acting Administrator,
Centers for Medicare & Medicaid Services
Attention:
CMS–1533–P, Mail Stop C4–26–05,
7500 Security Boulevard,
Baltimore, MD 21244–1850.

Dear Leslie Norwalk, Esq.,

As a 16-year member of the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) I feel compelled to comment on the initiative of including infectious events in the Present on Admission (POA) initiative, as it has the potential to impact me negatively as a healthcare consumer and, as an infection prevention and control professional. While I share the CMS vision of preventing adverse events in the patients our healthcare system serve, I worry about the financial and human resource issues this may unknowingly negatively impact.

Unlike the proposed POA items #3 (objects left during surgery), #4 (air embolism, and #5 (blood incompatibility), which have definitive and easily retrievable billing codes, those involving the proposed *infectious events* (#1 catheter-associated urinary tract infection, #2 pressure ulcers, and #6 Staphylococcus aureus septicemia) do not. The latter require a strong clinical component, as assessed by a trained medical professional, to cull out the presence of a healthcare-associated infection (HAI) as defined by the Centers for Disease Control and Prevention's, National Healthcare Safety Network (NHSN) definitions of infection. The billing codes are designed for reimbursement and not diagnosis; therefore, a human element must be present in identifying HAI specific POA's.

I believe a referenced and more comprehensive response is being forwarded by the APIC organization, and, am offering this letter as a succinct affirmation as a member of our 11,000 member organization dedicated to the prevention of infection and adverse events in healthcare.

Please contact me as outlined below for any clarification and/or if you have any questions.

Sincerely,

Patti Grant, RN, BSN, MS, CIC
Practitioner: Infection Prevention and Control
214-686-7249

CMS-1533-P-256 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Roger Sarao** **Date & Time:** **06/11/2007**

Organization : **New Jersey Hospital Association**

Category : **Hospital**

Issue Areas/Comments

Impact--Overall Conclusion

Impact--Overall Conclusion

Attached is a copy of the New Jersey Hospital Association's (NJHA) comments on the FY 2008 IPPS proposed rule.

While the NJHA 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), the cuts to capital payments, and the elimination of the imputed wage index floor for entirely urban areas. We also use this opportunity to voice our opposition to the expiration of the Sec. 508 reclassifications, though this provision is not technically part of the proposed rule.

Some of the impacts associated with the proposed reductions include:

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 to eliminate what you claim will be the effect of classification changes that do not reflect real changes in case-mix. For New Jersey hospitals, this will reduce Medicare operating payments by $864 million over five years.

Capital Payment Update

In addition to the 2.4 percent □behavioral offset□ reduction to capital payments in both FYs 2008 and 2009, 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 $221 million over five years to New Jersey hospitals □ all of which are classified as urban for Medicare payment purposes.

We also oppose the consideration of possible future cuts to the indirect medical education and disproportionate share hospital adjustments under the capital system. The elimination of these adjustments would result in additional reductions for New Jersey hospitals of $150 million over five years. CMS should not make any cuts or other adjustments to the capital PPS.

Expiration of the Imputed Floor

The NJHA is opposed to language included in the FY 2008 inpatient PPS proposed rule that would discontinue the imputed □rural□ floor wage index for all-urban states originally implemented as part of the FY 2005 inpatient PPS final rule. We urge you in the strongest possible terms to

make permanent the imputed rural floor policy which has led to a long-overdue climate of symmetry, equity and consistency in the Medicare reimbursement process for hospitals in New Jersey.

We firmly believe New Jersey being the only state in the nation that would benefit from this policy prospectively should not serve as rationale for eliminating the policy, but rather enhance and underscore the policy justifications for its continuation that CMS itself acknowledged and affirmed in 2005. The elimination of this vital provision would impact over 30 New Jersey hospitals by $62 million in FY 2008 alone or more than $300 million over the next five years.

CMS-1533-P-256-Attach-1.DOC

#256

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; Proposed Rule (Vol. 72, No. 85), May 3, 2007

Dear Ms. Norwalk:

On behalf of our 116 member hospitals, health systems and other health care organizations, the New Jersey Hospital Association (NJHA) 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 NJHA 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), the cuts to capital payments, and the elimination of the imputed wage index floor for entirely urban areas.

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** to eliminate what you claim will be the effect of classification changes that do not reflect real changes in case-mix. **For New Jersey hospitals, this will reduce Medicare operating payments by $864 million over five years.** In addition, the rule proposes continuing the three-year transition to cost-based relative weights, with two-thirds of the FY 2008 weight based on costs and one-third based on charges.

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

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

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

CAPITAL PAYMENT UPDATE

In addition to the 2.4 percent "behavioral offset" reduction to capital payments in both FYs 2008 and 2009, 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 $221 million over five years to New Jersey hospitals – all of which are classified as urban for Medicare payment purposes.**

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. The elimination of these adjustments would result in additional reductions for New Jersey hospitals of $150 million over five years.** CMS should not make any cuts or other adjustments to the capital PPS.

EXPIRATION OF THE IMPUTED FLOOR

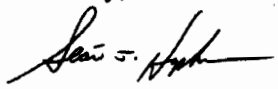
The NJHA is opposed to language included in the FY 2008 inpatient PPS proposed rule that would discontinue the imputed "rural" floor wage index for all-urban states originally implemented as part of the FY 2005 inpatient PPS final rule. We urge you in the strongest possible terms to make permanent the imputed rural floor policy which has led to a long-overdue climate of symmetry, equity and consistency in the Medicare reimbursement process for hospitals in New Jersey.

We firmly believe New Jersey being the only state in the nation that would benefit from this policy prospectively should not serve as rationale for eliminating the policy, but rather enhance and underscore the policy justifications for its continuation that CMS itself acknowledged and affirmed in 2005. **The elimination of this vital provision would impact over 30 New Jersey hospitals by $62 million in FY 2008 alone or more than $300 million over the next five years.**

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 Roger Sarao, assistant vice president of Health Economics, at 609-275-4026 or rsarao@njha.com.

Sincerely,



Sean J. Hopkins
Senior Vice President
Health Economics

New Jersey 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 NJHA 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. We also urge CMS to consider the American Hospital Association's (AHA) comments on CMS' interim report on the strategic plan required by the *Deficit Reduction Act of 2005* (DRA).

SEVERITY OF ILLNESS

For FY 2008, CMS proposes to refine the current DRG system by implementing Medicare-Severity DRGs (MS-DRGs), increasing the number of DRGs from 538 to 745. In addition, CMS

has undertaken an overhaul of today's complication and comorbidity (CC) list and created up to three tiers of payment for each DRG based on the presence of: a ***major*** complication or comorbidity (MCC), ***a*** complication or comorbidity, or ***no*** complication or comorbidity.

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 NJHA opposes the "behavioral offset," which will cut *operating* payments to New Jersey hospitals by $864 million over the next five years. We do not believe that this cut is warranted – it is a backdoor attempt at budget cuts.** [Note: we include the impact of the "behavioral offset" on capital payments, along with other proposed reductions to capital payments, in the section titled "Capital IPPS."]

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. The AHA 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. 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. The AHA 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, we disagree with the removal of many common secondary diagnoses.

The NJHA concurs with the AHA in making 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.

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.

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.

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 NJHA and the AHA (along with their 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.

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 – including the 2.4 percent "behavioral offset" reduction in both FYs 2008 and 2009 and the discontinuation of the IME and DSH adjustments – would amount to a decrease in capital payments to New Jersey hospitals of $371 million over the next five years that our hospitals cannot sustain in an already under-funded system.**

Capital cuts of this magnitude will disrupt hospitals' ability to meet their existing long-term financing obligations for capital improvements. Hospitals have committed to these improvements under the expectation that the capital PPS would remain a stable source of income. Reducing capital payments would create significant financial difficulties and amounts to Medicare reneging on the full cost of caring for America's seniors and disabled. **The NJHA 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. Thus, **hospitals in New Jersey will be disproportionately affected by these capital reductions, as 80 percent of our hospitals are considered "large urban" and half of our hospitals have teaching programs.** 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 NJHA 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.

WAGE INDEX

EXPIRATION OF THE IMPUTED FLOOR

The NJHA is opposed to the language included in the FY 2008 inpatient PPS proposed rule that would discontinue the imputed "rural" floor wage index for all-urban states originally implemented as part of the FY 2005 inpatient PPS final rule. **We urge you in the strongest possible terms to make permanent the imputed floor policy which has led to a long-overdue climate of symmetry, equity and consistency in the Medicare reimbursement process for hospitals in New Jersey.**

CMS has already acknowledged the clear financial and competitive disadvantage suffered by all urban states in the absence of an imputed floor wage index. In its FY 2005 inpatient PPS proposed rule, it referenced the existence of one predominant labor market in New Jersey and acknowledged that this situation "forces hospitals that are not located in the predominate labor market area to compete for labor with hospitals that are in that area" and that "because there is no "floor" to protect those hospitals not located in the predominate labor market area from facing continued declines in their wage index, it becomes increasingly difficult to compete for labor."

We submit to you that New Jersey's geographic disadvantage remains as significant today as it was when CMS originally acknowledged the situation in the above comments. New Jersey is unique from the rest of the country in that it is bordered by the first and fifth largest cities in the United States. Therefore New Jersey hospitals have been and continue to be forced to compete for labor resources and patients in each of these markets.

When first implemented, three states were impacted by the imputed floor: Massachusetts, New Jersey and Rhode Island. In the very first line of its explanation for discontinuing the policy in the FY 2008 inpatient PPS proposed rule, CMS states, "After further considering the issue, we do not believe that it is necessary to have an "imputed" rural floor in states that have no rural areas or no rural floors...the imputed floor would not apply to two of the three states: it is not necessary for Rhode Island and is no longer necessary for Massachusetts."

We firmly believe New Jersey being the only state in the nation that would benefit from this policy prospectively should not serve as rationale for eliminating the policy, but rather enhance and underscore the policy justifications for its continuation that CMS itself acknowledged and affirmed in 2005. **The elimination of this vital provision would impact over 30 New Jersey hospitals by $62 million in FY 2008 alone or more than $300 million over the next five years.**

Further, CMS has contradicted itself by stating in the FY 2008 proposed rule that "we believe the policy should apply only when required by statute." However, in the FY 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" by citing Social Security Act (SSA) section 1886(d)(3)(E) as the basis of 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, CMS has repeatedly in the past 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.

The absence of the imputed wage index floor for all-urban States in the Medicare wage index calculation would once again subject New Jersey's hospitals to a significant competitive disadvantage and dramatically impact their ability to continue providing affordable, accessible and quality healthcare to the residents of our State.

Again, we urge you to make permanent the imputed rural wage index floor for all-urban states in the final FY 2008 inpatient PPS rule.

EXPIRATION OF MMA SEC. 508

Although not part of the FY 2008 inpatient PPS proposed rule, the NJHA would like to take this opportunity to comment on the expiration of another wage index-related provision – the one-time reclassification opportunities provided under Section 508 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We urge you to extend this critical provision, which is now set to expire in September 2007.

Section 508 directed CMS to create a one-time geographic reclassification procedure for certain hospitals that fell just outside Medicare's existing criteria for reclassification from their current geographic areas into an adjoining area with higher payment rates, but were deemed to be in need of relief.

As a result of Section 508's implementation, 121 hospitals nationwide, including seven hospitals in New Jersey, were permitted to reclassify into a different labor market with a higher wage index, and therefore be reimbursed more appropriately by Medicare for the critical services they provide to our communities and constituents. These New Jersey hospitals, which must compete with hospitals in neighboring areas that enjoy more favorable reimbursement rates, would be negatively impacted should Section 508 not be extended.

In the waning days of the 109th Congressional session, Congress passed H.R. 6408, the Tax Relief and Health Care Act of 2006 (PL 109-432) that extended Section 508 for six months (from April 30 to September 30, 2007).

The NJHA is working with our congressional delegation for legislation to extend this important provision.

HOSPITAL QUALITY DATA

The DRA expanded quality reporting requirements for hospitals to be eligible to receive a full market basket update. The DRA provided the Secretary with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures on

the basis that they are no longer appropriate. In the proposed rule, CMS puts forward five new measures – four process measures and one outcome measure – to be included for the FY 2009 annual payment determination. To receive a full market basket update, hospitals would have to pledge to submit data on these and all measures currently included in the Hospital Quality Alliance's (HQA) public reporting initiative for patients discharged on or after January 1, 2008. In addition, hospitals would have to pass data validation tests for data submitted in the first three calendar quarters of 2006.

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

Adoption by the HQA is only one of three criteria that we believe all new measures included in the pay-for-reporting program should fulfill. In addition to HQA adoption, all measures should be endorsed by the National Quality Forum (NQF) through its consensus review process. We appreciate CMS' statement that, should any of the measures proposed for FY 2009 not receive NQF endorsement by the time of publication of the final rule, they will not be adopted for FY 2009. Finally, prior to inclusion in the pay-for-reporting program, all measures should undergo a field test to observe for any operational issues and assess the degree to which the measures can be implemented successfully by hospitals and data vendors.

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

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

We commend CMS for including in the proposed rule the measures that hospitals will be required to report to receive their full FY 2009 inpatient payments, as this early notice allows

hospitals sufficient time to establish the proper data collection processes. **We urge CMS to continue with this timely rulemaking to notify hospitals of the reporting requirements for the next fiscal year.**

Measure maintenance. The NJHA 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.

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 NJHA 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.

If the validation process that is used calls into question the data submitted by a hospital, 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 NJHA 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.

RURAL FLOOR – BUDGET NEUTRALITY ADJUSTMENT

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 NJHA 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 NJHA supports implementation of a physician-ownership disclosure requirement.**

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

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

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

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

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

PATIENT SAFETY MEASURES

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

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

While these requirements may sound reasonable, we believe they miss the mark on the real issue to be addressed: safety concerns in physician-owned specialty hospitals.

It makes sense to apply special requirements like these to physician-owned specialty hospitals, but not to all hospitals. The reason: The safety concerns that have been raised with physician-owned specialty hospitals occur because these facilities operate outside the traditional network of care delivery in this country. They are free-standing facilities, are generally not part of a larger system of care, most often have no transfer agreements with other hospitals or providers of care in a community, and tend to specialize in one type of care delivery, challenging their ability to treat the unexpected event or emergency.

This is not the case with full-service community hospitals. Full-service community hospitals are part of a network of care in their community, involving referrals from local physician practices, reliance on local trauma support networks, participation in local emergency medical transport systems and transfer agreements among facilities. Even small and rural hospitals located in more remote areas are part of a planned network of care and patient triage. Small and rural hospitals often stabilize and transport patients to other facilities, but that transport is communicated, the receiving hospital is alerted and the patient's clinical information collected at one hospital goes with the patient to the next hospital. Small and rural hospitals also are often connected to a system of care through telemedicine, which allows for access in more remote areas to specialists and other clinical expertise available at larger, more urban hospitals. Applying additional requirements for this group of hospitals is unnecessary and costly.

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

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

IME ADJUSTMENT

In the FY 2007 final rule, CMS finalized a policy to exclude residents' time spent in non-patient care activities from the resident count for purposes of IME (in all settings) and direct graduate medical education (in non-hospital settings) payments. Since that time, the agency has received questions about the treatment of vacation or sick leave and orientations. While recognizing that

this time is neither devoted to patient care nor non-patient care, but rather a third category, the proposed rule would treat vacation and sick time differently than it would treat orientation time. Orientation time would continue to be included as part of the full-time equivalent (FTE) count, as it always has.

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

The NJHA 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.

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 NJHA also is disappointed that CMS has not increased the marginal payment rate to 80 percent rather than 50 percent, consistent with the outlier payment methodology, as we previously requested.**

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

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

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in committee language for the MMA, recommended that the Secretary undertake the regulatory process to

upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology, as required under the *Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000.*

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

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

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

We strongly recommend that the Secretary expeditiously undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS. HHS should take the necessary steps to avoid being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than to respond to the significant problems that will likely result in unreasonable implementation time frames. It is imperative that the rulemaking process start immediately.

CMS-1533-P-257 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Stanley Shrodo** **Date & Time:** **06/11/2007**

Organization : **Central NJ Brain Tumor Support Group**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

Thank you for your consideration of this important matter!

Stanley J Shrodo
sshrodo@optonline.net

CMS-1533-P-258 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Virginia Shrodo** **Date & Time:** **06/11/2007**

Organization : **Central NJ Brain Tumor Support Group**

Category : **Individual**

Issue Areas/Comments
DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

You propose the following titles for these MS-DRGs:

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

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

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

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

Thank you for your consideration of this important matter!

Virginia K Shrodo
vshrodo@optonline.net

CMS-1533-P-259 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Teri Caughlin** **Date & Time:** **06/11/2007**

Organization : **Ms. Teri Caughlin**

Category : **Individual**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

I agree with National APIC and do not support the following three preventable events identified by CMS: number 1, catheter-associated urinary tract infections; (2) pressure ulcers and (6) Staphylococcus aureus septicemia, because each condition depends on the ability to identify them properly as well as accurate use of POA codes. Two states currently using POA codes report a minimum of two years needed to achieve reliability much longer than the January 1, 2008 timeframe proposed by CMS.

CMS-1533-P-260 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Susan Schuster** **Date & Time:** **06/11/2007**

Organization : **Wyoming Valley Health Care System**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-260-Attach-1.DOC

WYOMING VALLEY
HEALTH CARE SYSTEM

June 11, 2007

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

RE: CMS 1533P, Inpatient Prospective Payment Systems Proposed Rule

Dear Ms. Norwalk:

Wyoming Valley Health Care System is a not for profit community hospital of over 400 beds located in Northeastern Pennsylvania. We are appreciative of 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) as published in the Federal Register on May 3, 2007. Our comments will be addressed to the following sections of the proposed rule.

Medicare Severity Diagnosis Related Groups

CMS has proposed the implementation on October 1, 2007 of MS DRGs. While our hospital is in agreement that a severity adjusted DRG system is necessary, the immediate impact of beginning the MS DRGs on October 1, 2007 will be extremely detrimental to our facility. We anticipate a decrease in our reimbursement of approximately $2 million dollars due to these new DRG's. Since one of the fundamental values of a prospective payment system is the ability of providers to reasonably estimate payments in advance in order to adequately budget, market and staff their facilities, a radical and unknown system such as the MS DRGs will not meet any of these fundamental values.

While we concur that the MS DRGs are a step towards refinement of the existing DRG system, it is the abrupt and rushed execution of this system that greatly concerns us. This system will create extensive changes in the way accounts are coded and paid and as of this moment in time we are unable to access an MS DRG grouper with which to analyze our data, orient our nursing staffs and train our coding staffs along with our physicians. With the publication of a final rule on or about August 1, 2007, it will be very difficult to be fully prepared to be thoroughly versed and educated in this new system within the 60 days till it is mandated.

We recommend that CMS adopt a multi year transition to this more extensive classification system, similar to how the change from charge based weights are in the process of being transitioned to cost based weights for the DRGs. This transition involving a recalibration of the existing DRG weights and the new MS DRG weights should not begin until FY 2009. This will give CMS adequate time to finalize data and a CC list, introduce and test software for case classification and payment and train its fiscal agents. This one year deferral will also give hospitals adequate time to implement and test the new system and adjust their operations and staffing for predicted revenues. It will also allow vendors and state agencies time to incorporate such changes into their respective software and information systems.

Given the estimated massive shifting of dollars within the system amongst hospitals, a three or four year transition would be seemly.

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".

Without adequate data to support this decrease, it is patently unfair to hospitals to penalize them for an anticipated result without concrete proof of its occurrence. The MS DRG system is a refinement of the present DRG system, not a completely new coding system. The same coding rules that applied before still apply under the new system but with enhancements. There is simply not that much room in legitimate coding to create this type of potential opportunity.

We vehemently oppose this 2.4% behavioral offset and feel it should be removed from the final rule.

Capital IPPS

A separate capital prospective payment system was created to pay hospitals for items such as depreciation, interest, taxes, insurance and similar expenses for new facilities, renovations and additions to existing facilities, and new expensive clinical equipment and systems. CMS is proposing in this rule to eliminate the 0.8% capital update for all urban hospitals and the 3% large urban hospital add-on, while still proposing to update capital payments by 0.8% to rural hospitals. Along with this would be the elimination of the IME and DSH adjustments included in the capital payments.

Hospitals are faced with increasingly expensive price tags on new clinical equipment necessary to remain current and up to date with their services. Buildings must also be built and or renovated to deal with the changing inpatient/outpatient mix of patients and ancillary programs. The majority of hospitals are not making money on the capital component of the IPPS.

Taking away the capital update will hurt hospitals and make it very difficult to continue to purchase items and systems such as the EMR or electronic medical record. Large urban hospitals and teaching hospitals are extremely disadvantaged by these reduced payments and they are the facilities in which much of the innovative and cutting edge technologies are offered to patients.

Occupational Mix Adjustment

We feel that CMS' proposal to use the area's average adjustment for non-responsive hospital and the national average adjustment for non-responsive counties is reasonable, but that for FY 2009 and beyond a better method needs to be developed so that hospitals are required to report and those neighboring hospitals which do report would not be penalized.

Wage Index

The contracted services section of the wage index is a component of the IPPS which is subject to much debate and manipulation. All wages, whether direct patient related or contracted for overhead services, should be included in a hospital's wage index to accurately account for the true costs of labor in operating the hospital. As the current methodology for the calculation of wage index is presently under review by both MedPac and CMS, it is recommended that no further arbitrary changes be made to the wage index calculation at this time. The calculation process already creates vast inherent discrepancies in hospital payment rates due to the current systems lack of consistency in applying data relative to average wages. By example, for those organizations that utilize a service organization structure for the employment of certain low paying but necessary support positions such as environmental services and dietary, hospitals with said structure can avoid counting the hours and lower wages within the calculation of their "average hourly wage" thus inflating their resulting wages for the purposes of wage index. Until such time that the system forces consistency as to which wages must be calculated and accounted for within all hospitals, the average wage number will be inaccurate and able to be manipulated for the purposes of wage index calculations. We therefore propose no further arbitrary calculations be incorporated until such time that the MedPac and CMS proposals for long-term and permanent changes to this process be proposed and assessed.

WYOMING VALLEY
HEALTH CARE SYSTEM

IME Adjustment

The proposed rule would remove vacation and sick time from the total time which would be counted in the Full Time Equivalent status of a resident. While it is agreed that this time is not technically either patient care nor non patient care, this proposal would treat this benefit time differently than it does time spent by a resident in orientation. Removing sick and vacation time from both the numerator and denominator of the FTE calculation would result in lower FTE counts for some hospitals and higher counts for other hospitals, solely due to their benefit policies and this change.

This would be administratively unmanageable. The sick and vacation time would need to be allocated somehow amongst the residents rotations during the year and could only lead to other specific areas of time being reviewed to the point where the residents would be spending more time tracking their time for lunches, meetings, etc, than being involved in patient care.

We suggest that this sick time and vacation time be continued to count as patient care time, the same way that the time is currently counted.

Replaced Devices

CMS in the 2007 OPPS final rule adopted a policy in which a payment to a hospital will be reduced when a device is provided to the hospital at no cost. CMS is proposing in this inpatient rule to reduce the amount of the Medicare inpatient PPS payment when a full or partial credit towards a replacement device is made or when the device is replaced without cost to the hospital or with full credit for the removed device. CMS is proposing that new condition codes be used to report these instances which would then require manual processing by fiscal intermediaries. It would also require the hospital to provide a paper invoice or other information to the FI or MAC to show the normal cost of an item and the amount of credit received.

