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Haywood Regional Medical Center

DAVID O. RICE
President

June 8, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of Haywood Regional Medical Center, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the FY'07 Medicare Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 *Federal Register*. Given the complexities of CMS' proposal to revise the diagnosis-related group (DRG) system and the magnitude of impact this could have on our hospital is writing to urge a one-year delay in implementing these policy proposals.

CMS proposes to move from the historical charge-based DRG system to a cost-based system and to implement hospital-specific relative weights by October 1, 2006. CMS also proposes modifying the DRG classification system to account for differences in patient severity and allow for a payment amount that more closely tracks the cost of providing care. In its proposal, CMS states that it would replace the current 526 DRGs with either the proposed 861 consolidated severity-adjusted DRGs by FY'08 or a similar system that accounts for the level of patient severity, developed in response to public comments that it receives.

Haywood Regional Medical System supports meaningful improvement to Medicare payments for inpatient services and applauds the tremendous effort CMS has put forth to devise a DRG system that more accurately reflects the costs of providing inpatient services. I recognize that your agency has taken these steps to make payments fairer to hospitals and to assure beneficiary access to services in the most appropriate setting. In the proposed rule, CMS seeks input on the proposed methodologies and solicits alternatives to the consolidated severity-adjusted DRG model. While we welcome the opportunity to work with CMS and other stakeholders in ensuring that any system

implemented accomplishes the stated goals, we are extremely concerned with the tight timeline provided for developing comments and the implementation dates outlined in the proposal. Restructuring the DRG system as proposed in the rule would represent the most significant policy change to the IPPS since its inception. A change of this magnitude warrants a thoughtful and thorough review by hospitals, a task not easily accomplished during a 60-day comment period, given the complexity of the proposals.

As such, we strongly urge CMS to delay implementing both the proposed DRG reclassification and the changes to the relative weights until FY'08. The additional time will allow Haywood Regional Medical Center and other hospitals to more thoroughly evaluate the proposals and offer constructive feedback to your agency.

Again, thank you for the opportunity to share our comments on the DRG provisions of the proposed IPPS rule.

Sincerely,

David O. Rice
President

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June 8, 2006

Mark B. McClellan, MD, PhD
Administrator
Medicare – Medicaid Services
Dept Health and Human Services
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P.O. Box 8010
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Re: Proposed Changes to Hospital In-Patient Perspective
Payment Systems – Fiscal Year 2007 Rates
Docket #: CMS-1488-P

Dear Dr. McClellan,

I appreciate the opportunity to submit comments related to the proposed 2007 Centers for Medicare-Medicaid Services (CMS) Hospital Inpatient Perspective Payment System (IPPS), related on April 12, 2006 and published in the Federal Registrar on April 25, 2006. My comments are submitted on behalf of my position as Director Heart Services with Marion General Hospital, Marion, Ohio.

Here at Marion General Hospital, it is my role to develop and refine concepts and practices in the field of cardiovascular and other specialty cardiology related healthcare administration to promote and advance the use of that knowledge in professional development and personal achievements to continuing education, research, and healthcare management. One of my primary roles is the personal responsibility as the person responsible at Marion General Hospital for implementation of management issues regarding cardiology technology and otherwise impacting cardiovascular care here at Marion General.

I appreciate the considerable effort you and your staff members have put into development and improvement of the inpatient perspective payment system (IPPS) and specifically recognizing to continually evolve the payment system to reflect the current landscape within the field of medical services. I further recognize the significant complexities associated with gathering reasonably accurate cost data, data that serve as the foundation of payment systems such as the proposed IPPS.

CMS is proposing to make the most significant changes to the hospital IPPS since the late 1980's. The proposed changes appear to have their roots in the Medicare payment advisory commission (MedPac) 2005 report to congress on Medicare payments for a certain subset of specialty hospitals. The MedPac report raised concerns that specialty hospitals were selecting those preferable cases in their area, leaving the other acute-care hospitals with less profitable services. Rather than addressing this issue of specialty hospitals in the independent fashion, MedPac recommended changing the payments for all acute-care hospitals to reduce the incentives on the overall inpatient payment system that fueled the growth of specialty hospital facilities.

CMS should certainly weigh the issues and concerns raised in the MedPac report when considering policy changes. However, the proposed changes to the inpatient payment system are equivalent of throwing the baby out with the bath water. Efforts to address issues identified in the MedPac report should begin and end with the specialty hospitals subset and should not occur in conjunction with payment systems at large for all other hospital facilities.

Setting aside these views associated with the specialty hospitals, I know two major areas of concern with the proposed IPPS. First, the proposed incorporates an estimated cost based system, rather than a charge based system for determining the payment weights for each patient category in 2007. Second, the proposed endeavors to change the method of identifying the variation in patients' severity of illness that would be implemented in 2008, or potentially 2007. Each change is significant and in previous years would be considered a major modification to the payment system. Proposing both changes in a single regulation, with implementation in 2007, is unprecedented.

CMS proposes to base payments on costs. In many senses this is a positive move and is consistent with private insurer's costs associated with technology. However, the primary difference between CMS's methodology and the private insurers is the timing of cost data. Private insurers are utilizing data in "real time" and are paying actual invoice costs for technology used in care of patients. In CMS's cost for a particular category of patients is not an approximation of the actual price the hospital pays for the items and services required to treat patients; rather it is a rough approximation of costs. To calculate the costs of estimates for fiscal 2007 payments, Federal CMS proposes to utilize hospital claims data from fiscal year 2005 and hospital costs reports from fiscal year 2003. The cost reports provide the actual costs and the actual charges for all patients (non Medicare – Medicaid patients). The use of any data from fiscal year 2003 fails to account for current technology costs, namely drug eluting stents and bi-ventricular pacemakers / defibrillators, mainstays in cardiac care landscape. As

such the estimates on costs CMS will use to put forth its rates in 2007 will necessarily be incorrect and will inadequately compensate hospitals for care of Medicare patients. Marion General Hospital does not use a uniform approach to mark-up strategies for technology. Higher cost technology, such as those used in the treatment of cardiac patients, is often marked up at a lower rate than lower cost items. This leads to an inappropriate reflection of costs when attempting to apply derived averages.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by approximately 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced by 24% - 34%, ICD implants will be reduced by 22% - 24%, and pacemakers will be reduced 12% - 14%, severely impacting these services.

These proposed reductions to cardiac services are severe and are not rooted to any type of realistic mechanism for assessing costs to provide treatment. While it is appropriate to pursue a better understanding of actual costs to treat cardiac patients, any such efforts must be made with the intention of producing accurate information; the end result will be an alteration in the existing infrastructure for cardiac services reimbursement. However, the existing proposal simply cannot be implemented in its current form, as the impact for cardiac programs across the country will be serious and may potentially eliminate patient access to leading edge technology (because hospitals will not be able to adequately recover their acquisition costs). This is clearly not what CMS intends to achieve with this proposal. As such, delaying the implementation of any changes to cardiac services' reimbursement until such times as accurate and appropriate information to treat and manage patients with cardiovascular disease can be compiled and is the only prudent approach that can be taken.

Sincerely,

James R. White

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Via Electronic and U.S. Mail

June 9, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
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200 Independence Ave, S.W.
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File Code CMS-1488-P: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide this **comment letter on payment issues** in the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2007 rates (CMS-1488-P), (hereinafter referred to as "Proposed Rule" or "NPRM"). **AdvaMed is providing a second letter on proposed quality issues.** AdvaMed is the largest medical technology trade association in the world. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed shares CMS's goal of assuring beneficiary access to services, and believes that improving the accuracy of payments will help achieve this goal. AdvaMed supports

movement toward improved accuracy in reimbursement under the inpatient prospective payment system (IPPS), and appreciates that CMS has worked very hard to produce a set of proposed changes that would affect all of IPPS. However, we do not believe that the wholesale changes to the IPPS contained in the Proposed Rule are either the appropriate solution or ready for implementation in FY 2007. AdvaMed supports maintaining the current methodologies for assigning DRG relative weights and determining patient classifications in FY 2007. Regardless of the IPPS changes that CMS ultimately implements or the timeframe in which those changes are implemented, we believe that the following issues are of paramount importance and need to be addressed:

- **The hospital-specific relative value methodology ignores any hospital-level variation that is not explained by the PPS case-mix index, which may include meaningful and valid cost variations. If certain services are provided predominately in hospitals with higher average costs, this method will produce lower DRG weights for these services. If legitimate costs are not recognized, Medicare beneficiaries' access to care may be diminished.**

- **Using 10 cost center groupings within the Hospital Specific Relative Values (HSRVs) to calculate DRG relative weights ignores detailed data in the cost reports that could be used to derive a more accurate set of weights. This will exacerbate many of the more problematic aspects inherent in the use of weights based on estimated costs, including data lags, data omission, and charge compression.**

- **CMS proposes to implement a new severity-adjusted patient classification system in 2008 or earlier. However, the Proposed Rule models the impact of these changes using FY 2004 inpatient claims, instead of the FY 2005 inpatient claims used to model the estimated cost-based DRG weight changes. This discrepancy, and the fact that CMS did not make the new patient classification system software (the "grouper") available when the regulation was released, made it impossible to accurately assess the impact of both changes from tables provided in the Proposed Rule.**

- **When calculating payment weights, CMS did not use standard methods to weight hospital payment data and trim Medicare claims data. CMS omitted data from 238 hospitals, representing 25 percent of routine hospital charges. This omission and failure to apply appropriate weights significantly decreased the payments for technology intensive cases. These methodological flaws need to be evaluated and addressed by CMS prior to the imposition of any cost-based methodology scenario.**

Due to the magnitude of the changes, the lack of complete information to fully assess the proposed changes, and the importance of improving the accuracy of the payment rates,

AdvaMed supports maintaining the current methodologies for assigning DRG relative weights and determining patient classifications in FY 2007.

- **AdvaMed would support implementation of an estimated cost-based weight system in FY 2008, with an appropriate phase-in, analogous to the methodology that is currently used in the outpatient PPS system, as CMS makes changes that would result in improved timeliness and accuracy of the cost report information used to calculate estimated costs and makes a full adjustment for charge compression. To determine methods of improving hospital cost reports, CMS should assemble an expert panel or work group comprising hospital finance experts, prospective payment authorities, hospital charge master personnel and other experts. This group could make timely recommendations on how to refine the cost reports to yield more accurate and timely data that may be used in setting PPS weights. In this letter, AdvaMed is proposing a methodology to address the issue of charge compression when cost-based weights are implemented.**

- **AdvaMed also would support simultaneous implementation of a revised estimated cost methodology and a DRG classification methodology that accounts for patient severity of illness, complexity and patient benefit. These DRG refinements would make allowances for specific DRG assignments that have been previously approved through notice and comment rulemaking. AdvaMed recommends that CMS start with the current DRG system and provide overlays for severity, complexity and patient benefit.**

- **AdvaMed would oppose a two-step implementation, whereby CMS would implement the movement from charge-based weights to estimated cost-based weights in one year followed by wholesale refinement of DRGs based on patient classification reforms in a following year. Making these changes simultaneously would minimize swings in payment rates for many diagnosis-related groups.**

The Proposed Rule seeks to both create and implement the most significant and complex changes in Medicare reimbursement since the IPPS was implemented more than 20 years ago. And, it does so in just one regulatory cycle, providing stakeholders only one 60 day comment period to review the regulation, analyze the methodological changes, and provide input. The details of these complex proposals were neither discussed nor scrutinized in any public forum prior to the release of the Proposed Rule. Nor were the methods used to arrive at these proposals validated by anyone other than CMS.

Upon the release of the Proposed Rule on April 12, 2006, stakeholders, including AdvaMed, began to work diligently to perform the detailed analyses that were necessary to replicate the methodology of the CMS proposals. We acknowledge the enormity of the task that CMS faced in making the recommendations contained in the Proposed Rule.

We applaud CMS for the its ability to complete the new methodologies in time for release in the Proposed Rule, and for releasing the MedPAR data in advance of the Proposed Rule. However, many other necessary pieces of information were not available to enable stakeholders to perform a thorough evaluation of the proposed changes when the Proposed Rule was released.

AdvaMed has exerted intensive efforts to model and assess the impact of these proposals prior to the expiration of the comment period. Nevertheless, we believe that 60 days is insufficient time given the complexity of the changes proposed by CMS. Additionally, we believe that the time between the close of the comment period (June 12) and the August 1, 2006 expected publication of the Final Rule, is insufficient to fully consider, test and implement the significant, substantive changes of the magnitude contained in the Proposed Rule.

The decision to delay implementation of any changes until FY 2008 would allow CMS, hospitals, patients, physicians, device manufacturers and other stakeholders the opportunity to fully assess any proposed changes before these are applied to every Medicare participating hospital and the services provided to Medicare beneficiaries. Assessment of these changes in the current cycle is simply not possible due to the complexity of the changes proposed, the potential overlay with a completely different DRG system, and the lack of available data and sufficient time to do the assessment that is necessary.

I. HSRV Weights, Cost-Based Weights and Cost Reports (*"HSRV Weights"*)

AdvaMed supports the goal of improving accuracy within the IPPS. Before CMS implements an estimated cost-based payment system, it should address a number of significant concerns raised by the use of cost-based weights. Estimated cost-based weights would be derived, in part, from Medicare cost reports, which were not designed for use in a prospective payment system. The cost reports are a vestige of the "reasonable cost" based reimbursement system that was implemented when Medicare began in 1966. When the hospital inpatient prospective payment system was implemented in 1983, hospitals began to be paid a fixed amount based on the patient's diagnosis, rather than incurred costs. Under IPPS, reimbursement became independent of the actual costs incurred, and the cost report no longer played a key role in the reimbursement received by hospitals, with some limited exceptions for items such as bad debt, graduate medical education, pass-through, or outlier payments.

There are several serious problems in using cost reports to derive estimated costs which are then used to calculate DRG relative weights that should be carefully considered and addressed. These include: 1) the accuracy of the cost-report data and limited auditing; 2) the overall timeliness of the cost report data; 3) the omission of data on new

technologies; 4) comparability of costs reports due to variability in how hospitals allocate costs; and 5) the compression of the weights both across and within cost centers.[1 2 3]

Accuracy of Reporting and Limited Auditing--Under prospective payment systems, providers' payments are not based on their actual incurred costs. Hospitals have little incentive to report accurately and completely for the items and services provided during the patient encounter or length of stay. The cost reports were not designed to establish payment rates for individual services and, as such, do not contain the detailed costs that are necessary to accurately determine estimated costs at the DRG level. Instead, cost reports provide payment, costs, and some reimbursement totals by department or cost center. An analyst must make several assumptions and perform complex calculations before she can translate cost reports into the estimated costs of individual items and services used to determine DRG payments.

CMS and fiscal intermediaries perform limited auditing of cost reports. If DRG weights are based on costs, they will be based on largely un-audited cost reports and, perhaps, extrapolation of average audit findings to un-audited cost reports. According to CMS, approximately 15% of hospital cost reports are audited each year. These audits are limited scope audits that focus primarily on factors that affect Medicare payment, such as bad debt or medical education. Full scope audits are done only rarely. Instead, audits for IPPS providers mostly involve payments for one or more items including DSH, GME, IME, bad debts, and organ acquisition. The fiscal intermediary determines what issue(s) will be audited based on the desk review and experience with the particular provider. Validation audits are not conducted by fiscal intermediaries. If cost reports are to be used to calculate DRGs, additional auditing might be advised. MedPAC estimated that a full scale audit could require 1,000 to 2,000 hours from a fiscal intermediary, as well as additional time and resources from the hospital.[4]

Overall Timeliness of Cost Report Data--The cost report data are old, significantly older than the charge based data currently used to determine payment weights under the IPPS. In the current system, the DRG weights are calculated using claims that are 2 years older than the payment year. Under an estimated cost-based IPPS system, the DRG weights are calculated using cost report data that is 3 to 4 years older than the payment year. The quality of the information is reduced because it is outdated. The use of

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[1] J. Ashby, "The Accuracy of Cost Measures Derived from Medicare Cost Report Data," Intramural Report I-93-01, March 1993; MedPAC, "Sources of Financial Data on Medicare Providers," Report to Congress, June 2004.

[2] Cost-based weights would further exacerbate the problem of "charge compression," which has been observed in the early years of IPPS (when cost-based weights were used) as well as in a number of studies and in the current OPPS. AdvaMed has conducted a study that documents the effects of charge compression using current MedPAR data.

[3] A 1998 study by MedPAC's predecessor, ProPAC noted concerns with cost report data such that "cost report data may, in some cases, produce imprecise DRG weights." ProPAC further noted that the "Secretary [of HHS] should verify the accuracy of cost report data and implement changes as necessary."

[4] MedPAC, op cit., p. 17

estimated cost-based weights requires matching billed charges from over 13 million hospital claims to cost reports for each individual hospital. Under the estimated cost-based system in the Proposed Rule, CMS used hospital claims data from FY 2005, and hospital cost reports from FY 2003. AdvaMed supports an approach that uses the most recent claims data available.

Omission of Data on New Technologies--Inherent lags between the time period covered by the cost reports and the payment year mean that recent important medical technology advances are omitted from the costs, which in turn determine the cost-to-charge ratios that are used to calculate cost-based DRG weights. Data that are three to four years old would exclude many of these technological advances in the calculation of cost-to-charge ratios. The older the data, the greater the omission of new technologies. This will translate into reduced accuracy in DRG weights.

For example, cost-based DRG weights as proposed by CMS could systematically underpay for new technologies because the proposed methodology assumes that hospital ancillary cost-to-charge ratios (CCRs) will not change with the introduction of new technology. The illustrations below demonstrate how a new technology that reduces routine charges by allowing patients to be discharged sooner results in a lower DRG payment under cost-based DRG weights, even under a scenario where total charges are unchanged (due to higher ancillary costs from the new technology). While total charges remain the same after introducing the new technology (resulting in no payment change under the current charge-based method), applying a CCR from an earlier period results in a reduced estimate of costs. Over several years, the ancillary CCR would eventually reflect the new technology; however, the methodology proposed by CMS would reward a hospital that maintains the older treatment with the longer length of stay, due to a higher 'cost-based' payment rate.

Patient Treated with High Concentration of Routine Services and Longer Length of Stay

	Charges
Routine Services (85% CCR)	$15,000
Ancillary Services (34% CCR)	$5,000
Total Charges	$20,000
Estimated Costs Based on Proposed CCR	$14,500

Patient Treated with High Concentration of Ancillary Services (Supplies and Equipment) with Shorter Length of Stay

	Charges
Routine Services (85% CCR)	$5,000
Ancillary Services (34% CCR)	$15,000
Total Charges	$20,000
Estimated Costs Based on Proposed CCR	$9,350

By comparison, the current charge-based system, if continued through FY 2007, would use 2005 hospital claims data to set the IPPS DRG weights. Switching to cost-based weights would entail the use of cost report data from FY 2003 and new technologies that were approved for use subsequent to 2003 would not be reflected in the cost report data. The use of estimated cost-based weights thus induces greater systemic bias against newer technologies by omitting them from the cost report data and the rate calculations.

Comparability of Cost Reports due to Variability in How Hospitals Allocate Costs -- The high degree of variability of hospital cost reports is attributable to several causes, including the allocation of joint costs, such as hospital administration costs, to various revenue generating sectors. This presents a problem for the accurate measurement of other costs such as inpatient, outpatient and skilled nursing costs. Hospitals have a range of options to allocate their overhead costs. Some of the methods of allocation, such as square footage, can result in an over-allocation of costs to secondary services compared to other, core function services. These allocation decisions have a significant impact on the comparability of the cost report data across hospitals.