We totally disagree with this proposal. The DRG system is developed based upon averages and prior history of claims. Therefore the average cost or lack of cost should be already in the historical files from which CMS derives the cost weights for those selected DRG's which involve implantations. Direct costing of the device on a patient specific basis would be creating additional cost in and of itself to implement.

Sincerely,
Wyoming Valley Health Care System
575 North River Street
Wilkes-Barre, PA 18764

CMS-1533-P-261 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Edward Karlovich** **Date & Time:** **06/11/2007**

Organization : **UPMC**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attached letter for comments

CMS-1533-P-261-Attach-1.DOC

#261

June 11, 2007

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

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." ...
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> "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."...
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> " 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." ...
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> "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

CMS-1533-P-262 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Scott Taylor** **Date & Time:** **06/11/2007**

Organization : **St. Catherine Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-262-Attach-1.PDF

#262

CATHOLIC HE .
INITIATIVES

St. Catherine Hospital

June 11, 2007

Leslie Norwalk, Esq.
Acting Administrator
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, D.C. 20201

REF: CMS-1533-P

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates; Proposed Rule, May 3, 2007

Dear Ms. Norwalk:

St. Catherine Hospital appreciates the opportunity to comment on the proposed rule CMS-1533 -P. St. Catherine Hospital is a faith-based, mission-driven health system that includes 72 hospitals, 42 long-term care, assisted-living and residential units, and two community health service organizations in 19 states.

Our national hospital associations will be providing you with more extensive comments on the proposed rule that reflect many common concerns. St. Catherine Hospital would like to offer input on the following selected issues:

DRG REFORM AND PROPOSED MS-DRGS:

Severity of Illness

For Fiscal Year (FY) 2008, the Centers for Medicare and Medicaid Services (CMS) proposes refinement of the current DRG system by implementing Medicare-Severity Diagnosis Related Groups (MS-DRGS), increasing the number of DRGs from 538 to 745.

CMS also proposes revision of the current complication and comorbidity (CC) list with up to three tiers of payment for each DRG based on the presence of a major complication or comorbidity, complication or comorbidity, or no complication or comorbidity.

St. Catherine Hospital supports the adoption of a new or revised DRG classification system to better account for differences in patient severity and resource consumption. The proposed MS-DRG system may be a substantial improvement over the current system. However, the proposed changes have not been reviewed by the RAND Corporation, the company retained by CMS to evaluate alternative classification systems. We believe an independent review and evaluation of the MS-DRGs should be undertaken before the new system is implemented to make sure this is the best approach.

Hospitals should not be subjected to the administrative burdens and financial consequences of changing to a new DRG system only to have it change again if the system is found to be flawed. Hospitals need stability and predictability in their payments to respond to the health care needs of their communities. When a new severity DRG is implemented, hospitals will also need an adequate transition period to prepare for the significant redistribution of payments that will occur with the changes.

St. Catherine Hospital urges CMS to delay implementation of the MS-DRGs for one year to allow independent review of the proposal's ability to differentiate cases based on severity of illness and resource consumption. When and if a new severity DRG system is implemented, CMS should provide an adequate transition period to allow hospitals time to prepare for and adjust to significant redistribution of payments that will occur as a result of these changes.

Behavioral Offset

The proposed rule includes a 2.4% cut in Medicare payments to hospitals in FY 2008 and 2009 to eliminate what CMS claims will be the effect of coding or classification changes under the revised DRG system that do not reflect real changes in case-mix. CMS proposes this "behavioral offset" based on assumptions that we believe are not supported by data or experience.

This behavioral offset would cause significant and unjustified financial harm to St. Catherine Hospital. The behavioral offset appears to be a back-door attempt to budget cut rather than a valid regulatory proposal.

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, looking at claims between 1986 and 1987 at the beginning of the inpatient prospective payment system (PPS), showed only a 0.8% 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.

Once 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

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is necessary. CMS is not required to make an adjustment beforehand and should not do so without an understanding of whether there will even be coding changes in the first few years of a refined system. CMS can always correct for additional payments made as a result of coding change in a later year if there is sufficient evidence to warrant an adjustment.

St. Catherine Hospital urges CMS to remove the 2.4 percent behavioral offset for FY 2008 and FY 2009.

CAPITAL IPPS:

For FY 2008 and FY 2009, CMS proposes no capital update for urban hospitals (a 0.8 percent cut) and a 0.8% update for rural hospitals. For FY 2008 and beyond, CMS proposes elimination of the large urban hospital add-on (an additional 3 percent cut). CMS is considering discontinuing the IME and DSH adjustments to capital payments.

CMS also proposes applying the same 2.4 percent cut to capital payments that it proposes applying to operating payments as a behavioral offset in anticipation of the new MS**DRGs.**

These cuts are unnecessary and inappropriate. CMS justifies the capital cuts based on an analysis that purports to show that hospitals are experiencing substantial positive margins under the capital payment framework. This analysis was based on a snapshot of capital margins rather than the full capital cycle of 15-20 years. Hospitals have capital expenditure cycles that involve a period of replacing/accumulating capital reserves and another period of making substantive capital expenditures. This cycle runs over the course of years, not annually.

The Medicare Payment Advisory Commission (MedPAC) has determined that overall Medicare margins will reach a 10-year low in 2007 at negative 5.4 percent. Whether or not hospitals experience a narrow positive margin for their capital payments is of small consequence to a hospital losing money, on average, every time it treats a Medicare beneficiary.

Capital cuts of the magnitude proposed by CMS would disrupt hospitals' abilities to meet their existing long-term financing obligations for capital improvements. Hospital have committed to these improvements under the expectation that the capital PPS would remain a stable source of income. Reduced capital payments would make buying the advanced technology and equipment that patients expect much more difficult for our hospitals and could slow clinical innovation. In addition, investments in information technology will become even more challenging.

St. Catherine Hospital urges CMS to provide a full update in FY 2008 for urban and rural capital payments; maintain the large urban hospital capital add-on; eliminate the -2.4 percent behavioral offset for capital payments; and continue

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indirect medical education and disproportionate share hospital adjustments to capital payments.

HOSPITAL ACQUIRED CONDITIONS:

The Deficit Reduction Act of 2005 required the selection, by October 1, 2007, of at least two conditions that are: 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 second diagnosis; and could reasonably have been prevented through the application of evidence-based guidelines. Beginning October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission. CMS has identified 13 conditions it is considering and proposes six conditions for implementation in FY 2009.

St. Catherine Hospital supports implementation of this policy but believes CMS should start with a small number of conditions because there are significant challenges to correctly identifying cases that meet the criteria laid out by Congress. The use of secondary diagnoses to identify these conditions may not accurately identify hospital-acquired conditions as well as they should, particularly with regard to infections. Once the policy is implemented, CMS should study the first 6 months' experience with a validation process to make sure that hospital-acquired conditions are actually being identified.

CMS should start with the three conditions for FY 2009 that are identified by discrete ICD-9 codes and that can be coded by hospitals. Appropriate conditions to include for FY 2009 are: object left in during surgery; air embolism; and blood incompatibility. These are events that can cause great harm to patients and for which there are known methods of prevention. St. Catherine Hospital is committed to patient safety and strives to ensure that these events do not happen in our hospitals.

The remaining three of the six proposed conditions – catheter-associated urinary tract infections, pressure ulcers and staphylococcus aureus septicemia – are serious concerns but these conditions are not ready for inclusion in 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 implementation of present-on-admission coding has 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 and it will take time and intense educational efforts to achieve reliable data.

St. Catherine Hospital urges CMS to delay implementation of the payment classification changes for cases involving pressure ulcers, catheter associated urinary tract infections, and staphylococcus aureus until the necessary steps are taken to permit accurate identification of the relevant cases.

HOSPITAL QUALITY DATA:

401 East Spruce Street Garden City, KS 67846-5679
620.272.2222

In the proposed rule, CMS puts forward five new measures – four process measures and one outcome measure — to be included in the FY 2009 annual payment determination. To receive a full market basket update, hospitals must to pledge to submit data on these five new measures, as well as the 27 existing quality measures, for patients discharged on or after January 1, 2008.

St. Catherine Hospital appreciates this early notice on measures that hospitals will be required to report to receive their full FY 2009 inpatient payments. Significant lead time is needed to make arrangements with vendors and establish abstracting procedures for new quality measures. We encourage CMS to continue this practice.

We also appreciate that CMS has proposed adding measures that have already been adopted by the Hospital Quality Alliance (HQA) and agreed not to adopt any measures for FY 2009 that have not also been endorsed by the National Quality Forum (NQF) by the time of publication of the final rule.

St. Catherine Hospital urges CMS to continue to provide hospitals with advance notice of quality measures for the next fiscal year and to only require reporting of measures that are NQF-endorsed and HQA-adopted.

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.

We have no objection to this approach but CMS should remove the compounding effect of erroneously applying the budget-neutrality adjustment for the rural floor to the standardized amount annually since 1998. The rural floor budget-neutrality adjustment was repeatedly applied without first reversing the prior year's adjustment as is done with the outlier calculation each year.

CMS should remove the effects of the adjustments made from 1999 through 2006 by increasing the positive budget-neutrality adjustment proposed for the standardized amount to reverse the 2007 adjustment. None of these changes should limit the rights of affected hospitals to appeal for appropriate relief from the understated standardized amounts.

St. Catherine Hospital urges CMS to remove the compounding effect of applying the budget-neutrality adjustment for the rural floor to the standardized amount annually since 1998.

IME ADJUSTMENT:

CMS proposes removing vacation and sick leave from the total time considered to constitute a full time equivalent (FTE) resident for purposes of indirect medical education

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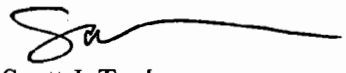
(IME) and graduate medical education (GME) payments, effective for FY 2008. CMS will continue to count time spent by residents in orientation activities for both IME and GME payments.

The proposal is not operationally practical. Hospitals would not only have to keep track of the leave for each resident but would also have to somehow apportion the leave to each of the hospitals the residents rotate through.

St. Catherine Hospital urges CMS to treat vacation and sick leave in the same manner as orientation time and include them as part of the FTE count.

Thank you for the opportunity to review and comment on the proposed IPPS rule for Fiscal Year 2008. If you have any questions, please feel free to contact me at 303-383-2693.

Sincerely,



Scott J. Taylor
President & CEO

SJT/ph

401 East Spruce Street Garden City, KS 67846-5679
620.272.2222

CMS-1533-P-263 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Audra Nowowiejski** **Date & Time:** **06/11/2007**

Organization : **Empire Health Services**

Category : **Nurse**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

please see attachment.

CMS-1533-P-263-Attach-1.DOC

Key points from APIC letter to Leslie Norwalk, Esq, Acting Administrator, Center for Medicare & Medicaid Services

- APIC and the CMS have a shared vision of preventing any adverse event, specifically infectious complications, in patients served in their respective care settings.
- APIC supports CMS in their effort to identify appropriate conditions that should not occur in our hospitals, thereby meeting criteria defined by Congress and also ensuring accuracy in the billing data that enables the appropriate identification of cases.
- The implementation of the MS-DRG system requiring implementation of "present on admission (POA)" codes will demand enormous resources in a very short time period for training and education of clinical and coding staff
- Of the six serious preventable events identified by CMS, APIC supports the following: number 3, object(s) left during surgery; (4) air embolism, and (5) blood incompatibility, whereas these conditions have been identified and supported by NQF; are identifiable by discrete ICD-9 codes and can be coded for by hospitals without dependence on POA codes.
- These extremely harmful events have known methods of prevention.
- APIC does <u>not</u> support the following three preventable events identified by CMS: number 1, catheter-associated urinary tract infections; (2) pressure ulcers and (6) Staphylococcus aureus septicemia, because each condition depends on the ability to identify them properly as well as accurate use of POA codes. Two states currently using POA codes report a minimum of two years needed to achieve reliability—much longer than the January 1, 2008 timeframe proposed by CMS.
- APIC looks to CMS to provide the educational support needed to reliably determine POA codes.
- APIC does not believe conditions 1, 2, and 6 are always reasonably preventable, even when reliable science and appropriate care processes are applied in the treatment of patients; not all infections can be prevented, and each of these conditions carry with them unintended, far-reaching consequences.
- APIC recommends that CMS continue to address the coding challenges for ventilator-associated pneumonia, vascular catheter-associated infections, and surgical site infections in order to determine if these conditions warrant inclusion in the CMS's hospital-acquired conditions policy in the future, since they are important causes of healthcare-associated mortality and morbidity. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic.
- APIC suggests and supports two approaches that do not depend on POA codes, but instead require coding and cross referencing for vascular-associated infections (which includes infections associated with all vascular devices, implants and grants) and infections such as septicemia; both of which would necessitate the creation of a unique ICD-9-CM code.
- While there is no specific code for catheter-associated blood stream infections, there are specific codes for insertion of catheters.
- While there are prevention guidelines for surgical site infections, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, APIC suggests selecting a single high volume surgical procedure, such as coronary artery

bypass graft codes (without valve), for which there is a CC code for mediastinitis and for which there are guidelines addressing preventability.

- APIC proposed consideration of post-operative sepsis, using a specific procedure code such as CABG (with or without valve)
- APIC requests clarification from CMS on how hospitals may appeal a CMS decision if an error in coding occurs and if a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or co-morbidity DRG payment.

CMS-1533-P-264 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs.** **Date & Time:** **06/11/2007**

Organization : **Intermountain Healthcare**

Category : **Hospital**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

See attached document

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

Proposed Selection of Hospital-Acquired Conditions

We urge CMS to consider the following regarding conditions that will be classified as present on admission (POA).

? 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; in those cases the physician would need to be queried prior to code assignment which would delay the billing process and have added pressure on coders and physicians. 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, 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.

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.

Please also 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. This would also increase utilization and costs for laboratory services that may not be necessary.

CMS-1533-P-265 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

Submitter : **Ms. Susan Brockman** **Date & Time:** **06/11/2007**

Organization : **Meriter Hospital**

Category : **Hospital**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

June 11, 2007

Leslie Norwalk, Esq.,
Acting Administrator,
Centers for Medicare and 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)

Dear Ms. Norwalk:

Meriter Hospital appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule for the fiscal year 2008 hospital inpatient prospective payment system (PPS). We oppose the proposed behavioral offset cuts related to the move to severity- adjusted diagnosis-related groups (DRGs) and the cuts to capital equipment.

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

' FY 08 No changes to payment; instead use the time to prepare: release a GROUPER and complication or comorbidity 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 on old DRGs.
' FY 10 Pay based on two-thirds MS-DRGs and one third on old DRGs.
' FY 11 Pay based fully on MS-DRGs.

Capital PPS
We oppose the capital inpatient PPS cuts 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 our existing long-term financing obligations for capital improvements. These cuts also could impede our adoption of information technology, clinical research and upgrades to our hospital infrastructure.

Thank you for the opportunity to respond.

Sincerely,

James L. Woodward
President and CEO

cc: Steve Brenton, Wisconsin Hospital Assn.
Meriter Leadership Council

CMS-1533-P-266 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Date & Time:** **06/11/2007**

Organization : **Intermountain Healthcare**

Category : **Hospital**

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

Coronary artery stents:Since the October 2005 ICD-9-CM revisions require three separate code assignments for angioplasty with coronary stent insertion, and since CMS only uses the first six reported procedures in the DRG classification process,we are concerned that significant procedures may be missed in future DRG analysis data because they are not sequenced within the first six procedures.With more care being provided on an outpatient basis,hospital inpatients tend to be sicker than in the past.There also has been an increasing demand for greater coding specificity.Both of these trends mean higher numbers of reportable diagnoses and procedures for many hospitals. For these reasons,please consider using all reported diagnoses and procedures, not just the first nine diagnoses and 6 procedures,in their DRG analysis and DRG classification process.Multiple level spinal fusion: For the proposed new DRG for non-cervical spinal fusions with a principal diagnosis of curvature of the spine or malignancy, codes 737.40-737.43 are included in the list of applicable principal diagnoses.However, these codes are manifestation codes, and, according to ICD-9- CM conventions,can never be sequenced as the principal diagnosis.The underlying etiology would be sequenced as the principal diagnosis.Therefore, these codes should not be included in the list of principal diagnoses for proposed DRG 546.Newborn age edit:As long as CMS has an age edit in the MCE,it should be accurate, up-to-date, and not include codes that could appropriately be assigned to older children or adults.If there are errors in this edit, an adult Medicare claim could be rejected due to inappropriate triggering of the newborn age edit.The introduction for Chapter 15 in ICD-9-CM states that the chapter includes conditions, which have their origin in the perinatal period even though death or morbidity occurs later.Some of those conditions in this chapter may potentially persist into adulthood.CMS should utilize the necessary expertise to develop and maintain pediatric edits on an up-to-date basis, or consider deleting this edit from the MCE.
Coding of Sepsis:ICD-9-CM requires that all patients admitted with sepsis have the underlying systemic infection to be coded as principal diagnosis.Invariably,this is grouping to MS-DRG 872.The SIRS codes, 995.91 and 995.92 are excluded as CCs under the proposed rule.However, since the underlying causes are NOT excluded, those qualifying as a MCC will always group to MS-DRG 871.For example, all SIRS due to pneumonia,even those without organ dysfunction, will group to MS-DRG 871 since pneumonia is a MCC.Since SIRS has relatively loose criteria (WBC over 12,000, Temp above 101, 'left shift') and since most pneumonias requiring hospitalization meet these criteria,there may be a push to document SIRS due to pneumonia on even the simplest case that have only a 2-3 day length of stay.The following is recommended:For DRGs 871 and 872 the underlying infections that are present on admission be excluded from qualifying as CCs or MCCs.Since septicemia or systemic infection has an underlying cause,the underlying cause should not count.This would prevent all the SIRS due to pneumonia from automatically grouping to DRG 872.We recommend that 995.93 and 995.94 not be excluded as CCs w/ pancreatitis.Patients with systemic inflammatory response due to pancreatitis meet Ranson's criteria and are sicker.Those that have acute organ dysfunction are even sicker than those without.That would be the case for burns,major trauma,and pancreatitis,995.93and 995.94 should qualify as a CC.Should they develop acute organ failure, those would qualify for a DRG with a MCC.Categorize 995.91as a CC whereas 995.92 be categorized as a MCC.Consider that 995.92 be only a CC since there is no differentiation between organ dysfunction and organ failure in this code

DRG Reform and Proposed
MS- DRGs

DRG Reform and Proposed MS-DRGs

We appreciate CMS efforts to better match resource use and payments through the proposed adoption of a severity-adjusted DRG system.However,the implementation of a severity-adjusted system should not occur on 10.1.07for the following reasons.The final RAND report is not due until 9.1.07.If the report indicates that one of the proprietary systems should be adopted, software vendors and hospitals will incur significant and unnecessary administrative burden to implement the MS-DRG classification system on 10/1/07 and a different severity-adjusted DRG classification system a year or two later. CMS should wait until the RAND report is published before selecting the severity-adjusted classification system that should be adopted by Medicare.Given the uncertainty about whether or not the proposed MS-DRG system will be implemented, most software vendors will likely wait to program the new classification system until after CMS publishes its final FY 2008 rule.This will make the timely implementation of the system extremely difficult for hospitals.Since adopting severity-adjusted DRGs represents the most significant change since the initial implementation of DRGs, there should be a minimum one-year period between the final rule for MS- DRGs and its effective date.This will allow software vendors□ time to program the new system,and it will give facilities time to update their computer systems as well as to educate personnel about the new system.In contrast,if one of the alternative proprietary systems is selected,there should be a two-year period between the final rule announcing the selected system and its effective date.Additional implementation time would likely be needed with the selection of a prietary system since the required programming by software vendors will probably be more complex, and some hospitals may also have to negotiate revised or new grouper software contracts.CMS says that it will reduce payment rates by 2.4% each year in FY 2008 and FY 2009 to account for increased case-mix growth due to improved documentation and coding changes.CMS assumption that the improved documentation and coding that occurred in Maryland under APR DRGs will occur in the entire nation under MS-DRGs does not seem reasonable.First, they are completely different systems.APR DRGs recognize severity of illness and risk of mortality vs.MS-DRGs that only recognize severity. The list of CCs used by the two systems to define severity of illness are different.The coding improvement related to the entire population of one small State cannot accurately project what will occur in just the Medicare population of all States.The proposed rule does not even provide enough information to know whether the coding improvement occurred uniformly across all APR DRGs vs.just for specific services, such as neonates and deliveries, which would not apply to the Medicare population.Maryland□s hospitals are paid under a state rate-setting system where an incentive to code accurately did not significantly affect what a hospital was paid.The classification system recently adopted by Maryland is much more complicated than what CMS is proposing and changed the coding incentives for Maryland hospitals.Generalizing the Maryland experience to the rest of the nation□s hospitals is an invalid comparison.
It was suggested in the preliminary RAND report that coders were practicing □effective□ coding (which was defined as coding only until a CC condition was found)Vs.□complete□ coding (which is coding the health record adhering to all coding guidelines, regardless of the DRG or presence of CC conditions.MS-DRGs are a refinement of the CMS DRG which coders have been using for 24 years;coders have and will continue to code utilizing official coding guidelines which advocates □complete□ coding;wedo not feel that there will be any change in coder behavior.By decreasing the payment rate by 2.4% or potentially 4.8% would be an unwarranted financial burden to health care proivers.

CMS-1533-P-267 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Marie Fornof** **Date & Time:** **06/11/2007**

Organization : **Mrs. Marie Fornof**

Category : **Nurse**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

I support the CMS vision to preventing adverse events and support the change in prospective payment for objects left during surgery, air embolism, and blood incompatibility as these conditions are readily identifiable by the ICD-9 codes and supported by NQF and my professional organization, APIC. They are also preventable in all circumstances. I do NOT support withholding payment for catheter-associated urninary tract infections, pressure ulcers, ventilator-acquired pneumonia and Staphlycoccus aureus septicemia.
There is much variation in the attempt to identify them properly as well as accurate use of POA codes. Indeed in 2 states using these codes for mandatory reportng, about 2 years was needed to assure even an apporach to accuracy. Additionally, while many of these infections and conditions are preventable, not all of them all. The APIC stance on zero-tolerance is not necessarily the same as zero infections. Those of us working in the field realize this well. As an example, SSIs are a gorup that can be extremely difficult to associate with a hospital event due to the definitions and variables that are a part of them. This is especially true since the majority of that time in most patients is not spent in the hospital but at home or in another institution. So, if we have a patient for 3 days, they have surgery, and go to a long-term care facility and on day 29 end up with an infeciton, who is penalized? This is very difficult to determine. We count infections out to 30 days if no implant and deep ones out to one eyar with an implant if we follow the CDC definitions. And, most of us use them and this is supported by APIC and SHEA since it gives us a common point of reference.
Aonther example of my concers is the reporting of a Staphylococcus aureus bacterimia. The way the regulation is now written it is not identified as only those due to a central-line. As the patient can also be the source of their own infection, the fact that it is not just the central-line bacterimias but ALL of them that would penalize us unnecessarily. These measures would be especially punative to those of us who are working in high-risk safety net hospitals and care for a larger percentage of our patients having poor access to medical care. This whole issue of prospective payment makes me cringe as less honorable facilities, and I will esp. single out for-profit institutions here, the right to refuse admission, unless in emergencies. This will force them to a safety-net facilitiy such as ours. Then you will see an overall downward spiral as we will be forced to care for more paitents and patients with a higher chance of complications while receiving fewere dollars for care. Even not-for-prifit, private facilites with narrow operating margins may selectively choose to underserve certain populaitons. I feel that the bill as it now stands has the potential for even more unfairly decreasing access to healthcare for certain population groups.
The bill must also provide better clarification of the appeals process for when errors do occur. CMS must be sure that coding issues are addressed and standardized in order to fairly pay facilities providing care to patients.
Marie E. Fornof, RN, BSN, CIC
Infection Prevention Manager
Denver Health and Hosptial Authority
777 Bannock St. MC 0980
Denver, CO. 80204

marie.fornof@dhha.org

CMS-1533-P-268 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

Some of the selected conditons, such as C-difficile associated disease and MRSA, are caused by treatment protocol prescribed for a principal diagnosis, and at other times, the patient is simply immuno-copromised. These patients are at risk for C-diff and MRSA. If hospitals start practicing defensive medicine, it will only add to the cost of care. There are sequelae and risks to any treatment which should not equate to poor care.

CMS-1533-P-269 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Dianne Ciccone** **Date & Time:** **06/11/2007**

Organization : **Ms. Dianne Ciccone**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

Thank you for your consideration of this important matter.

CMS-1533-P-270 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

Staphylococcal aureus Septicemia - There's recently beena "community-acquired" staph aureus septimcemia described in literature. Why penalize a provider for identifying and treating a complication, if this was caused by sloppy technique and/or a hospital that is seeing frequent infection?

CMS-1533-P-271 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

Catheter-Related UTI - At what point would a UTI be considered 'cathether-related'? Anytime a UTI develops after the placement of a Foley? Most physicians do not described UTIs in this way. So, even though there are ICD-9-CM codes to designate the condition (so that it meets the POA selection criteria), the likelihood is very slim that physicians will document the conditon as 'catheter-related' so that it may coded as such.

CMS-1533-P-272 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

Catheter-related UTI - Some surgical patients are more at risk than others for developing a catheter-related UTI. Patients who have had manipulation of their urinary tract are especially prone to UTIs. Hospitals would be unfairly penalized for this group of patients if catheter-related UTI were not present on admission.

CMS-1533-P-275 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Jeff Hastings** **Date & Time:** **06/11/2007**

Organization : **Indvidual**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

I am a 7 year survivor of an Anaplastic Astrocytoma grade 3. I'm stable right now, but I will have to have this treatment or a similar one in the future. Please keep it available for me.

Jeff Hastings
Wenatchee, Wa.

CMS-1533-P-276 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Douglas Payne** **Date & Time:** **06/11/2007**

Organization : **Bridgeport Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#276

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-1533-P-277 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Humberta Goncalves-Babbitt** **Date & Time:** **06/11/2007**

Organization : **Goncalves Law Office**

Category : **Attorney/Law Firm**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

I am the daughter of a recently diagnosed brain tumor patient and am writing to urge you in the strongest terms possible to change the structure of proposed MS-DRGs 23 and 24 so that all craniotomy cases involving the implantation of a chemotherapeutic agent (ICD-9-CM procedure code 00.10) would be assigned to MS-DRG 23.

You propose the following titles for these MS-DRGs:

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

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

I am urging that the DRGs be restructured so that their titles are the following:

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

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

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

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

Thank you for your consideration of this vitally important matter!

CMS-1533-P-278 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Vicki Wright** **Date & Time:** **06/11/2007**

Organization : **Mercy Hospital Western Hills, Cincinnati**

Category : **Nurse**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

As an Infection Control & Prevention specialist/ RN and member of the Association for Professionals in Infection Control, these are my concerns:
*APIC members support CMS in the effort to identify appropriate conditions that should not occur in hospitals, thereby meeting criteria defined by Confress and ensuring accuracy in the billing data enabling the appropriate identification of the cases. *Implementation of the MS-DRG system requiring implementation of "Present on admission (POA)" codes will demand enormous resources in a very short time period for training and education of clinical and coding staff.
*APIC does not support the following three preventable events identified by CMS: 1) catheter- associated urinary tract infections; 2)pressure ulcers; and 3) Staphylococcus aureus septicemia, because each condition depends on the ability to identify them properly as well as accurate use of POA codes
*APIC looks to CMS to provide the educational support needed to reliable determine POA codes.
*APIC does not believe these three conditions are always reasonable preventable: not all infections can be prevented
* APIC recommends that CMS contiune to address the coding challenges for ventilator-associated pneumonia, vascular catheter-associated infections, and surgical site infections in order to determine if these conditions warrant inclusion in the CMS's hospital-acquired conditions policy in the future, since they are important causes of healthecare-associated mortality and morbidity.
*APIC requests clarification from CMS on how hospitals may appeal a CMS decision if an error in coding occurs and if a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or co-morbidity DRG payment.
Thank you for your attention to this very important matter.

CMS-1533-P-279 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. laurie dobson** **Date & Time:** **06/11/2007**

Organization : **Mrs. laurie dobson**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Please keep this coverage--gliadel wafers have worked for my husband and it was vital that the aggressively treat the tumor in the early stages which this provided him. Thank you.
Laurie Dobson

CMS-1533-P-280 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Justine Coffey** **Date & Time:** **06/11/2007**

Organization : **American Society of Health-System Pharmacists**

Category : **Pharmacist**

Issue Areas/Comments

Hospital Quality Data

Hospital Quality Data

See attachment

Impact--Capital IPPS

Impact--Capital IPPS

See attachment

CMS-1533-P-280-Attach-1.DOC

CMS-1533-P-280-Attach-1.DOC

#280

American Society of
Health-System Pharmacists
7272 Wisconsin Avenue
Bethesda, Maryland 20814
(301) 657-3000
Fax: (301) 664-8877
www.ashp.org

June 11, 2007

Centers for Medicare & 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 Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the proposed change to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates. ASHP represents pharmacists who practice in hospitals and health systems. The Society's more than 30,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings, including inpatient, outpatient, home care, and long-term-care settings.

ASHP will comment on two sections of the proposed rule: (1) Capital IPPS and (2) Hospital Quality Data.

Capital IPPS

ASHP strongly recommends that CMS eliminate the capital cuts contained in the proposed rule. In particular, the elimination of the large urban hospital add-on adjustment to capital IPPS payments and the capital update for all urban hospitals could significantly impact on the ability of hospitals to purchase advanced technology and equipment, ultimately having a negative impact on patient safety and patient care.

ASHP policy supports the use of electronic information systems that enable the integration of patient-specific data that is accessible in all components of a health system, as well as technology that allows the transfer of patient information needed for appropriate medication management across the continuum of care. ASHP also strongly

encourages health systems to adopt machine-readable coding and point-of-care technology to (1) improve the accuracy of medication administration and documentation, (2) improve efficiencies within the medication-use process, and (3) improve patient safety. The identity of all medications should be verifiable through machine-readable coding technology and all medications should be electronically verified before they are administered to patients in health systems.

If CMS institutes these cuts in capital, hospitals will be hard-pressed to purchase and develop the advanced technology and equipment necessary to improve the accuracy of medication administration and patient safety. As a result, patient safety and patient care will be compromised.

Hospital Quality Data

The Deficit Reduction Act of 2005 (DRA) provides that the payment update for FY 2007 and each subsequent fiscal year will be reduced by 2.0 percentage points for any hospital paid under the Inpatient Prospective Payment System that does not submit certain quality data as specified by the Secretary. This proposed rule provides the proposed new quality measures, which include 1 new outcome measure and 4 new process measures, to be used for the FY 2009 annual payment determination.

ASHP commends CMS for including its proposed new quality measures for FY 2009 in the proposed rule, since this early notification will provide hospitals with time to prepare for the anticipated changes. As a member of the National Quality Forum (NQF), ASHP is also pleased that CMS will not finalize any measures that have not been endorsed by the National Quality Forum (NQF) prior to the publication of the FY 2008 IPPS final rule. ASHP believes that health care quality improvement programs should adopt standard quality measures that are developed with the involvement of pharmacists, are evidence-based, and promote the demonstrated role of pharmacists in improving patient outcomes.

ASHP appreciates this opportunity to present its written comments on the proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs

CMS-1533-P-281 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Scott Rodriguez** **Date & Time:** **06/11/2007**

Organization : **Mr. Scott Rodriguez**

Category : **Individual**

Issue Areas/Comments
DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

I am a family member and caregiver of a brain tumor patient. We are continually hopeful for research giving improved treatment options. One of these important treatments of late is the implantation of a chemotherapeutic agent at the time of surgery. The remarkable thing about this is that it attacks the cancer cells directly where it is implanted where as most chemotherapeutic agents would attack generally in the hopes of killing all cancer cells in the body, getting healthy tissue as well.

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

You propose the following titles for these MS-DRGs:

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

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

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

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

The financial impact of this change, would it occur, would be devastating to brain tumor patients and their families. Brain cancer has surpassed leukemia as the #1 cancer disease in children and is the #3 to cause death by disease in adults. Join us in the fight against brain cancer. Change the structure of the new MS-DRGs to allow all cases involving the implantation of devices to be assigned to MS-DRG 23, even without a MCC.

Thank you for your consideration of this important matter!

CMS-1533-P-282 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Stacie Rodriguez** **Date & Time:** **06/11/2007**

Organization : **Mrs. Stacie Rodriguez**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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Thank you for your consideration of this important matter!

CMS-1533-P-283 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Kelly McMullen** **Date & Time:** **06/11/2007**

Organization : **Mr. Kelly McMullen**

Category : **Individual**

Issue Areas/Comments
DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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Thank you for your consideration of this important matter!

CMS-1533-P-284 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Amy McMullen** **Date & Time:** **06/11/2007**

Organization : **Mrs. Amy McMullen**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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Thank you for your consideration of this important matter!

CMS-1533-P-285 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Gwen Mayes** **Date & Time:** **06/11/2007**

Organization : **Abiomed, Inc.**

Category : **Device Industry**

Issue Areas/Comments

DRG Reclassifications

DRG Reclassifications

(□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.

New Technology

New Technology

(□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.

CMS-1533-P-285-Attach-1.WPD

CMS-1533-P-285-Attach-1.WPD

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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 manufacturers 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 cardiotomy. 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

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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[1] 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[2]; 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.[3]

Two subsequent changes to the impatient 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.

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[1] 67 Federal Register 49990.
[2] 59 Federal Register 45330 (Sept. 1, 1994)
[3] 67 Federal Register 49991.
[6] H040006 approved September 5, 2006
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm> [accessed May 3, 2007]

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Chart 1: Charge and LOS Comparisons for DRG 525

		LOS			Total Charges		
Principle Procedure	Number of Cases	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."[6]

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

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Deleted: In September 2006, the company's AbioCor® Implantable Replacement Heart received designation as an HDE ("humanitarian device exemption") from the Food and Drug Administration. 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 HDE designation. Not surprisingly, no cases are coded to ICD-9 37.52 ("implantation of total replacement heart system")in FY 06 MedPAR data. Based upon economic data from 14 patients in the AbioCor clinical trial between 2001 and 2004, inhospital costs per patient can average $500,000 to $1,000,000 with a length of stay approximately four to five months. ¶
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HDE designation; however, its inclusion in DRG 525 is inappropriate.[7] 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.

[7] No cases were coded to ICD-9 37.52 ("implantation of total replacement heart system") in FY 06 MedPAR data.

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Please contact me at gmayes@abiomed.com or 202-652-2281 should you have any questions regarding these comments.

Sincerely,

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

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Chart 1: Charge and LOS Comparisons for DRG 525

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

FY 06 MedPAR data

CMS-1533-P-286 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Bob Twining** **Date & Time:** **06/11/2007**

Organization : **Jefferson Regional Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1533-P-286-Attach-1.DOC

#286

June 8, 2007

VIA FEDERAL EXPRESS

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

Dear Sir or Madam:

Jefferson Regional Medical Center, a 373 bed acute care facility located in suburban Pittsburgh, Pennsylvania, wishes to add its voice to the collective body of serious concern regarding the proposed Inpatient Acute Care Rule for Medicare PPS.

First, we applaud the breadth of your proposal and the willingness of CMS to improve financial, clinical and operational performance via a series of what certainly could be termed revolutionary changes. Unfortunately, we take exception to a number of the proposed provisions as outlined below.

I. DRG Reclassification(s)

In the promulgated federal fiscal years 2006 and 2007 final rules recommendations numbered 1-3 have or will continue to be implemented in fiscal year 2008. Here are our issues with those rules (as proposed):

A. Base DRG Weights on Costs (vs. Charges) with Three-Year Phase In (Transition):

For the second year of a three-year phased implementation you engaged RTI (consulting firm) for recommendations on improving the accuracy and predictive value of cost-based DRG's. The consultant detailed a proposed expansion of Hospital Cost Centers (grouped) from 13 (thirteen) to 19 (nineteen). These cost centers include:

- Disaggregating emergency services from the catchall all other departments
- Disaggregating blood products from the catchall all other departments
- Separating implantable supplies from other supplies
- Separating IV solutions from other drugs
- Separating CT and MRI from other radiology services

CMS, despite recognizing the superior cost predictive value of the proposed changes, declined to adopt these changes. Your rationale included how RTI's proposed changes will interact with other proposed changes and you express concern about the combined impact of all changes. This appears disingenuous as CMS is proposing so many changes that the interaction of the various components cannot be estimated. You express concern about instability in IPPS payments over several years (RTI vs. HSRVcc methodologies) caused by switching systems, yet your severity adjusted proposed rule specifically raises the possibility of radically different and administratively complex and burdensome systems being sequentially implemented and discarded. Your concern regarding IPPS payment stability appears selective given the substantial redirective nature and the absolute decline in reimbursement for capital. Additionally, you write regarding making changes to cost reports to accommodate RTI's recommendation: "We have limited information systems resources and we will need to consider whether the time constraints ... in conjunction with the inconvenience ... will justify the infrastructure cost to our information systems of incorporating these variables." Hospitals find the defense of scarce resources, compressed implementation lead times and cost justification vis a vis outcomes an interesting option for CMS given the fact that it is manifestly unavailable to hospitals who have similar issues. CMS expresses a mandate to improve cost and resource predictive value and then ignores fully developed recommendations of its own consultant. We urge expedited implementation of the 19 cost center approach ASAP to better predict costs. It is unacceptable that you do not use the best, most granular level detailed cost information that yields the most predictive cost information. We also urge the early adoption of carving out intermediate (step-down) level nursing care costs. You also note that the trend towards redistributing payments away from surgery towards medicine is partially reversed using the refined RTI methodology. The search for objective reality should take CMS wherever the best available data leads it. Finally, you note that changes to cost reporting formats may be required and that would take time to implement. CMS is NOT giving the provider community time to respond to the far more revolutionary severity adjustment system (or vendors for that matter) yet requests additional time for its changes.

B. <u>DRG Reform and Proposed MS DRG's</u>

CMS stated that a preliminary review of the Rand Corporation's review of alternative DRG classification systems (four systems) notes that Rand utilizes a linear regression model to explain and predict costs using each system and comparing it to the current state. All systems (including CMS new proposed MS DRG's) improve the predictive value (i.e. R2 or correlation coefficient) from the current state. CMS proposes a variant of the APR DRG system grafted into a proposed DRG classification system. Administrative simplification, open system architecture, timeliness of update, vendor's ability to accommodate changes given the legacy of coding and billing systems are all considerations for selection criteria to be balanced against predictive accuracy.

With regard to CMS redefining the complication/comorbidity (CC's) lists, the proposal makes a comprehensive set of changes and essentially remove the vast majority of chronic (as opposed to acute exacerbations) conditions from consideration as CC's. It is unclear (and no stated criteria were included) whether any rigorous analysis of the CC's removed had any impact on explaining variations in resource utilization. Simple, transparent criteria like a CC causing a specific or defined variation in ALOS or costs should have been used and disclosed rather than "medical judgment and mathematical formulation" without specificity.

We note that CMS reserves the right to implement an interim system (MS DRG's) and then subsequently replace it with another system (one of the four commercial systems). We find that to be an administrative nightmare, creating provider and vendor unsolvable issues. CMS has control over the largest component of the health care sector of the economy and its decisions will have a profound impact on the payment and delivery of inpatient healthcare in this country. The provider and vendor community deserves and demands rational, well thought-out, tested and evaluated methodologies, NOT partially formulated interim and long-term solutions. We urge CMS to complete its study, carefully evaluate its findings and only then implement the objective best severity adjusted DRG system taking into account all variables. An interim solution followed by an entirely different final solution is impossible. CMS and other federal entities have impressed a series of unfunded mandates and other administratively burdensome requirements (HIPAA, POA, ICD-10, NPI, mandated E/R level coding, quality indicators) that have seriously impeded an already highly regulated provider community. I highly recommend COLLAPSE by Jared Diamond (Pulitzer Prize Winning Author) which details how systems or civilizations respond (or do not respond) to rapid changes. The salient point is that rapid change creates a fatigue that fatally weakens the entity for the next change. This should be required reading for governmental entities and agencies. It is our belief that CMS is creating a dangerous, unstable environment with its exponential changes.

JRMC urges a modified implementation of MS DRG's based on objective and disclosed CC criteria and/or a careful evaluation of all competing systems. We urge CMS to finalize its systems selection and only then promulgate its rule. Delaying severity adjustment and implementing year two of the cost based weights, in addition to implementing the hospital acquired conditions and staging for "value based purchasing", are reasonable goals for fiscal year 2008.

If CMS chooses to go forward with its requirement to implement MS DRG's, we urge a three to four year phase-in on the recalibrated weights to mitigate the impact on providers. We recommend FFY 2008 be used to identify, prepare and test the new classification system. The next three years shall represent a blend of DRG weights conceptually similar to the transition from charge to cost based weights. Each of the three years would have a 1/3 phase in or blending of weights.

II. Behavioral Offset

JRMC strenuously objects to the two year behavioral offset as erroneous in concept, offensive to the integrity of providers, and counterintuitive to the proposed MS DRG system.

First, citing the Maryland experience is misleading because the increase in CMI is directly attributable to a documentation improvement analogous to what has already occurred with the rest of the nation's hospital community over the entire life of Medicare PPS. Since Maryland was not subject to a PPS DRG system and a laboratory for other experiments in payment systems, it is our belief that their experience is (1) irrelevant, (2) misleading, and (3) similar to the evolutionary though process already experienced by the rest of the nation. Since that is most probably true, the base CC capture experience by U.S. hospitals is much higher and hence opportunities to improve on such base are minimal.

Second, it is counterintuitive that by removing the vast majority of chronic and temporary/transitory CC codes that the remaining high-end residual CC's would be subject to significant DRG creep. To give hospitals credit for their sophistication on the one hand, and then infer that significant major CC's and CC's were missed, is contradictory.

Third, on page 75 of your proposed rule you noted that of the five proposed systems MS DRG's (CMS' proposal) has the "lowest risk of case mix index increase" (i.e. creep), yet CMS proposes to remove 2.4% for two years (each) of the hospital update.

Fourth, in a survey of Western PA Hospitals conductor by this author, 100% of directors of medical records departments indicated that their more sustained effort is to code all diagnoses, not just simply to obtain CC's. Hence, the probability of incremental coding for dollars is minimal.

Fifth, CMS asserts the Hospital's ability to immediately upcode, yet the final rules will not be published for sometime. This proposal represents the greatest change in DRG history with mind numbing complexity. To assume mastery and optimization immediately is ludicrous.

The Maryland experience was based on APR DRG's whereas CMS proposes MS DRG's. APR DRG's consider multiple CC's and the interaction amongst principal and secondary diagnoses and procedures whereas MS DRG's does not include such a system. Multiple CC's do not yield more revenue than a single CC under MS DRG's. Using either the Rehabilitation or Psychiatric Provider experiences are also irrelevant because those are entirely new systems with coding conventions that had no impact or reimbursement previously (cost based reimbursement).

III. Capital Component Update

In CMS' proposed rule it makes substantial changes to the capital component to the base rate. CMS notes a disparity between urban and rural hospitals and propose economic redistribution with a 0.0% inflation update, removal of the 3% large urban add-on, the (2.4%) behavioral offset and, as always, the use of the GAF update. Finally, CMS proposes the elimination of capital IME/DSH adjustments. CMS cites ongoing continuing positive margins for capital from 1996 to 2004 and the programs ability to recoup savings.

First, inflationary updates for capital need to occur. Many hospitals are in the process of significant eHIM (EMR) system implementations that require significant capital expenditures and many other costly cyclical expenditures. Also, significant advances in diagnostic imaging for the advancement of patient care require enormous investments.

Second, we believe the behavioral offset to be inappropriate as detailed previously.

Third, we believe there is a methodology flaw that may explain the margins experienced by large urban hospitals. That flaw is the GAF which is applied to the entire base capital component. The GAF flaw is that capital expenses are less bricks and mortar (subject to local variations) and more diagnostic imaging equipment and software expenditures, both of whom are not subject to CBSA/MSA cost fluctuations but represent nationally determined expenses. Since many/most MSA/CBSA's in major metropolitan areas have a GAF greater than 1, this may create artificial profitability. In Western Pennsylvania a GAF of 0.8668 artificially deflates capital reimbursement.

CMS notes a 5.1% margin on capital payments as justification to reduce payments whereas a negative margin of (5.4%) overall on the acute care program. JRMC would gladly accept the 5.4% overall increase to make whole overall in addition to whatever is done with capital.

JRMC's recommendations for capital update are as follows:

- **0.8% update to rural and urban**
- **Elimination of behavioral offset (2.4% reduction)**
- **Rebasing of GAF to account for mix of bricks/mortar/equipment/software**
- **Three year phase out of large urban update with rurals receiving help on a commensurate basis**

Capital expenses by its nature require a multi-year commitment and are cyclical in nature. Radical changes, including purposeful reengineering to redistribute reimbursement are not conducive to long-term stability and planning, both central to capital planning.

IV. Hospital Acquired Infections

There appears to be a lack of clinician consensus on what constitutes accurate identification of cases where the condition was Hospital acquired. Significant practice pattern changes including screenings, diagnostic testing and prophlylactic treatment of patients leading to antibiotic resistant organisms are to be expedited. Another unintended consequence will be the treatment of compromised elderly often admitted from skilled nursing facilities that may have access jeopardized due to access. Considerations include the probability of pre-existing conditions impacting this rule and quality benchmarks and hence avoidance of this most vulnerable segment of beneficiaries.

JRMC urges the early adoption of ICD-10 to capture coding nuances and additional specificity.