Compression of Charges Within Cost Centers-- CMS uses hospital cost-to-charge ratios (CCRs) to covert charge data into estimated costs of individual items and services. CMS uses a single CCR for the many items and services in a single department. This process assumes that hospitals apply the same uniform percentage mark-up when setting the charges of each item in the department. Many observers have noted that hospitals do not act this way, but instead use a lower percentage mark-up for high cost items than they use for lower cost items. Hospitals may reduce the mark-ups for higher-cost items to avoid "sticker shock."[5] If hospitals do not use a constant percentage mark-up for items in the department, methodologies that rely on uniform CCRs underestimate the cost of

[5] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106

more expensive items and overestimate the cost of less expensive ones, resulting in a systematic distortion of the estimated costs, and of prospective payment rates.

Recent research showed statistical evidence for this type of charge compression in Medicare claims data.[6] The researcher found a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the fraction of cases with high-cost devices increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the researcher also showed that cases with very high device and supply charges led to a stronger impact on the device and supply CCR. A one-unit increase in the fraction of cases with very high cost devices (device and supply charges over $30,000) was associated with a much larger increase in the average device and supply CCR than was a one-unit change in the fraction of cases with moderate- to high-cost devices (device and supply charges over $20,000), which in turn had a stronger impact than a one-unit change in the lowest measure (device and supply charges exceeding 15,000). These results are consistent with previous analyses demonstrating charge compression in hospitals' billing patterns for high cost devices and drugs.[7]

II. HSRVcc Methodology Exacerbates Problems Inherent in Estimated Cost Based Weights (*"HSRV Weights"*)

AdvaMed does not support the use of the HSRVcc methodology in the Proposed Rule because it exacerbates many of the problems that are otherwise present with the use of estimated cost-based weights. Under HSRVccs, CMS calculates charge-based weights for each hospital at the cost center level. It is important to note that the HSRVcc methodology proposed by CMS differs both from what MedPAC proposed and from how CMS calculates *cost-based* weights for the outpatient prospective payment system. AdvaMed believes that the CMS methodology produces inaccurate and distorted DRG weights due to at least four major deficiencies.

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[6] C. Hogan, Direct Research LLC., March 2005. Significantly, this study was conducted exclusively on Medicare claims data with no use of external data.

[7] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106, GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: http://www.gao.gov/highlights/d04772high.pdf . The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003. The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings, The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

- First, the cost (revenue) centers are collapsed from the full set of at least 37 cost centers into only 10 centers.[8] Although each of the 37 cost centers has a unique cost-to-charge ratio, the CMS grouping methodology employs only 10 cost-to-charge ratios. This approach essentially throws out detail that is available on the cost report and that CMS uses in calculating the outpatient prospective payment system rates. AdvaMed is concerned that CMS disregards information that would increase accuracy and does so as part of an initiative intended to improve accuracy.

- Second, the national cost-to-charge ratio approach eliminates the specificity of cost-to-charge ratios for supplies and equipment in individual hospitals that perform more procedures involving implantable devices. These hospitals in general have higher cost-to-charge ratios for supplies than other hospitals, and using the hospital-specific CCR for supplies and equipment instead of the national CCR better reflects the mix of patients in the hospital and the accompanying costs. [These hospitals still experience charge compression for implantable devices and an adjustment to address this issue (described below) is important in any move to cost-based weights.]

- Third, the HSRVcc methodology proposed by CMS contains two serious mathematical flaws that affect the DRG weights very materially. These problems arise due to the manner in which CMS proposes to implement the HSRVcc methodology. They can be corrected, and the corrected results are illustrated in the table below, or the problems would be removed altogether if CMS abandons the HSRVcc methodology and adopts the methodology used for the outpatient prospective payment system, as AdvaMed recommends. **Fixing these flaws will have a significant impact on hospital-level payments and hospitals that may have assumed that their payments would increase may see reductions.**

[8] CMS's HSRVcc methodology uses two cost centers for routine services (routine days and intensive care services) and eight for ancillary services (drugs, supplies and equipment, therapeutic services, operating room, cardiology, laboratory, radiology, and other services and charges).

The following examples show the dramatic effect that correcting the flaws would have on the weights for selected DRGs.

IMPACT ON SELECTED DRGs OF HSRVcc		CMS	Corrected
558	Percutaneous Cardiovascular Proc W Drug-Eluting Stent W/O Maj Cv Dx	-35%	-21%
557	Percutaneous Cardiovascular Proc W Drug-Eluting Stent W Major Cv Dx	-26%	-15%
125	Circulatory Disorders Except Ami, W Card Cath W/O Complex Diag	-28%	-20%
124	Circulatory Disorders Except Ami, W Card Cath & Complex Diag	-19%	-14%
535	Cardiac Defib Implant W Cardiac Cath W Ami/Hf/Shock	-26%	-16%
536	Cardiac Defib Implant W Cardiac Cath W/O Ami/Hf/Shock	-25%	-13%

The HSRVcc is a complex calculation that begins with calculating charge-based weights for each cost center for each DRG for every hospital. At this stage, CMS has 10 hospital-specific, charge-based weights for each DRG – one such weight for each of the 10 collapsed cost centers. Next, CMS combines these hospital-specific charge-based weights for each cost center for each DRG to get a set of 10 national charge-based weights for each cost center for each DRG. In computing the national weights for each cost center for each DRG, CMS properly weighted each individual hospital number by the hospital's count of cases in the DRG.

Both of the major flaws occur in the final phase of determining the DRG weights. In this stage, CMS is combining the 10 cost center weights to get a single weight for each DRG and simultaneously converting from charge-based to cost-based weights. Both flaws arise as CMS calculates national cost-to-charge ratios to use in converting charges to costs.

Flaw #1: In calculating the national cost-to-charge ratios (CCRs), CMS severely over-trimmed the data and threw out hospital data with CCRs for routine days with a value less than 0.26. These CCRs appear to be real and valid, however. They apply mostly to about 238 very large hospitals that contribute roughly one-quarter of all routine day charges. In dropping these data, CMS is not only throwing out a large amount of valid data, but it is distorting the results by omission of such a significant segment of hospitals with a unique pattern of CCRs. This problem is compounded because CMS retained these hospitals for other steps in calculating the national DRG weights. The table below shows the impact of CMS's trimming.

Trimming of Routine Accommodation Charge Per Day				
CMS CCR trim action	Hospitals	Charges ($ in billions)	Days (in millions)	Charge per Day
Not Trimmed	3133	$ 34.11	39.1	$ 873
Trimmed	238	$ 12.37	3.3	$ 3,723
Total	3371	$ 46.48	42.4	$ 1,097
Source: Direct Research. Ltd. estimate based on 2003 cost reports matched to edited 2005 MedPAR file.				

Flaw #2: In calculating the national CCRs for each of the 10 cost centers, CMS uses the geometric mean of the individual hospital CCRs, after they are erroneously trimmed as discussed above. CMS's calculation of the national CCRs does not account for the volume of charges and costs across hospitals. It is important to note that similar calculations in other CMS prospective payment systems and fee schedules use an appropriate weighting methodology rather than counting each hospital equally. Only with appropriate weighting will the calculated number actually equal the overall national average. In this case, weighting should be based on the aggregate amount of charges in each hospital. Specifically, national CCRs should be calculated using the charge-weighted arithmetic mean. As shown in the table below, the flaw causes a substantial over-estimate of the aggregate national level of costs incurred by prospective payment system hospitals. Routine costs are so overstated by the proposed CMS methodology that total costs compared to total actual payments on the MedPAR file show that hospitals would have lost $23 billion dollars in 2005, or about 29 percent, on care provided to Medicare beneficiaries. We know from MedPAC and CMS reports that this is not true, and that hospitals experienced a small positive margin on inpatient care provided to Medicare beneficiaries. Consistent with this fact, the correct weighting methodology provides an estimated patient care margin of 2.2 percent, as shown below:

	With CMS CCRs[9]	With Charge-Weighted CCRs
▪ Total charges on MedPAR file	$ 315	$ 315
▪ Estimated 2005 costs before charge inflation adjustment	$ 134	$ 107
▪ Estimated 2005 costs after charge inflation adjustment (.92 X previous line)	$ 123	$ 98
▪ Actual 2005 payment on MedPAR	$ 100	$ 100
▪ Estimated 2005 payment-to-cost ratio	0.812	1.022

9 All numbers listed in billions.

The combined impact of the two flaws significantly decreases the payments for technology intensive cases as noted above. AdvaMed strongly urges CMS to fix these problems if it continues to use the HSRVcc methodology, though, as noted above, we recommend an entirely different approach for cost-based weights.

- Fourth, the hospital relative value methodology (HSRV) is unnecessary, compresses the DRG weights, and particularly and unjustifiably cuts payment rates for cardiac care. Under the current standardization methodology, DRG weights are set by determining the average per-case standardized charges or costs in a DRG across all hospitals and dividing that figure by the average per-case standardized charges or costs for all cases in the DRG system. The key is that the weights are based on pooled charges or costs from across all hospitals nationally. This helps to assure appropriate valuation of all services, including services which tend to be highly concentrated in limited centers, such as cardiology services.

  Under hospital specific relative values, rather than pooling charges or costs across hospitals, CMS first creates relative weights from the charges or costs within each hospital for each DRG to get a hospital-specific weight and then averages those hospital-specific weights across all hospitals (using a case-weighted average) to arrive at a single weight for each DRG. In this manner, average charges or costs in a particular DRG are compared with average charges or costs in each hospital rather than with average charges or costs across all hospitals. The hospital-specific relative value (HSRV) methodology reduces the weights for DRGs that are performed predominantly in hospitals with higher average charges or costs. This is true even if the costs are valid and if these hospitals are the only hospitals where the particular services are performed.

  Under the hospital-specific relative value approach, each hospital's data is scaled up or down so that its costs or charges match the level predicted by the hospital's case mix index. All other variation in costs or charges is simply ignored. The hospital-specific approach removes from the data all the hospital-level variation that is not accounted for by case mix. No other hospital-level variation in costs or charges is allowed to affect the calculation of the DRG weights. HSRV contrasts with the current standardization approach which removes from the charge or cost data *only* the hospital-level variation that Medicare will pay for in another part of the payment formula: wage index, indirect teaching and disproportionate share. Under current IPPS, all other hospital-level variation (anything the IPPS does not pay for) is allowed to affect the calculation of the DRG weights.

  The main difference between these two approaches is how you treat charge or cost variation that is not otherwise explained with IPPS payment factors. In the standardization approach, any variation in hospital costs or charges that is not explained with CMS payment factors is allowed to affect the calibration of the DRG weights. The hospital-specific approach, by contrast, ignores any hospital-

> level variation that is not explained by the IPPS case-mix index. The current standardization methodology recognizes that hospital-level variations should not be ignored just because they cannot be explained. In throwing out otherwise unexplained variation in hospital-level costs or charges, the HSRV methodology risks ignoring meaningful and valid cost variations. To the extent that certain services are provided predominantly in hospitals with higher average costs, the HSRV methodology predictably will result in lower DRG weights for these services. If these hospitals' legitimate costs are not recognized, Medicare beneficiaries' access to care for these services could be jeopardized.

AdvaMed strongly believes that HSRV is unnecessary and inappropriate under cost-based weights. If under cost-based weights the cost of care in each DRG has been estimated as accurately as possible, then it is not sound policy to ignore part of what was estimated, as occurs under HSRV. AdvaMed recommends that HSRV be dropped and that costs or charges be standardized using the current methodology. If CMS wishes to remove other sources of cost variation from calculation of the DRG, the standardization process could be expanded to include other factors beyond wage index, indirect teaching and disproportionate share. Such a factor-specific approach would lead to more precise and valid adjustments than the "black box" approach of HSRV.

There are several excellent research studies on the impact of the hospital-specific relative value methodology and, though many of these date from the early 1990's, their findings are remarkably consistent with the impact of HSRV in the Proposed Rule. In general, the HSRV approach tends to lower relative weights for the higher weighted DRGs and reduce the range of DRG weights between the lowest and highest weighted DRGs. Since the inception of the Medicare inpatient prospective payment system, such compression of the DRG weights has been a closely watched issue due to concern that patients might experience reduced access to the higher cost DRGs if compression became a problem and the DRG weights were too low for high cost cases. Finally, considering type of service, research has consistently shown that cardiology services would be hit especially hard by a change to HSRV. In fact, for hospitals that lose under HSRV, they lose more on cardiology services than they lose overall (they make up some of their cardiology losses on other services). Earlier research found that about 83 percent of hospitals losing under HSRV engaged in cardiac surgery compared to 5 percent for other hospitals.

Cardiology services, especially interventional cardiology services, are performed primarily in the type of hospitals that are disadvantaged by the HSRV methodology. Hospitals performing cardiology services tend to mark up their charges for those services less than they mark up their charges for other services. Hospitals performing cardiac surgery charge more than average for typical cases, therefore their charges for the very expensive cardiac cases are down-weighted in calculating the HSRV weights. In addition, surgical cardiac services tend to be higher weighted services and thus are disadvantaged by the compression of the DRG weights that is a hallmark of the HSRV

methodology. These collective effects cause particular disadvantage to cardiac surgery and interventional cardiology services.

Clearly, adopting HSRV is a policy choice with significant implications for hospitals. We seek opportunities to work with CMS to assure that services are paid appropriately and that patient access to these life-saving services and technologies is not diminished. We strongly believe that changes in the Proposed Rule are necessary both to preserve access to care and to continue to encourage the technological innovation and adoption of new technologies that has brought substantial reductions in mortality and morbidity for patients.

III. Charge Compression (*"HSRV Weights"*)

To determine the cost of individual items and services, CMS generally takes hospitals' charges for an individual item or service and converts them to an estimated cost. Specifically, CMS converts charges to costs by "backing out" the average mark-up calculated for each department. Thus, if a department had an average mark-up in which charges averaged twice the department's costs, then a charge of $1,000 would be reduced to a cost of $500.

Basing the estimate of the cost for each item and service on the average mark-up in a particular department implicitly assumes that hospitals apply the same percentage mark-up to set the charge level of each item in the department. Many experts and studies have noted, however, that hospitals generally do not apply a uniform percentage mark-up and that, in fact, the percentage mark-up for high cost items is significantly less than the one used for lower cost items. According to a study commissioned by MedPAC, hospitals may reduce the mark-ups for higher-cost items to avoid "sticker shock."[10] This phenomenon is called charge compression. To the extent that charge compression is present, the current CMS rate-setting methodology underestimates the cost of more expensive items and over-estimates the cost of less expensive ones, resulting in a systematic distortion of prospective payment rates.

Charge compression occurs when items with different markups are combined in the same cost center. The HSRVcc methodology would combine estimated costs into only 10 cost centers nationally, increasing the variation of items placed in a particular cost center. Modeling of the HSRVcc methodology confirms that the degree of charge compression inherent in the use of cost-based weights is exacerbated under the HSRVcc methodology.

To examine further the empirical evidence of charge compression, AdvaMed recently commissioned research to investigate whether Medicare claims data provided statistical evidence of charge compression. The results indicated a strong statistical relationship

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[10] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106

between a hospital's case-mix and the device cost-to-charge ratio (CCR). Specifically, the study found that there is a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the device case-mix increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the research also showed that basing the case-mix index on the percentage of cases with higher device and supply charges led to a stronger impact. A one-unit increase in the fraction of cases with very high cost devices (device and supply charges over $30,000) is associated with a much larger increase in the average device and supply CCR than is a one-unit change in the fraction of cases with moderate- to high-cost devices (device and supply charges over $20,000), which in turn has a stronger impact than a one-unit change in the lowest measure (device and supply charges exceeding 15,000). The results of this research are consistent with previous analyses demonstrating charge compression in hospitals' billing patterns for high cost devices and drugs.[11] It is significant that this study was conducted exclusively on Medicare claims data with no use of external data.[12]

IV. An Alternative Cost-Based Method Should be Used to Calculate Cost-Based Weights and the Detailed Impacts Should be Provided for Public Comment (*"HSRV Weights"*)

AdvaMed supports efforts to improve the accuracy of inpatient hospital payments. The HSRVcc methodology is too complex, omits important data, and results in a systematic bias against the hospitals that provide patients access to many medically advanced technologies. Rather than improving the accuracy of the payments, it further distorts payments by using a distorted estimate of costs. If CMS chooses to move to a cost-based payment system, we recommend a cost-based payment methodology similar to the one used to calculate the hospital outpatient prospective payment rates, with adjustments for both charge compression and biases in the Medicare cost report that lead to over-estimation of routine costs and under-estimation of ancillary costs.

To calculate hospital outpatient prospective payments, CMS matches outpatient hospital claims to Medicare costs reports using hospital-specific cost-to-charge ratios to determine

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[11] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106, GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: http://www.gao.gov/highlights/d04772high.pdf . The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003. The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings, The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

[12] C. Hogan, Direct Research LLC., March 2005

estimated costs for each hospital encounter. These are then combined to determine the payment rates after adjusting for certain factors. While there are several problems associated with the hospital outpatient PPS, the general methodology of adjusting the most recent claims data using hospital specific and department specific cost-to-charge ratios could be used for inpatient hospital payments.

We support using a modified version of the OPPS methodology in determining cost-based relative payment weights for the inpatient setting. Such a methodology would provide an improvement over the proposed HSRVcc methodology in that it would produce estimated costs that would better reflect the variation in costs across hospitals and procedures. At least two modifications are needed in the outpatient methodology. First, as discussed below, CMS must adjust for charge compression. Second, the weight calculation methodology needs to account and adjust appropriately for known biases in the Medicare cost report that lead to over-estimation of hospitals' routine costs and under-estimation of ancillary costs. Further research may be needed on the magnitude of this bias and options to correct for it. The recommended one-year delay allows time for this additional work.

Although evidence of the effect of charge compression is not new, research that could support an adjustment to offset charge compression was not previously available. Research just completed now presents a solution. It takes advantage of the detailed coding of supplies charges by revenue center on Medicare claims data to split the single cost-report CCR into separate CCRs for each supplies sub-category. Five supplies sub-categories are used: general supplies, implantables, sterile supplies, pacemakers (and defibrillators), and all other supplies. The division is based on a strong statistical association between the mix of supplies charges (by revenue center) in a hospital and the overall supplies CCR in a hospital. By pooling the information from all hospitals, research using regression analysis was able to develop one set of CCR adjustments reflecting national average CCRs for each of the five supplies sub-categories. Next, the research applied this national-average set of adjustments to each hospital (combining the adjustments with each hospital's actual supplies CCR), and inserted a "decompressed" estimate of cost on each MedPAR record.

The research found a strong and statistically robust relationship between the mix of charges across supplies sub-categories in a hospital and the hospital's overall average CCR for supplies. Hospitals with a higher share of charges in the pacemaker and implantable device revenue centers (0275, 0278) have higher supplies CCRs. CMS could use the coefficients from a regression model such as this to develop a data-driven adjustment for creating CCRs for sub-categories of supplies. Using the available MedPAR data, only four of the supplies sub-categories have enough charges, on average, to allow such a statistical estimate. The research found, on net after all budget-neutrality adjustments, the average CCRs for the supplies sub-categories which are shown in the table below. The average CCR for all supplies together was 0.33 (top line), but the regression analysis showed substantial variation in CCR by category. The pacemaker

category (which also includes hospital charges for a significant portion of defibrillators) has an estimated CCR of 0.46 (or just slightly more than a 100% average markup). The category of general supplies, by contrast, has an estimated CCR of 0.24 (or just over a 300% average markup).

Estimated Cost-to-Charge Ratios for Supplies Sub-Categories	
Supplies Subcategory	**Net Average CCR After Budget-Neutrality Adjustment**
Supplies, Total	0.33
0270 (general supplies)	0.24
0278 (implantables)	0.43
0272 (sterile supplies)	0.27
0275 (pacemaker (and defibrillator))	0.46
all other supplies	0.29
Source: Direct Research, Ltd. analysis of 2004 5% standard analytic file and hospital cost report data. May 2006.	