CONCLUSION

JRMC recommends the following:

- Full market basket with no behavioral offset
- Continuation of transition to cost based weights using best available methodologies
- Careful, deliberate selection of severity adjusted DRG's in final form only
- **If MS DRG's are implemented, a multi-year blending of weights to cushion the impact should be implemented**
- Mandated criteria for CC inclusion/exclusion based on impact on ALOS/resource utilization
- All hospitals to have capital update
- Rebasing of GAF to reflect capital mix of bricks/mortar, equipment and software
- Three year phase out of large urban update for capital
- Early publication of hospital acquired condition payment changes with clear consensus on applicability
- Full and fair disclosure of "value based purchasing" criteria (i.e. pay for performance)

CMS has a moral, ethical and fiduciary responsibility to the program, hospitals, recipients and the health care sector of the economy. Its proposal, while ambitious, is severely flawed in its implementation and does not take into account the complexity and the multi-collinearity of variables. For those of us who wished for severity adjustment and quality measures this provides a cautionary example of "be careful what you wish for" and the "devil is in the details". CMS' backdoor attempts to cut reimbursement via behavioral offsets should be seen for what they are. The principle rule of medicine is "first do not harm". You have proposed economic and administrative harm to a healthcare delivery system that has only recently recovered by the BBRA of 1997, regulatory changes that proved devastating to hospitals and its patients. JRMC has modeled the impact of these changes for all payors paying Medicare DRG's. The payment reduction from full market basket, on an annualized basis, is in excess of $3 million. The reduction

(again from full market basket) is almost (3.9%). The impact of DRG recalibration alone is in excess of $1.4 million on an annualized basis or 3.1 basis points of CMI or a 2% decline. These payment reductions effectively wipe-out our operating margin and threaten JRMC's ability to provide its patients with the future programs, equipment and technologies that will be required. JRMC believes that its administrative and clinical costs will also demonstrably increase and that the opportunity for artificial DRG case mix index increase is minimal or non-existent. You should and could have done better.

Sincerely,

Robert J. Twining
Director, Revenue Cycle,
Managed Care & Decision Support

RJT:laa

cc: Brian Aiello, IKON
Ronald Boron, M.D.
Janet Cipullo
Richard Collins, M.D.
Robert Frank
Judy Hall
James Hoover
Robert Horn
Thomas Timcho
Louise Urban

CMS-1533-P-287 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. David Buckley** **Date & Time:** **06/11/2007**

Organization : **St. John Health**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1533-P-287-Attach-1.DOC

#287

June 11, 2007

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

Submitted Via e-Rulemaking

Re: CMS-1533-P, Fiscal Year 2008 Medicare Proposed Inpatient PPS Rules

Dear Sir or Madam:

St. John Health (SJH), a not-for-profit, faith based, health system located in Southeast Michigan currently training over 400 residents in our accredited allopathic and osteopathic teaching programs welcomes this opportunity to provide the following comments on the proposed rule to update the Medicare Inpatient prospective payment System for Fiscal Year (FY) 2008.

SJH Hospitals include:

1) St. John Hospital & Medical Center- Detroit, Michigan

2) St. John Detroit Riverview Hospital- Detroit, Michigan

3) Providence Hospital & Medical Centers- Southfield, Michigan

4) St. John Oakland Hospital- Madison Heights, Michigan

5) St. John Macomb Hospital- Warren, Michigan

6) Brighton Hospital- Milford, Michigan

7) St. John River District Hospital- East China, Michigan

Three of our hospitals, St. John Hospital & Medical Center, St. John Detroit Riverview, and St. John Oakland also participate in the 340B drug purchasing discount program due to the significant volume of indigent care they currently provide.

SJH comments are as follows:

Graduate Medical Education Payments-Resident Vacation Time Adjustment

CMS proposes to change its policy regarding resident vacation and sick leave time to eliminate this time from the total FTE resident count for direct GME and IME purposes. 72 Fed. Reg. 24680, 24813-15 (May 3, 2007). SJH teaching hospitals have two concerns about this proposed change: (1) that it results in a systematic reduction of a hospital's FTE count any time a single resident counts as less than 1.0 FTE (which is often), and (2) that it imposes an unnecessary record-keeping burden on the hospitals.

SJH is concerned that removing resident vacation time from the FTE count will systematically reduce providers' overall FTE counts, thereby depriving these hospitals of much-needed graduate medical education funding. Although CMS "acknowledge(s) that removing vacation and sick leave time from the denominator of the FTE count for both IME and direct GME could have some impact on the FTE count," it fails to explain this impact, instead merely stating that "the impact is fact-specific." *Id.* at 24814. CMS states that "in some cases, [eliminating vacation time from the denominator] would result in a lower FTE count, and in some cases, it would result in a higher FTE count," but it fails to support this conclusion with any explanation or analysis.

CMS is correct that the actual effect of its proposed rule on a hospital's FTE count would depend on the specific facts, but it fails to acknowledge that the effect of its rule is to decrease FTE counts in every case in which a resident is counted as less than one full FTE. Given that (at least for IME payments) the current rules regarding countable time do not permit every moment of a resident's time to be counted (for example, time a resident spends in research activities may not be included in the FTE count), this proposed rule would result in unjustified, across-the-board cuts in medical education reimbursement. We have prepared a calculation to demonstrate the negative effects of the vacation time proposal on a hospital's GME and IME FTE count. The following calculation shows the effects of 28 days (four weeks) of vacation time taken under both the current and the proposed rules. As shown by the chart below, if the proposed rule is implemented, SJH teaching hospitals will experience a drop in their resident FTE counts for any residents for whom any portion of their time is non-countable.

Effect of 28 Vacation Days on FTE Count

Situation A: All of a Resident's Time is Countable		
	Current Rule:	365/365 = 1 FTE
	Proposed Rule:	337/337 = 1 FTE
	Decrease in FTE Count:	0
	Percentage Change:	0 Percent
Situation B: Resident Spends 8 Weeks (56 Days) in Non-Countable Research		
	Current Rule:	309/365 = .847 FTE
	Proposed Rule:	281/337 = .833 FTE
	Decrease in FTE Count:	.014 FTE
	Percentage Change	-1.4 Percent

Eliminating time spent in didactic teaching from the denominator of the fraction prior to removing vacation time from the equation would exacerbate even further this drop in hospital FTE counts.

SJH teaching hospitals are not teaching fewer residents; nor are they spending less money educating them. And they continue to pay residents for time spent on vacation. Therefore, a rule that eliminates vacation time from the FTE count and that has the effect of systematically reducing the FTE count is unjustified and should not be finalized. There is no reasonable basis why vacation time should not continue to be counted GME Payment purposes, when providers are fully compensating residents for their vacation time, and when taking vacation time enables residents to remain focused on their residency programs.

CMS's discussion of its proposed rule ignores entirely the fact that a rule eliminating vacation time from the FTE count imposes a new record-keeping burden on providers. For SJH teaching hospitals, resident vacation time is coordinated between residents and their supervising physicians and is not otherwise generally recorded by other departments within the hospital, such as payroll. The proposed rule would require SJH hospitals to adopt an entirely new record-keeping mechanism for the sole purpose of tracking vacation time that is not even going to be applied toward the resident's FTE count.

In addition to these two central concerns, it appears that the proposed rule does not resolve the difficulties and inequities in counting FTEs that arise when residents rotate to other hospitals. The effect of CMS's proposed rule is to allocate the full loss of time from vacation days to the hospital to which the resident was assigned when the time off was taken, and to potentially increase unfairly the FTE count at the other location.

This situation is illustrated by the following example. If a resident spends 39 weeks of the year at Hospital A (75 percent of the year) and takes all four weeks of vacation time while at that hospital, and spends 13 weeks of the year at Hospital B (25 percent of the year) and takes no vacation time during this rotation, Hospital A can claim only 39/48 (72.9 percent) of an FTE and Hospital B can claim 13/48 (27.1 percent) of an FTE. While the resident in this example remains 1.0 FTE, Hospital A bears the full burden of the vacation time, while Hospital B experiences a windfall (for no reason) of 2.1 percent of an FTE. The opposite occurs when residents choose to take their vacation time while at Hospital B.

This additional record keeping requirement is especially burdensome for health care systems such as SJH who file for Medicare Affiliated group status due to the significant number of intra-health system rotations that occur to ensure the highest quality training experience for our residents. Due to our high number of rotations among our teaching hospitals, the detailed calculations and time to properly report the various resident rotations for annual IRIS reporting and calculate the necessary affiliated group adjustments for the health system are expected to increase.

Teaching hospitals historically have been subjected to substantial and burdensome documentation requirements to substantiate the resident FTE counts they report for DGME and IME payments. The academic medical community has accepted these burdens because we recognize that DGME and IME payments represent significant outlays from the Medicare trust fund and resident counts are a key determinant in the level of these payments.

If for some reason CMS chooses to finalize its policy, we feel strongly that the policy cannot be implemented unless and until the Medicare intern and resident information system (IRIS) is modified to accommodate such changes. In order to demonstrate that no training "overlap" is occurring between hospitals, SJH teaching hospitals document each resident's time on IRIS. Requiring hospitals to now accommodate vacation and sick time intervals in IRIS requires that IRIS be significantly modified. It would be unfair and wrong for CMS to implement the vacation/sick time policy without first making modifications to IRIS.

Based upon these comments, SJH strongly urges CMS to rescind the proposal regarding how vacation and sick time is accommodated in the resident FTE calculations for IME and DGME payment purposes or to modify it make it consistent with how the Agency proposes to account for resident orientation time.

Capital IPPS – 0.8 Percent Update

SJH is concerned that the proposed Capital IPPS rule for fiscal year 2008 will severely hamper the ability of the Wayne County hospitals to keep pace with rising costs and the growing need of Medicare beneficiaries for modern healthcare equipment, facilities and technology. At a time when hospital capital and operating costs are rising, the proposed Capital IPPS rule would not only deprive the hospitals of the expected 0.8 percent update to the capital standard Federal rate for FY2008, but it would also eliminate the 3.0 percent additional payment that hospitals located in large urban areas have received since the inception of the Capital IPPS system in 1991. Coupled with the 2.4 percent offset (discussed below), large urban hospitals would experience an absolute decline in payment of over 6 percent for Medicare capital. As CMS itself acknowledges in the proposed rule, large adjustments to capital funding should be avoided in order to prevent disruption to hospital finances. In this instance, there is an insufficient basis for the substantial cut in capital reimbursement for large urban hospitals. We request, therefore, that CMS withdraw its proposal, implement a 0.8 percent update and maintain the 3.0 percent adjustment for hospitals in large urban areas.

Under § 1886(g)(1) of the Social Security Act, the Medicare program is required to provide for a capital prospective payment system effective for cost reporting periods beginning October 1, 1991. CMS (then the Health Care Financing Administration, or HCFA) published the final rule establishing the new Capital IPPS. 56 Fed. Reg. 43358 (Aug. 30, 1991). The Capital IPPS rule also provided that a yearly update to the capital standard Federal rate would be calculated through fiscal year 1995 based on actual increases in Medicare capital-related cost data. From federal fiscal year 1996 on, CMS calculated the yearly update based on an analytical framework taking "into consideration increases in the capital market basket and appropriate changes in capital requirements resulting from new technology and other factors." *Id.* at 43360.

The analytical framework adopted in 1991 is still in use by CMS today. The agency's analysis takes into account changes in the capital input price index (CIPI) and other variables. CMS acknowledges in the proposed capital IPPS rule that, based on this analytical framework and utilizing the best data available at this time, the update factor for the capital standard Federal rate for fiscal year 2008 should be 0.8 percent. 72 Fed. Reg. 24821 (May 3, 2007). Nevertheless, CMS proposes not to apply its longstanding methodology for determining the capital payment update factor, and instead proposes a 0.0 percent update to the capital standard Federal rate for all urban hospitals.

SJH identifies the following reasons why this proposal should not be finalized:

1. The agency's data showing that hospitals are enjoying a margin on capital payments is several years old and the trend was to smaller margins;

2. For policy decision making purposes, margins on capital cannot properly be segregated from margins on operating costs;

3. Profitability on capital payments reflects reduced capital expenditures which often is caused by financial distress, and does not reflect excess payments;

4. The capital cycle is long and CMS's data does not show that payments over the capital cycle produce the reported margins;

5. All providers face the need to make significant investments in electronic medical records;

6. The country has enjoyed an extended period of low interest rates that is unlikely to continue;

7. CMS has not found an error in its analytical framework used to calculate the 0.8 percent update factor; and

8. As CMS, itself, acknowledges, with capital payments especially, predictability and consistency are important.

1. CMS's Data Goes Only to 2004.

CMS's data on capital costs goes only to 2004. Thus, this data is four years out-of-date for the federal fiscal year 2008. It is important that the lowest reported margins were in the most recent year for which CMS has data, 2004. At a minimum, CMS should test its assumption that capital margins have persisted, and if so, in what amounts.

2. By Themselves, Capital Margins Are Not Meaningful and Should Not Be Used to Set Important Payment Rates.

From an accounting perspective, capital costs differ from operating costs because capital costs relate to assets whose useful lives extend beyond one accounting period. From a managerial perspective, however, both capital costs and operating costs constitute expenses for furnishing hospital services. The category of an expense is not nearly so important to a manager as the fact of the expense. For this reason, and as explained in greater detail below, it is not useful to analyze capital profit margins apart from operating profit margins.

Indeed, CMS, itself, has recognized the interrelatedness of capital and operating costs. The 3 percent adjustment for the capital payments to large urban hospitals had initially been proposed as a 1.6 percent adjustment. In moving from the proposed to final rule, CMS increased the 1.6 percent proposed adjustment to a 3.0 percent adjustment because it used a model including *both* operating and capital costs in the statistical analysis of the appropriate amount of the adjustment.

MedPAC reports that hospital margins on Medicare for 2007 will be *negative* 5.4 percent. In the face of that number alone, cutting capital rates is indefensible.

There is considerable variation of capital costs from hospital to hospital. Much of this relates to where a hospital is in its "capital cycle." Some variation, however, relates to decisions that hospitals make in how to operate. There are trade-offs between labor and capital expenditures. For example, there are robots that will distribute meals, medications, or even mail. Alternatively, those functions can be performed by employees. If robots are used, the bulk of the expense is a capital expense; if employees are used, the bulk of the expense is an operating expense. Another example is telephone expense—hospitals can purchase very expensive

telephone systems, which are a capital cost, or they can obtain services through their local telephone companies which utilize equipment on the premises of the vendor. In the former instance, the expense is a capital expense; in the latter an operating expense. One of the reasons that CMS cited to support including capital costs in hospital inpatient PPS was to remove incentives on management to favor capital expenditures over operating expenditures:

> [T]he current system [cost reimbursement] favors debt financing over equity financing and capital investment over operating expenditures.

56 Fed. Reg. at 43363, col. 3. Thus, CMS has recognized that the same functions can be performed with different mixes of capital and operating expense. Therefore, margins on capital payments should not be analyzed separately from margins on operating payments. MedPAC's March 2007 Report to Congress states that overall Medicare margins are negative, and are projected to fall in 2007 to a low of -5.4 percent. This information shows that one likely explanation for positive margins on capital payments is that hospitals do not have the resources to make needed capital expenditures and hence capital costs are falling or not increasing as rapidly as would be consistent with maintaining physical plants at current levels. Accordingly, positive capital margins reflect insufficient payments and not excessive payments.

b. The Accounting Distinction Between Capital and Operating Costs Is Blurred in Specific Factual Instances.

Beyond the fact that the same hospital services can be furnished with different blends of capital and operating expense, there are accounting distinctions that affect the relative amounts of capital and operating expense. Prior to capital payments being rolled into inpatient PPS, there were constant disputes on which costs were capital and which were not. For example, "betterments and improvements" are capitalized while repairs are not. Prov. Reimb. Man. (CMS Pub. 15) §§ 108.2 & 2806.1. In reality, however, the distinction between a repair and a betterment and improvement is not always clear. In addition, there are certain leases that Medicare does not treat as capital expenses. 42 C.F.R. § 413.130(b), *see e.g. Naeve Hlth Care Ass'n,* PRRB Dec. 90-D3, MEDICARE & MEDICAID GUIDE (CCH) ¶ 38,428. Indeed, under CMS's regulations, maintenance may be either a capital cost or an operating cost depending on whether it is included in lump-sum charges or is segregated into separate charges. 42 C.F.R. § 413.130(b)(7). Planning costs are a capital expense while abandoned planning costs are not. Prov. Reimb. Man. (CMS Pub. 15) § 2806.2(h). The point is not whether various CMS policies defining what is and what is not a capital cost are proper; but rather, the point is that the application of those policies to specific factual circumstances is often unclear.

3. Positive Capital Margins Could Reflect Financial Distress Rather than Profitability.

Positive margins on capital payments do not necessarily reflect financial health or overall profitability. When a hospital is experiencing cost pressures, one of the first things that management cuts are capital expenditures. Doing so avoids lay-offs and more painful cost-cutting that will have a more immediate impact. The effect of deferring capital expenditures is to limit the increase in capital expenditures resulting in less depreciation, less interest expense, lower lease expenses, etc., in comparison to what capital costs would have been if there had been greater resources sufficient to fund a capital budget to sustain services over the long term. When there are declining and/or negative operating margins, it is not unlikely that the capital margin will increase because of the reduction in new capital expenditures.

The data show that in the late 1990s and early 2000s, the increase in demand for healthcare services has far outstripped the growth in capital spending to help provide those services. From 1997 to 2001, capital spending increased from $23 billion to $23.7 billion.[1] During the same period, annual hospital admissions grew from 31 million to 33.4 million - an increase of 7.7 percent. Likewise, annual outpatient visits grew from 450 million in 1997 to 538 million in 2001 – a jump of 19.6 percent.

At the same time, almost half of all hospitals reported that their capital expenditures and acquisitions were not keeping pace with the depreciation of their existing capital assets – 41 percent of hospitals reported that capital expenditures were less than annual depreciation.[2] The median age of physical plant for hospitals is rising, up from 9.2 years in 1997 to 9.5 years in 2001. The facilities and equipment of these hospitals are aging and becoming technologically obsolescent at the same time that demand upon them is increasing. This trend cannot continue. Indeed, some estimates show that it is already reversing, with hospital construction increasing 11 percent in 2002.

4.Capital Cycle

As CMS noted in early work on capital payments, there is a long "capital cycle." A hospital will have the highest capital expenses relative to operating costs and relative to other hospitals when it constructs a new facility or makes a major plant addition. Capital costs will be high because construction costs are high, especially compared to hospitals constructed in prior years. Capital expense will also be high because interest expense is highest in the early years of debt since the ratio of interest to principal payments is highest in the early years of a financing. As time elapses, a hospital's capital costs will decrease relative to other more newly constructed hospitals and relative to operating costs. The estimated useful life for a building, the most expensive capital asset, is 40 years for the building shell. Many building components have a useful life of 20 years. The period that CMS cites in the preamble to the proposed rule, from

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[1] HealthCare Financial Management Association Report Financing the Future Report 2: How Are Hospitals Financing the Future? Capital Spending in Healthcare Today, available online at http://www.hfma.org/library/accounting/capitalfinance/FinancingtheFuture.htm.

[2] As capital costs increase, a hospital spending only its depreciation expense on new capital is actually falling behind.

1996 to 2004 is a relatively short period in comparison to the capital cycle. CMS should be very cautious in using data from such a short period of time in making a decision with such far-reaching consequences.

5.Need for Capital Expenditures for "Interoperable" Health Records

The current administration, and Secretary Leavitt in particular, have been insistent and emphatic that all providers need to move to electronic medical records. Similarly, there have been calls for moving to much greater reliance on electronic ordering systems to reduce the probability of errors. All providers will be called upon to make significant capital expenditures to acquire and operate systems that support electronic medical records and electronic ordering. The anomaly with capital expenditures in this area is that the entities incurring the expense will not directly benefit from the return on the investment. Rather, the return on investment will be manifested in improved care and fewer duplicated tests, i.e., reduced costs to payers. These are laudable and important objectives, but they cannot be achieved without expense. Rather than not increasing the capital portion of Medicare inpatient PPS rates, CMS should be considering how investments in interoperable medical records can be financed.

6. Interest Rates Have Been Very Low for an Extended Period.

The nation has experienced an extended period of low interest rates, with rates at levels that had not been seen for decades. Interest is, by itself, one of the single largest expenses for most hospitals (just as it is for the federal government). This extended period of low rates corresponds with the period of time that CMS has used to calculate capital margins. How long such low rates will continue is speculative, but history instructs that the low rates that we currently enjoy are not sustainable. CMS Cites No Error or Flaw in Its "Analytical Framework."

CMS's basis for its proposed cut in the update to the capital rate for urban hospitals is simple: it argues that all urban hospitals, on average, have too high a margin on capital payments. More specifically, CMS argues that the Medicare capital margins (the difference between Medicare capital payments and costs, divided by Medicare capital payments) for urban hospitals have remained too stable and too positive for too long. While recognizing that under the capital PPS system, some hospitals might regularly achieve positive margins and others negative margins, CMS argues that a "correctly calibrated" PPS should not permit hospitals to sustain positive Medicare margins. Notably, CMS does not criticize or propose modifying the analytical framework that it developed as part of capital PPS and has relied upon consistently up to this proposed rulemaking. If the framework contains no apparent flaws, it is likely that the margins on capital rates are attributable to other factors, such as those discussed above. It is hardly as though the analytical framework has resulted in capital payment rates increasing at a rapid rate; the framework produces an increase for FY 2008 of only 0.80 percent. CMS needs to explain what is wrong, if anything, with its analytical framework; and if nothing is wrong with it, it should stick with the increase that would be promulgated using that framework. If something is wrong with it, CMS should identify what that is and how it should be changed so that there is predictability in future rate changes, as discussed in more detail below.

7. Predictability in Capital Payment Rates

CMS's position here appears to be that the fact that Medicare capital margins have remained positive over the past several years is a sign that the system is not working. This fails to take into account that the central purpose of the prospective payment systems in general, and the Capital IPPS in particular was to provide stability in Medicare payments, both for the program and the providers, so that providers might have the information necessary to plan for large capital investments and expenditures, making such changes only when it was most efficient to do so. When CMS promulgated the final capital IPPS regulation, it observed that capital costs in years prior to 1992 had increased at a high rate—"Medicare hospital inpatient capital has increased almost 100 percent, while capital input prices have grown less than 20 percent." 56 Fed. Reg. at 43363, col. 2. CMS also noted that the "growth in capital spending has occurred despite a decline in hospital admissions and occupancy since 1984," and observed that there was "substantial excess capacity." *Id.* By moving to prospective payment for capital, CMS achieved exactly what it sought to achieve, a reduction in capital expenditures. The excess capacity that had previously existed has now been absorbed. As noted in HFMA reports cited above, hospital capital expenditures in the late 1990s increased at an annual rate of approximately 1 percent while inpatient admissions and outpatient visits increased at much higher rates. Reduced capital expenditures which are reflected in the data from 1996 to 2004 that CMS cites in the proposed rule are anomalous when compared to prior capital expenditures, and are unsustainable when 41 percent of hospitals are not making capital expenditures that equal their annual depreciation expense. By departing from its analytical framework and by making a cut of over 6 percent for large urban hospitals, CMS undermines the stability and predictability that has always been the primary goal of the prospective payment systems.

In support of its proposed cuts, CMS notes that Congress has twice adjusted the capital standard Federal rate (once in 1994, and once in 1998). In particular, the proposed rule points to the statutory language used in the 1998 rate adjustment, where Congress reduced the Federal rate "to apply the budget neutrality factor used to determine the Federal capital payment rate in effect on September 30, 1995 . . . to the unadjusted standard Federal capital rate" for FY 1998 and beyond. 72 Fed. Reg. 24820 (May 3, 2007). The agency argues that this statutory language supports a conclusion that Congress did not intend for the Capital IPPS to permit sustained positive Medicare capital margins.

The evidence, however, simply does not support CMS's argument. What the 1994 and 1998 statutory amendments show is that if Congress determines that sustained capital margins, or any other Medicare capital-related datum, warrant an adjustment to the capital standard Federal rate, Congress is fully capable of making such an adjustment by statute. In any event, Congress is not restricted by the statutory standards for payment; by definition, Congress can alter the statute for budgetary reasons alone without regard to logic, equity, or consistency with prior policy. CMS does not enjoy the same liberty as Congress.

In any event, the numbers themselves undercut CMS's argument with regards to what implications can be drawn from the statutory adjustments. As shown in the table of Hospital Inpatient Medicare Capital Margins, the total capital margins for all Medicare IPPS hospitals

dropped sharply for fiscal year 1998. This presumably reflects the cut Congress made in the capital Federal rate effective for FY 1998. Since then, from fiscal year 1998 to fiscal year 2004 (the latest year for which we have cost data), the hospital capital margins have stayed within a percentage point or two, ranging from a low of 6.8 percent in FY 1999 to a high of 8.7 percent in FY 2002, with the average over the time period being 7.2 percent. If Congress' goal in adjusting the capital standard rates in 1998 was to stabilize hospital capital margins at a lower level, then it succeeded. There has been no dramatic increase in hospital capital margins since fiscal year 1998 to indicate that a further cut to the Federal rate is necessary. Indeed, for 2004, the agency's own records show that Medicare capital margin dropped to 5.1 percent - both the lowest margin since 1996 and the largest drop since the 1998 statutory adjustment. While capital margins for urban hospitals remain positive, the Medicare Payment Advisory Committee's (MedPAC) March 2007 report to Congress indicates overall Medicare margins are low and cost trends suggest that they will continue to fall between 2005 and 2007. MedPAC projects that the overall Medicare margin for PPS hospitals will be -5.4 percent for fiscal year 2007. Clearly, overall positive Medicare margins are not the problem that CMS suggests in the proposed Capital IPPS rule.

Capital IPPS – Add-on Payment for Large Urban Hospitals

CMS presents no additional or different evidence in support of its proposition that the 3.0 percent add-on payment for large urban hospitals should be eliminated. Since 1991, CMS has provided hospitals located in large urban areas an additional payment equal to 3.0 percent of what the hospital would be paid under the capital standard Federal rate. The provision is embodied in the regulations at 42 C.F.R. § 412.316(b), and was implemented as part of the original Capital IPPS Final Rule. As originally proposed, the large urban update was to have been only 1.6 percent. 56 Fed. Reg. 43359 (Aug. 30, 1991). CMS decided, however, to calculate the capital payment adjustments, including the large urban adjustment, using both total operating and capital costs as part of a case regression analysis. Under the new analytical framework, the large urban add-on payment increased to 3.0 percent. 56 Fed. Reg. 43361 (Aug. 30, 1994). Although CMS reports that Medicare capital margins have remained positive, they decreased from fiscal year 2003 to 2004. According to MedPAC's March 2007 report to Congress, overall Medicare margins are negative and are projected to fall in 2007 to a low of -5.4 percent. Given that since 1991 the large urban add-on payment has been calculated using both capital and total operating costs, it seems irrefutable that CMS's own analytical framework, as it has been applied for nearly two decades, would call for the full 3.0 percent update for large urban hospitals.

D. DRG Reform and Proposed MS-DRGs

CMS proposes to institute a new system of "Medicare-Severity DRGs" (MS-DRGs) for IPPS, which would increase the number of DRGs by almost a third. In conjunction with this proposal, CMS proposes to cut IPPS payments across-the-board by 2.4 percent to account for predicted (though unsubstantiated) "upcoding" behavior practices by hospitals under the new MS-DRG system.

SJH supports CMS proposal to utilize a more precise system of payment for inpatient DRG services. However, CMS proposes a switch from the current system of 538 DRGs to a new system of 745 MS-DRGs. As described by CMS, the new MS-DRGs would reflect not only complications and comorbidities associated with the principal diagnosis, as with the current DRG system, but the severity of any such complicating factors. In practice, however, it is unknown how a particular case would cross-walk from the existing system to the new one. If there is a new DRG system, there necessarily must be a "grouper" for that system to operate. Yet CMS has not made a grouper available for public use. The "crosswalk" that CMS has made available does not function as a grouper and it is a practical impossibility for a hospital to analyze how its existing case mix would be paid under the proposal. Without a grouper for the proposed MS-DRGs, we have no practical ability to evaluate this proposal.

CMS is currently speculating that the new system would create a risk of increased levels of payment as a result of greater documentation and coding using the new system. CMS notes in the preamble that "we are concerned that the large increase in the number of DRGs will provide opportunities for hospitals to do more accurate documentation and coding of information contained in the medical record." Yet CMS is unable to substantiate this comment.

SJH doubts that documentation and coding would be materially affected by the proposed change. Training of our physicians and mid-level practitioners on the importance of complete and accurate documentation is an important and ongoing process at SJH. This training does not, and could not practically, focus on the level of detail that affects coding for specific DRGs. Rather, the message to physicians and other practitioners is simple—Document fully the results of the history and physical; give a diagnosis with the maximum level of detail; explain the basis for medical decision-making; and refer to those diagnostic test results that lead to the diagnosis and treatment plan. A refined DRG system does not change this message.

CMS's estimate of a 4.8 percent "upcoding," and the basis for that estimate, both militate in favor of more study of the proposed new DRGs. The 4.8 percent estimated increase in payments (above the update factor) is *huge*. This contrasts with a budget neutrality factors, always computed to six places past the decimal, which are a small fraction of 4.8 percent. For example, the budget neutrality factor in the FY 2007 rule was 0.995662. 71 Fed. Reg. 59886, 59890 (Oct. 11, 2006). Greater accuracy in DRG weights so that they better reflect necessary resource utilization is highly desirable, but any new DRG system that has so much uncertainty associated with it that CMS thinks it needs a "fudge factor" of 4.8 percent is a system that has not been adequately reviewed and tested prior to being put into place. The immensity of the 4.8 percent estimate is shown by how it compares with hospital profitability—many hospitals do not have an operating margin of 4.8 percent.

Refining the accuracy of DRG payments to better reflect severity should be continued by CMS. The Medicare payment system will benefit from a system that more accurately measures severity of service provided. However, the incremental benefit of this enhancement in accuracy pales in contrast to the uncertainty of a system for which CMS is guessing will result in a 4.8% increase in payments from changes in coding. Therefore, SJH urges CMS not implement any rate reduction to account for its unsubstantiated prediction of "upcoding" behavior practices by hospitals under the new MS-DRG system.

Wage Data\ Wage Index Adjustors

CMS expanded its collection of contract labor to include administrative and general, housekeeping, dietary, plus management and administrative services for cost reporting on or after October 1, 2003. Thus, the FY 2008 proposed wage index is the first year in which CMS has data to determine what impact such contract labor data would have in the wage index. SJH supports CMS full inclusion of contract labor data in FY 2008.

In FY 2009 CMS is required to consider changes to the area wage index. SJH supports changes to the wage index such as inclusion of this contract labor data and proposes CMS expand their data collection to include all contract labor services data in calculation of the wage index. Exclusion of some personnel and inclusion of others from the wage index calculation is inappropriate as CMS' policy currently encourages the outsourcing of lower wage services within a wage area as a means to manipulate and overstate an area's actual wage index.

By including all labor data for a given wage area, the CMS wage index process should result in a more representative Average Hourly Wage for each hospital and wage index for each wage area.

Thank you for your review and consideration of these comments. Please contact me at david.buckley@stjohn.org with any questions regarding these comments you may have.

Sincerely,

David R. Buckley

David R. Buckley

Corporate Director of Reimbursement

St. John Health

CMS-1533-P-288 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Virginia Crouch** **Date & Time:** **06/11/2007**

Organization : **Carilion Franklin Memorial Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-288-Attach-1.DOC

#268

CARILION®

Franklin Memorial Hospital

180 Floyd Avenue
Rocky Mount, VA 24151

June 11, 2007

To Whom It May Concern:

I am the Infection Control Practitioner at Carilion Franklin Memorial Hospital in Rocky Mount, Virginia. I am writing to comment on the implementation of the MS-DRG system with POA codes. As the Infection Control Practitioner at my facility, my role is to assist the organization with preventing infections in the patients we serve.

I do not support the following three preventable events identified by CMS for inclusion in the MS-DRG system: (1) catheter-associated urinary tract infections, (2) pressure ulcers and (6) Staphylococcus aureus septicemia. These events will be difficult to identify properly by untrained personnel. The CDC's definitions for healthcare acquired infections have strict criteria which involve thorough investigation in order to identify these infections properly.

Conditions 1, 2, and 6 are not always preventable events, as not all infections can be prevented. Healthcare organizations utilize current prevention guidelines to assist in preventing infections but multiple variables, including populations served, have a great deal of impact on the outcomes of these prevention strategies.

Our facility would request clarification from CMS on how our facility could appeal a CMS decision if an error in coding occurs. We would also like to request educational support for determining POA codes and sufficient time to reallocate our resources of clinical and coding staff which are currently taxed.

Thank you for the opportunity to provide comments.

Virginia Crouch
Carilion Franklin Memorial Hospital
Infection Control

CMS-1533-P-289 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Debra McNulty** **Date & Time:** **06/11/2007**

Organization : **Debra McNulty**

Category : **Individual**

Issue Areas/Comments

Hospital Reclassifications and Redesignations

Hospital Reclassifications and Redesignations

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

Thank you for your consideration of this important matter!

CMS-1533-P-290 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Incorrect CC designation, Stage V CKD - Depending on the staging system used, Stage V may be the most severe form of CKD (National Kidney Foundation stages only 1 through V). We believe that Stage V CKD should be designated as a Major CC because these patients often require hemodialysis or transplant and because of the differences in the CKD staging systems.

CMS-1533-P-291 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Hong Lan** **Date & Time:** **06/11/2007**

Organization : **Mr. Hong Lan**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

Thank you for your consideration of this important matter!

CMS-1533-P-292 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Linda Miller** **Date & Time:** **06/11/2007**

Organization : **Mrs. Linda Miller**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Dear Leslie Norwalk, Esq., As a 10-year member of the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) and a Registered Nurse for 23 years, I would like to comment on the initiative of including infectious events in the Present on Admission (POA) initiative. While I support the POA initiative, I believe that the inclusion of infectious event has the potential to impact me negatively as a healthcare consumer and, as an infection control practitioner. I know first hand, the benefits of preventing adverse events in the patients we serve, but I am concerned about the inancial and human resource issues this may negatively impact.

Unlike the proposed POA items #3 (objects left during surgery), #4 (air embolism, and #5 (blood incompatibility), which have definitive and easily retrievable billing codes, those involving the proposed infectious events (#1 catheter-associated urinary tract infection, #2 pressure ulcers, and #6 Staphylococcus aureus septicemia) do not have definitive billing codes. As an ICP, I have frequently review discharge complication list based on billing codes to identify infectious outcomes and found very little correlation. Billing codes were often discrepant as it relates to POA vs. HAI.

The determining of infectious events require a strong clinical component, as assessed by a trained medical professional, to determine the presence of a healthcare-associated infection (HAI) as defined by the Centers for Disease Control and Prevention's, National Healthcare Safety Network (NHSN) definitions of infection. The billing codes are designed for reimbursement and not diagnosis; therefore, a human component must be present in identifying infection specific POA's.

I believe a referenced and more comprehensive response is being forwarded by the APIC organization, and, as a Chapter officer, I am also offering this letter as affirmation as a member of our 11,000 member organization dedicated to the prevention of infection and adverse events in healthcare.

Thank you for the opportunity to address my concerns.

Sincerely,

Linda Miller, RN, BS, CIC
Infection Control & Prevention Practitioner

CMS-1533-P-293 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Dehydration and Volume Depletion - We believe that dehydration and volume depletion (276.5x) should not be eliminated because of the importance to prpoerly recognize and treat the condition when present - before the patient goes into acute renal failure or shock.

CMS-1533-P-294 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Daran Rumbaugh** **Date & Time:** **06/11/2007**

Organization : **Central New Jersey Brain Tumor Support Group**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

Thank you for your consideration of this important matter!

CMS-1533-P-295 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Kathryn Hawkins** **Date & Time:** **06/11/2007**

Organization : **The Methodist Hospital**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

I share APIC's concern regarding POA codes and the inclusion of catheter-associated UTI, pressure ulcers and Staph. aureus septicemia.

CMS-1533-P-295-Attach-1.DOC

#295

Key points from APIC letter to Leslie Norwalk, Esq, Acting Administrator, Center for Medicare & Medicaid Services

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- APIC and the CMS have a shared vision of preventing any adverse event, specifically infectious complications, in patients served in their respective care settings.
- APIC supports CMS in their effort to identify appropriate conditions that should not occur in our hospitals, thereby meeting criteria defined by Congress and also ensuring accuracy in the billing data that enables the appropriate identification of cases.
- The implementation of the MS-DRG system requiring implementation of "present on admission (POA)" codes will demand enormous resources in a very short time period for training and education of clinical and coding staff
- Of the six serious preventable events identified by CMS, APIC supports the following: number 3, object(s) left during surgery; (4) air embolism, and (5) blood incompatibility, whereas these conditions have been identified and supported by NQF; are identifiable by discrete ICD-9 codes and can be coded for by hospitals without dependence on POA codes.
- These extremely harmful events have known methods of prevention.
- APIC does <u>not</u> support the following three preventable events identified by CMS: number 1, catheter-associated urinary tract infections; (2) pressure ulcers and (6) Staphylococcus aureus septicemia, because each condition depends on the ability to identify them properly as well as accurate use of POA codes. Two states currently using POA codes report a minimum of two years needed to achieve reliability—much longer than the January 1, 2008 timeframe proposed by CMS.
- APIC looks to CMS to provide the educational support needed to reliably determine POA codes.
- APIC does not believe conditions 1, 2, and 6 are always reasonably preventable, even when reliable science and appropriate care processes are applied in the treatment of patients; not all infections can be prevented, and each of these conditions carry with them unintended, far-reaching consequences.
- APIC recommends that CMS continue to address the coding challenges for ventilator-associated pneumonia, vascular catheter-associated infections, and surgical site infections in order to determine if these conditions warrant inclusion in the CMS's hospital-acquired conditions policy in the future, since they are important causes of healthcare-associated mortality and morbidity. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic.
- APIC suggests and supports two approaches that do not depend on POA codes, but instead require coding and cross referencing for vascular-associated infections (which includes infections associated with all vascular devices, implants and grants) and infections such as septicemia; both of which would necessitate the creation of a unique ICD-9-CM code.
- While there is no specific code for catheter-associated blood stream infections, there are specific codes for insertion of catheters.
- While there are prevention guidelines for surgical site infections, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, APIC suggests selecting a single high volume surgical procedure, such as coronary artery bypass graft codes (without valve), for which there is a CC code for mediastinitis and for which there are guidelines addressing preventability.
- APIC proposed consideration of post-operative sepsis, using a specific procedure code such as CABG (with or without valve)
- APIC requests clarification from CMS on how hospitals may appeal a CMS decision if an error in coding occurs and if a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or co-morbidity DRG payment.

CMS-1533-P-296 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Seizure Disorder - Code 780.39 should not be eliminated as a CC. This code is assigned when a patient has a seizure (cause unknown) and also when a physician uses the terminology "seizure disorder". "Seizure disorder" has replaced the use of the "epilepsy" in the last 30 years because of the stigma patients bear when they are labeled "epileptic". Hospitals should not be penalized because of trends in physician documentation or for any deficiencies in the coding system. Most of the codes representing epilepsy are CCs. Therefore, 780.39 should also be so designated. In addition, a patient who has a current seizure (cause unknown) may require intensive care and 780.39 could/should be designated a CC on that basis alone.

CMS-1533-P-297 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Edward Kalman** **Date & Time:** **06/11/2007**

Organization : **National Association of Long Term Hospitals**

Category : **Health Care Provider/Association**

Issue Areas/Comments

MS LTC-DRGs

MS LTC-DRGs

Semi-annual rulemaking applicable to LTCHs.

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#297

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June 11, 2007

VIA ELECTRONIC MAIL

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Re: Comments on "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates" Proposed Rule Published at 72 *Fed. Reg.* 24,680 *et seq.* (May 3, 2007)

Dear Administrator Norwalk:

The National Association of Long Term Hospitals ("NALTH") welcomes the opportunity to submit these comments on proposed rules published on May 3, 2007 at 72 *Fed. Reg.*, 24,680 *et seq.* NALTH is committed to research, education and public policy development which further the interest and understanding of the very ill (and many times debilitated) patient populations that receive services in long-term care hospitals ("LTCHs") throughout the nation. NALTH's membership is composed of the nation's leading LTCHs, which serve approximately one-third of the Medicare beneficiaries who are admitted to LTCHs in the United States. The membership of NALTH is diverse and includes: not-for-profit and for-profit urban LTCHs with Medicare-approved teaching programs and over 200 beds; LTCHs located in underserved rural areas; LTCHs which are owned and operated by large integrated health care systems throughout the United States; and, publicly-owned LTCHs.

In the comments which follow, we recommend that the Secretary cease the twice annual rulemaking which currently occurs for LTCHs and, instead, engage in a single yearly rulemaking for LTCHs, as is the case for all other Medicare provider types.

We also strongly recommend that the Secretary not reduce MS-LTC-DRG weights by 2.4%. NALTH commissioned the Lewin Group to analyze both the policy justifications and the fiscal effects of the proposed coding adjustment to the MS-LTC-DRG relative weights. The report, which NALTH has received from the Lewin Group, is entitled "Evaluation of the Proposed Coding Adjustment to the DRG Relative Weights for Long-Term Care Hospitals for FY 2008" (June 11, 2007) and is included as Appendix A to these comments. In the following discussion, we refer to this report as the "Lewin Report."

I. CMS Should Have A Single, Annual Rulemaking for LTCHs

NALTH requests that the Secretary revise the time period during which he engages in routine rulemaking to make adjustments to the LTCH-PPS. Currently, the Secretary engages in a semiannual rulemaking process. An LTCH-PPS update regulation is proposed in February and becomes effective on July 1st. A second rule is proposed in April or May of each year with regard to the acute hospital ("IPPS") update regulation and becomes effective on October 1st. This second rulemaking revises LTC-DRG weights and makes other changes to LTC-DRGs. Both of these annual rulemakings often include additional policy changes.

This dual rulemaking process has resulted in instability in the hospital budget and planning process. *LTCHs are the only Medicare provider type which is subject to a double rulemaking process to establish a single year's prospective system of payment.* This problem is complicated further because the two rulemakings are interrelated. It is not reasonable to expect NALTH and other components of the LTCH industry to comment on the rationality of a payment level proposed in February when that payment level is subject to change in a second rulemaking proposed in April or May of the same year. Other classes of providers are able to plan their annual budgets with advance knowledge of what Medicare payment rates and policies will be for the upcoming twelve-month period. At best, LTCHs are able to budget with knowledge of the upcoming nine-month period. They have to make assumptions about what will occur in the last three months of their rate year. Incorrect guesses (for example, an assumption that the market basket will stay in the 3.6% range when, instead, CMS reduces it to 0.71%, as it did for RY 2008), leave LTCHs either operating at a loss or having to modify or forgo important staff recruitment activities and capital projects. The current process of subjecting LTCHs to rulemaking twice a year derogates from the important principle of prospective rate setting that providers should know their rates in advance so that they can engage in an orderly process of providing the medical resources necessary to provide Medicare beneficiaries with quality care. LTCHs are at a clear disadvantage in this regard due to the imposition of an additional rulemaking each year, which can, and has, had the effect of destabilizing the annual hospital budgeting process.

Accordingly, NALTH strongly recommends that, in the preamble to the FY 2008 final IPPS Update Rule, CMS announce a policy that, **commencing with RY 2009**, *it will make routine annual adjustments to the LTCH-PPS only once per year, as is the case for all other provider types.* We suggest the single rulemaking occur on the same

schedule as that used for IPPS hospitals in order to maintain the normal cycle for the establishment of LTCH-PPS weights. We further recommend that, in the first year only (*i.e.* RY 2009), CMS implement a three-month update to the LTCH-PPS standard amount (from July 1, 2008 to September 30, 2008), with no other policy change. A full twelve-month update (from October 1, 2008 to September 30, 2009) with any appropriate policy changes then could be implemented. In its Rate Year 2008 LTCH-PPS Final Rule, CMS stated that it "appreciated" the suggestion that it consolidate the LTCH-PPS update and the development of LTC-DRG weights in one publication cycle. CMS stated that it "will evaluate whether such a consolidation is a workable alternative to [CMS'] present schedule." 72 *Fed. Reg.* 26874 (May 11, 2007).

II. Medicare Severity DRGs for LTCHs ("MS-LTC-DRGs")

In the preamble to the notice of proposed rulemaking, CMS states that, in order to "eliminate the effect of changes in coding or classification of discharges that do not reflect real changes in case-mix, we are proposing to reduce the IPPS standardized amounts by 2.4 percent each year for FY 2008 and FY 2009." 72 *Fed. Reg.* 24710-11 (May 3, 2007). Similarly, CMS is "proposing to adjust the DRG relative weights that are used for the LTCH PPS by -2.4 percent (0.976) in FYs 2008 and 2009 to account for the anticipated increase in case mix from improved documentation and coding." 72 *Fed. Reg.* 24711 (May 3, 2007). CMS states that:

> this proposed budget neutrality adjustment is necessary to ensure that estimated aggregate LTCH PPS payments would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the proposed LTC–DRG reclassification and update of the relative weights. As discussed earlier with regards to the IPPS, we have estimated that a 2.4 percent adjustment is needed to maintain budget neutrality. We believe an adjustment of at least 2.4 percent for both FYs 2008 and 2009 is appropriate under the LTCH PPS because LTCHs have an average inpatient length of stay greater than 25 days and due to the comorbidities of these patients, LTCHs will have a significantly increased opportunity to better code for these patients under the proposed MS–LTC–DRG system.

The proposed -2.4% is inappropriate for LTCHs. The LTCH-PPS has been in place since 2003 and the proposed coding adjustment is being applied prospectively, without observing the effect of the changes to the LTCH-PPS classification system. In its preamble to the RY 2008 LTCH-PPS Final Rule, CMS stated its "belief that several factors have affected the changes to the LTC-DRG relative weights over the past 4 years, including actual improvements in coding so that **cases are appropriately assigned to LTC-DRGs**." 72 *Fed. Reg.* 26880 (May 11, 2007) (emphasis added). With appropriate coding, a reduction will not result in the budget neutrality which CMS intends: it will have a negative impact on the LTCH industry.

The proposed 2.4% reduction assumes that all discharges from LTCHs are paid based on the standard amount. This is accurate in the short-term acute care hospital ("ACH") scenario (where even transfer cases are paid on a *per diem* basis, based upon the IPPS standard amount) but not in the LTCH scenario. Approximately 34% of LTCH cases are paid under the short-stay outlier ("SSO") policy) and, therefore, are paid at or below cost, with no opportunity for upcoding. *See* Exhibit 5 of the Lewin Report, at p. 10.

In the ensuing comments, NALTH will use the following terminology:

"Severity Level"
The proposed MS-DRGs and MS-LTC-DRGs can have up to 3 severity levels.
- Severity Level 1 is the most severe.
- Severity Level 2 is intermediate.
- Severity Level 3 is the least severe and sometimes is referred to as the "**Base DRG**."

"DRG Family"
A group of related MS-DRGs or MS-LTC-DRGs sometimes is referred to as a "DRG family." It is possible to have a 3-member, a 2-member or a 1-member DRG family.