The research showed that this variation in CCRs across sub-categories has a significant impact on some DRG weights. Cost-based DRG weights would increase for DRGs with substantial charges in the implantable devices and pacemaker/defibrillator revenue centers.

AdvaMed strongly believes that any change toward cost-based weights, whether accompanied by the hospital relative value methodology or not, must address the distortion caused by charge compression. The recently completed research demonstrates that such an adjustment is possible and provides a solid analytical basis for a specific adjustment.

V. Severity-based DRGs (*"DRGs: Severity of Illness"*)

CMS solicited comments on a consolidated, severity-based DRG system (CS-DRGs) in the Proposed Rule. The CS-DRGs are similar, though not identical, to the All Patient Refined DRGs (APR-DRGs). CMS stated in the Proposed Rule that it was seeking comments on the CS-DRGs as well as alternatives that could be used to capture DRG severity and complexity. CMS also requested comments on a time frame for implementation (FY 2007 or FY 2008) of a severity-based DRG system.

AdvaMed's ability to conduct modeling on the impact of the proposed CS-DRGs was hampered by the fact that there was only limited information available from CMS at the time the Proposed Rule was released. As noted above, CMS did not provide the necessary "grouper" software to analyze the CS-DRG impacts.

In its specialty hospital recommendations last year, MedPAC recommended the use of severity-based DRGs in conjunction with hospital specific weights and cost-based weights. MedPAC examined APR-DRGs and recommended that CMS implement a severity-based DRG system, similar to APR-DRGs, but did not recommend that APR-DRGs be used.

In the Proposed Rule, CMS noted that implementation of APR-DRGs without modification caused several concerns, including the volatility of rates for low-volume procedures and the potential incentives for more thorough coding of severity due to financial incentives provided by severity-based DRGs.

AdvaMed believes that CMS should not implement CS-DRGs or any severity-based DRG system in FY 2007. We support a DRG classification methodology that accounts for patient severity of illness, complexity and patient benefit. These DRG refinements would make allowances for specific DRG assignments that have been previously approved through notice and comment rulemaking. AdvaMed recommends that CMS start with the current DRG system and provide overlays for severity, complexity and patient benefit.

CMS notes in the Proposed Rule that the CS-DRGs do not capture complexity of treatment, but provides no suggested mechanism for doing so in the future. We would like to work with CMS in ensuring that any DRG system that will be used by the Agency will fully recognize complexity and patient benefit. AdvaMed believes that it is <u>essential</u> for any DRG refinements to fully acknowledge these factors.

AdvaMed conducted extensive modeling of one version of severity-based DRGs after MedPAC made its recommendations last year and in November 2005, shared with CMS a number of potential concerns with moving to severity-based DRGs. Included in those concerns were the failure of the severity-based DRGs to recognize newer technologies with an appropriate payment weight and associated payment level. Our analysis of the proposed CS-DRGs reveals that concerns still needs to be addressed. The following examples illustrate several problems with the proposed CS-DRG that call into question the readiness of the proposed severity-based DRG system that fails to recognize such important categorizations.

Improper Classification Under CS-DRGs--Our analysis has revealed that the movement from the current system to CS-DRGs places procedures into inappropriate categories. These mis-categorizations fail to accurately describe accurately the procedure itself, the technology being used, or the resources, complexity or patient benefit of the procedure. Examples are as follows:

- **Current DRGs 118, 551** – In 1997, CMS moved ICD lead and ICD generator/replacement to the pacemaker system with AMI, HF, Shock DRG as justified by average charges (Federal Register, Vol. 62, 45974, August 29, 1997).

Under the CS-DRGs, generator replacement procedures for pacemakers, implantable cardiac defibrillators (ICD), cardiac resynchronization therapy pacemakers (CRT-P) and cardiac resynchronization therapy defibrillators (CRT-D) would be inappropriately categorized together into the same CS-DRGs 243, 244 and 245 (Cardiac pacemaker and defibrillator device replacement with a severity of illness (SOI) levels 1-3) and the ICD lead procedures would map to CS-DRGs 246-248 (Pacemaker & ICD revision). Changing the logic so that ICD generator/replacement map with pacemaker replacements and the ICD lead procedures map with pacemaker and ICD revisions would reverse CMS's 1997 decision without data to justify the change. This, in addition to the fact that there is no variation in the CS-DRGs based upon the type or complexity of the device, would result in a significant penalty to hospitals that treat patients needing implantable defibrillators, which are more complex and resource intensive than pacemakers.

- **Current DRGs 518, 555, 556, 557, & 558** – All of these DRGs would group to CS-DRGs for Percutaneous Cardiovascular Procedures both with and without acute myocardial infarction (CS-DRGs 237-242). DRGs 557 and 558 include drug-eluting stents, and would be placed inappropriately into the same category with bare metal stents.

- **Current DRGs 471, 544 & 545** -- These DRGs for either bilateral or major joint replacement procedures, group to CS-DRGs 414 – 419, which are solely for either hip joint or knee joint replacement. The CS-DRGs thus fail to differentiate between single replacement procedures and revisions, which are more resource intensive and complex. The only distinction made by the CS-DRGs is the distinction based on whether the procedure is performed on a hip or on a knee. Under CS-DRGs, the DRG weight for performing bilateral knee replacement is approximately equal to the payment for one knee replacement.

- **Current DRG 496 (combined anterior/posterior spinal fusion)** -- Based on the CS-DRG descriptions, it does not appear that there is an appropriate CS-DRG crosswalk from current DRG 496. The effect is that combined anterior/posterior spinal fusion procedures, which require two separate incisions and turning the patient over during surgery, get regrouped with all other spinal fusions. This inappropriate categorization ignores the resource intensive nature and greater length of stay associated with this procedure, and is also contrary to CMS policy dating back to the FY 1998 Final IPPS Rule.

- **Current DRGs 110 and 111** – Endovascular aneurysm repair (EVAR), a new generation of surgical services, will experience payment reduction in excess of 12% due to the proposed shift of EVAR into proposed CS-DRGs 234 – 236. EVAR for treatment of Abdominal Aortic Aneurysms (EVAR-AAA) was first approved in late 1999. EVAR for treatment of Thoracic Aortic Aneurysm

(EVAR-TAA) was approved in early 2005. The benefits that this technology offers to patients were reinforced by the implementation of a new "Welcome to Medicare" screening benefit for AAA, enacted under the Deficit Reduction Act of 2005, with implementation effective January 1, 2007, and an award of "New Technology" status for EVAR-TAA in FY 2006. EVAR reduces hospital stays, risk of complications and risk of death resulting from surgery, and is an alternative for many patients where limited or no suitable options were previously available.

Classification of EVAR into CS-DRGs 234 – 236 is inappropriate, and ignores the patient benefit and complexity of these procedures. The CS-DRGs 234 – 236 "Other Vascular Procedures" primarily contain surgeries for peripheral arterial disease – primarily PTA (w, w/o stent) and surgical bypass of the lower limb. This inappropriate classification for EVAR that does not recognize the significant clinical and resource differences (i.e. "complexity") inherent in the treatment of aortic and thoracic aneurysms versus peripheral disease. The disparity of net resource consumption for EVAR versus other procedures in the classification is large, yet would not be recognized under CS-DRG reclassification.

Difficult to Obtain a High Severity Level Absent Adverse Patient Consequences-- Our analysis has also identified concerns regarding the fact that patients may need to suffer adverse consequences in order for the case to be assigned to a higher severity level. While in certain cases this may appropriately reflect the greater use of resources, our analysis uncovered that in some cases it was impossible to obtain a higher severity level unless the patient had a life-threatening complication. We believe that the severity grouping should reflect complexity and patient benefit as well, and should allow for an increased severity/complexity level even without adverse patient consequences. Our examination of this issue led us to review a number of related procedures for arterial repair or occlusion as follows:

- **DRGs 014, 110, 533, 534, 553, 554, and 559** -- When many of the resource intensive procedures within these DRGs are mapped to the proposed CS-DRGs, there are large reductions in payment as virtually none of the procedures map to either of the two highest severity levels. In order to reach the highest severity levels, the patient must have a number of comorbidities that are unrelated to the basic nature of the procedure, such as a severe infection or renal failure.

CS-DRGs Fail to Adequately Recognize Patient Benefit--Our analysis revealed that CS-DRGs appear to be markedly inadequate to recognize patient benefit. One example that demonstrates this deficiency occurs in the context of the use of a more expensive, but longer lasting medical device, such as a hip with hard-bearing or other novel surfaces, that may be dictated by a beneficiary's greater health, activity level and greater potential utility over the individual's lifespan. A subset of today's Medicare patients who undergo total joint replacement are very active and have life expectancy rates that may challenge

some of the older implant designs. Implant longevity has been the focus of significant clinical study and development for this sector of the medical technology industry.

Additionally, implant fixation and range of motion requirements are much more demanding for these patients. Some providers are working to identify patients that are most appropriate to receive these implants based upon such things as family history, overall health and activity level. Unfortunately, the tendency toward better health and higher activity level of these patients would work against them receiving an implant that would be better tailored to their needs, because under the CS-DRGs, such patients would be categorized into the lower level severity. We believe the severity adjustment is flawed because it does not capture resource utilization or the utility of technologies that would be more appropriate for beneficiaries who are more active, healthier, and require a greater range of motion.

Reversal of Recent DRG Refinements--AdvaMed's analysis has revealed that the CS-DRGs, if implemented in FY 2007, would arbitrarily eliminate several important changes to DRGs deemed necessary to encourage promising new technologies. This is illustrated by the following examples:

- **Current DRGs 544 and 545** – In last year's Final Rule, CMS eliminated DRG 209 for primary and revision total hip and knee replacement procedures and replaced it with DRGs 544 (primary total hip and knee replacement) and 545 (revisions hip and knee replacement). CMS also created new and updated existing ICD-9 procedure codes to map to DRG 545 for a more accurate description of the various permutations of potential hip and knee revisions. Under CS-DRGs, revision procedures would map to CS 415 (hips) and 418 (knees) with weights reduced approximately 19 to 20%. Relative weights for bilateral total joint replacement, could likewise decline by as much as 40 to 45%. In the FY 2006 rule, CMS noted that

  > "we examined data in the FY 2004 MedPAR file on the current hip replacement.... as well as the replacements and revisions of knee replacement. . . . We found that revisions were significantly more resource intensive than the original hip and knee replacements."

  It is difficult to understand how CMS can suggest complete reversal of a categorization in FY 2007 that was not only just implemented in FY 2006, but also supported by CMS with the award of additional ICD-9 procedure codes.

- **Current DRGs 110 and 111** – As stated previously, CMS agreed that endovascular aneurysm repair (EVAR) for treatment of Thoracic Aortic Aneurysm (EVAR-TAA) merited the award of a new technology add-on payment in FY 2006. This technology was also made part of the "Welcome to Medicare" screening benefit under the Deficit Reduction Act of 2005, implemented effective

January 1, 2007. Implementation of the CS-DRGs would move these procedures inappropriately to CS-DRGs 234-236 (for more general vascular surgeries), serving to nullify or minimize these recent policy decisions recognizing this technology.

- **Current DRGs 557, 558** – CMS agreed, effective after April 1, 2003, to increased payments for drug-eluting stents. These changes, deemed necessary and appropriate by CMS after careful examination and analysis, would simply be eliminated under movement to CS-DRGs. In 2005, CMS noted that the resource differences between bare metal and drug-eluting stents, stating

  > "We recognize that the resources surrounding bare metal stents and drug-eluting stents differ appreciably and will continue to keep these cases separate..." Federal Reg. Vol. 70, 47294, August 12, 2005.

- **Current DRGs 551-552**. In FY 2006, CMS introduced new severity classifications for a number of cardiovascular DRGs based on the presence major cardiovascular conditions (MCV). CMS stated: "Using the MCV list, we tested our assumption that these conditions described a more severe set of cardiovascular surgery patients. We grouped all the cardiovascular surgery patients within MDC 5 based on the presence or absence of an MCV condition. We found that this split was predictive of significantly increased resource use for nine surgical cardiovascular DRGs."

  Under the proposed CS-DRGs, pacemaker implants would be grouped to CSA-DRGs 228-233 (Permanent Cardiac Pacemaker Implant With & W/O AMI, Heart Failure or Shock), reverting back to classification based on presence or absence of heart failure, AMI, or shock, rather than major cardiovascular condition.

- **Current DRG 103** – In last year's Final Rule, CMS made a significant coding change to account for the use of an external heart assist devices to recover native heart function. Heart assist devices designed for recovery are increasingly used to treat acute heart failure, thus, avoiding the need for heart transplantation. However, patients with recoverable heart conditions may be as ill and utilize as many hospital resources as a heart transplant patient. CMS recognized the need to accurate reimburse for the use of recovery heart assist devices in the FY 2006 Final Rule, and noted that

  > ". . .our data do support that patients having an external heart assist device implanted and removed during the same admission are comparable to in costs and average length of stay to heart transplant and implantable heart assist system patients in DRG 103. . . . we believe that consideration of the comments is best served by recognizing this unique subset of patients,

and making a DRG change that acknowledges the increased resources required for improvement in their care. "

The implementation of CS-DRGs would de-couple external heart assist devices from heart transplantation and regroup them with considerably less costly devices. As a result, reimbursement for external heart assist devices would be reduced significantly and the coverage decision made less than one year ago would be nullified. There has been no clinical data or considered policy justification for this change and it is difficult to understand the rationale for CMS to propose undoing their carefully crafted analysis in less than one year.

AdvaMed is against the elimination of carefully considered DRG reclassifications, performed with stakeholder input and/or pursuant to notice and comment rulemaking -- some as recently as last year -- that would occur if CS-DRGs were to be implemented. We believe that the CS-DRGs are therefore not ready for implementation in FY 2007, and should not be implemented until the problems noted above are addressed fully. Rather than revisiting past policy decisions, AdvaMed believes that CMS should develop and propose a system that establishes severity adjustments for the current DRGs (after eliminating the current CC/no-CC splits), including all of those DRGs that reflect complexity of treatment for some patients. We note that CMS indicated in the Proposed Rule that "a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system." A good first step would be to continue to recognize those technologies that have already been deemed to be worthy of additional consideration under the DRG system.

AdvaMed believes CMS should devote significant additional study to the implementation of any refined or revised DRG system, and seeks opportunities to work with CMS in making revisions to the current DRG system to ensure appropriate recognition for severity, complexity and patient benefit.

VI. DRG Reclassifications

"DRGs: Carotid Artery Stents"

In the Proposed Rule, CMS rejects requests to create a new DRG(s) for carotid stenting or to assign all carotid stenting cases paid under DRGs 533 (Extracranial Vascular Procedures with C/C) and 534 (Extracranial Vascular Procedures w/o C/C) to DRG 533 on an interim basis for FY 2007. Instead, CMS proposes continuing to pay for carotid stenting procedures under DRGs 533 and 534, which would result in payment decreases of 2-3% under the proposed HSRVcc weights.

AdvaMed strongly disagrees with CMS's proposal to keep the current DRG assignments for CAS, as this step would not adequately reflect the resources consumed in the procedure.

Stroke is a leading cause of death and disability for Medicare beneficiaries. Carotid stenting provides an alternative, less invasive treatment option for beneficiaries at risk of stroke but who are not good candidates for surgery. FDA has approved two carotid stent systems for use in the population at high risk for surgery and it is expected that FDA will approve additional manufacturers' carotid stent systems in 2006. CMS has recognized the value of carotid artery stenting by expanding coverage to a subset of the Medicare population that is at high risk for surgery. Adequate payment for carotid stenting is essential to assure that Medicare beneficiaries have access to the therapy.

In the Proposed Rule, CMS includes an analysis of the 2005 MedPAR data which compares the charges and length of stay ("LOS") associated with carotid stenting procedures to the average charges and LOS for all procedures in DRGs 533 and 534. The analysis finds that while the average length of stay was slightly shorter for the carotid stenting cases than for all other cases in DRGs 533 and 534, the average charges for the carotid stent cases were higher by $6,968 in DRG 533 and $7,804 in DRG 534. The average charge for a carotid stent case in DRG 534 is $25,000, much closer to the average charges for DRG 533 ($26,376) than the average charges for DRG 534 ($17,196).

The charge data presented by CMS suggests that carotid stenting cases are underpaid in both DRG 533 and 534. However, CMS suggests that the higher charges associated with carotid stenting may result from higher device mark-ups rather than higher procedure costs. Specifically, CMS observes most of the cases assigned to these DRGs, unlike carotid stent placements, do not involve a device cost. For this reason, CMS concludes that "the higher average charges and lower length of stay for the cases involving carotid artery stents are likely accounted for by the cost of the device." Yet despite acknowledging that the device "likely" accounts for the higher costs, the Agency goes on to speculate that the "hospital's charge markup may also explain the higher charges but lower average length of stay," citing a national average CCR for medical equipment and supplies of approximately 34 percent.

However, CMS does not provide any actual evidence that markup -- and not the cost of the device -- accounts for the charges associated with carotid stenting. Likewise, estimating device markups based on the national average CCR for the category of medical equipment and supplies is inappropriate. This broad category encompasses products with very different markup levels, ranging from higher cost, low-markup devices like stents to lower-cost, high markup medical supplies. As described above in our discussion of the need for an adjustment to address the issue of charge compression, implantable devices typically have lower mark-ups than other supplies and equipment rather than higher mark-ups as suggested by CMS, so the overall charges for carotid stenting are probably deflated relative to other procedures in the DRG. Given our findings above on charge mark-ups for implantable devices, we recommend that CMS rely on its standard current methodology of using MedPAR charge data to determine appropriate DRG assignment for carotid stenting.

In addition to questioning whether carotid stenting cases actually are underpaid, CMS is proposing postponing resolution of this issue until the consolidated severity-adjusted DRG system is implemented. We disagree with this proposal. CMS already has acknowledged that the severity-adjusted DRGs as currently constituted do not adequately capture the costs associated with many medically complex procedures that use advanced medical technology, and that refinements will need to be adopted. CMS has given no indication of how those refinements might work, however, or the time frame for implementation of such refinements. Thus, relying on future severity adjustments is not a viable alternative for addressing the current inadequacy of payment for carotid stenting procedures – especially since CMS already has the authority to modify payment in FY 2007 under the current DRG framework.

AdvaMed urges CMS to create a new DRG or pair of DRGs for carotid artery stenting effective FY 2007.

Alternatively, as an interim solution, we urge CMS to assign all carotid artery stenting cases to DRG 533 for FY 2007, pending further analysis of MedPAR data and the possible future implementation of severity-adjusted DRGs.

This would enhance the DRG groupings in several important ways:

- **Mean standardized charges for DRGs 533 and 534 would be more tightly aligned:** The difference in mean standardized charges for the proposed DRG 533 (all discharges) and the proposed DRG 533 (CAS cases only) is 12% (versus 26% as currently configured);

- **Little or no impact to overall standardized charges for both DRG 533 and DRG 534:** (0% impact to standardized charges for DRG 533 and -3% impact to standardized charges for DRG 534 if proposed changes are implemented);

- **Greater predictability within both DRGs:** standard deviations for DRGs 533 and 534 would be slightly reduced if CAS cases were all grouped to DRG 533; and

- **Clinical criteria for procedures in each DRG are more appropriately aligned,** given that all CAS patients eligible for Medicare coverage are at high risk for surgery due to the presence of a detailed list of complications and comorbidities. By definition, these patients require a higher level of procedural complexity and resource intensity, which justifies all CAS cases being assigned to DRG 533.

"DRGs: Neurostimulators"

Kinetra is an implantable dual array neurostimulator pulse generator used in deep-brain stimulation for the treatment of Parkinson's disease that was approved for a new technology add-on payment beginning in FY 2005. The add-on payment will end at the close of the current fiscal year, but a request was made to reassign the therapy from DRGs 001-002 to DRG 543, a more clinically and cost coherent DRG.

While on average the charges associated with Kinetra procedures are significantly more consistent with the charges in DRG 543 than DRGs 001-002, CMS rejected the proposed reassignment on the basis that it believed the charges associated with the device (and thus the overall procedure) were marked up excessively, and because it wanted to postpone resolution of the issue until the consolidated severity-adjusted DRG system was implemented.

Similar to our comments on the proposed reclassification of carotid stent procedures, we disagree with CMS's statements that mark-ups associated with the Kinetra device are excessive and overstate the total charges of the implant procedure. As described above, we are submitting information in this letter that we believe conclusively finds that hospital charge mark-ups for implantable devices are in fact significantly lower than for other, lower cost supplies and equipment. (Based on this finding, we are submitting a proposal that would make adjustments to correct for the impact of charge compression in the setting of cost-based weights).

We therefore believe that, if anything, the total charges found in MedPAR associated with Kinetra implant procedures may be understated relative to other procedures in DRGs 543, 001, and 002, and that the reassignment of the technology to DRG 543 is fully warranted. Given that we are recommending deferral of the implementation of the consolidated severity DRGs until at least FY 2008, we believe the CS-DRGs should not be a factor in CMS's decision to make DRG reassignments this year. **We strongly encourage CMS to reclassify the Kinetra procedure – determined by CMS to be a significant clinical improvement over previous therapy for Parkinson's disease – to the more appropriate DRG 543.**

VII. New Technology DRGs (*"New Technology"*)

AdvaMed believes that the new technology add-on program is a vital payment mechanism that helps to ensure patient access to new medical services and technologies and to recognize the often higher costs of new technologies more quickly than would otherwise be possible through the underlying DRG system. AdvaMed has worked extensively with both Congress and CMS to create and improve the program so that it most effectively meets the goal of earlier patient access to new medical technologies. AdvaMed and its member companies are committed to continuing to work with CMS to

ensure that the program works as smoothly as possible, and continues into the foreseeable future.

In the Proposed Rule, CMS indicated that it intended to develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments. CMS invited public comment on this issue. AdvaMed believes that the new technology add-on payment is an absolutely essential element of hospital inpatient reimbursement, and that it should be maintained regardless of whether CMS moves toward an estimated cost reimbursement system.

Given the sweeping and complex changes, and uncertainties regarding this year's Proposed Rule, and the potential for a large degree of refinement prior to implementation, AdvaMed supports a robust new technology add-on program that fully recognizes new technologies. At a minimum, we believe that CMS should follow the MMA's report recommendation and raise the new technology add-on payment percentage from 50% to 80% of the difference between the standard DRG payment and the cost of the procedure with the new technology. Doing so would offer some stability and consistency for hospitals providing their patients access to new technologies.

CMS appeared highly non-committal to initial new technology applicants in this year's Proposed Rule. There were three technologies that were proposed for an initial application for the new technology add-on payment, and CMS declined to be definitively positive on any of them. CMS noted that one, C-Port met the threshold criteria, but also noted an FDA finding that the device was 'substantially equivalent' to predicate devices.

In its discussion of NovoSeven, CMS disclosed very little analysis regarding whether the product met the "newness" criterion. It appears that CMS will wait to see if the device gains FDA approval before it engages in definitive analysis. However, as we have pointed out in past comment letters, we believe that CMS should clearly signal its intentions while awaiting additional information. The comment period after the Proposed Rule is released is the last opportunity for many of these technologies to engage in meaningful dialogue with CMS on whether they meet the criteria, and CMS should define its position as thoroughly as possible in the Proposed Rule to allow the best opportunity for input during the comment period. CMS's reluctance to disclose its preliminary views on these new technology applicants hampers discussion during the comment period.

The third new applicant, the X-Stop Interspinous Decompression System, was found by CMS to satisfy both the newness and cost threshold criteria, although CMS expressed concerns regarding whether the device met the substantial clinical improvement criteria. CMS was again non-committal when it offered no preliminary indication on whether it believes X-STOP meets the substantial clinical improvement criterion, and noted that it will await receipt of additional comments before making a decision.

AdvaMed appreciates that CMS took a firm preliminary position on the new technology renewal applicants, and proposed to continue all but one. However, we would like to see CMS be more willing to indicate its preliminary views regarding initial new technology applicants, as this would enhance stakeholder dialog with the Agency on these issues during the comment period.

AdvaMed supports movement toward improved accuracy under the IPPS, so that patients continue to have access to advanced medical technologies. We look forward to working with you and your staff to address the issues discussed in this letter. Please contact us directly if you have any questions or concerns. We thank you for the opportunity to provide comments, and look forward to continuing to work with you on these important issues.

Sincerely,

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Saint Raphael Healthcare System

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June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
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Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates: Proposed Rule

Dear Dr. McClellan:

On behalf of the Saint Raphael Healthcare System, we appreciate the opportunity to comment on CMS' proposed rule on the FY 2007 Medicare Inpatient Prospective Payment System ("IPPS") published in the April 25, 2006 Federal Register. The comments that follow explain some significant effects that the proposed operational and policy changes will have on our System and its primary subsidiary, the Hospital of Saint Raphael ("Saint Raphael's" or "the Hospital").

Overall Impact of the Market Basket and Other Adjustments

For the second year in a row, the Medicare market basket increase along with other targeted adjustments neglects to recognize the realities of the healthcare marketplace. The proposed IPPS market basket update and other proposed rule changes for FY 2007 will result in a net 0.4% increase for Saint Raphael's effective October 1, 2007. This follows a final rule in FY 2006 that provided a net 0.5% increase after application of the market update, transfer rule changes, and other adjustments. Mind you this is in addition to a State Medicaid program that has not provided an inpatient adjustment for six years in a row.

Saint Raphael's operates in one of the costliest labor markets in the country compounded by an acute shortage of nursing staff at all levels. Realistically, this existing nursing labor market alone has commanded increases far in excess of inflation and in fact, had the Hospital limited its salary adjustments to only 0.4% or 0.5%, it would have been assured of having inadequate staff to meet the basic needs of its patients while much of its professional nursing staff would have flocked to other venues with more competitive wage structures.

The resulting realities of this marketplace have meant that the Hospital has had to reduce its staffing in other important programs and has also had to forego a great deal of its planned capital infrastructure replacement and repair to meet the competitive labor climate.

We recommend that as a matter of policy, Medicare should provide that no hospital receives less than a floor of 2% or alternatively, no less than ½ of the market basket adjustment in any given fiscal year.

DRG Changes

The most significant change in the IPPS provides for a new relative weights calculation in the DRGs to account for patient severity, with likely implementation for FY 2007. Yet this severity-based system, the CS-DRG system, has not been appropriately vetted and shared with the healthcare community. In fact, the proprietary nature of the CS-DRG Grouper makes it virtually impossible for a hospital such as Saint Raphael's to determine the impact of these changes and to plan accordingly for their implementation. While we applaud the concept of attempting a fairer methodology of applying DRG payments across the spectrum of severity, there has not been adequate sharing of any severity-based DRG information to even make the determination whether a fairness standard applies.

Saint Raphael's also appreciates Medicare's efforts to reign in the proliferation of specialty hospitals that drain off high margin DRG categories, particularly as it relates to surgeries involving cardiac and orthopedic implantables. However, using the payment system to disincentivize the use of implantables yet again ignores the realities of the marketplace. Many hospitals like Saint Raphael's have worked tirelessly to standardize its allowable implantables and negotiate pricing on the most favorable terms it can acquire from its vendors. But it is the vendors that have the greatest control on the technology and the price, not the hospitals. Most of us would like to believe that our practicing surgeons use only implantables that are required for a case, and consequently the costs of such technology is appropriate. However, the initial education of a surgeon's use of implantable technology is typically provided by the vendor in anticipation that the surgeon will utilize the technology. And they do. To ignore that market reality is to suggest that somehow the technology and its proper use will appear from thin air. That simply is not the market dynamic at play and no amount of disincentives will change that.

To put it in perspective for Saint Raphael's, the base payment for seven (7) of these targeted DRGs alone (515, 557, 535, 558, 471, 551, and 104) will reduce its reimbursement by nearly $2.1million. There is no offset to expenditures available that even comes close to the reduction in revenues associated with just these seven (7) DRGs.

On these issues, we respectively request that CMS delay its implementation of the severity-based DRG system for at least a year, and give further consideration to altering its planned reduction to cardiac and orthopedic DRGs involving implantable devices.

Cost Outlier Threshold

The rule proposal for establishing the fixed-cost outlier threshold results in a payment cut to hospitals based on a flawed methodology of charge inflation. This is an inappropriate method that ignores real cost inflation and further ignores the fact that this is called a "cost outlier threshold", not a "charge outlier threshold". There have been methodologies proposed (most notably by the AHA) that suggest incorporating both cost inflation and charge inflation. We highly recommend consideration of a combined methodology that will result in a lower threshold and fairer reimbursement for serving this patient base, one that adequately realizes the cost and charge levers.

Wage Index

While we understand the broader need to revise across the board the methodology for applying area wage index reclassifications, we support the extension of Section 508 of the Medicare Modernization Act and respectfully request continued support of extending this provision through the legislative process until such time as a broader wage index revision takes place.

Recognizing that CMS must comply with the court-mandated application of the occupational mix adjustment, we are concerned that moving from a 10 per cent adjustment factor to a 100 per cent factor will be an inadequate measure of real mix, particularly given the short period of time in which hospitals such as Saint Raphael's have had to compile and submit the data. To compound the timing problem, the second submission of data will be extremely close to the implementation date. We suggest a much more measured approach of a staged phase-in over some period of fiscal years or the use of corridors as has been past practice.

Quality

We applaud the efforts of CMS to expand its initiatives in the area of quality measures. At Saint Raphael's, these efforts have prompted improvements in data collection, quality programs, and ultimately, consistency in quality of care. However, a system is needed to verify that the data submitted has been accurately received by CMS. Given that quality measures are now being utilized as a payment methodology, it is imperative that hospitals receive what is fair – no more and no less. We would also suggest that data collection be required to be prospective, not retroactive. The resource consumption on retroactive data collection is burdensome and unnecessary.

Value-Based Purchasing

Saint Raphael's mission and its sponsorship by the Sisters of Charity of Saint Elizabeth assures our patients of its commitment to high quality healthcare with appropriate stewardship of its resources. However, the Hospital has watched those resources erode through Medicare reimbursement updates of no more than ½ of 1% per year (actual FY 2006 and proposed FY2007) and no real update to the Medicaid inpatient program for six

(6) years. At the same time, it is being required to increase administrative overhead in this environment of insufficient reimbursement to meet goals of value-based purchasing, more commonly known as pay-for-performance.

Pay-for-performance models, while great in theory, have only a short-term impact (positive or negative depending on one's alacrity to adopt the measures) while the population generally determines what it has to do to achieve the best measure of reimbursement. Eventually, most or all reach the goal and it is then set higher or a new payment philosophy replaces the existing one.

It is refreshing that CMS has asked six (6) important questions for comment before any rule making occurs for value-based purchasing. No doubt it will receive hundreds of suggestions for each of the questions. However, if the goal is to truly make an impact on patient care in a given community, a pay-for-performance model should reward a hospital such as Saint Raphael's based on its improvement over existing performance to ensure its community is reaping the benefit of any increased payment streams.

Finally, on behalf of Saint Raphael's, we want to thank you for the opportunity to comment on the proposed FY 2007 IPPS rule and ask that you kindly consider these comments prior to publishing the final rule.

Sincerely,

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President and Chief Executive Officer

Paul D. Storiale
Vice President and Chief Financial Officer

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VHA®

June 12, 2006

Via Hand Delivery

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Re: CMS-1488-P – Comments Regarding Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

On behalf of VHA Inc. ("VHA"), I am writing to provide comments on the "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates," published in the April 25, 2006 Federal Register (the "Proposed Rule").[1] Given the significant impact the Proposed Rule would have on the inpatient prospective payment system ("IPPS") and related regulations, we appreciate your consideration of our concerns and requests, as set forth below.

VHA is a national alliance of leading not-for-profit health care organizations that work together to improve the health of the communities they serve. VHA delivers industry leading supply chain management services and enables regional and national member networks to improve clinical and operational performance and to drive sustainable results. Based in Irving, Texas, VHA has 18 local offices serving more than 2,400 health care organizations across the United States.

I. DRG Reclassifications (HSRV Weights and DRGs: Severity of Illness)

CMS proposes watershed changes to the calculation of DRG relative weights. Two key components of these changes are (1) the use of hospital-specific relative values ("HSRV") and cost-based weights instead of charge-based weights, and (2) the refinement of DRGs to capture patient severity of illness through more comprehensive all-patient refined DRGs ("APR-DRGs"). CMS refined and consolidated the APR-DRGs into 861 consolidated severity adjusted DRGs ("CS-DRGs").

Given that the proposed changes represent some of the most significant changes to the IPPS since its inception, **VHA strongly encourages CMS to delay implementation of these proposed DRG**

[1] 71 Fed. Reg. 23,996 (April 25, 2006).

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changes for at least one-year. This additional time will provide CMS and various stakeholders the opportunity to work together to address serious concerns with the HSRV and the CS-DRGs.

VHA supports CMS' interest in moving towards a DRG-weighting methodology based on hospital costs rather than charges. However, VHA remains concerned that CMS' proposed methodology is flawed. Evolving evidence from various analyses, such as those commissioned by the American Hospital Association ("AHA"), the Association of American Medical Colleges and the Federation of American Hospitals, suggests fundamental flaws in the proposed methodology that raise significant questions about CMS' approach and emphasize the need for further analysis and study before any changes to the current methodology are made.

In addition, VHA does not support CMS' proposal for a new CS-DRGs classification system beginning in FY 2008 or earlier. The proposed rule fails to show that the change would result in an improved hospital payment system. Moreover, owing to the proprietary nature of the CS-DRG GROUPER, neither VHA nor other commenters are in a position to analyze the system and furnish meaningful comments. **If the need for a new classification system is ultimately demonstrated, VHA urges CMS to implement any such change simultaneously with the new weighting system to provide better predictability and help ease some of the instability and imbalance created by sequential implementation.**

Finally, to balance the magnitude and impact of these changes, VHA recommends that any changes should be implemented over a three-year transitional period that incorporates a gradual blend of the old DRG weights with the new DRG weights.

II. Reporting of Hospital Quality Data

By law, CMS must reduce the standard market basket update for any IPPS hospital that does not submit data on a set of 10 quality indicators previously established by HHS. Under the Proposed Rule, CMS proposes to implement the expansion of the hospital quality data reporting elements, as directed by the Deficit Reduction Act of 2006 ("DRA"). CMS proposes to incorporate the additional 11 clinical measures recommended by the National Quality Forum, to bring the total number of reportable quality indicators to 21.

CMS also is proposing that hospitals be required to pledge to report the full set of 21 quality indicators retroactive to January 1, 2006 in order to be eligible for the full market basket update. Stated otherwise, the Proposed Rule would require a hospital to satisfy CMS' data validation requirements for all 21 quality indicators as of January 1, 2006 or risk receiving the reduced update of 1.4 percent (a reduction of 2.0 percentage points).

VHA supports robust quality data reporting. We have concerns, however, regarding the retroactivity proposed by CMS and the penalties imposed if a hospital does not or cannot report on all 21 quality indicators as of January 1, 2006. In light of possible technical and administrative glitches associated with the implementation of any new processes, and the severe consequences associated with failing to report on all 21 quality indicators as of January 1, 2006, we believe it is inappropriate to impose a retroactivity requirement on a hospital's reporting on all 21 quality measures. While most hospitals would be willing to report on the 21 quality indicators, they should not be punished if they

cannot do so for reasons outside their control. **VHA strongly opposes CMS' proposal to require retroactive reporting to January 1, 2006 and urges CMS to begin the required reporting period with services on or after July 1, 2006.** This delay would afford hospitals the opportunity to coordinate their systems for the additional reporting requirements and ensure a smoother transition of these additional obligations.

Additionally, the DRA authorized the Secretary to further expand the quality measures that must be reported by hospitals in order to qualify for the full market basket update in future years. **VHA recommends that CMS limit its selection of additional measures to those used by the Hospital Quality Alliance to ensure that meaningful and reliable measures are used. VHA also recommends that hospitals be given adequate notice of the new measures by having CMS propose them at least one full year prior to the date they become effective.**

III. Operating Payment Rates (Outlier)

CMS proposes increasing the Fiscal Year ("FY") 2007 fixed-loss cost outlier threshold from $23,600 to $25,530. **VHA is concerned that the proposed threshold is too high and therefore unwarranted, especially when considering that CMS estimates that it spent only 3.8 percent of total payments on outliers in FY 2005 and will spend 4.6 percent in FY 2006, despite the fact that 5.1 percent of total IPPS payments were set aside for outliers in both years.** Based on analyses by AHA, the methodology used by CMS to estimate the fixed-loss cost outlier threshold results in an inappropriately high threshold, effectively cutting payments to hospitals. **VHA believes CMS should consider adopting a more appropriate methodology to set the outlier amount, incorporating both cost inflation and charge inflation.** VHA endorses the proposal set forth by AHA, according to which the outlier threshold for FY 2007 would be set at $24,000.

IV. Occupational Mix Adjustment

CMS proposes continuing to phase in the occupational mix adjustment to the wage index calculation so that only 10 percent of the wage index for FY 2007 would be adjusted for occupational mix, which is the same approach taken by CMS during FY 2006. However, a recent court decision requires CMS to collect new data on the occupational mix of hospital employees and fully adjust the area wage index for FY 2007.

Hospitals are required to collect the hours and wages for employees from January 1 through June 30, 2006. This data initially was to be collected by July 31; however, hospitals are required to submit data by June 1 for the first calendar quarter of the year (January 1 through March 31), and by August 31 for the second calendar quarter (April 1 through June 30). Data from the first quarter will be used to adjust the FY 2007 area wage index, while data for the full six month period (January 1 through June 30) will be used to adjust the area wage index for FYs 2008 and 2009.

While we understand that CMS is under severe time pressure due to the timing of the court's decision, we do not believe that the 30-day comment period was sufficient, as hospitals were busy during this time trying to meet the new survey deadline and answering requests for information from their intermediaries. In addition, it would be appropriate for CMS to take comments on the calculation

after the initial results of the survey are tabulated and posted, given that the results of the survey could be material. For instance, if the segregation of RNs who are in management versus RNs who are staff does not produce reliable results, CMS might consider consolidating the two groups for purposes of the calculation. While CMS might not have time to make such changes for FY 2007, it could entertain comments on the implementation for FYs 2008 and 2009. **Thus, VHA urges CMS to publish the occupational mix adjustment changes as an interim-final rule in August with a comment period.**

In addition, while CMS clarified the confusion regarding the placement of certain employees, VHA recommends that CMS re-evaluate where these employees belong on a go-forward basis. **However, such changes should not be made to the ongoing collection of wage data, as it would necessitate the re-submission of the first calendar quarter's data to ensure that both quarters could be used for FYs 2008 and 2009.**

VHA supports CMS' clarification that only nursing personnel within the cost centers listed should be included in that category for the purposes of consistency. VHA recommends that CMS consider refining the list for future wage data collections to ensure better adaptability to the various methods hospitals use for attributing costs to the cost centers.

VHA also supports the AHA's recommendations for addressing hospitals that do not participate in the data submissions as an appropriate balance between enriching data collection and penalizing non-participants.