"3-Member DRG Family" or "Multi-Member DRG Family"
- Severity Level 1 = condition "with MCC" (major complications and comorbidities)
- Severity Level 2 = condition "with CC" (complications and comorbidities)
- Severity Level 3 (Base DRG) = condition "without CC/MCC"

"2-Member DRG Family" or "Multi-Member DRG Family"
- Severity Level 1 = condition "with CC/MCC" or condition "with MCC"
- Severity Level 3 (Base DRG) = condition "without CC/MCC"

"1-Member DRG Family" or "Single-Member DRG Family"
- Severity Level 3 (Base DRG) = condition "without CC/MCC"

As discussed in the Lewin Report, there are a substantial number of categories of LTCH discharges for which LTCHs have no opportunity to engage in upcoding whatsoever, and others for which they have very little potential to do so. NALTH urges CMS to consider the following:

A. Categories of LTCH Discharges Which Cannot Be Upcoded.

i. Nearly 62% of Current LTCH Discharges Already Are Coded at What Would Be the Highest Severity Level Under the New MS-LTC-DRG System.

The Lewin Group accurately states the fact that LTCHs' patient populations have a high severity level and that a:

> higher initial proportion of LTCH patients in the highest severity categories potentially limits the ability of LTCHs to further increase the severity level (and thus the payment per case) of the patient population. Consequently, the opportunity for "upcoding" would be more limited for LTCHs than ACHs.

Lewin Report at p. 5.

The Lewin Report contains a finding that 61.54% of all LTCH discharges already are assigned to the highest severity level of the applicable DRG family. This is almost triple the number of ACH discharges that appear in the highest severity level MS-DRGs. *See* Exhibit 1 of the Lewin Report, at p. 6. In other words, these discharges are assigned to the highest-weighted DRG in a multi-member DRG family. Therefore, "improved coding" *will not* and *cannot* move them to a higher level: *no higher level exists.*

ii. Nearly 13% of Current, Non-SSO, LTCH Discharges Already Are Coded in DRGs Which Would Have No Higher Severity Level Available Under the New MS-LTC-DRG System.

The Lewin Report found that approximately 12.56% of all non-SSO LTCH cases (versus only 9.81% of all ACH cases) already are assigned to a base DRG which is the only DRG in a single-member DRG family.[1] *See* Exhibit 5 of the Lewin Report, at p. 10. That means there is no related DRG with a higher severity level available. Therefore, no amount of "improved coding" could place these cases at a higher level, since *no higher level exists.*

B. Categories of Discharges Which Are Not Paid Based on an LTC-DRG (and Will Not Be Paid on an MS-LTC-DRG) Basis

i. SSO Cases

The Lewin Report found that approximately 33.97% of all LTCH discharges are not paid on a DRG basis because they are paid on a cost basis under the short-stay outlier ("SSO") policy. *See* Exhibit 5 of the Lewin Report, at p. 10. As the Lewin Report states, most SSO cases are paid at cost and the rest are paid at less than cost. Therefore, these cases "have mitigated opportunity to upcode." Lewin Report at p. 6. In comparison, ACHs have zero SSO cases. *See* Exhibit 5 of the Lewin Report, at p. 10. It is clear that no opportunity exists for LTCHs to improve coding for these cases because they are paid on a non-MS-LTC-DRG basis.

ii. 25% Rule Cases

A significant number LTCH discharges would not be paid on an MS-LTC-DRG basis because they are paid under the 25% rule. This means that they are paid the lesser

[1] This percentage excludes those discharges which are coded in a single-member DRG family and which also fall under the SSO policy. All SSO discharges are discussed separately, in Section II.B., below.

of: (i) the amount otherwise payable under LTCH-PPS; or, (ii) an amount "equivalent to" what would be paid under the IPPS. Effectively, this means they will be paid at rates that are similar to IPPS rates and *not* based on MS-LTC-DRGs. When analyzing CMS' Proposed RY 2008 LTCH-PPS Update Rule, the Lewin Group found that LTCHs would receive, on average, only $479.17 per day for patients who become subject to the 25% rule, while the cost per day for these same patients is approximately $1,275.[2] Since 25% rule cases are paid significantly less than cost, any possible upcoding under the proposed MS-LTC-DRG system would have an insignificant effect. It is important to remember that ACHs have zero 25% rule cases.

C. Discharges Which Have Little Potential for Upcoding

The Lewin Report also analyzed all the LTCH discharges which would have potential for upcoding (*i.e.*, the discharges are not coded at the highest level in a multi-member DRG family, they are not coded using the base DRG in a single-member DRG family and they are not SSO cases[3]). There are approximately 35,355 of these discharges, which equals 25.90% of all LTCH discharges. *See* Exhibit 5 of the Lewin Report, at p. 10. Approximately 97% of these discharges (which equals 25.12% of all LTCH discharges) are in the category which has the least potential for upcoding. *See* Exhibit 3 of the Lewin Report, at p. 9. The Lewin Group determined this by calculating "upcode ratios." For a given multi-level DRG family, the Lewin Group has taken the relative weight of the highest severity level DRG (Level 1, "with MCC" or "with CC/MCC") and divided it by the relative weight of the base DRG, which is at the lowest severity level (Level 3, "w/o CC/MCC"). For example:

$$\frac{\text{Relative Weight of DRG 64 (Intracranial hemorrhage or cerebral infarction w MCC)}}{\text{Relative Weight of DRG 66 (Intracranial hemorrhage or cerebral infarction w/o CC/MCC)}}$$

$$= 1.90 \div 0.85$$

$$= 2.22$$

Since a single-member DRG family would result in a ratio of 1.0, ratios that are closer to 1.0 have little reason to upcode. Put another way, if an LTCH upcoded a discharge in a DRG family with an upcode ratio of 1.17, it would receive only one-fourth of the increase in payment that it would receive if it upcoded a discharge in a DRG family with an upcode ratio of 4.68 (1.17 x 4 = 4.68). As previously stated in this Part II.C. of these comments, the Lewin Group analyzed those LTCH discharges which would have potential for upcoding and 97% of them fall into the lowest upcode ratio quartile, with very little potential for upcoding. 0% of the LTCH discharges which possibly could upcode fall into the highest upcode ratio quartile (which would have the most reason to

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[2] According to the Lewin Report, "25% rule cases ... are already paid at significantly reduced rates ... and, therefore, are not affected by DRG relative weights." Lewin Report, at p. 9.

[3] However, some of these remaining cases would fall under the 25% rule. Therefore, any possible upcoding would have an insignificant effect because they still would be paid at far below cost, rather than based on a full MS-LTC-DRG.

upcode). ACH discharges, on the other hand, are spread fairly evenly among the upcode ratio quartiles. 45% of the ACH discharges which possibly could upcode fall in the lowest two quartiles (with the least potential for upcoding) and 55% fall in the highest two quartiles (with the most potential for upcoding).

D. There Is No Reasonable Scenario Which Would Justify the Proposed 2.4% Reduction

Using MedPAR 2006 data, the Lewin Group looked at the discharges within DRGs that have multiple severity levels and built a scenario "whereby all the cases in the lower severity levels were coded to the highest severity level within the DRG family." In other words, the Lewin Group determined what the change in case mix index ("CMI") would be if *every* LTCH, upcoded *every* discharge to the *highest* possible severity level. Even in this scenario, LTCHs' *maximum* potential for upcoding would only result in a 3.61% increase in CMI. *See* Exhibit 4 of the Lewin Report, at p. 9.

Since CMS' proposed 2.4% reduction is supposed to "eliminate the effect of changes in coding or classification of discharges that do not reflect real changes in case-mix," 66% of all LTCH cases that could be upcoded would have to be upcoded to their *maximum* level in order to make the proposed 2.4% decrease in the LTCH weights budget neutral (66% of 3.61 = 2.4). This also assumes that QIOs, which are required to review LTCH discharges and assess the accuracy of coding, would agree with all 66% of these cases. It is not reasonable for CMS to assume that a potential exists for LTCHs to improve coding, to the maximum extent possible, for 66% of all their patients.

E. Summary

i. The Vast Majority of all LTCH Discharges – More Than 74.10% – Provide No Opportunity to Upcode.

- 27.57% (excluding SSO discharges) already are coded at the highest severity level
- 12.56% (excluding SSO discharges) are coded in single-member DRG families
- 33.97% are paid at or below cost because they are subject to the SSO policy

74.10%

This does not include those discharges which are paid far below cost as a result of being subject to the 25% rule (and for which any possible upcoding under the proposed MS-LTC-DRG system would have an insignificant effect).

ii. A Further 25.12% of All LTCH Discharges Are in the Lowest Upcode Ratio Quartile and, Therefore, Have Little Potential for Upcoding

- After excluding the 74.10% of LTCH discharges that fall in the categories outlined in Part II.E.i., above, 35,355 LTCH discharges remain. *See* Exhibit 5 of the Lewin Report, at p. 10. 97% of these fall into the lowest upcode ratio quartile.

See Exhibit 3 of the Lewin Report, at p. 9. This is equal to 25.12% of all LTCH discharges (0.97 x 35,355 ÷ 136,504 = .2512).

- 74.10% + 25.12% = **99.22%** of discharges which either have no opportunity or little reason to upcode. This percentage does not include those discharges which are paid far below cost as a result of being subject to the 25% rule (and for which any possible upcoding under the proposed MS-LTC-DRG system would have an insignificant effect).

iii. A 2.4% Reduction in LTCH Weights Would Not Be Budget Neutral

- A 2.4% reduction in LTCH weights is not reasonable because it is based on the untenable assumption that LTCHs will ignore coding standards and, instead, will upcode virtually every case which can be upcoded. If LTCHs upcoded every discharge which possibly could be upcoded, it would result in an increase in CMI of only 3.61%. This means that two-thirds of all LTCH cases which could be upcoded would have to be upcoded to the highest level, and each instance of upcoding would have to be accepting upon QIO review, in order to make the proposed 2.4% reduction budget neutral. Such a scenario defies common sense and should point decidedly toward CMS' not imposing a reduction on MS-LTC-DRG weights.

F. CMS' Rationales for the Proposed Coding Adjustment Are Problematic

i. Maryland Experience

In July of 2005, Maryland finished a transition period and, as a result, all of its ACHs now are paid using All Patient Refined DRGs ("APR-DRGs"). At p. 24709 of the preamble, CMS states:

> Hospitals in Maryland improved coding and documentation in response to the adoption of APR DRGs. As a result of this improved documentation and coding, reported CMI increased at a greater rate than real CMI. Given the similarity between coding incentives using the APR DRGs in Maryland and the MS–DRGs that are being proposed for Medicare, we analyzed Maryland data to develop an adjustment for improved documentation and coding.

There are, however, only four LTCHs in Maryland and these hospitals are not paid under the APR-DRG system but, rather, on a cost basis. *See* p. 4 of the Lewin Report. Therefore, payments to the four Maryland LTCHs were *not* part of any "improved" coding which resulted in the CMI increase of 2.8% in Maryland during the time of the adoption of the APR-DRGs. *Ibid.*

Furthermore, in its analysis of the Maryland situation, the Lewin Report states that "[d]rawing a parallel with the experience of Maryland hospitals has several problems." *See* p. 4 of the Lewin Report. Aside from the fact that the State of Maryland does not provide for payment of LTCHs on an APR-DRG basis, the Lewin Group emphasizes that MS-LTC-DRGs and APR-DRGs "are two completely different systems for classifying patients." Since there are more categories of APR-DRGs (1,290 categories), they provide more room for increasing CMI through upcoding. Furthermore, Maryland has different rate-setting practices from the rest of the country and "Maryland hospitals clearly are very different from other hospitals in terms of their coding methodologies and responsiveness to coding changes." *Ibid.*

ii. RAND Report

In FY 2006 and FY 2007, under the Inpatient Rehabilitation Facility ("IRF") PPS, CMS adjusted the IRF standardized amount to account for case mix increases due to improvements in documentation and coding. CMS based this adjustment on a technical report published by the RAND Corporation. CMS maintains that the same "analysis ... will apply to both the IPPS and the LTCH PPS" under the new MS-DRGs and MS-LTC-DRGs (72 *Fed. Reg.* 24708). Therefore, the RAND report serves as one of CMS' rationales for its proposed 2.4% payment reduction. The Lewin Report analyzed the Rand report and determined that it was not relevant for the new MS-DRGs and MS-LTC-DRGs. For instance, the circumstances surrounding the adjustment to the IRF-PPS were very different from those surrounding CMS' proposed -2.4% adjustment to the IPPS standard amount and the LTCH weights. The Rand report analyzed "changes in payments that resulted from moving from a cost-based system to a PPS." Lewin Report, p. 4. The Lewin Report concludes that:

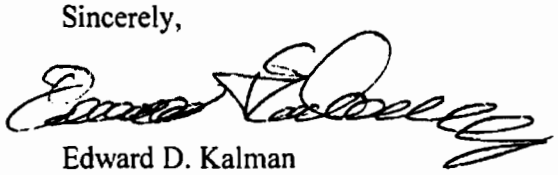
> Since the proposed change to the MS-DRGs (and MS-LTC-DRGs) from DRGs is not as drastic as a change from a cost-based system to a PPS, the coding adjustment for IRF-PPS is not an appropriate precedent for the proposed IPPS MS-DRG/MS-LTC-DRG coding adjustment.

G. Conclusion

The vast majority of LTCH discharges present no opportunity to upcode and most of the remaining LTCH discharges provide little potential to do so. It is unreasonable to think that LTCHs would upcode rampantly enough – or that QIO review would allow them to do so – to make the proposed 2.4% reduction budget neutral. A comparison of LTCH cases to ACH cases shows a marked disparity in the opportunities to upcode and, therefore, in the maximum potential to change CMI. *See* Exhibit 5 of the Lewin Report, at p. 10. Therefore, if CMS continues to believe that a reduction is necessary, it should differentiate accordingly between a reduction applied against the IPPS standard amount (related to expected improved coding in MS-DRGs) and a reduction applied against LTCH weights (related to expected improved coding in MS-LTC-DRGs). See the Lewin Report, at p. 10.

NALTH thanks the Secretary for consideration of these comments. Please contact the undersigned should you need further assistance.

Sincerely,



Edward D. Kalman
General Counsel

Appendix A

The Lewin Group

Evaluation of the Proposed Coding Adjustment to the DRG Relative Weights for Long-Term Care Hospitals for FY 2008

Prepared for:

National Association of Long Term Hospitals

Prepared by:

Allen Dobson, Ph.D.
Namrata Sen, M.H.S.A.
Ted Kirby
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June 11, 2007

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I. PURPOSE

The Lewin Group was commissioned by National Association of Long Term Hospitals (NALTH) to assist in responding to the proposed reduction in Medicare payment amounts for FY 2008 and FY 2009, as stated in the Inpatient Prospective Payment System (IPPS) Notice of Proposed Rule Making (NPRM) for FY 2008. The Centers for Medicare and Medicaid Services (CMS) believes that the adoption of Medicare severity adjusted DRGs (MS-DRGs) would create a risk of increased aggregate levels of payment as a result of improved documentation and more accurate coding. Consequently, CMS has proposed to adjust the relative weights that are used for the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) by -2.4 percent (0.976) in FYs 2008 and 2009 to account for the anticipated increase in case mix from improved documentation, coding and other sources.[1]

A hospital's case mix index (CMI) measures the expected treatment cost of the mix of patients treated by a particular hospital. CMS has stated in the preamble to the NPRM that the case mix could change for two reasons.

- Treating a more resource intensive patient mix – real change in case mix
- Changes in documentation and coding practice – "upcoding"

Under section 1886(d)(3)(A)(vi) of the Act, CMS may adjust payments so as to eliminate the effect of changes in coding or classification of discharges that do not reflect real changes in case mix. With the adoption of the MS-DRGs, CMS is concerned that the increase in the number of DRGs will incentivize hospitals to do more accurate documentation and coding of information in the medical record. CMS also believes that the potential for more accurate and complete documentation and coding will apply equally under the acute hospital Inpatient Prospective Payment System (IPPS) and the LTCH-PPS because the inpatient MS-DRGs will be used to develop Medicare Severity DRGs for LTCHs (MS-LTC-DRGs). That is, the same DRG grouping system will be used for both payment systems. However, as we note below, the actual codes used in each payment system will vary dramatically in practice.

CMS provides two rationales for the proposed coding adjustment.

- CMS considerations of the recent experience of the State of Maryland with adopting the All-Patient Refined Diagnosis Related Group (APR-DRG) system.
- CMS' previous experience in adjusting the standardized amount under the Inpatient Rehabilitation Facility (IRF)-PPS to account for case mix increases due to improvements in documentation and coding, based on a technical report published by RAND.

[1] 72 Federal Register, pg. 24711.

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In order to evaluate the proposed 2.4 percent reduction of the MS-LTC-DRG relative weights, The Lewin Group conducted three sets of interrelated analyses as follows:

(1) Examined the logic used by CMS to propose a reduction in the DRG relative weights to account for coding changes

(2) Analyzed the ability of long-term hospitals to "upcode"

(3) Investigated the potential for LTCHs to code into higher weighted DRGs.

II. BACKGROUND

When a cost-reimbursement system is replaced by a prospective payment system (PPS), providers have an increased incentive to report all appropriate codes for their patients, because of the corresponding increase in payment. For a new system to be budget-neutral in the first year of a PPS system, CMS must set payment rates based on the codes reported in the pre-implementation period. Improved documentation and more accurate coding on the part of providers in later years can lead to higher payments for providers than anticipated under the assumptions used to set the payments in the first year of the new system. Such unanticipated payment increases are often called "upcoding" or "code creep" since the increases are caused by changes in coding practices rather than actual increases in the intensity of resources to treat patients.

This potentially higher payment – due to the impact of coding changes in the first year as compared to later years of implementation – can be measured in terms of the case mix index. In the past, CMS retrospectively has adjusted DRG weights and payments to account for possible "upcoding."

In response to the recommendation contained in the March 2007 MedPAC report to Congress[2] for CMS to develop and implement a severity-adjusted DRG system, CMS has proposed the creation of a new DRG system. CMS is calling the new DRG system Medicare Severity DRGs (MS-DRG). The MS-DRGs are based on the current CMS DRGs, which have been regrouped into "families" of DRGs and assigned weights based on the severity of the underlying conditions.

The development of the MS-DRGs involved three steps – consolidation of the existing DRGs into base DRGs or families of DRGs, categorization of each code as containing MCCs (major complications and comorbidities), CCs (complications and comorbidities) or not containing MCCS and/or CCs. Each MS-DRG family is subdivided into subclasses based on the presence or lack of MCCs and/or CCs.

This subdivision of DRG families creates more MS-DRG codes than exist in the current (Grouper Version 24) DRG system. With the higher number of DRGs under MS-DRGs, CMS is

[2] MedPAC, March 2007. *Report to Congress: Medicare Payment Policy.*

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concerned that hospitals would improve their coding practices, which could result in cases being coded under higher paid MS-DRGs. In the following discussion, we note several reasons why this fear may be ungrounded for LTCHs. Most importantly, we note that MS-LTC-DRGs contain fewer "working" DRGs with different sets of severity ratings than MS-DRGs and also that the LTCH-PPS has different payment characteristics than the IPPS, resulting in markedly less ability for LTCHs to upcode than is assumed in the notice of proposed rulemaking.

Each MS-DRG family contains one to three codes. For the purposes of this analysis, we assigned each MS-DRG a severity level based on the presence or absence of "MCC" and "CC" in the DRG description. This methodology leads to the following severity levels for MS-DRG families that contain three codes (or three "family members"). The severity levels are as follows (in order of decreasing severity):

1. with MCC, the most severe
2. with CC
3. without CC/MCC, the least severe

For 2-member families, the severity levels are (in order of decreasing severity):

1. with CC/MCC (or with MCC), more severe
2. without CC/MCC, (or without MCC) less severe

For 1-member families, there is only one severity level:

1. without CC/MCC

The MS-DRG families with multiple members (i.e., two or three codes in the family) are the families that would be susceptible to "upcoding" since the weight (and thus the payment for the case) increases as the severity level increases. Upcoding within MS-DRG families containing only one severity level is impossible since there is no weight increase possible within a one code family.

III. EXAMINED THE LOGIC USED BY CMS TO PROPOSE A REDUCTION IN THE DRG RELATIVE WEIGHTS TO ACCOUNT FOR CODING CHANGES

CMS offers two rationales for their proposed reduction in DRG relative weights to account for coding changes:

- Recent Maryland experience in converting to APR-DRGs.
- Evidence supplied in a RAND report, relative to the IRF-PPS.

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A. CMS' Interpretation of the Case Mix Effects of the Adoption of the APR-DRG System by the Hospitals in the State of Maryland

CMS' rationale for the 2.4 percent coding adjustment is based in part on the recent transition of Maryland hospitals to All Patient Refined Diagnosis Related Groups (APR-DRGs)[3]. The case mix index for the hospitals increased by 2.8 percent during the time of the adoption of APR-DRGs in FY 2005.

Drawing a parallel with the experience of Maryland hospitals has several problems. First, MS-DRGs and APR-DRGs are two completely different systems for classifying patients. Due to the higher number of categories (1,290 categories), APR-DRGs provides greater potential for increasing case mix index though "upcoding". Second, due to rate-setting practices exclusive to the state, Maryland hospitals clearly are very different from other hospitals in terms of their coding methodologies and responsiveness to coding changes. Most importantly, there are only four LTCHs in the State of Maryland and about 400 LTCHs in the MedPAR data. Based on our discussion with Maryland Health Services Cost Review Commission, none of the four LTCHs were included in the adoption of APR-DRGs. Also, LTCHs in Maryland are reimbursed on a cost basis. Hence, the 2.8 percent case mix change and consequently, the 2.4 percent coding adjustment has no relevance to LTCHs.

B. CMS' Interpretation of the RAND Report

The circumstances of the coding adjustment applied to the IRF-PPS and the proposed coding adjustment for IPPS are very different. RAND was commissioned by CMS to study the case mix changes as a result of the IRF-PPS implementation. That is, the purpose of the study was to analyze changes in payments that resulted from moving from a cost-based system to a PPS.

RAND analyzed the changes in the case mix from pre-IRF-PPS data of 1999 to post-IRF-PPS data of 2002 and decomposed the change into changes due to real case mix increase versus provider coding practices. The IRF-PPS coding adjustment was applied four years after PPS implementation. IPPS has been in place since 1983 and the proposed coding adjustment is being applied prospectively without observing the effect of the changes to the IPPS payment classification system. Since the proposed change to MS-DRGs (and MS-LTC-DRGs) from DRGs is not as drastic as a change from a cost-based system to a PPS, the coding adjustment for IRF-PPS is not an appropriate precedent for the proposed IPPS MS-DRG/MS-LTC-DRG coding adjustment.

[3] The APR-DRG system is a 3M proprietary severity-adjusted DRG system. Each APR-DRG is assigned four weights that vary by the Severity of Illness (SOI) level. SOI 1 is the least severe (i.e., has the lowest relative weight) while SOI 4 is the most severe (i.e., has the highest relative weight within the DRG).

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Exhibit 1: Comparison of Distribution for LTCH and ACH Cases Across DRGs with Different Severity Levels

[illegible]	[illegible]	ACH	[illegible]
Severity Level 1 (with MCC or with CC/MCC DRGs + SSO	Number of Discharges	2,381,360	84,007 (46,374 SSO cases + 37,633 Severity Level 1 w/o SSO cases)
	Percent of Discharges	20.74%	61.54%
Severity Level 2 (with CC DRGs) w/o SSO	Number of Discharges	2,421,234	19,793
	Percent of Discharges	21.08%	14.5%
Severity Level 3 (None) w/o SSO	Number of Discharges	6,681,514	50,650
	Percent of Discharges	58.18%	23.9%
Total	Total Discharges	**11,484,108**	**136,504**

Percentages in this column are percentages of the 136,504 LTCH discharges represented in this table.