V. Hospital Redesignations and Reclassifications (Reclassification Under Section 508)

Section 508 of MMA provided $900 million over 3 years for a one-time geographic reclassification opportunity, which expires March 31, 2007. Because the Section 508 reclassifications expire mid-year and hospitals may not receive their funding at the same time as any other form of reclassification, CMS is proposing special provisions for accepting or denying partial-year reclassifications for FY 2007. **VHA commends CMS for addressing the concerns voiced regarding the Section 508 reclassifications and supports CMS' proposal.**

VI. Sole Community Hospitals ("SCH") and Medicare Dependent Small Rural Hospitals ("MDH")

CMS is proposing to require approved SCHs or MDHs to notify the appropriate CMS regional office of any change that would affect the providers' classification as such. To date, this has been the fiscal intermediaries' responsibility.

First, requiring SCHs or MDHs to monitor and report any change affecting their classification status appears to inappropriately shift to the hospitals a responsibility that was and should be placed on the intermediaries. For instance, hospitals are neither involved in, nor have any control over, the construction of new roads or new hospitals and they should not be responsible for monitoring and reporting such changes. In addition, hospitals do not always know when there were prolonged severe weather conditions that closed area roads, or when there were changes to posted speed limits and traffic

patterns. Furthermore, some of the qualifying criteria, such as inpatient admissions at other regional hospitals, would be hard to monitor since hospitals do not have open access to the data of their competitors. In short, requiring SCHs and MDHs to constantly monitor whether they continue to meet their respective classification requirements would impose a tremendous and unreasonable administrative burden on hospitals. **VHA recommends that this function remain the responsibility of the intermediaries, which are in a better position to monitor these circumstances. If CMS requires hospitals to report changes in circumstances, then the specific types of situations should be noted and should only include aspects of their operation that are within their control (e.g., number of beds).**

Second, CMS' proposal to retroactively withdraw the SCH or MDH status of a hospital if it does not appropriately self-report a change in circumstances affecting its classification could be financially devastating to affected hospital and the patients it serves. CMS should, at minimum, give consideration to whether the hospital had knowledge of the disqualifying circumstances. Accordingly, CMS should develop a prospective process for withdrawing the hospitals' SCH or MDH status. Moreover, a 30-day timetable for losing SCH/MDH status is unrealistic given the financial implications of such a change and the inability of a hospital to foresee this outcome. **CMS should re-evaluate the proposed timetable for revoking the SCH/MDH status of a hospital when it is found to be disqualified or self-reports disqualification, and the hospital's status as a SCH or MDH, as the case may be, should be revoked effective the beginning of the following cost-reporting period.**

In addition, a SCH or MDH may apply for special payments if it experiences a decrease of 5% or more in its total number of patient discharges from one cost reporting period to the next, and the SCH or MDH had no control over the decrease. If the hospital experiences such a decrease, it must demonstrate that it took measures to scale back its nursing force commensurately. CMS believes only "core staff and services" should be covered by these special payments. CMS has used the AHA's HAS/Monitrend Data Book (the "Data Book") to compare staffing to other hospitals in the area to determine if a hospital is staffing its units appropriately. The Data Book, however, has not been updated since 1989 and is outdated. CMS proposes to use occupational mix adjustment data currently being collected for wage index purposes to calculate nursing hours per inpatient date for hospital in question and local peer hospitals.

With respect to the volume decrease adjustment, the occupational mix adjustment was only partially implemented in its first three years, primarily due to the questionable data and results. The current collection, which is occurring again under rushed circumstances, may also result in questionable data and results. **VHA has strong reservations regarding CMS' assumption that the occupational mix adjustment data will be appropriate for this use. VHA agrees with the AHA that the data within the AHA annual survey is sufficient for CMS to determine the nursing levels per patient day.**

VII. Emergency Medical Treatment and Labor Act ("EMTALA")

CMS proposes to clarify that hospitals with specialized capabilities must accept appropriate transfers under EMTALA, even if they do not have an emergency department, provided they have the capacity to treat the patient. **VHA urges CMS to consider further guidance on the definition of "specialized capability."**

CMS also is proposing to change existing regulations to allow a qualified medical person other than a physician to certify false labor, if it is within his/her scope of practice according to the hospital's medical staff bylaws and state law. **VHA supports CMS' proposal to allow qualified medical personnel other than a physician to certify false labor, as it recognizes that licensure and scope of practice should remain under the purview of state law and regulation.**

VIII. Graduate Medical Education ("GME") Payments (Resident Time Spent in Non-patient Care Activities as Part of Approved Residency Programs)

CMS purports to clarify that resident training that occurs at non-hospital sites must be related to patient care if a hospital seeks to count that time for direct and indirect GME payment purposes. CMS further states that resident time spent in didactic activities (non-patient care activities), such as educational conferences and seminars that take place at non-hospital sites, would not be counted for GME payment purposes. **VHA strongly opposes CMS' position and believes this "clarification" represents a significant departure from existing practice that otherwise would require CMS to formalize it through appropriate public notice and comment.** These activities are critical to the continuing development and training of medical professionals, irrespective of whether the activity occurs within the four walls of the hospital or in non-hospital settings. **VHA urges CMS to abandon this policy change. If not, then VHA respectfully notes that this change should be subject to the Administrative Procedure Act rulemaking as it is not a "clarification" but rather a substantial change in policy.**

IX. Transparency of Health Care Information

CMS seeks suggestions on improving transparency of health care information, in part to expand the availability of information on health care quality and pricing. The AHA, the Federation of American Hospitals and the Association of American Medical Colleges partnered with CMS and others to form the Hospital Quality Alliance ("HQA"), and the efforts of HQA have led to the voluntary reporting of 21 quality indicators on the Hospital Compare Web site. More measures of hospital quality and patient satisfaction are planned for the future. While progress has been made in quality transparency, similar information on hospital pricing is less accessible. **VHA commends CMS for seeking public input on shaping future policy in this area. However, VHA strongly opposes CMS' intent to implement such policies through the imposition of additional conditions of participation ("CoP"). Moreover, we recommend that CMS examine opportunities for offering financial support for the implementation of costly health care information technology solutions. Finally, VHA supports the AHA's proposal to promote state-based efforts on transparency of health care information.**

X. Value-Based Purchasing

The DRA requires CMS to develop an implementation plan for hospital value-based purchasing (pay-for-performance or "P4P") beginning in 2009. As we have noted above, **VHA continues to support the work of HQA and believes that the continued evolution of pay-for-performance programs should build on the work of HQA to ensure the maximum utility and efficiency from their wealth of knowledge and expertise.**

However, VHA remains concerned with premature efforts to implement pay-for-performance measures, particularly if payments are tied to vague and indefinite concepts such as efficiency of care. VHA recommends continued analysis of these incentive programs and the measured implementation of such programs to ensure the proper alignment of hospital and physician incentives driven toward improving the quality of care and providing medically appropriate care.

XI. Hospital-Acquired Infections

The DRA requires CMS to identify by October 1, 2007 at least two conditions that could lead to payment in a complication or co-morbidity DRG. The conditions must be either high cost, high volume or both, result in the assignment of a case to a DRG that has a higher payment rate when present as a secondary diagnosis, and be reasonably preventable through the application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals would not receive additional payment for cases in which one of the selected conditions was not present on admission. The DRA also requires hospitals to submit the secondary diagnoses that are present at admission when reporting payment information for discharges on or after October 1, 2007.

In the Proposed Rule, CMS is seeking input about which conditions and evidence-based guidelines should be selected. VHA notes that such suggestions should come from the collaboration of a broad array of experts to effectively implement any such proposal.

* * * *

In closing, on behalf of VHA and its members, I would like to thank CMS for providing us this opportunity to comment on the Proposed Rule. Please feel free to contact me at (202) 354-2607 if you have any questions or if VHA can provide any assistance as you consider these issues.

Respectfully submitted,

Edward N. Goodman

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June 9, 2006

Via Electronic and U.S. Mail

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File Code CMS-1488-P: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide this **comment letter on quality-related issues** in the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2007 rates (CMS-1488-P), (hereinafter referred to as "Proposed Rule" or "NPRM"). **AdvaMed is providing a second comment letter on proposed changes in reimbursement.** AdvaMed is the largest medical technology trade association in the world. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

This letter summarizes our positions on three key quality provisions contained in the Proposed Rule: hospital quality data; value-based purchasing; and transparency of health care information.

HOSPITAL QUALITY DATA

AdvaMed supports CMS efforts to improve the quality of care delivered to Medicare beneficiaries. The Deficit Reduction Act requires that CMS expand the "starter set" of 10 quality measures that it has used since 2003, by adopting the baseline set of performance measures as set forth in the 2005 report issued by the Institute of Medicine (IOM) of the National Academy of Sciences, effective for payments beginning with FY 2007. These IOM measures include the Hospital Quality Alliance measures, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS®) patient perspective survey, and three structural measures. In addition, CMS was given broad discretion to add other quality measures that reflect consensus among affected parties, and to replace measures when they are no longer appropriate.

Furthermore, CMS is required to establish procedures for making quality data available to the public, after ensuring that a hospital has the opportunity to review its data in advance. CMS is also required to report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in inpatient settings on the CMS Web site.

AdvaMed believes that quality measures should conform to clinically appropriate care established by peer-reviewed literature or professional consensus. Furthermore, we believe that financial incentives to encourage providers to meet standards based on quality measures of this kind are appropriate. Financial incentives must allow sufficient flexibility to meet the unique needs of individual patients, and not encourage providers to avoid the most difficult cases.

The 21 quality measures selected for implementation appear to meet AdvaMed's requirements that they conform to clinically appropriate care established by professional consensus, as they were recommended by the IOM and endorsed by the National Quality Forum (NQF). As CMS expands quality measures in the future, it should recognize the special challenges that could occur with measures related to new technology.

AdvaMed believes that process measures of quality should not specify a particular brand or model of device. Quality measures should be flexible enough to allow access to new, improved technology or devices, and should be reviewed and updated periodically to reflect new benchmarks and standards of care. If all providers satisfy a particular measure, it should be removed to reduce the burden of reporting.

If CMS were to adopt a process quality measure that assesses whether or not a provider uses a particular medical device or technology, it should consider allowing exceptions. Providers who use a different new device or technology could be excluded from measurement on this indicator, by exclusion from both the numerator and denominator for the measure. Providers who use a different new device or technology could be

required to report this use through a separate measure. As use of new devices or technologies often begins in a particular locality, CMS should allow for variation in measures across the country to capture this variability. If CMS does not recognize use of new devices or technologies when evaluating providers on the basis of process measures, it runs the risk of freezing medical treatment in place, even after it has become outdated. Medical innovation and successful patient outcomes would be inhibited by such limits.

As CMS continues to examine potential new quality measures, we urge you to assure that all relevant stakeholders are part of the process. Manufacturers of medical technology and patients who benefit from this technology should have a seat at the table when quality and cost measures are developed. Potential interested parties should not have to pay a membership fee or any other fee to participate fully in the deliberations and decision making about quality measures.

Since the current CMS hospital quality reporting program ties receipt of a full update to *reporting* of hospital quality data, not the *values* of the hospital quality data, adequate and appropriate risk adjustment and other technical standards, such as sample sizes, are of lesser concern. However, because CMS publicly reports the percent of a hospital's cases that meet quality standards on Hospital Compare, appropriate risk adjustment and technical standards should be applied to the publicly reported data to assure fair treatment of hospitals. Medicare patients, Medicare Advantage plans, and other public and private sector patients and payers have access to the quality information reported on Hospital Compare. As more measures are reported covering more conditions and services, hospitals and others need to be guaranteed that they will not be penalized for treating patients who are frail, have multiple chronic conditions, and fail to comply with treatment orders.

CMS is charged with reporting on hospital efficiency and costs of care. AdvaMed strongly believes that reports on cost cannot be separated from reports on quality, and that both cost and quality are components of efficiency. We define efficiency as delivering high quality care at the lowest cost. An efficient provider is not one who provides low cost care, but one who provides high quality care at low costs. We encourage CMS to develop measures that examine quality and costs of care within and across settings and over time.

We prevail upon CMS to continue its policy of affording hospitals the opportunity to view information regarding their performance before it is made public. We believe that CMS should establish a formal mechanism for provider appeals of performance ratings, if providers believe that the information being made public about their performance is inaccurate.

VALUE-BASED PURCHASING

AdvaMed's comments on value-based purchasing focus on measures, data infrastructure, incentive methodology, public reporting, considerations related to certain conditions and

health information technology. CMS defines the best value as quality services at the best possible price. We support a value-based purchasing program for hospitals that encourages the delivery of high quality care with appropriate payment. In addition, the association supports rewarding providers for delivering high quality care.

Measures

A value-based purchasing program is based on measures of efficiency, which consider both quality and cost of care over an appropriate time period, such as an episode of care. AdvaMed agrees with the IOM criteria that measures of quality of care should focus on effectiveness, safety, patient-centeredness and timeliness. We believe that the two other IOM criteria – efficiency and equity – can only be determined for a high level of quality. We also believe that efficiency measures must be based on robust measures of the patient's outcome of care.

We are especially concerned that the measures and the incentive structure be designed to address the potential conflict between appropriate treatment and less cost. We do not support a value-based purchasing program based on efficiency measures that degenerates into incentives to provide the lowest cost care. For this reason, AdvaMed opposes using process measures to assess quality in the context of efficiency and supports using patient outcome measures instead. Reliance on process measures of quality when assessing efficiency could inhibit access to new technologies. Incentives should be aligned such that physicians and other providers are encouraged to deliver high quality care with patient access to advanced medical technologies. In addition, physicians who participate in clinical trials should not have the data from those trials included in their ratings. This would allow for the development of new procedures and other innovations.

AdvaMed believes that costs of care measures must conform to clinically appropriate care as established by peer-reviewed literature or professional consensus. Examples of costs of care measures that meet these standards are those that accurately calculate the savings from reducing medical errors, reducing rates of surgical complications, reducing preventable hospitalizations, reducing inappropriate use of emergency rooms, eliminating services that have been shown as unnecessary and possibly harmful, and eliminating duplicative procedures through better coordination among providers. AdvaMed strongly believes that costs of care measures should not be used to compare the "efficiency" of providers who do not deliver the same quality of care.

We note the work that CMS has undertaken with relevant stakeholders and consensus building organizations to develop quality measures to date. While consensus building organizations have recommended 21 measures of quality of care for use in Medicare, they have made no recommendations regarding the costs or equity of care. As development of additional measures and revision of existing measures occurs, we urge CMS to consider appropriate episodes of care for assessment of quality, cost and equity. For example, some Medicare patients who undergo total joint replacement are very active and have life expectancy rates that may challenge some of the older implant designs.

Implant longevity has been the focus of significant clinical study and development for this sector of the medical technology industry. Newer implants are more durable but more expensive. When comparing the value of treatment with a new device versus an older device, CMS must consider the long-term benefits and costs. A one-year period would be an insufficient to assess the benefits to patients of many new technologies.

AdvaMed supports the open process that CMS has used to develop quality measures, and urges that an open process be used to develop cost of care measures. This process includes the goals that performance measures be based on appropriate evidence, effectively related to desired outcomes, derived through a transparent process involving all relevant stakeholders, and routinely updated. We encourage CMS to collaborate with consensus-building organizations that allow input from all stakeholders and guarantee transparency when developing, selecting and updating performance measures. AdvaMed's experience with the AQA (formerly the Ambulatory Care Quality Alliance) indicates that some consensus-building organizations are not completely transparent in their operations.

Data Infrastructure

CMS must plan for the reporting, collection and validation of performance measures, including both quality and cost of care measures. AdvaMed urges CMS to develop a strategy for allowing comparisons of quality and costs of care over extended periods of time. This is particularly important with respect to medical devices and technologies that often provide benefits that are realized over an extended timeframe. A one year timeframe for measuring costs and quality is often too short, and may inappropriately favor procedures and services that are less expensive in the short run but provide more value over the long-term.

Incentive Methodology

CMS notes that incentives could reward hospitals for meeting a particular standard of performance, for improvement over a baseline level of performance, or for both. In its Premier demonstration, CMS provides incentives for high achievers and penalties for those who fail to meet established minimum levels of performance. MedPAC recommended rewarding providers, including hospitals, for both improving care and exceeding benchmarks in order to improve care for as many beneficiaries as possible, and to ensure that all providers would be encouraged to improve care and have an opportunity for rewards.

Consider the dilemma which could occur if CMS uses both attainment and improvement in the same market and provides the same rewards for both. Suppose the market contains two hospitals, both of which receive the same payment under the CMS inpatient prospective payment system. Hospital A meets the CMS standards for performance, while Hospital B does not. However, Hospital B does meet the CMS standards for improvement. If CMS rewards both Hospital A and Hospital B with the same incentives,

it would pay the same amount for the delivery of high quality care as it would for the delivery of lower quality, albeit improved, care. This example argues for differential rewards for attainment versus improvement, with a larger reward for Hospital A than for Hospital B.

The situation becomes more complicated if the market includes a third hospital, Hospital C, which delivers care that exceeds the quality provided by Hospital B, but meets neither the standard for performance nor the threshold for improvement over baseline. In this case, Hospital C would not receive any increase in payment, but Hospital B, which delivered lesser quality care would receive a bonus payment. As long as all hospitals in a given market start out at the same payment rate, which they do under the current payment system, there is no way to guarantee that this result can be avoided.

Although little research has been conducted on the size of incentives necessary to stimulate hospitals to improve performance, CMS has experience with hospitals' almost complete willingness to report data on 10 measures when a 0.4 percent reduction in payments was on the table, and will have additional experience through expansion of the reporting requirement to 21 measures with a possible 2 percent reduction for non-reporting. AdvaMed urges CMS to continue to monitor its programs and the types and sizes of incentives offered by other payers for performance improvement.

AdvaMed urges CMS to carefully monitor performance to ensure that quality is not diminished and that patients continue to have access to new treatments and technologies. We agree with CMS that value-based purchasing methods are still under development, and that CMS will need to assess incentives and evaluate their effects in order to revise them quickly as it learns more about their impact on hospitals and Medicare beneficiaries.

When determining the timing of incentive payments in relation to performance, CMS should consider that the quality and costs of some procedures involving medical devices and technology are realized over an extended timeframe. When medical care includes use of a device of technology, many years may elapse before the quality and cost of that care can be accurately assessed. Incentive payments should be distributed only after the full effect of the care is known – which in some cases may be 5 or 10 years after care was delivered.

Public Reporting

Public disclosure of information on hospital performance has the potential to increase the delivery of quality health care using appropriate types and quantities of services. Public disclosure of this information also has the potential to limit access for beneficiaries who are difficult to treat because they are frail, have multiple chronic conditions, or often ignore physicians' orders. Such disclosure could also lead to reliance on older, less effective, less costly services, procedures, equipment, or devices in order for a hospital to appear less costly, or more efficient.

In order to reap the advantages of public reporting without the disadvantages, CMS should develop standards for public reporting with input from the many stakeholders who will use these reports for a variety of reasons. Patients and physicians may use public reports on hospital performance to select where to receive or deliver care. Payers may use these reports to identify hospitals that they wish to include in their networks, to negotiate payments, or to vary patient cost-sharing to provide incentives for patients to use particular hospitals. Hospitals may use the reports to gauge their performance relative to other hospitals, and to identify areas for improvement.

We believe that the most important aspect of public reporting is that performance measures on costs not be reported without performance measures on quality for the same services. Informed decision making about performance cannot occur if costs are reported divorced from quality.

We also believe that it is critically important for providers whose performance is being reported have the opportunity to review the reports before they are made public, and to work with CMS if questions of accuracy are raised. We applaud CMS's decision to inform hospitals before their quality ratings are posted on Hospital Compare, and urge CMS to develop a formal procedure for review of appeals from providers who disagree with their performance ratings.

Considerations Related to Certain Conditions

AdvaMed supports the collection of all secondary diagnoses for all hospital admissions. The association believes that this data will provide useful information about hospital quality related to hospital-acquired infections. It will also provide information that could be used to adjust for patient risk and patient complexity.

Health Information Technology

AdvaMed supports widespread, rapid adoption of health information technology (HIT) throughout the health care system, including universal adoption of electronic health records. We believe that any value-based purchasing system should include incentives for adoption and use of HIT. In addition, we support removal of barriers to the dissemination of resources (financial, equipment or otherwise) from hospitals to physicians to allow for the use and adoption of HIT.

AdvaMed supports incentives to reward new modes of providing services that result in quality improvement or cost reduction for patient care, such as remote patient monitoring, computer-assisted surgery, imaging, telemedicine, and virtual physician visits.

TRANSPARENCY OF HEALTH CARE INFORMATION

AdvaMed supports dissemination of accurate information on the value of health care services. We urge CMS to use caution when releasing such information to ensure that the care being measured is appropriate, that all costs and benefits are included, and that the episode of care examined spans the full period over which benefits and costs accrue.

CMS states that part of the reason that health care costs are rising is patients' lack of information about the actual costs and quality of their care. Furthermore, many patients are shielded from the full costs of services because insurance pays much of these costs. CMS argues that these factors produce few incentives or means for patients to shop for providers offering the best value, or for providers to offer the best value to patients. CMS defines the best value as quality services at the best possible price.

CMS argues that consumers must have accessible and useful information on price and quality of health care items and services to choose providers that offer the best value. On June 1, 2006, CMS posted Medicare payment information on its web site for 30 common elective procedures, by Diagnostic Related Group (DRG). These procedures include heart operations and implanting cardiac defibrillators, hip and knee replacement, kidney and urinary tract operation, and other surgical and non-surgical admissions. This information shows the number of procedures performed by each hospital in FY 2005, and gives a range of Medicare payment information for the procedure at the county level. This payment information does not reflect variation in the technology used within the DRG. Hospitals that provide patients with medically advanced technologies that improve patient outcomes are not identified. Most importantly, no information is presented about the quality of care provided by the hospital.

CMS proposes to identify several regions in the US where health care costs are high and where there is significant interest in reducing costs while improving quality. When identifying these regions, CMS should ensure homogeneity within the area and heterogeneity outside. For example, all hospitals in an MSA may not exhibit the same levels of cost or quality. Even within hospitals, some departments may deliver high quality care at reasonable cost, while others may not.

CMS presumes that quality information available through Hospital Compare is sufficient to cover quality of care issues. AdvaMed believes that any pricing information that is made public should be accompanied by evidence-based quality information in order for consumers of that information to assess the value of services. This is not the case for the recently posted Medicare pricing for 30 common elective procedures.

CMS cites three possibilities for publishing pricing information: lists of hospital charges and/or Medicare payment rates; lists of hospitals' prices for the uninsured or policies for discounts or other assistance for the uninsured; and posting Medicare payments for an episode of care. To better serve the uninsured, hospitals should be required to inform potential patients about their possible out-of-pocket costs and hospital policies to help

defray those costs for the needy. Posting estimated payments for an episode of care, such as hip replacement surgery or cardiac bypass surgery, assumes that certain conditions should be treated in certain ways. In fact, individual patients may have very different needs and therefore, general pricing information should not attempt to identify the appropriate treatment for a particular condition.

AdvaMed urges CMS to consider posting pricing and quality information on appropriate evidence-based protocols. A provider may perform a certain procedure, or deliver care at the lowest possible cost, yet the procedure may not represent appropriate care. For example, a hospital may provide high quality, low cost hysterectomies, but if those hysterectomies are not appropriate treatment, the quality and cost are irrelevant. Delivering the best value medicine requires delivering appropriate evidence-based protocols, not unnecessary high quality, low cost procedures.

AdvaMed also urges CMS to consider the time-frame over which quality and costs are assessed. If an episode of care encompasses a too-short time frame, costs and quality may be inaccurately determined. For example, use of an implant for total joint replacement may have to be assessed over the lifetime of the patient, or implant, which may extend over a period considerably longer than one year.

AdvaMed applauds CMS's efforts to increase the quality of care provided to Medicare's seniors and persons with disabilities. We believe that hospital reporting on the expanded set of quality measures is appropriate. Furthermore, we concur that CMS should develop a comprehensive plan for a hospital value-based purchasing program with input from the public and for increasing transparency of health care information. Our overarching concern is that information on costs of care not be reported, or used as a basis for payment, without consideration of the quality of care provided. Low cost, low quality care is not our goal. We strive to provide patients access to advanced medical technology to improve their health. Please contact us directly if you have any questions on this letter. We thank you for the opportunity to provide comments, and look forward to continuing to work with you on these important issues.

Sincerely,

Ann-Marie Lynch
Executive Vice President
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ABIOMED
Recovering Hearts. Saving Lives

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June 2, 2006

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RE: Comments on CMS-1488-P, Changes to the Hospital Prospective Payment System for Fiscal Year 2007

Dear Mr. Kuhn,

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 2007 [CMS-1488-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. These two devices are the only FDA-approved mechanical cardiac assist devices indicated for use in all forms of recoverable heart failure. More than 8,000 patients worldwide have been supported with ABIOMED devices, and all top five *U.S. News and World Report* ranked heart hospitals utilize ABIOMED recovery technology.

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 recently received FDA approval to conduct clinical trials of the 2.5LP IMPELLA in the U.S.

The company's AbioCor® Implantable Replacement Heart is currently under review for designation as an HDE ("humanitarian device exemption") with the Food and Drug Administration but has not yet been approved for commercial distribution. If approved, the AbioCor would be the first totally implantable replacement organ brought to market.

Both the AB5000 and BVS5000 are reimbursed as "heart assist devices" under DRG 525 or DRG 103. In October 1, 2005, CMS announced a change in coding for external heart assist devices, such as the AB5000 or BVS5000, that assist patients through recovery of native heart function within a single hospital admission. This change allowed for the combined implant and explant of an extracorporeal ventricular assist device to map to DRG 103 instead of DRG 525. This put reimbursement for heart recovery with an external ventricular device on par with internal ventricular assist devices used for destination therapy and bridge-to-transplant, and heart transplantation. From a policy perspective, this was a solid acknowledgement that hospitals should be accurately reimbursed for treating extremely ill patients with failing heart function regardless of whether the failure is acute or chronic.

ABIOMED is wholly committed to providing technology that successfully recovers native heart function. This requires intervention in a timely, aggressive manner. Using a voluntary data registry, we reported last fall on a multi-center US experience for treating patients suffering from cardiogenic shock post myocardial infarction with AB5000 VAD technology.[1] Between October 2003 and July 2005, 50 patients were supported in 25 US centers and data was reviewed for demographics, patient management, and survival outcomes.

Preimplant conditions of these 50 patients included IABP 88%, mechanical ventilation 83%, pre-implant arrhythmia 71%, CPR 58%, vasopressors 83%, inotropes 90%, hyperbilirubinemia 50%, and hypercreatinemia 52%. Bi-Ventricular support was necessary in 48% of the patients. Hemodynamics were immediately stabilized after implantation of the AB5000 with significant improvements in cardiac index (1.7±0.5 to 2.6±0.5 L/min/m^2, $p<0.002$), systolic aortic pressure (77±15 to 112±16 mmHg, $p<0.0001$), central venous pressure (21±7 to 16±4 mmHg, $p=0.002$) and pulmonary arterial pressure (44±9 to 36±6 mmHg, $p=0.001$). The thirty day survival rate was 42% (n=21) for this patient population. Of the survivors 71% (n=15) recovered native heart function, 24% (n=5) were transplanted, and 5% (n=1) were transitioned to a destination device. The median support duration for recovery was 19 days (range 4-96 days).

For patients who are not implanted and explanted within the same admission, DRG 525 is available for procedures involving solely the "implant" or "replace and repair" of an external ventricular assist device.

Overall, ABIOMED supports a more accurate payment system and as a manufacturer of advanced medical technology, recognizes the complexity of establishing an accurate payment system that appropriately reflects changing technologies, an aging population and increasing strains on a publicly-funded health care system. The challenge before CMS is clearly daunting and ABIOMED supports their efforts to reshape the inpatient

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[1] Present in part by Anderson M, Acker M, Kasirajan V, et al. Mechanical circulatory support improves recovery outcomes in profound cardiogenic shock post acute myocardial infarction: a US multicenter study . *Am J Cardiol.* 2006;96:11H.

payment system to more accurately reflect provider economics and the realities of today's health care financing.

Our concern, however, is that CMS is attempting to accomplish too much, too fast, with too little understanding of the impact on today's much needed technology. Heart disease is the leading cause of death among both men and women. The American Heart Association reports that one in 3 Americans is living with some form of cardiovascular disease. Approximately 163,000 Americans die from sudden cardiac arrest *outside* the hospital setting each year and about two-thirds of all sudden cardiac deaths occur in individuals with no known heart disease.

Nearly 770,000 patients were discharged in 2003 with a primary diagnosis of acute myocardial infarction. Literature reports that 7-8% of them experience cardiogenic shock requiring advanced technology such as ABIOMED's available for immediate response. As the population ages, these heart failure patients will present with more secondary complications and co-morbities than ever before. It will be vitally important that patients have access to newer, innovative technology as the need arises.

While physicians will always be the best judge as to the appropriate clinical course to pursue, today's health economics necessitate that part of that decision making process does indeed include forethought to hospital and physician payment. Any measures to reshape the inpatient prospective payment system must, at a minimum, safeguard the clear and unbiased clinical decisions so important to the delivery of care. ABIOMED believes the CMS proposed rule for changes to impatient hospital payment for implementation in FY 2007 puts in jeopardy these decisions by disproportionately disadvantaging newer, innovative health technologies.

ABOIMED's comments are as follows:

"HSRV Weights"

CMS proposes to adopt MedPAC's recommendation that CMS replace its charge-based relative weight methodology with cost-based hospital-specific relative value (HSRV) weights because it is believed that the charge-based system has introduced "bias into the weights due to differential markups for ancillary services among DRGs." It is believed using cost-based relative weights will help reduce this bias and in some part, level the playing field among hospitals.

ABIOMED has three concerns with this approach. First, relying upon cost data will inherently disadvantage newer technologies such as heart assist devices designed for recovery because hospital cost data lags behind charge data. It is impossible to use data from FY 2004 and accurately reflect the utilization and benefit of newer technology. For example, ABIOMED heart assist devices, the most advanced of which was FDA approved in 2003, have successfully recovered Medicare patients under DRG 103 who have experienced acute heart failure, been supported through recovery to explant, and been discharged home without need for mechanical support. In FY 2004, 48 patients over the age of 65 benefited from support of this nature, whereas, within one year, this number had nearly doubled to 91 in FY 2005. The trend will only continue as the proven benefits of the technology become more fully rooted in clinical knowledge. Utilizing older cost data cannot capture this growth and utilization to establish accurate payment to hospitals.

Second, industry experts have identified technical flaws in the methodology CMS uses to calculate the cost-to-charge ratios that would be used in developing the HSRV weights. One involves the exclusion of data from a large volume of CMS hospitals from its analysis, which if included would result in different degrees of impact on new technology. Specifically to ABIOMED, utilizing modeling made available by Mr. Chris White, former MedPAC member and consultant to AdvaMed, ABIOMED's heart assist devices under DRG 525 would increase 2 percent according to CMS's approach, yet 11 percent with corrections for these technical errors.

And finally, we are concerned a cost-based system would be unreliable and perpetuate the common cost reporting errors and lack of timeliness that plagued hospitals prior to the change to a charge-based system in the early 1980s. Admittedly, because hospitals have full discretion in setting their charges they may not truly reflect actual costs and the reflection of resources, but neither are there safeguards and compliance within the reporting system to accurately report costs.

ABOIMED respectfully recommends that CMS retain for FY '07 a prospective payment system based on charge data because it will reflect the most current hospital expenditures for newer technology. ABIOMED is also concerned that the methodology proposed by CMS involves iterate steps and assumptions that are not transparent making it nearly impossible to determine the full impact of the proposed change to cost-based HSRV weights. Although we applaud an attempt to more accurately pay hospitals and eliminate variability among hospitals, the approach proposed needs further consideration and analysis before implementation.

"DRGs: Severity of Illness"

CMS proposes to adopt in FY 2008 (or earlier) a consolidated version of the 3M "all patient refined" (APR) DRG system to take into consideration severity of illness among patients within a DRG. CMS states that this refinement will be based on "complexity" defined as the relative volume and types of diagnostic, therapeutic, and bed services required fro the treatment of a particular illness. This, CMS proposes, would be referred to as consolidated severity of illness (SOI) DRGs and would increase the actual number of DRGs from 526 to 861 (and a decrease form the APR-DRG system of 1258).

In its proposed rule, CMS states the following in regard to the current DRG system.

> "The CMS DRG [referring to the current one] makes some DRG modifications difficult to accommodate. For example, high severity of illness diseases that occur in low volume are difficult to accommodate because the only choice is to form a separate base DRG with relatively few patients. Such an approach would lead to a proliferation of low-volume DRGs. Alternatively, these cases may be included in DRGs with other patients that are dissimilar clinically or in costs. [emphasis added] Requests for new base DRGs formed on the use of a specific technology may also be difficult to accommodate. Based DRGs formed based on the use of a specific technology would result in the payment weight for the DRG being dominated by the price set by the manufacturer for the technology."

Implicit in CMS's statement is a need to better refine the DRG system so that patients with variable degrees of illness will be accounted for and that hospitals will be

reimbursed based on these differences. To do so, CMS is proposing consolidated SOI DRGs that would stratify illnesses based on a formula that includes consideration of "patient volume" and "similarity of hospital charges across all four severity of illness subclasses and clinical similarity of the base APR DRGs."

ABIOMED supports CMS efforts to account for different patient conditions and degrees of illness; however, the restructuring of the DRG system is a vastly significant change from the current system and has an extremely deleterious impact on heart assist devices such as the ABIOMED AB5000 and BVS5000. This impact is primarily due to the regrouping of heart assist devices with procedures that represent far different technologies indicated for a completely different population of heart patients.

To determine the full impact of CMS proposed consolidated SOI DRGs, ABIOMED contracted with the Lewin Group, Falls Church, Virginia, to analyze the proposed rule to determine the mapping of DRG 103 and DRG 525 under the consolidated SOI DRG approach and its potential impact to reimbursement. [see attached Final Report]. From a review of 3M's APR DRG documentation, Lewin determined that heart assist devices were assigned to APR-DRG 161 ("Cardiac Defibrillators and Heart Assist Devices") along with several other cardiac procedures. It is this classification into a group of procedures ranging from cardiac defibrillators to total replacement hearts to IABP to ventricular assist devices that is most worrisome to ABIOMED.

Lewin's analysis stresses the significant negative impact to ventricular heart assist devices should the CMS proposed consolidated SOI DRG system be implemented as proposed. We summarize some of our concerns here.

Reimbursement for heart assist devices will be grossly underpaid under the proposed consolidated SOI DRG system. On average, under the consolidated SOI DRG system, the relative weight for heart assist device procedures would decline by approximately 34 percent for procedures now mapped to DRG 525 and 54% for recovery procedures now mapped to DRG 103. This significant reduction in reimbursement is due to simple arthmetic: relative weights are based on the average cost of all cases in the DRG and under the proposed grouping of consolidated SOI DRGs, heart assist devices would account for less than one percent of all cases in each of the four SOI DRGs.[2] Thus, although much more costly, their contribution to the "average" relative weight is negligible.

Moreover, the average charge for defibrillator cases and heart assist devices can differ between 25-299% depending upon the patient's SOI level. Resource intensity between the procedures are very different; e.g., the average length of stay for SOI Level 3 cardiac defibrillator patient is 6.7 days and for a heart assist device patient 14.5 days.

It is worth noting that this analysis would not apply to external ventricular assist devices that were recoded to DRG 103 effective October 1, 2005 because CMS's analysis (and thus the analysis by Lewin) was on 2004 MedPAR data. Thus, it is a safe assumption that these differences and the negative impact to the "recovery" reimbursement are grossly underestimated and could be far greater than can be determined at this time.

[2] Based on 2004 MedPAR data.

Grouping patients with failing hearts, many in bi-ventricular failure awaiting transplantation or with an acute, but life threatening condition such as viral myocarditis, with those receiving defibrillators for rhythm disorders is inappropriate. As noted in the multi-clinical trial described above, patients in need of ventricular assist devices have had multiple prior surgeries, advanced forms of mechanical support and often have multi-organ system failure due to a lack of adequate oxygenation and perfusion. Their situation requires immediate attention, instead of elective intervention as often is the case with cardiac defibrillators. Furthermore, ventricular assist devices are inserted in the operating room under anesthesia whereas defibrillators are placed by electrophysiology cardiologists generally without general anesthesia.

Because of these differences it is not surprising that 95% of the ventricular assist device cases would be assigned to SOI Level 3 or 4 under the proposed consolidated SOI DRG system. This creates the potential for frequent outlier payments (see comments below) and defeats CMS's stated goal of differentiating among patients within a DRG. Considering CMS is attempting to account for differences in patient sickness by proposing consolidated SOI DRGs, this grouping seems to be appositive with their goal.

And finally, this grouping would also include the total replacement heart, a technology that has been 25 years in the making and is earmarked for patients in biventricular failure who are too sick to benefit from heart transplantation but who have the potential for an extended life. Although in his letter dated April 26, 2006 from you to ABIOMED it was made clear that there is currently no Medicare coverage for the "total replacement heart" (ICD-9-CM codes 37.52 and 37.53), we raise the issue again in the context of CMS's proposed consolidated SOI DRGs. Of all procedures within this grouping, the one potentially most out of line with reimbursement.

ABIOMED respectfully recommends that CMS revisit the consolidated SOI DRG 207, 208, 209, and 204 and decouple ventricular assist devices and the total replacement heart from other procedures as proposed within those DRGs and consider implementation of one of the following.

a) Create a SOI DRG for ventricular assist devices and replacement hearts that would include external and internal heart assist devices that are FDA approved and indicated for destination therapy, bridge-to-transplant and recovery where recovery is defined as the implant and explant of an external heart assist device within the same hospital admission or the replacement and explant of a heart assist device within the same hospital admission. As the number of procedures this will alleviate CMS's concerns that low-volume DRGs are in essence, a mirror-imagine of what manufacturers want to charge for new technology. Additionally, CMS will have access to trends in ventricular assist devices through the newly established INTERMAC database (a joint CMS-FDA-NIH project) specifically aimed at better understanding the benefits, risks and utilization of ventricular assist devices.

b) Group heart assist devices with the proposed consolidated SOI DRG for heart transplantation. According to Lewin, the average length of stay for "recovery" patients was 46.1 days and the average cost was $742.265.[3] This is substantially higher than the average length of stay and charges for defibrillators (for example, SOI level 3,

[3] Based on MedPAR 2005 data. A total of 19 cases were analyzed.

6.7 days and $118,825); however, more in line with heart transplantation and implantable heart assist devices as shown here.

Procedure	Code	ALOS	Average Total Charge/Case	Average Standardize Charge/Case
Heart Transplant	37.5	41.1	$403,340	$286,334
Implantable Heart Assist Devices	37.66	47.2	$575,343	$433,576
Non-implantable Heart Assist Devices for AMI heart "recovery"	n/a at time of analysis	43.2	$378, 903 $405,350 (for bi-vad support)	$285,690 $267,050 (for bi-vad support)

Source: Lewin, "An Analysis of Medicare DRG Assignment for Heart Recovery Using External Heart Assist Devices," May 9, 2003, submitted as ABIOMED's official public comments to IPPS changes for FY 06.

Moreover, less than one year ago, CMS were persuaded to make a coding change to DRG 103 based on this data. Nothing has changed that would warrant splitting external heart assist devices from heart transplant reimbursement.