Source: The Lewin Group analysis of MedPAR 2006.
Note: MCC – Major Complications and Comorbidities; CC – Complications and Comorbidities
ACH – Acute Care Hospital; LTCH – Long-Term Care Hospital; SSO – Short-Stay Outlier

About 34 percent of LTCH cases in the 2006 MedPAR data are short-stay outliers (SSOs) ***(Exhibit 1-A)***. The reimbursement for these cases is at cost or less than cost. For the SSO cases that are paid at cost, there is no payment effect, as the DRG weight does not factor into the calculation. The other cases are paid at less than cost and have mitigated opportunity to upcode.

Exhibit 1-A: Percentage of LTCH Discharges that Are SSOs

[illegible]	[illegible]
Number of Discharges	**136,504**
Number of SSO Cases	**46,374**
Percent of SSO Cases	**34%**

Eliminating the SSO cases significantly reduces the number of cases that LTCHs could, potentially, "upcode." The number of non-SSO cases in the lowest severity category (Severity level 3) as a percentage of all LTCH discharges is approximately 24 percent, which is less than half of the proportion of ACH discharges in this severity category. We also note that many LTCH cases would be paid under the "25 percent rule," which significantly reduces payment and further reduces the effect of upcoding.

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B. LTCHs have a higher proportion of codes not subject to upcoding than ACHs

Not all cases in the "None" severity category are subject to "upcoding." As indicated above, this category includes both the DRGs in the MS-DRG/MS-LTC-DRG families that have only one code, and the lowest severity DRG of the multiple-member MS-DRG families.

For example, DRG 69 (Transient Ischaemia) is in a single-member MS-DRG Family. Thus, hospitals will be unable to "upcode" within this MS-DRG family since there is only one severity level. However, providers might be able to "upcode" in the MS-DRG 64 family. This family includes cases involving intracranial hemorrhage or cerebral infarction and includes three severity levels ("w MCC," "w CC," and "w/o CC/MCC"). It may be possible for hospitals to "upcode" from the lower-severity DRG 66 to one of the higher-severity members of the family.

DRG	Description
64	Intracranial hemorrhage or cerebral infarction w MCC
65	Intracranial hemorrhage or cerebral infarction w CC
66	Intracranial hemorrhage or cerebral infarction w/o CC/MCC

With this distinction in mind, we further analyzed the cases included within the lower severity classes. We compared the case counts across hospital type.

Exhibit 2 shows that of the 79,520 LTCH cases in the lower severity categories, about 37 percent (29,430 / 79,520) are in single-member MS-DRG families and, thus, not subject to upcoding. This compares with about 12 percent (1,126,760 / 9,102,748) of lower-severity ACH cases occurring in single-member MS-DRG families. Therefore, ACHs have much more opportunity to upcode within MS-DRG families compared to LTCHs. In fact, the proportion of ACH cases that may allow such upcoding is over 3 times the proportion of such LTCH cases.

Exhibit 2: Distribution of Cases in Lower-Severity DRGs (Severity Levels 2 & 3) - Comparison of Acute Care and Long Term Care Hospitals

	Hospital Type					
	Acute Care Hospitals			Long-Term Care Hospitals		
Statistic	DRGs in Multiple-Member Families	DRGs in Single-Member Families	Total	DRGs in Multiple-Member Families	DRGs in Single-Member Families	Total
Total Discharges	10,357,348	1,126,760	11,484,108	107,074	29,430	136,504
Discharges at Lower Severity Levels (Severity Levels 2 & 3)	7,975,988	1,126,760	9,102,748	50,090	29,430	79,520

Source: The Lewin Group analysis of MedPAR 2006

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Exhibit 3: Distribution of "Upcode Ratios" by Hospital Type

MS-DRG "Upcode Ratio" Quartile	Percent of discharges with "Upcode Ratios" in Quartile	
	ACH	LTCH*
First Quartile (1.24 - 1.64)	25	97
Second Quartile (1.64 - 1.69)	20	1
Third Quartile (1.69 - 2.01)	30	1
Fourth Quartile (2.01 - 4.68)	25	0
TOTAL	100	100

Note: Percentages may not add up to 100 because of rounding.
* LTCH distributions are similar when excluding SSO cases.

Based on our analyses of MedPAR 2006 data, we attempted to determine the change in case mix index which would result if hospitals aggressively changed their coding practices. Using the cases within the multiple severity level DRGs, we built a scenario whereby all the cases in the lower severity levels were coded to the highest severity level within the DRG family. For instance, cases assigned to DRGs 66 and 65 were coded so as to be assigned to DRG 64. This simulation determines the "maximum upcoding" possible, as defined above.

Exhibit 4 shows that the CMI for LTCHs under the "maximum upcode" scenario would rise from 0.993 to 1.029, an increase of 3.6 percent.

Exhibit 4: Change in Coding due to Maximum Upcoding

LTCHs	0.993	1.029	3.61%

We note that the 3.61 percent increase in CMI does not take into consideration the reduction in upcoding possibilities for LTCHs because of the SSO and 25% rule cases that are already paid at significantly reduced rates (i.e., at cost or less), and, therefore, are not affected by DRG relative weights.

VI. CONCLUDING COMMENTS

As part of the proposed changes to the IPPS, CMS is introducing a new severity adjusted DRG system. Under this system, current IPPS DRGs are replaced by Medicare Severity DRGs (MS-DRGs). Also, a version of these DRGs will be created for LTCHs, called MS-LTC-DRGs. As in the past, MS-LTC-DRGs are based on (IPPS) MS-DRGs.

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Because of the potential for "upcoding" under the new MS-DRG system, CMS has proposed reducing payments to hospitals by 2.4 percent, either by reducing the Standardized Payment Amount (for IPPS cases) or by reducing the MS-LTC-DRG weights (for LTCH-PPS cases). Implicit in this recommendation is the assumption that ACHs and LTCHs have equal opportunities to "upcode" their cases to take advantage of the higher payments for higher-severity MS-DRGs.

We have shown, from numerous vantage points, that LTCHs have far less potential than ACHs to "upcode" under the move to MS-DRGs. Thus, it would be inappropriate to reduce LTCH payments by the same amount as ACH payments.

Our analyses demonstrate that the CMS arguments for prospective payment reductions associated with hypothetical coding increases for LTCHs are highly implausible. At the very least, if CMS decides to continue with the coding adjustment, the coding adjustment for LTCHs should be considerably less than that applied to ACHs.

Exhibit 5 provides a summary of cases which cannot be upcoded to higher relative weights among MS-DRGs (ACH) and MS-LTC-DRG (LTCH). For ACHs, Severity Level 1 and single-member family MS-DRG cases would not be amenable to upcoding. These cases represent approximately 31 percent of all ACH cases. For LTCHs, severity level 1, short stay outliers (SSO) and single-member family MS-LTC-DRG cases would not be amenable to upcoding. These cases represent approximately 75 percent of all LTCH cases. These numbers suggest that LTCHs are about 2.5 times less likely to upcode than ACHs (75/31 = 2.42). If CMS applies the proposed coding adjustment of -2.4 percent to ACHs, this would imply, at most, a 0.99 percent adjustment to LTCHs. This reduction should be further reduced to account for the 25 percent rule and the level of upcoding (the upcode ratios) possible for LTCHs.

Exhibit 5: Summary of Cases Which Cannot be Easily Upcoded

	ACHs		LTCHs	
	Number of Cases	Percent of Cases	Number of Cases	Percent of Cases
Severity Level 1 w/o short stay outliers	2,381,360	20.74%	37,633	27.57%
Short Stay Outliers	NA	NA	46,374	33.97%
DRGs in Single Member Families	1,126,760	9.81%	17,142	12.56%
Cases that Can Be "Upcoded"	7,975,988	69.45%	35,355	25.90%
Total Cases	11,484,108	100%	136,504	100%

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CMS-1533-P-298 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Atrial Fibrillation - Unfortunately, the coding system does not allow differentiation between a controlled and an uncontrolled atrial fibrillation. We agree that a controlled atrial fibrillation does not place the patient at a severity level worthy of CC designation. However, we believe that a new-onset atrial fibrillation or an uncontrolled atrial fibrillation (with a rapid ventricular rate, with CHF) indicates a higher level of severity. By eliminating code 427.31, hospitals would be unfairly penalized when caring for the patient with a new-onset or uncontrolled atrial fibrillation. We continue to believe that hospitals should not be penalized in the MS-DRG system because of deficiencies in the coding system.

CMS-1533-P-299 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Date & Time:** **06/11/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

IME Adjustment

IME Adjustment

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-1533-P-300 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Carla Terry** **Date & Time:** **06/11/2007**

Organization : **Idaho Hospital Association**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-300-Attach-1.DOC

#300

June 6, 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:

On behalf of our 39 member hospitals, the Idaho Hospital Association (IHA) 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 IHA 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 to all hospitals over five years** – to eliminate what you claim will be the effect of classification changes that do not reflect real changes in case-mix. In addition, the rule proposes continuing the three-year transition to cost-based relative weights, with two-thirds of the FY 2008 weight based on costs and one-third based on charges.

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

The hospital field supports meaningful improvements to Medicare's inpatient PPS. While we believe that the MS-DRGs provide a reasonable framework for patient classification, a transition is necessary given that

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the change redistributes between $800 million and $900 million among all hospitals and specifically cuts payments to Idaho hospitals by $4.6 million for FY '08.

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 all 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.

More detailed comments are as follows:

DRG REFORM AND PROPOSED MS-DRGS

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

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

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

However, payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Even with the DRG changes proposed by CMS, physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving uninsured, Medicaid and other low-income patients, practice similar forms of selection for outpatient services and drive up utilization. We urge CMS to address the real issue of self-referral: to rigorously

examine the investment structures of physician-owned, limited-service hospitals and consider our comments on CMS' interim report on the strategic plan required by the *Deficit Reduction Act of 2005* (DRA).

SEVERITY OF ILLNESS

For FY 2008, CMS proposes to refine the current DRG system by implementing Medicare-Severity DRGs (MS-DRGs), increasing the number of DRGs from 538 to 745. In addition, CMS has undertaken an overhaul of today's complication and comorbidity (CC) list and created up to three tiers of payment for each DRG based on the presence of: a ***major*** complication or comorbidity (MCC), ***a*** complication or comorbidity, or ***no*** complication or comorbidity.

Last year, the AHA 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.

Our 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 all 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 IHA opposes the "behavioral offset," which will cut payments to all hospitals by $24 billion over the next five years and is estimated to cut payments to Idaho hospitals in FY '08 by $6.6 million. 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. The AHA 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. The AHA 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, the AHA is unable to determine why significant secondary diagnoses requiring additional resources have been removed from the 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.

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.

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. Sometimes the mismatching problem is caused by edits in the FIs payment system which limit the provider's choice of assigning to an appropriate revenue center. 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 IHA 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 to all hospitals of $880 million over the next five years that urban hospitals cannot sustain in an already under-funded system.

Capital cuts of this magnitude will disrupt hospitals' ability to meet their existing long-term financing obligations for capital improvements. Hospitals have committed to these improvements under the expectation that the capital PPS would remain a stable source of income. Reducing capital payments would create significant financial difficulties and amounts to Medicare reneging on the full cost of caring for America's seniors and disabled. **The IHA 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 IHA also opposes possible future cuts to the IME and DSH adjustments under the capital system. CMS has no analysis of the impact of these proposed changes on the high-caliber medical education of our future physicians and the community-wide services on which hospitals often lose money providing, such as burn and neonatal units. It is irresponsible of CMS to make such changes without a clear understanding of the broader ramifications.

DRGS: HOSPITAL-ACQUIRED CONDITIONS

The DRA requires CMS to identify by October 1, 2007 at least two preventable complications of care that could cause patients to be assigned to a CC DRG. The conditions must be either high cost or high volume or both, result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and be reasonably preventable through the application of evidence-based guidelines. The DRA mandates that for discharges occurring on or after October 1, 2008, the presence of one or more of these preventable conditions would not lead to the patient being assigned to a higher-paying DRG. That is, the case would be paid as though the secondary diagnosis were not present. Finally, the DRA requires hospitals to submit the secondary diagnoses that are present on admission when reporting payment information for discharges on or after October 1, 2007. CMS recently announced that the start date for coding what is present on admission would be delayed until January 1, 2008 due to technical difficulties in software programming to accept the new information.

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

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

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

<u>Conditions to include for FY 2009</u>. The IHA believes that three of the six conditions representing the serious preventable events identified by CMS – object left in during surgery, air embolism and blood incompatibility – are appropriate conditions to include for FY 2009. Because these conditions are identified by discrete ICD-9 codes, they can be coded by hospitals. More importantly, these are events that can cause

great harm to patients and for which there are known methods of prevention. America's hospitals are committed to patient safety and strive to ensure that these events do not happen.

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

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

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

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

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

the agency should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers because, in these cases, the condition may not be reasonably prevented.

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

  In addition, after talking with infectious disease experts, we believe the category of staphylococcus aureus septicemia is simply too large and varied to be able to say with confidence that the infections were reasonably preventable. **We urge CMS to narrow this category to include only patients for whom it is reasonably clear that the hospital was the source of the infection and that it could have been reasonably prevented.** We are happy to work with CMS in helping to more accurately identify these patients.

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

Unintended consequences. The IHA 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 IHA would like clarification from CMS on how hospitals may appeal a CMS decision that a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or comorbidity DRG payment.

HOSPITAL QUALITY DATA

The DRA expanded quality reporting requirements for hospitals to be eligible to receive a full market basket update. The DRA provided the Secretary with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures on the basis that they are no longer appropriate. In the proposed rule, CMS puts forward five new measures – four process measures and one outcome measure – to be included for the FY 2009 annual payment determination. To receive a full market basket update, hospitals would have to pledge to submit data on these and all measures currently included in the Hospital Quality Alliance's (HQA) public reporting initiative for patients discharged on or after January 1, 2008. In addition, hospitals would have to pass data validation tests for data submitted in the first three calendar quarters of 2006.

New quality measures. We are pleased that CMS has proposed adding only measures that have been adopted by the HQA for public reporting in FY 2009. The HQA's rigorous, consensus-based adoption process is an important step towards ensuring that all stakeholders involved in hospital quality – hospitals,

purchasers, consumers, quality organizations, CMS and others – are engaged in and agree with the adoption of a new measure, and CMS should continue to choose from among the measures adopted by the HQA in linking measures to payment. The measures proposed for FY 2009 are well-designed, represent aspects of care that are important to patients, and provide insights into the safety, efficiency, effectiveness and patient-centeredness of care.

Adoption by the HQA is only one of three criteria that we believe all new measures included in the pay-for-reporting program should fulfill. In addition to HQA adoption, all measures should be endorsed by the National Quality Forum (NQF) through its consensus review process. We appreciate CMS' statement that, should any of the measures proposed for FY 2009 not receive NQF endorsement by the time of publication of the final rule, they will not be adopted for FY 2009. Finally, prior to inclusion in the pay-for-reporting program, all measures should undergo a field test to observe for any operational issues and assess the degree to which the measures can be implemented successfully by hospitals and data vendors.

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

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

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

Measure maintenance. The IHA 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.

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 IHA 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.**

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 IHA 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 IHA 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. The AHA workgroup, comprised of state, regional and metropolitan hospital association executives as well at other national hospital associations, ranked their concerns as follows:

1. Volatility of wage index year to year.

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

3. Unrealistic geographic boundaries.

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

5. Inaccurate measure of actual labor costs.

6. Fiscal intermediaries are inconsistent in their interpretations.

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

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

Regarding MedPAC's recommendation, which will be released in its June report, the workgroup 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 IHA 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 IHA supports implementation of a physician-ownership disclosure requirement.**

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

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

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

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

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

PATIENT SAFETY MEASURES

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

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

While these requirements may sound reasonable, we believe they miss the mark on the real issue to be addressed: safety concerns in physician-owned specialty hospitals.

It makes sense to apply special requirements like these to physician-owned specialty hospitals, but not to all hospitals. The reason: The safety concerns that have been raised with physician-owned specialty hospitals occur because these facilities operate outside the traditional network of care delivery in this country. They are free-standing facilities, are generally not part of a larger system of care, most often have no transfer agreements with other hospitals or providers of care in a community, and tend to specialize in one type of care delivery, challenging their ability to treat the unexpected event or emergency.

This is not the case with full-service community hospitals. Full-service community hospitals are part of a network of care in their community, involving referrals from local physician practices, reliance on local trauma support networks, participation in local emergency medical transport systems and transfer agreements among facilities. Even small and rural hospitals located in more remote areas are part of a planned network of care and patient triage. Small and rural hospitals often stabilize and transport patients to other facilities, but that transport is communicated, the receiving hospital is alerted and the patient's clinical information collected at one hospital goes with the patient to the next hospital. Small and rural hospitals also are often connected to a system of care through telemedicine, which allows for access in more remote areas to specialists and other clinical expertise available at larger, more urban hospitals. **Applying additional requirements for this group of hospitals is unnecessary and costly.**

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

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

IME ADJUSTMENT

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

Under the proposed rule, vacation and sick time would be removed from the total time considered to constitute an FTE resident. Thus, it would be removed from both the numerator and denominator of the

FTE calculation. CMS acknowledges that this would result in lower FTE counts for some hospitals and higher counts for other hospitals, solely because of this regulatory change.

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

REPLACED DEVICES

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

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

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

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

DRG payments are fundamentally based on averages of historical costs and charges. To reduce the payment for cases involving replacement of a medical device assumes that either these types of cases have not occurred in the past or are occurring at such a dramatic increase as to materially skew the averages used to develop the DRG weights. In fact, CMS notes that "we believe that incidental device failures that are covered by manufacturers' warranties occur routinely." This statement acknowledges that incidental device failure has occurred in the past and was likely covered by the manufacturer warranty. If so, this practice is part of the historical cost and charge data used to develop the current DRG weights for cases involving implantation. Reducing payment for certain cases involving a re-implantation would ignore the average DRG weight for those cases that already implicitly include this reduction. **Therefore, we ask CMS to reconsider implementing this proposal.**

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

NEW TECHNOLOGY

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

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

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

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

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

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

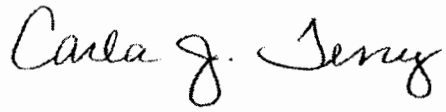
musculosketal system, circulatory system, etc.) were available. The plan was to use codes in chapter 00 first and then begin populating chapter 17.

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

We strongly recommend that the Secretary expeditiously undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS. HHS should take the necessary steps to avoid being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than to respond to the significant problems that will likely result in unreasonable implementation time frames. It is imperative that the rulemaking process start immediately.

We thank you for this opportunity to comment. If you have any questions, I can be reached at (208) 338-5100 or cterry@teamiha.org.

Sincerely,



Carla Terry
Vice President Finance

CMS-1533-P-301 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Susan Kraska** **Date & Time:** **06/11/2007**

Organization : **Memorial Hospital**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

I do SUPPORT the the following preventable events under the POA codes (3) object(s) left during surgery, (4) air embolism, %(5) blood incompatability. These harmful events have known preventable methods of prevention.
I DO NOT support the following 3 events: (1) catheter associated urinary tract infections, (2) pressure ulcers & (6) staphylococcus aureus septicemia as each condition depends on the ability to identify them as well as accurate use of POA codes. Two states currently using POA codes report a minimum of 2 years needed to achieve reliability; much longer than the Jan 1 2008 timeframe proposed by CMS.
I would suggest that active infection prevention programs are making measurable reductions in the areas of 1,2, &6 but they are not easily identified under current coding logic.
Creating more unique ICD-9-CM codes that would allow coding & cross referencing seems more sensable.
I would like clarification on how a hospital could appeal a CMS decision if an error occurred in coding & if a particular patient falls under the hospital-acquired conditions policy & is not eligiblefor a higher complication or co-morbidity DRG payment.
Thank you for considering my comments.
Susan Kraska, RN, CIC

CMS-1533-P-302 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

COPD and Emphysema - codes 496 and 492.8 should continue to be designated as a CC for those patients who are being treated with steroids, inhalers, etc. Patients with this level of severity in their disease, but not in acute exacerbation, require more care, and are at increased risk for other events such as a delay in weaning off a ventilator postoperatively. Hospitals should not be penalized for a deficiency in the coding system. Codes for the stages of the disease would solve the problem. Barring the development of new codes, specific coding rules regarding when to assign the codes should be developed. In the meantime,hospitals should not be penalized.

CMS-1533-P-303 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Date & Time:** **06/11/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

IME Adjustment

IME Adjustment

Orientation Activities

In the proposed rule, you state, 'the hospital (or in many cases, the medical school as the employer of the residents) is required to provide orientation for their residents.' and,

'We note that orientation activities in the hospital setting have historically been counted for direct GME payment purposes in accordance with the regulations at ?413.78(a) which state 'Residents in an approved program working in all areas of the hospital complex may be counted.'

The hospital complex consists of the hospital and any hospital based providers as defined in ?413.65 and subproviders (FR, Vol. 54, No. 188 dated September 29, 1989, pages 40286 and 40299). Therefore, if the orientation takes place in a related medical school, such time could not be counted for GME purposes. Please comment.

CMS-1533-P-304 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Congestive Heart Failure - Code 428.0 should continue to be designated as a CC. This code is an indicator of severity and is not inherent in the codes for diastolic or systolic heart failure. We agree that most physicians use the term "CHF" interchangeably with (or instead of) "diastolic" or "systolic" heart failure. However, to drop this code and allow the unspecified diagstolic heart failure code (428.30)to be designated a CC would be an injustice. The MS-DRG system should not be a way to improve physician description of diagnoses.

CMS-1533-P-305 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Blood Loss Anemia, Acute Posthemorrhagic Anemia - Codes 280.0 and 285.1 should continue to be designated as a CC. Both of these conditions, when at a certain level of severity, can and do impact resources, length of stay and risk of mortality. It is particularly confusing to see these conditons eliminated when codes for a 'Precipitous Drop in Hematocrit', 790.01, and 'Blood in Stool', 578.1, are designated as a CC. Code 790.01 may have some use in the outpatient setting but it is rarely, if ever, used as a 'diagnosis' in an inpatient setting. We recognize that blood loss anemia and post-hemorrhagic anemia have been troublesome because the coding system lacks criteria about when it is appropriate to assign codes to these diagnoses. 'Query the physician' should no longer be the only guiding light for coders on the appropriateness of when to assign codes. The codes should either be developed further to specify the acuity of the anemia or criteria/guidelines should be issued. In the meantime, hospitals should not be penalized for the shortcomings in the system.

CMS-1533-P-306 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Jenny Nadoff** **Date & Time:** **06/11/2007**

Organization : **Jenny Nadoff**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

Thank you.

CMS-1533-P-307 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Type 1 Diabetes Mellitus - Codes which indicate Type 1 diabetes with a specific complication such as retinopathy, neuropathy, and nephropathy should continue to be designated as a Major CC. Type 1 diabetes without a complication (250.01) should be designated as a CC. This type of diabetes is an indicator of severity and always requires more intensive monitoring, potential adjustments of insulin and diet considerations.