In addition, CMS states in the proposed rule that it "did not consolidate any of the pre-MDC DRGs that are DRGs to which cases are directly assigned on the basis of ICD-9-CM procedure codes." ABIOMED requests clarification as to whether this applies to other procedures within DRG 103, such as external heart assist devices for recovery. If so, ABIOMED seeks an explanation for why these procedures were handled differently than cardiac transplantation if all are currently reimbursed under DRG 103.

c) Establish separate consolidated SOI DRGs for cardiac procedures based on medical etiologies of rhythmic and vascular disorders versus pumping, valve or chamber dysfunction. To account for differences in length of stay, resource utilization, patient severity of illness, and immediacy in response, consideration should be given to distinguishing cardiac patients based on rhythmic and vascular disorders that require elective intervention generally by a cardiologist in a catheter lab from those patients with pumping, chamber, or valve disorders that require more aggressive technology performed in an operating room.

"Cost-Based Weight: Outlier Threshold"

In the proposed rule CMS acknowledges that it has limited statutory authority over the outlier payment system and that "we have not completed a detailed analysis of MedPAC's outlier recommendation because we do not have the authority to adopt such a change under current law." However, CMS goes on to say that they would "consider changes that would reduce or eliminate the effect of high-cost outliers on the DRG relative weight." By adopting the 3M proposed "all patient refined" DRG system with some modification for SOI, CMS is attempting to reduce outlier payments indirectly.

As stated in the above, utilizing 2004 MedPAR data, the Lewin Group determined that nearly 95 percent of all heart assist device procedures would be designated as SOI Level 3 or SOI Level 4 under the proposed consolidated SOI DRG system. This, coupled with anywhere from a 25 to 299 percent difference in reimbursement between heart assist devices and cardiac defibrillators, would most assuredly put heart assist devices into an outlier reimbursement category. This is directly at odds with what CMS

is attempting to accomplish by adopting the SOI DRG system. Instead of lowering the average outlier payment, this grouping could potentially increase it.

ABIOMED respectfully recommends that CMS adopt one of the three recommendations above to more accurate reimburse hospitals for heart assist devices, thus, eliminating the frequency of outlier cases that will most inevitably result from grouping these procedures with much less costly procedures such as cardiac defibrillators.

Requested coding change

ABIOMED uses this opportunity to respectfully request that CMS reconsider an earlier request that the reimbursement for external ventricular assist devices be modified to map the combined "repair and replace" (code 37.63) and "explant" (code 37.64) of a external heart assist device in a single admission to DRG 103. Your response dated April 26, 2006 to our original request leads us to believe we could better clarify our position and justification for requesting this change.

Although the number of procedures is small, the importance to improved patient outcomes is significant. Patients implanted with an external heart assist device who are transported to a tertiary hospital often undergo a second surgical procedure to "switch" the short-term external heart assist device to a more advanced, long-term device to give the heart adequate time to recover (see research herein indicating optimal recovery time is 19 days). This additional time may be necessary to stabilize clotting factors, restore nutritional balance, improve tenuous neurological conditions and wean the patient from respiratory support. The AB5000, a long-term external heart assist device, allows time for these improvements in patient outcomes and also allows the patient to ambulate, an important component of patient rehabilitation and recovery.

According to MedPAR 2004 data the average charges for combined "repair/replace" and "explant" were $375,561 and those for combined "implant" and "explant" were $371,211 (excluding one charge of $2M). Not surprisingly, these charges are very close. The resources, time, and personnel needed to surgically repair or replace the initial heart assist device to a second long-term device are comparable to the initial implant. Plus, the hospital course of these two populations of assisted patients is very similar. However, it is important to recognize that patients who are "switched" to a another device are given the advantage of a longer window of opportunity to recover their native heart function. This advantage results in additional use of resources that should be reflected in accurate payment.

Less than on year ago, CMS determined that the recovery approach ("implant" and "explant") utilizing an external assist device required a more accurate level of reimbursement. Similarly, patients who undergo a second procedure for placement of a long-term heart assist device utilize a comparable level of resources, have similar lengths of stay and according to MedPAR data, incur similar charges as patients who were implanted and explanted at the same hospital.

ABIOMED respectfully recommends that CMS revisit their review of this request and map a combined "repair/replace" (37.63) and "explant" (37.64) of an external heart assist device in a single admission to DRG 103.

In summary, ABIOMED supports CMS's efforts to change the inpatient prospective payment system to more accurately reflect costs as closely as possible and appreciates the efforts to implement the recommendations of the MedPAC 2005 Report to Congress. However, we believe CMS's proposed rule is problematic for several reasons. First, the use of cost-based weights inherently leads to the use of older data and lags behind charge-based data which disadvantages and misrepresents modern technology such as the AB5000 which has proven to be successful in the recovery of native heart function. While the impact of this approach would have a modest impact on the reimbursement of ABIOMED technology, it represents a wholesale change to the current system that is poorly understood.

Most importantly, ABIOMED is concerned about the proposed consolidation SOI DRG approach that would group ventricular heart assist devices with other procedures that involve much less aggressive technology and are intended for a much different patient population. ABIOMED does not support this approach and recommends alternatives to this grouping that improves on payment accuracy. Ultimately, patients in need of treatment for heart failure should be able to have access to technology that is fully recognized and reimbursed appropriately through reasonable and responsible changes to the payment system.

Please let us know if you have any questions regarding our comments or the Lewin Group report that we have attached. We request that it be made a part of our official public comment. We look forward to working with you and your staff to address these concerns and issues.

Sincerely,

Andrew Greenfield

Andrew Greenfield
Vice President
Abiomed, Inc.

Attachment.

The Lewin Group
3130 Fairview Park Dr.
Suite 800
Falls Church, VA 22042

May 16, 2006

Gwen Mayes
Director of Reimbursement
Abiomed Inc.
22 Cherry Hill Road
Danvers, Massachusetts 01923

Dear Gwen:

As you requested, The Lewin Group reviewed the Centers for Medicare and Medicaid Services' (CMS) proposal to consider using Consolidated Severity-Adjusted Diagnosis Related Groups (DRGs). CMS recently published their proposed changes for the Inpatient Prospective Payment System (IPPS) for 2007, which discusses the potential use of consolidated severity-adjusted DRGs for fiscal year 2008.

This report identifies the Consolidated Severity-Adjusted DRG assignments for heart assist device procedures. The report also assesses whether the DRG assignments are appropriate for heart assist device procedures, based on hospital resource utilization for these patients. For these analyses, we used federal fiscal year 2004 hospital discharge data for all Medicare patients. Although 2005 data is currently available, CMS only provided the consolidated severity-adjusted DRGs on the 2004 data. Also, the 2004 data was used by CMS and 3M to develop the consolidated severity-adjusted DRGs.

1. Consolidated Severity-Adjusted DRG Assignment for Heart Assist Device Procedures

CMS used the All Patient Refined DRGs (APR-DRGs) developed by 3M as the basis for the consolidated severity-adjusted DRGs. CMS mapped each APR-DRG plus severity of illness level (SOI), which there are four SOI levels for each DRG, to a consolidated severity adjusted DRG. APR-DRG/SOI levels with low patient volumes (usually SOI level4) were often combined with others that were clinically similar.

We reviewed 3M's APR DRG documentation and found that all heart assist device procedures, except for removal of external heart assist device (37.64), are assigned to APR-DRG 161 (Cardiac Defibrillator and Heart Assist Device Implants). In order for a patient to be assigned to APR-DRG 161, they must have

a principal diagnosis of cardiovascular disease and one of the procedures listed in ***Figure 1*** below.

Figure 1
Procedures Included In APR-DRG 161
(Cardiac Defibrillator and Heart Assist Device Implants)

ICD9 Code	Description
00.51	Implant CRT defibrillator total system
37.52	Implant total replacement heart system
37.53	Replace or repair thoracic unit total replacement heart system
37.54	Replace or repair other total replacement heart system
37.62	Insert non-implantable heart assist device
37.63	Repair heart assist system
37.65	Implant external heart assist system
37.66	Insertion of implantable heart assist device
37.67	Implant cardiomyostimulation system
37.68	Insert percutaneous external heart assist system
37.94	Implant/replace cardiodefibrillator total system
00.52 & 00.54	Implant CRT defibrillator leads and pulse generator
37.95 & 37.96	Implant cardiodefibrillator leads and pulse generator
37.97 & 37.98	Replace cardiodefibrillator leads and pulse generator

Source: www.aprdrgassign.com

Under APR-DRG 161, heart assist device implant procedures are included in the same APR-DRG as cardiac defibrillator implant procedures. However, CMS proposes to separate patient cases that are assigned to APR-DRG 161 into four different consolidated severity-adjusted DRGs depending on the patient's SOI level. ***Figure 2*** shows CMS's proposed consolidated severity-adjusted DRG assignment for heart assist implant procedures.

Figure 2
Consolidated Severity-Adjusted DRG Assignment for Heart Assist Implant Procedures

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	APR-DRG	SOI Level	APR-DRG Description
204 1/	Cardiothoracic Procedures SOI 4	161	4	Cardiac Defibrillator & Heart Assist Implant SOI 4
207	Cardiac Defibrillator & Heart Assist Implant SOI 1	161	1	Cardiac Defibrillator & Heart Assist Implant SOI 1
208	Cardiac Defibrillator & Heart Assist Implant SOI 2	161	2	Cardiac Defibrillator & Heart Assist Implant SOI 2
209	Cardiac Defibrillator & Heart Assist Implant SOI 3	161	3	Cardiac Defibrillator & Heart Assist Implant SOI 3

1/ Consolidated severity-adjusted DRG 204 also includes APR-DRGs 160-major cardiothoracic repair of heart anomaly, 162/163-cardiac valve procedures, 165/166-CABG procedures, and 167-other cardiothoracic procedures. All with SOI level 4.
Source: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY 2007 Rates.

The SOI is defined by 3M as the extent of physiological decomposition or organ system loss of function [1]. The SOI subclasses used in the APR-DRGs are numbered from 1 to 4 indicating 1-minor, 2-moderate, 3-major and 4-extreme severity of illness. The SOI levels are dependent on the patient's underlying problems, so that patients with high SOI levels are usually characterized by multiple serious illnesses.

Under the APR-DRGs, each secondary diagnosis is assigned a SOI level of 1 to 4. The overall SOI assignment for the patient takes into consideration the SOI levels of all secondary diagnoses, the interaction between secondary diagnoses, patient age, principal diagnosis and the presence of certain operating room procedures. The process for determining the SOI level for a patient consists of the following three steps:

- the SOI level of each secondary diagnosis is determined;
- determine a base SOI level for the patient based on all secondary diagnoses; and
- final SOI level for the patient is determined by incorporating the impact of principal diagnosis, patient age, operating room procedure, multiple procedures, and combinations of categories of secondary diagnoses.

In order to determine how heart assist device procedures are distributed by SOI level, we analyzed the 2004 Medicare MedPAR database, which contains all inpatient Medicare discharges for federal fiscal year 2004 and was used by CMS to develop and evaluate the consolidated severity-adjusted DRGs. *Figure 3* shows that about 75 percent of heart assist procedures would be categorized as severity level 4 and 95 percent as severity level 3 or 4.

Figure 3
SOI Level Assignment for Heart Assist Device Procedures in FY 2004 [1/]

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	Medicare Cases in FFY 2004	Percent of Cases by SOI Level	DRG Relative Weight [2/]
207	Cardiac Defibrillator & Heart Assist Implant SOI 1	4	1%	3.8849
208	Cardiac Defibrillator & Heart Assist Implant SOI 2	18	4%	4.4273
209	Cardiac Defibrillator & Heart Assist Implant SOI 3	99	20%	5.4582
204	Cardiothoracic Procedures SOI 4	367	75%	9.3274
	All Heart Assist Implant Procedures	488	100%	n/a

1/ Includes implantable and non-implantable heart assist device procedures.
2/ DRG relative weights provided by CMS.
Source: Lewin Group analysis of the 2004 MedPAR database.

[1] 3M Health Information System, "All Patient Refined Diagnosis Related Groups (APR-DRGs), Methodology Overview", 2006

2. Consolidated Severity-Adjusted DRG Assignment for Removal of Heart Assist Device

Procedure code 37.64 (removal of external heart assist device) was not included in APR DRG 161, but was included in APR-DRG 173 (Other Vascular Procedures), which is consistent with the current CMS DRG assignment.

Under APR-DRG 173, the heart assist device removal procedure is included with 49 other vascular procedures [2]. Similar to APR DRG 161 above, CMS proposes to separate patient cases that are assigned to APR-DRG 173 into four different consolidated severity-adjusted DRGs depending on the patient's SOI level. *Figure 4* shows CMS's proposed consolidated severity-adjusted DRG assignment for heart assist device removal procedures.

Figure 4
Consolidated Severity-Adjusted DRG Assignment for Removal of Heart Assist Device

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	APR-DRG	SOI Level	APR-DRG Description
205 1/	Vascular Procedures SOI 4	173	4	Other Vascular Procedures SOI 4
234	Other Vascular Procedures SOI 1	173	1	Other Vascular Procedures SOI 1
235	Other Vascular Procedures SOI 2	173	2	Other Vascular Procedures SOI 2
236	Other Vascular Procedures SOI 3	173	3	Other Vascular Procedures SOI 3

1/ Consolidated severity-adjusted DRG 205 also includes APR-DRGs 169-major thoracic & Abdominal vascular procedures, SOI level 4.
Source: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY 2007 Rates.

In order to determine how heart assist device removal procedures are distributed by SOI level, we analyzed the 2004 Medicare MedPAR database. *Figure 5* shows that 99 percent of heart assist device removal procedures would be categorized as severity level 3 or 4.

[2] www.aprdrgassign.com, "3M APR DRG v23.0 Definitions Manual, Volume 1", page 211

Figure 5
SOI Level Assignment for Removal of Heart Assist Device in FY 2004 [1/]

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	Medicare Cases in FFY 2004	Percent of Cases by SOI Level	DRG Relative Weight [2/]
234	Other Vascular Procedures SOI 1	0	0%	1.5918
235	Other Vascular Procedures SOI 2	1	1%	2.0045
236	Other Vascular Procedures SOI 3	32	46%	3.1716
205	Vascular Procedures SOI 4	37	53%	6.7708
	All Removal of Heart Assist Devices	70	100%	n/a

1/ Includes implantable and non-implantable heart assist device procedures.
2/ DRG relative weights provided by CMS.
Source: Lewin Group analysis of the 2004 MedPAR database.

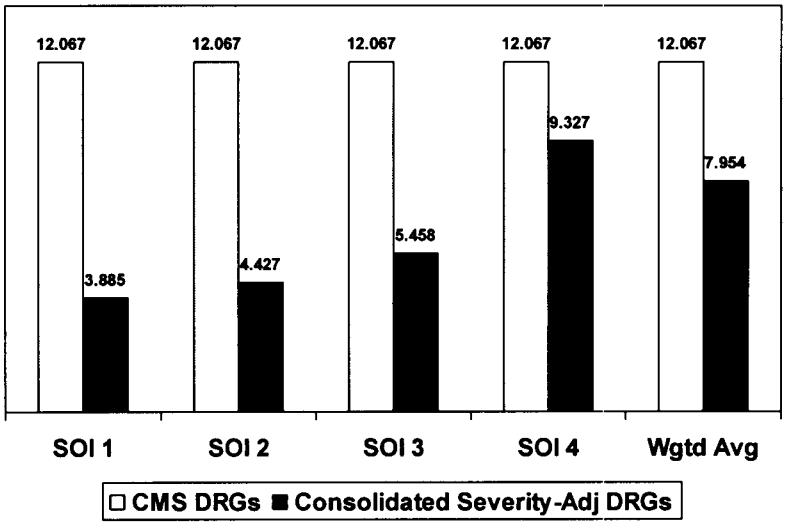
3. Impact on Medicare Payment Rates for Heart Assist Device Implant Procedures

Medicare payment for inpatient hospital services is based upon a hospital's base payment rate multiplied by the relative payment weight for the DRG assigned to the patient stay. CMS proposes to increase the Medicare base payment rate by 3.4 percent for 2007. The current DRG relative weight for non-implantable heart assist system procedures (DRG 525) for 2006 is 11.4282. The proposed DRG relative weight for 2007 for these procedures is 12.0673, which is a 5.6 percent increase. When the base payment rate increase is factored into the equation, hospitals will see an increase in Medicare payment for non-implantable heart assist device procedures of about nine percent (3.4% + 5.6%) for 2007.

The estimated relative payment weights that were computed by CMS for the consolidated severity-adjusted DRGs are significantly lower than the relative weights proposed under the CMS DRGs for 2007. As shown in *Figure 6*, the consolidated severity-adjusted DRG relative weights are lower than the CMS DRG relative weights for each SOI level including SOI level 4.

As discussed above, the majority of non-implantable heart assist cases are assigned to higher severity DRGs, which would be paid using the higher relative weights. We accounted for this by computing a weighted average DRG relative weight using the number of non-implantable heart assist system procedure cases for each SOI level. We computed the weighted average relative weight under the consolidated severity-adjusted DRGs to be 7.954, which is about 34 percent lower than the CMS DRG weight for DRG 525 that is proposed by CMS for 2007.

Figure 6
Proposed DRG Relative Payment Weights for Non-Implantable Heart Assist Device Procedures



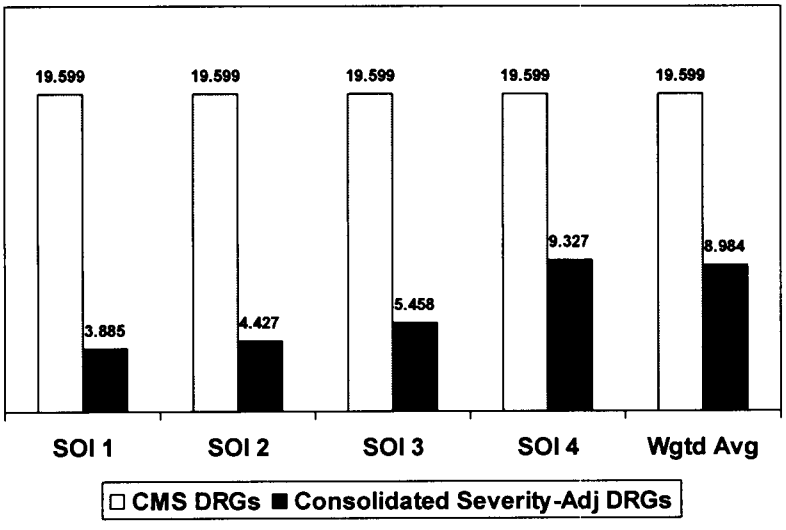
Weighted average DRG relative weight using the number of non-implantable heart assist system procedure cases for each SOI level.
Source: Lewin Group analysis of the 2004 MedPAR database.

The current DRG relative weight for implantable heart assist system procedures and heart recovery procedures (included in DRG 103) for 2006 is 18.5617. The proposed DRG relative weight for 2007 for these procedures is 19.599, which is a 5.6 percent increase. When the base payment rate increase is factored into the equation, hospitals will see an increase in Medicare payment for non-implantable heart assist device procedures of about nine percent (3.4% + 5.6%).

As shown in *Figure 7,* the consolidated severity-adjusted DRG relative weights are lower than the CMS DRG relative weights for each SOI level including SOI level 4. We computed a weighted average DRG relative weight using the number of implantable heart assist system procedure cases for each SOI level [3]. We computed the weighted average relative weight under the consolidated severity-adjusted DRGs to be 8.984, which is about 54 percent lower than the CMS DRG weight for DRG 103 that is proposed by CMS for 2007.

[3] The weighted average was based on implantable heart assist device implants and did not include heart recovery procedures because we used the 2004 data, which included only six heart recovery cases.