CMS-1533-P-308 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Systemic Lupus Erythromatosus (SLE) - Code 710.0 should not be eliminated as a CC. Many SLE patients are on methotrexate and/or high- dose steroids and aer immuno-compromised. This chronic condition usually has a significant impact on the evaluation and treatment plan when a patient is admitted for another reason.

CMS-1533-P-309 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Paul Winner** **Date & Time:** **06/11/2007**

Organization : **American Headache Society**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Comment on Proposed MS-DRGs 102 and 103 for Inpatient Headache Cases

CMS-1533-P-309-Attach-1.DOC

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June 12, 2007

By E-Mail Delivery

The Honorable Leslie V. Norwalk
Administrator (Acting)
Centers for Medicare & Medicaid Services
Room 445-G, Hubert H. Humphrey Bldg
200 Independence Avenue SW
Washington, DC 20201

Attn: CMS-1533-P

Re: Proposed Hospital IPPS Rule for FY 2008;
DRG Classification of Inpatient Headache Cases

Dear Ms. Norwalk:

The American Headache Society ("AHS") is pleased to submit these comments in connection with CMS' proposed Medicare Severity DRG ("MS-DRG") system of classifying inpatient hospital cases. AHS represents headache specialists throughout the country involved in clinical care, research and education. The Society's members treat Medicare patients in both inpatient and outpatient settings for migraine and related disorders. They practice in varied settings, from community based care to highly specialized tertiary referral centers.

DRG Reform and Proposed MS-DRGs

AHS supports Medicare payment policies that recognize clinically appropriate distinctions and reflect demonstrated differences in severity of headache illness, and resulting differences in the intensity and cost of care. This is particularly true in inpatient hospital care where the differences between short stay acute interventions in community hospitals, and much longer and more intensive multi-disciplinary care in specialized programs, is quite substantial.

Historically, the DRG classification system has not adequately captured the differences in severity of illness experienced by Medicare patients suffering from severe, chronic headache. This was the case with respect to both the single DRG 564 now in use for FY 2007, and the previous DRGs 024 and 025 used prior to this year. Unfortunately, it appears that the proposed new MS-DRGs 102 and 103 also fail to capture the most relevant clinical

considerations, as expressed in secondary diagnoses, which drive the cost of care for the most complex inpatient headache cases. We believe this to result from the classification of secondary diagnoses into "complicating conditions" ("CCs") and "major complicating conditions" ("MCCs") for use with respect to all primary diagnoses, rather than the establishment of CCs and MCCs specific to headache.

Specifically, the Agency's proposed list of MCCs excludes certain medication overuse and dependency diagnoses that, when combined with underlying headache illness, makes the patient's care much more complex, resulting in much longer lengths of stay and higher hospital inpatient costs. To truly account for differences in severity of illness for inpatient headache cases, any new MS-DRG classification system needs to recognize the impact medication overuse, particularly opioid dependence, has on the progression of the illness, and the difficulty of achieving successful patient outcomes without aggressive and longer stay inpatient intervention.

AHS has reviewed the comments submitted to the Agency in this rulemaking by the Michigan Head Pain and Neurological Institute ("MHNI") which set forth the issues summarized here in much more detail, with supporting data from individual hospital experience, and the collective research and clinical judgment of headache specialists as reflected in the medical literature. AHS endorses those comments and urges CMS to carefully consider MHNI's recommendations as it develops a final rule.

AHS has supported the efforts of Dr. Joel Saper of MHNI, a former AHS President, to bring these matters to the attention of your staff. The Society very much appreciates the willingness of CMS to work with Dr. Saper and other leaders in the field to find solutions that appropriately value the contribution of inpatient programs dealing with the most severely ill headache patients. Without those solutions, access to these programs will be impaired, and Medicare patients will suffer.

I personally appreciate your consideration of these issues of great import to our Society, its members, and the patients they serve. If the Society and I can be of any assistance to you or your staff at any time, please call on us.

Respectfully submitted,

Paul Winner, DO

Paul Winner, DO, FAAN
President

{110713.DOC / 1}

CMS-1533-P-310 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Dorothy Hoyne** **Date & Time:** **06/11/2007**

Organization : **Mrs. Dorothy Hoyne**

Category : **Individual**

Issue Areas/Comments
DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

You propose the following titles for these MS-DRGs:

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

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

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

Thank you for your consideration of this important matter.

CMS-1533-P-311 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Michael Craig** **Date & Time:** **06/11/2007**

Organization : **Bloomington Hospital**

Category : **Hospital**

Issue Areas/Comments

RRCs

RRCs

Re: RRCs

CMS-1533-P-311-Attach-1.DOC

#311

June 11, 2007

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

Dear Acting Administrator Norwalk:

Re: RRCs

In response to the "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates" (file code CMS-1533-P), we submit the following comments regarding Rural Referral Centers (RRCs) for your consideration.

We appreciate the Centers for Medicare and Medicaid's (CMS) recognition that RRCs play a significant role in treating rural Medicare beneficiaries, regardless of whether they are physically located in a rural area or an urban area. Therefore, we are concerned that the Fiscal Year (FY) 2008 Inpatient Prospective Payment System (IPPS) proposed rule would prohibit urban hospitals that acquire rural status from maintaining their RRC designation if they are subsequently reclassified as urban through the Medicare Geographic Classification Review Board (MGCRB) process, unless the hospital was designated as an RRC in FY 1991 or they lost their RRC status as a result of an Office of Budget and Management redesignation of the area from rural to urban. This proposal is clearly in conflict with congressional intent.

In an effort to provide needed flexibility to urban hospitals that serve predominately rural Medicare beneficiaries, the Balanced Budget Refinement Act of 1999 (P.L. 106-113, Section 401) created a mechanism, separate and apart from the MGCRB, to permit certain urban hospitals to acquire rural status. P.L. 106-113 defines "certain urban hospitals" as subsection (d) hospitals that are located in urban areas (as defined in paragraph (2)(D) of the Social Security Act) and that satisfy any of the following criteria:

I. The hospital is located in a rural census tract of a metropolitan statistical area.
II. The hospital is located in an area designated by any law or regulation of such State as a rural area.
III. The hospital would qualify as a rural, regional, or national referral center or a sole community hospital if the hospital were located in a rural area.
IV. The hospital meets such other criteria as the Secretary may specify.

Hospitals qualifying under this provision are eligible for all categories and designations available to rural hospitals, including sole community hospitals (SCHs), Medicare-dependent, critical access, and RRCs. Additionally, qualifying hospitals are eligible to apply to the MGCRB for geographic reclassification to an urban area and are entitled to the exceptions extended to RRCs and SCHs, if such hospitals are so designated.

In light of the congressional intent surrounding Public Law 106-113, we do not believe the CMS proposal to remove RRC status once a hospital has terminated its acquired rural designation and/or to increase the minimum duration of acquired rural status under § 412.103 to be appropriate. In addition, CMS contends that the proposed rule is consistent with CMS's policy that a hospital cannot continue to be an RRC once it cancels acquired rural status under § 412.103. However, the historical facts point to just the opposite as summarized below:

1) In an August 1, 2000, Federal Register notice (65 FR 47089), CMS indicated its agreement "that Congress contemplated that hospitals might seek to be reclassified as rural under section 1886(d)(8)(E) of the Social Security Act in order to become RRCs so that the hospital would be exempt from the MGCRB proximity requirement and could be reclassified by the MGCRB to another urban area." CMS further stated, **"...we believe that the intent underlying this language (a description of the House bill) was to allow certain urban hospitals to become RRCs (upon reclassifying from urban to rural under section 1886(d)(8)(E) of the Act) and then reclassify under the MGCRB process (as RRCs, the hospitals would be exempt from the MGCRB's proximity requirements."** [Emphasis added].

2) The phrase "certain urban hospitals" is specifically defined at section 1886(d)(8)(E) of the Social Security Act to include urban hospitals that would qualify as RRCs if located in a rural area.

3) CMS expressed concern regarding the potential interface between rural reclassifications under section 401 and section 407(b)(2) of Public Law 106-113, which authorized a 30-percent expansion in a rural hospital's resident full-time equivalent count for purposes of Medicare payment for the indirect costs of medical education (IME) under section 1886(d)(5)(B) of the Social Security Act. Under the regulatory provisions at the time, an urban hospital could have potentially reclassified as rural under section 1886(d)(8)(E) of the Social Security Act for purposes of receiving the IME benefit while also reclassifying under the MGCRB process for purposes of a higher wage index. To prevent this situation from occurring, CMS revised the regulations governing MGCRB reclassifications by adding paragraph (a)(5)(iv) to section 412.230 stating that: "An urban hospital that has been granted redesignation as rural under Sec. 412.103 cannot receive an additional reclassification by the MGCRB based on this acquired rural status as long as such redesignation is in effect."

4) However, to address the congressional intent expressed in P.L. 106-113, CMS decided to revisit their policy decision on section 4202(b) of Public Law 105-33. Specifically, in the August 1, 2000, Federal Register (65 FR 47089), CMS stated its revised policy decision as follows: **"Accordingly, in light of section 1886(d)(8)(E) of the Act and the language in the Conference Report, we have decided to revisit our policy decision on section 4202(b) of Public Law 105-33. Effective as of October 1, 2000, hospitals located in what is now an urban area, if they were ever an RRC, will be reinstated to RRC status under section 4202(b) of Public Law 105-33."** [Emphasis added]. CMS goes on to explain how this policy revision will allow OMB redesignated hospitals to regain their former RRC status; however, nowhere in the policy statement does CMS indicate that urban hospitals who were once RRCs under section 1886(d)(8)(E) of the Act are exempt from the revised policy. In

fact, as indicated in the above quotation, CMS references section 1886(d)(8)(E) of the Act in the introduction to their revised policy decision.

5) In addition, we note the subsequent revision of the RRC regulations at section 412.96. In the August 12, 2005, Federal Register (70 FR 47485), CMS amended the regulation to eliminate all references to subsequent review of RRC status. This amendment validates the intent of the revised policy decision on section 4202(b) of Public Law 105-33 to allow all hospitals (regardless of their subsequent ability to meet any of the RRC criteria at § 412.96) to retain RRC status indefinitely once initially obtained under § 412.96. The CMS Central Office further clarified this policy in an email from Ms. Linda McKenna on January 27, 2005, which stated: "...an RRC cannot lose its status because of the failed triennial review, MGCRB reclass, or urban designation. I know of no other circumstances where an RRC could lose its designation (voluntarily withdraws perhaps)." [See attached copy].

Taken together these facts, at a minimum, imply the following allowances from CMS:

1) Certain urban hospitals (as defined by section 1886(d)(8)(E) of the Social Security Act) are allowed to reclassify as rural under § 412.103 and obtain RRC status under § 412.96.

2) Rural hospitals under § 412.103 are allowed to reclassify under the MGCRB only if they first terminate their acquired rural designation.

3) Effective October 1, 2000, any hospital located in an urban area, if they were ever an RRC, will be allowed to maintain its RRC status.

These allowances permit an urban hospital meeting the applicable criteria to obtain RRC status through rural designation under § 412.103, to subsequently terminate its acquired rural designation while still maintaining its RRC status, and to reclassify under the MGCRB process through a waiver to the proximity requirements. We believe this to be the only logical conclusion given the above occurrences took place during a time when the only benefit for an urban hospital to obtain RRC status was the waiver to the MGCRB proximity requirements. Any other conclusion would put CMS policy in direct violation with its understanding of congressional intent.

As a final comment, we note the number of urban hospitals pursuing the above mechanism to be extremely small for the following reasons:

- The urban hospital must be able to meet all remaining RRC criteria.

- The urban hospital's wage index would need to be at or very near the level of the State rural wage index to avoid a significant loss in reimbursement while designated rural under §412.103.

- The urban hospital's DSH payment percentage would need to be at or below 12%. Any higher and the hospital could lose significant reimbursement during the time between the effective date of rural designation and the effective date of RRC status (given the CMS

Regional Office has 60 days to review the rural designation request, hospitals would likely file the request at least 60 days prior to the start of their next cost reporting period to ensure RRC status for the following fiscal year).

- The urban hospital must be situated in an area where it is beneficial to reclassify to the closest urban area.

- The urban hospital must meet the 82% test under § 412.230(d)(3)(ii) of the MGCRB process.

Taking these factors into consideration, there are very few hospitals that would qualify for or benefit financially from the process. Market research indicates approximately 18 hospitals nationwide in which this mechanism would make sense from a financial feasibility perspective. These hospitals fit the profile of other existing urban RRCs. If it is CMS's desire to treat all RRCs on an equal basis, then these hospital's should not be prevented from maintaining their urban RRC status and successfully reclassifying under the MGCRB process.

Like their counterparts, these hospitals play a significant role in treating Medicare beneficiaries from surrounding rural areas, and this proposal would place them and the rural beneficiaries they serve, at a significant disadvantage to their urban RRC counterparts. We respectfully request CMS reconsider its proposed changes governing acquired rural status and RRCs.

Sincerely,

Michael L Craig
Director of Reimbursement & Financial Planning
Bloomington Hospital
Bloomington, IN
812-353-5819

CMS-1533-P-312 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. George Hoyne** **Date & Time:** **06/11/2007**

Organization : **Mr. George Hoyne**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

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

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

Thank you for your consideration of this important matter.

CMS-1533-P-313 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Arrest and Shock Codes - We disagree with the elimination of various arrest and shock codes as a Major CC any time the patient expires. We counter that it would only be appropriate if the patient expired within 24 hours of admission. Length of stay should be included in the logic of when to discount the arrest or shock code as a Major CC.

CMS-1533-P-314 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Allyn Ciccone** **Date & Time:** **06/11/2007**

Organization : **Mr. Allyn Ciccone**

Category : **Individual**

Issue Areas/Comments
DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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Thank you for your consideration of this important matter.

CMS-1533-P-315 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments
DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Epilepsy, Unspecified Form - Code 345.9x has never previously been designated as a CC and we believe this is a long-standing fault. If all other epilepsy codes are designated a CC, why not also this one?

CMS-1533-P-316 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Dr. Diane Donley** **Date & Time:** **06/11/2007**

Organization : **Munson Medical Center**

Category : **Physician**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

Blindness/Deafness - Codes representing blindness and deafness should be included as a CC. These are chronic conditins that have a significant impact on nursing care and patient care planning.

CMS-1533-P-317 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Kathleen Capalbo** **Date & Time:** **06/11/2007**

Organization : **Mrs. Kathleen Capalbo**

Category : **Individual**

Issue Areas/Comments
DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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Thank you for your consideration of this important matter!

CMS-1533-P-318 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Date & Time:** **06/11/2007**

Organization :

Category : **Consumer Group**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

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

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

Thank you for your consideration of this important matter!

CMS-1533-P-319 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Date & Time:** **06/11/2007**

Organization :

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1533-P-319-Attach-1.DOC

319

Leslie V. Norwalk, Esq.
Acting Administrator,
Centers for Medicare & Medicaid Services
Attention:
CMS–1533–P, Mail Stop C4–26–05,
7500 Security Boulevard,
Baltimore, MD 21244–1850.

Dear Leslie Norwalk, Esq., June 11, 2007

As an infection control practitioner, I would like to comment on the proposed process of including infectious events in the Present on Admission (POA) initiative. The POA initiative advocates important changes in preventing adverse events. However, I believe that including infectious events has the potential to negatively impact financial and human resources within healthcare institutions.

Proposed POA events #3 (objects left during surgery), #4 (air embolism), and #5 (blood incompatibility), have defined ICD-9 codes and are events with known methods of prevention. However, events #1 (catheter-associated urinary tract infection), #2 (pressure ulcers), and #6 (Staphylococcus aureus septicemia) do not have definitive ICD-9 codes. In addition, these events are not always completely preventable and also require an additional ability to properly identify them. The determining of infectious events requires a clinical background, therefore, an additional human component must be present in identifying infection specific POAs.

While I support the POA in preventing adverse events, I do not think it is in everyone's best interest to include all six of the specified events. Removing infectious events will allow the program to better focus on defined events with known methods of prevention.

Sincerely,

Kathy Lowery, MPH
Infection Control Practitioner

CMS-1533-P-320 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Ms. Baaerbel Merrill** **Date & Time:** **06/11/2007**

Organization : **Campbell County Memorial Hospital**

Category : **Health Care Professional or Association**

Issue Areas/Comments

DRGs: Hospital Acquired Conditions

DRGs: Hospital Acquired Conditions

see attachment

CMS-1533-P-320-Attach-1.DOC

#320

Key points from APIC letter to Leslie Norwalk, Esq, Acting Administrator, Center for Medicare & Medicaid Services

- APIC and the CMS have a shared vision of preventing any adverse event, specifically infectious complications, in patients served in their respective care settings.
- APIC supports CMS in their effort to identify appropriate conditions that should not occur in our hospitals, thereby meeting criteria defined by Congress and also ensuring accuracy in the billing data that enables the appropriate identification of cases.
- The implementation of the MS-DRG system requiring implementation of "present on admission (POA)" codes will demand enormous resources in a very short time period for training and education of clinical and coding staff
- Of the six serious preventable events identified by CMS, APIC supports the following: number 3, object(s) left during surgery; (4) air embolism, and (5) blood incompatibility, whereas these conditions have been identified and supported by NQF; are identifiable by discrete ICD-9 codes and can be coded for by hospitals without dependence on POA codes.
- These extremely harmful events have known methods of prevention.
- APIC does <u>not</u> support the following three preventable events identified by CMS: number 1, catheter-associated urinary tract infections; (2) pressure ulcers and (6) Staphylococcus aureus septicemia, because each condition depends on the ability to identify them properly as well as accurate use of POA codes. Two states currently using POA codes report a minimum of two years needed to achieve reliability—much longer than the January 1, 2008 timeframe proposed by CMS.
- APIC looks to CMS to provide the educational support needed to reliably determine POA codes.
- APIC does not believe conditions 1, 2, and 6 are always reasonably preventable, even when reliable science and appropriate care processes are applied in the treatment of patients; not all infections can be prevented, and each of these conditions carry with them unintended, far-reaching consequences.
- APIC recommends that CMS continue to address the coding challenges for ventilator-associated pneumonia, vascular catheter-associated infections, and surgical site infections in order to determine if these conditions warrant inclusion in the CMS's hospital-acquired conditions policy in the future, since they are important causes of healthcare-associated mortality and morbidity. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic.
- APIC suggests and supports two approaches that do not depend on POA codes, but instead require coding and cross referencing for vascular-associated infections (which includes infections associated with all vascular devices, implants and grants) and infections such as septicemia; both of which would necessitate the creation of a unique ICD-9-CM code.
- While there is no specific code for catheter-associated blood stream infections, there are specific codes for insertion of catheters.
- While there are prevention guidelines for surgical site infections, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, APIC suggests selecting a single high volume surgical procedure, such as coronary artery

bypass graft codes (without valve), for which there is a CC code for mediastinitis and for which there are guidelines addressing preventability.

- APIC proposed consideration of post-operative sepsis, using a specific procedure code such as CABG (with or without valve)
- APIC requests clarification from CMS on how hospitals may appeal a CMS decision if an error in coding occurs and if a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher complication or co-morbidity DRG payment.

CMS-1533-P-321 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mrs. Audra Frank** **Date & Time:** **06/11/2007**

Organization : **Mrs. Audra Frank**

Category : **Individual**

Issue Areas/Comments

DRG Reform and Proposed MS- DRGs

DRG Reform and Proposed MS-DRGs

I am a widow of a young man who lost his life to this terrible desease. IF you cancel any of the proceedures that can prolong a life, then that would be a terrilbe thing. I bet if any of you looking to get rid of this proceedure had someone who was batteling for his/her life, you would re consider what you are doing.
Thank you for your consideration in this matter.
Audra Frank

CMS-1533-P-322 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates**

Submitter : **Mr. Steven Fischer** **Date & Time:** **06/11/2007**

Organization : **Beth Israel Deaconess Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1533-P-322-Attach-1.DOC

#322

June 11, 2007

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services (CMS)
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.**

Dear Ms. Norwalk:

The Beth Israel Deaconess Medical Center (Boston) and the Beth Israel Deaconess (Needham) appreciate this opportunity to comment on the proposed rule for the FY 2008 Inpatient Prospective Payment System (IPPS) and this letter contains our comments on the proposal for allocating the wage data of multi-campus hospitals. In this letter, we comment on the multi-campus hospital wage data issue and provide specific suggestions for achieving the appropriate wage data allocation.

Wage Index for Multi-Campus Hospitals:
Congress' intent in establishing the area wage adjustment under PPS was to pay hospitals at rates that reflect the relative wage levels of the labor markets in which the hospitals are located. To fulfill this intent, it is necessary that the wage adjustment applied to payments for hospitals in a given area reflect the wages of all the hospitals and hospital campuses located in that area. Conversely, the wage adjustment for hospitals in a given area should not include data from hospitals, or hospital campuses, which are not located in that area. CMS does have the responsibility to use the authority granted to it to ensure that Congress' intent in establishing payment policy is met.

Yet in the case of the Boston-Quincy wage area, the wage index is calculated using data including the two Bristol County campuses of Southcoast Hospitals Group, despite the fact that the Bristol County campuses are located in another wage area. We further note that Medicare services provided by these campuses are not paid by Medicare at the Boston-Quincy wage index. Another definitive indication of the current policy contradiction with regard to treatment of this multi-campus hospital is that its Bristol County campuses have been reclassified by the Medicare Geographic Classification Review Board to the Boston-Quincy CBSA. ***We strongly appreciate and support CMS' recognition that this policy contradiction must be corrected by reallocating the multi-campus hospital's wage data among the two affected wage areas for purposes of accurately calculating Medicare wage indexes.*** Specifically, this reallocation will allow the wage data for the two Southcoast hospital campuses located in Bristol County to be removed from the calculation of the Boston-Quincy Wage Area Index.

We are hopeful that CMS will continue to be flexible regarding the methodology that will be used to implement this important proposal, particularly for this first "transition" year when the time to respond is limited to the 60 day comment period. The solution proposed by CMS would carve out the wage data for those campuses that are not located in the Boston-Quincy CBSA (in the case of

Massachusetts) by using FTE data. However, it may be more difficult to collect this data in the short timeframe allowed for purposes of FFY 2008 than anticipated by CMS, especially in the case of hospitals that have fully integrated operations. For instance, a large number of hospital employees in multi-hospital campuses do not work at a single location but provide services to all locations and such hospitals have difficulty deciding how to count the employees that are serving more than one campus. Given that hospitals may encounter difficulty in compiling and submitting the requested FTE data by the comment period deadline we request flexibility from CMS in allocating wage data for this "transition" year, after which the necessary reporting changes can be made to accurately allocate wage data.

We understand that the Massachusetts Hospital Association (MHA), on behalf of its member hospitals and health systems, has also submitted comments, including various options/methodologies for allocating the wages that are less administratively burdensome. We ask that CMS review MHA's submission and strongly consider one of the methods as a viable option.

We commend CMS' recognition of the fact it is unacceptable to continue to include the data for the Bristol county campuses of the Southcoast hospital group in the Boston-Quincy wage index. This recognition calls for flexibility in the actual methodology used to apportion the wage data and we urge CMS to consider the alternatives outlined above. ***The fact remains that it is far less important what administrative methodology is used for this purpose than it is to correctly calculate the Boston-Quincy wage index for FY2008 and to end this gross payment policy distortion.***

We hope you will give serious consideration to our comments and MHA's recommendations and thank you for your attention to this important issue.

Sincerely,

Steven P. Fischer
Senior Vice President
Chief Financial Officer