Figure 7
Proposed DRG Relative Payment Weights for Implantable Heart Assist Device Procedures for FY 2007 & 2008

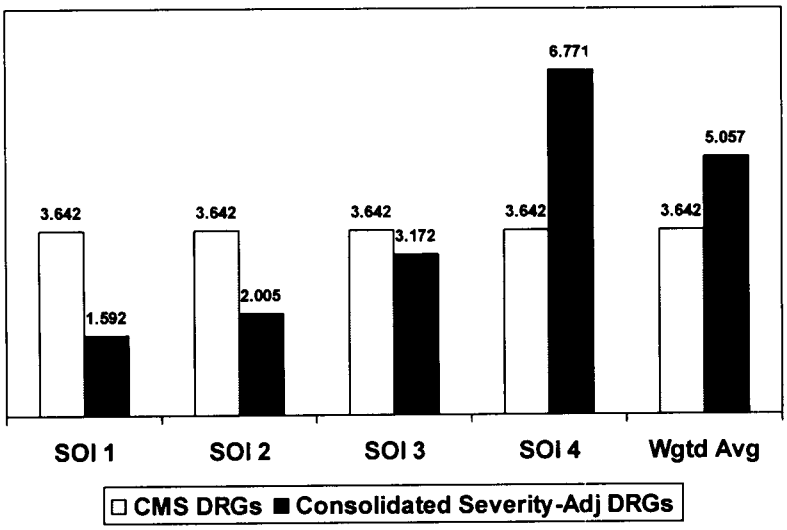


Weighted average DRG relative weight using the number of implantable heart assist system procedure cases for each SOI level.
Source: Lewin Group analysis of the 2004 MedPAR database.

The current DRG relative weight for a removal of heart assist system procedure (DRG 110) for 2006 is 3.8417. The proposed DRG relative weight for 2007 for this procedure is 3.642, which is a 5.2 percent reduction. When the Medicare base payment rate increase of 3.4 percent is factored into the equation, hospitals will see a net decrease in Medicare payment for removal of heart assist device procedures of about two percent (3.4% - 5.2%).

As shown in ***Figure 8,*** the consolidated severity-adjusted DRG relative weights are lower than the CMS DRG relative weights for each SOI level except SOI level 4, which is substantially higher. We computed a weighted average DRG relative weight using the number of implantable heart assist system procedure cases for each SOI level. Because most removal of heart assist system procedures are assigned to SOI level 3 or 4, the weighted average relative weight under the consolidated severity-adjusted DRGs is 5.057, which is about 39 percent higher than the CMS DRG weight for DRG 110 that is proposed by CMS for 2007.

Figure 8
Proposed DRG Relative Payment Weights for Removal of Heart Assist Device for FY 2007 & 2008



Weighted average DRG relative weight using the number of heart assist system removal procedures for each SOI level.
Source: Lewin Group analysis of the 2004 MedPAR database.

4. Comparison of Average Length of Stay and Charges Across Procedures within DRG (Cardiac Defibrillator & Heart Assist Implant)

The reason for the lower DRG relative weights for the heart assist device implant procedures is that CMS computes the relative weights based on the average cost of all cases in the DRG. Based on the 2004 MedPAR database, heart assist device procedures accounted for less than one percent of all cases in each of the four DRGs listed above (*Figure 9*).

Figure 9
ALOS and Average Charges for Cardiac Defibrillator and Heart Assist Cases in FY 2004

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	Total Cases in DRG	Heart Assist Device Cases in DRG	Percent Heart Assist Cases in DRG
207	Cardiac Defibrillator & Heart Assist Implant SOI 1	5,932	4	0.1%
208	Cardiac Defibrillator & Heart Assist Implant SOI 2	23,852	18	0.1%
209	Cardiac Defibrillator & Heart Assist Implant SOI 3	27,499	99	0.4%
204	Cardiothoracic Procedures SOI 4	23,077	367	1.6%
	Total	80,360	488	0.6%

Source: Lewin Group analysis of the 2004 MedPAR database.

However the resource intensity, as measured by average charges, for heart assist device cases is substantially higher than average charges for defibrillator cases. ***Figure 10*** shows that average charges for heart assist device cases are 60 percent higher for the SOI level 3 DRG and 94 percent higher for the SOI level 4 DRG, where the vast majority of the heart assist cases are assigned.

Figure 10
ALOS and Average Charges for Cardiac Defibrillator and Heart Assist Cases in FY 2004

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	ALOS Defib. Cases	ALOS Heart Assist Cases	Prcnt. Diff.	Average Charge Defibrillator Cases	Average Charge Heart Assist Cases	Prcnt. Diff.
207	Cardiac Defibrillator & Heart Assist Implant SOI 1	2.3	32.0	1,291%	$86,225	$344,271	299%
208	Cardiac Defibrillator & Heart Assist Implant SOI 2	3.7	11.3	205%	$97,647	$122,382	25%
209	Cardiac Defibrillator & Heart Assist Implant SOI 3	6.7	14.5	116%	$118,825	$189,933	60%
204	Cardiothoracic Procedures SOI 4	18.1	26.7	48%	$197,389	$382,612	94%

Includes implantable and non-implantable heart assist device procedures.
Source: Lewin Group analysis of the 2004 MedPAR database.

As described above, our analysis is based on 2004 data, which included very little data on heart recovery procedures (i.e., insertion and removal of external heart assist device during the same hospital stay). We analyzed the 2005 Medicare data and identified 19 heart recovery cases. The average length of stay for these cases was 46.1 days and the average charge was $742,265, which is also substantially higher than the average length of stay and charges for defibrillator cases.

One reason for the higher charges is that average length of stay is for heart assist device cases are substantially higher than for defibrillator cases. A second reason is that the cost of the heart assist device is much higher than the cost of defibrillators. (***would AdvaMed of Abiomed have data on this?***)

Since the heart assist cases account for less than one percent of the cases within each DRG, the average cost computed by CMS is heavily weighted toward the defibrillator cases in these DRGs. When CMS computes the DRG relative weights they use an average cost for the DRG that is nearly equal to the average defibrillator patient cost and the resulting Medicare payment for all procedures in the DRG is based on this average cost. Since the Medicare payment is based on this average cost, and the cost of heart assist device procedures is substantially higher than the average, then Medicare payment for heart assist device implant procedures will be substantially below its cost.

5. Comparison of Average Length of Stay and Charges Across Procedures within DRG (Other Vascular Procedures)

Based on 2004 Medicare hospital discharge data, average length of stay and average charges for heart assist device removal cases are similar to the 49 other vascular procedures included in those DRGs. ***Figure 11*** shows that average charges for heart assist device removal cases are less than eight percent different than the average charge for other vascular procedures included in the DRGs. This indicates that heart assist device removal procedures may be appropriate placed in regards to hospital's resources required for the procedure.

Figure 11
ALOS and Average Charges for Other Vascular Procedures and Heart Assist Device Removal Cases in FY 2004

Consolidated Severity-Adjusted DRG	Consolidated Severity-Adjusted DRG Description	ALOS Other Vascular Procedures	ALOS Heart Assist Device Removals	Prcnt. Diff.	Average Charge Other Vascular Procedures	Average Charge Heart Assist Device Removals	Prcnt. Diff.
234	Other Vascular Procedures SOI 1	2.9	n/a	n/a	$31,166	n/a	n/a
235	Other Vascular Procedures SOI 2	4.9	4.0	-18%	$38,449	$39,125	2%
236	Other Vascular Procedures SOI 3	10.6	9.7	-9%	$61,041	$65,093	7%
205	Vascular Procedures SOI 4	18.7	16.0	-14%	$126,927	$136,604	8%

Includes implantable and non-implantable heart assist device procedures.
Source: Lewin Group analysis of the 2004 MedPAR database.

6. Conclusion

Under the current CMS DRGs, most non-implantable heart assist device procedures are assigned to their own DRG, which is 525 (other heart assist system implants). Implantable heart assist devices are assigned to the same DRG as heart transplant cases (DRG 103). Also, the implant and removal of an external heart assist device during the same stay (heart recovery) is also assigned to CMS DRG 103. Heart assist device removal procedures are included in CMS DRG 110 (major cardiovascular procedures).

Under CMS's proposed consolidated severity-adjusted DRG, heart assist device implant procedures are included in the same DRG as cardiac defibrillator implant procedures. However, CMS proposes to separate these procedures into different consolidated severity-adjusted DRGs depending on the patient's SOI level.

We have drawn the following conclusions from the above analyses on the assignment of heart assist device procedures in these consolidated severity-adjusted DRGs:

- Heart assist device implant procedures should not be included in the same DRGs as cardiac defibrillator cases because the resource intensity between these types of procedures is very different;

- Medicare payments for heart assist device implant procedures would be dramatically reduced under the consolidated severity-adjusted DRGs;

- Average length of stay and average charges for implantable heart assist cases and heart recovery cases were extraordinarily higher than cardiac defibrillator cases and Medicare payments for these procedures could be reduced by more than 50 percent under the proposed consolidated severity-adjusted DRGs;

- Other non-implantable heart assist device procedures should be assigned their own consolidated severity-adjusted DRG because the resource intensity is very different from cardiac defibrillator procedures. Since about 93 percent of all non-implantable heart assist cases are assigned to severity levels 3 or 4, CMS could combine all non-implantable heart assist procedures into one or two DRGs.

- Finally, removing heart assist device procedures from the consolidated severity-adjusted DRGs 204, 207, 208 and 209 would have little impact on the relative weights for these DRGs since these procedures represent less than one percent of cases in each DRG (***Figure 12***).

Figure 12
ALOS and Average Charges For Consolidated Severity-Adjusted DRGs by Procedure in FY 2004

	Description	Number of Discharges	ALOS	Average Total Charges
DRG 207 - Cardiac Defibrillator & Heart Assist Implant SOI 1				
	Total DRG	5,932	2.3	$86,399
	All Defibrillator Implants	5,928	2.3	$86,225
	All Heart Assist System Implants	4	32.0	$344,271
DRG 208 - Cardiac Defibrillator & Heart Assist Implant SOI 2				
	Total DRG	23,852	3.7	$97,665
	All Defibrillator Implants	23,834	3.7	$97,647
	All Heart Assist System Implants	18	11.3	$122,582
DRG 209 - Cardiac Defibrillator & Heart Assist Implant SOI 3				
	Total DRG	27,499	6.7	$119,081
	All Defibrillator Implants	27,400	6.7	$118,825
	All Heart Assist System Implants	99	14.5	$189,933
DRG 204 - Cardiothoracic Procedures SOI 4				
	Total DRG	23,077	18.9	$187,932
	All Defibrillator Implants and Other Procedures	22,710	18.8	$184,786
	All Heart Assist System Implants	367	26.7	$382,612

Source: Lewin Group analysis of the 2004 MedPAR database.

Physician Hospital Alliance

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208-0
(2)

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of the Physician Hospital Alliance, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the FY'07 Medicare Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 *Federal Register*. Given the complexities of CMS' proposal to revise the diagnosis-related group (DRG) system and the magnitude of impact this could have on Kettering Medical Center Network, we are writing to urge a one-year delay in implementing these policy proposals.

CMS proposes to move from the historical charge-based DRG system to a cost-based system and to implement hospital-specific relative weights by October 1, 2006. CMS also proposes modifying the DRG classification system to account for differences in patient severity and allow for a payment amount that more closely tracks the cost of providing care. In its proposal, CMS states that it would replace the current 526 DRGs with either the proposed 861 consolidated severity-adjusted DRGs by FY'08 or a similar system that accounts for the level of patient severity, developed in response to public comments that it receives.

The Physician Hospital Alliance supports meaningful improvement to Medicare payments for inpatient services and applauds the tremendous effort CMS has put forth to devise a DRG system that more accurately reflects the costs of providing inpatient services. I recognize that your agency has taken these steps to make payments fairer to hospitals and to assure beneficiary access to services in the most appropriate setting. In the proposed rule, CMS seeks input on the proposed methodologies and solicits alternatives to the consolidated severity-adjusted DRG model. While we welcome the opportunity to work with CMS and other stakeholders in ensuring that any system

implemented accomplishes the stated goals, we are extremely concerned with the tight timeline provided for developing comments and the implementation dates outlined in the proposal. Restructuring the DRG system as proposed in the rule would represent the most significant policy change to the IPPS since its inception. A change of this magnitude warrants a thoughtful and thorough review by hospitals, a task not easily accomplished during a 60-day comment period, given the complexity of the proposals.

As such, we strongly urge CMS to delay implementing both the proposed DRG reclassification and the changes to the relative weights until FY'08. The additional time will allow Kettering Medical Center Network and other hospitals to more thoroughly evaluate the proposals and offer constructive feedback to your agency.

Again, thank you for the opportunity to share our comments on the DRG provisions of the proposed IPPS rule.

Sincerely,

Patrick J. Kenrick

Patrick J. Kenrick
President, Physician Hospital Alliance

209-O
(2)

June 7, 2006

BryanLGH
MEDICAL CENTER

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

My hospital is a 535-bed acute care hospital located in Lincoln, Nebraska. As a major health care provider in our area, we implant medical devices and perform other cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Because inpatient services are a key component of what we provide, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases. As a result, my technology costs could be underpaid.

The payment methodology changes that CMS has proposed would have a severe financial impact on my hospital – without accurate data to justify the change. This is particularly true for device

intensive cardiology DRGs where the proposed payment level is often significantly less than my hospital's actual cost to deliver the service.

The reduction in payment for cardiology services would also have a severe impact on the infrastructure I have built up over the years to treat the number one killer in America today - heart disease. In addition to requiring the potential dismantling of this infrastructure I would now face the uncertainty of knowing that next year, or any other year, CMS could decide to under-fund whatever service area I build up next to meet patient needs. Obviously, as I'm forced to scale back or not develop service capacity due to payment swings and financial uncertainties, patient access could be negatively affected.

I respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments.

Thank you for your consideration.

Sincerely,

Brad Sher
Vice President Managed Care/Public Policy

:cre

cc: US Senator Ben Nelson
US Senator Chuck Hagel
US Representative Jeff Fortenberry
Laura Redoutey, Nebraska Hospital Association

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IOWA HEALTH
DES MOINES
Methodist • Lutheran • Blank

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June 8, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the PPS

Dear Dr. McClellan:

The proposed regulations pertaining to relative weights and transplant reimbursement have many potential flaws. Disparity with regard to patient complexity and severity, types of services provided and disparity in the organ pool all must be considered prior to approving changes to the current payment system.

Please consider delaying the proposed DRG changes for a minimum of one year to allow appropriate review and analysis of the complex factors associated with transplantation. This delay would also allow time to prepare a more valid cost-based weighting system that addresses and responds to all the unique factors specific to transplant reimbursement.

If you have any questions about my remarks , you may reach me at 515 241-4131.

Sincerely,

Jean Shelton, Executive Director

CC: Diane Messer, Nurse Manager; Cass Franklin, M.D., Medical Director

St. Alexius Medical Center
PrimeCare

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June 8, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

This letter serves as St. Alexius Medical Center's response to the Centers for Medicare & Medicaid Services (CMS) request for comments on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) and occupational mix adjustment proposed rules.

The rule proposes substantial changes in the calculation of diagnosis-related group (DRG) relative weights, by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc). It further proposes refining the DRGs to account for patient severity.

The rule also updates the payment rates, outlier threshold, hospital wage index, quality reporting requirements, and payments for rural hospitals and medical education, among other policies. While we have serious concerns related to the outlier threshold and the wage index, our primary concern relates to the changes to the DRG weights and classifications.

The impact of the proposed changes would lead to a significant negative impact in hospital payment. We would like to see CMS delay implementation of these changes until more study has been conducted to validate the methodology.

We also are extremely concerned about the impact the proposed rule would have on cardiac subspecialties. At St. Alexius Medical Center, the detrimental results of these changes would be severe. Final FY2006 estimates for reimbursement compared to those proposed for 2007 would result in the following negative percent change in cardiology procedures:

Electrophysiology	(18.0%)
Cardiac Cath	(28.1%)
Cardiac Surgery	(4.5%)

When we examine specific cardiac surgical DRGs, we find the following negative percent change:

106: Coronary artery bypass w/PCTA	(12.6%)
515: Cardiac defibrillator implant w/o cardiac cath	(22.6%)
518: PCI w/o coronary artery stent or AMI	(28.9%)
535: Cardiac defibrillator implant w/cardiac cath w/AMI/HF/Shock	(23.8%)
536: Cardiac defibrillator implant w/cardiac cath w/o AMI/HF/Shock	(22.2%)
551: Cardiac pacemaker implant w/maj. CV DX or AICD lead or GNTR	(12.5%)
552: Other permanent cardiac pacemaker implant w/o maj. CV DX	(13.3%)
555: PCI w/maj. CV DX	(21.0%)
556: PCI w/ non drug-eluting stent w/o maj. CV DX	(34.1%)
557: PCI w/drug-eluting stent w/maj. CV DX	(23.5%)
558: PCI w/drug-eluting stent w/o maj. CV DX	(33.4%)

Because of this negative impact, we support the following AHA recommendations:

• **One-year Delay:** Delay implementation for one year to address the serious concerns with the HSRVcc and CS-DRG methodology. We would be happy to volunteer to work with AHA and CMS to address these concerns.

• **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, using methodology other than the HSRVcc. However, while we believe change of some kind is warranted, the proposed conversion factor of a 0.25 cost-to-charge ratio is flawed.

• **A New Classification System Only if the Need Can Be Demonstrated:** Considering how long the current classification system has been in place, it seems that more study of the variation within DRGs should be done before moving to the CS-DRGs or any other new classification system.

• **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.

• **Three-year Transition:** Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.

Thank you for your attention to this matter. We appreciate your support of hospitals.

Sincerely,

Andrew L. Wilson
President and Chief Executive Officer

c: US Senator Kent Conrad
US Senator Byron Dorgan
US Representative Earl Pomeroy

NDHA
North Dakota Healthcare Association

Vision
The North Dakota Healthcare Association will take an active leadership role in major healthcare issues.

Mission
The North Dakota Healthcare Association exists to advance the health status of persons served by the membership.

June 7, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of our member hospitals and health care systems, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) and occupational mix adjustment proposed rules.

New DRG Weights: HSRVCC
The proposed changes calculating diagnosis-related group (DRG) relative weights are the most significant since 1983. Additional study is needed on these significant changes.

The proposal creating cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc) is flawed by the HSRVcc methodology. The CMS proposal appears to be a short-cut to the MedPAC approach to HSRVs and cost-based weights.

The NDHA believes more time is needed to allow for developing a sound methodology approach to create cost-based weights and to understand their potential. One of the concerns is the CMS weighting approach gives equal weights to each hospital in the national cost-to-charge ratio calculation. Hospitals in ND may range in size from less than 25 beds to 500 beds.

We question the need for changing the patient classification system. If there is a need for change, a more careful analysis is needed. There needs to be greater access to the specifics of CMS' methodology and the new GROUPER.

The NDHA requests that there be a one-year delay in the proposed DRG changes. We have serious concerns with the HSRVcc and CS-DRG methodology.

We do not support a new classification system at this time. Additional work and understanding of the variation within the DRGs and the best classification system to address that variation is needed before CS-DRGs or any other system is to be considered.

If additional work and study indicate the need for a new, more effective classification system, it should be implemented at the same time as changes to weights. The simultaneous adoption will provide better predictability and smooth the volatility created by the two, generally off-setting changes.

Finally, if changes are implemented, we recommend that CMS allow a three-year transition with a blend of the old DRG weights and the new DRG weights. This transition will lessen the magnitude of payment redistribution across DRGs and hospitals. The American Hospital Association (AHA) is submitting recommendations for the transition process. AHA is committed and willing to work with CMS in the development and evaluation alternatives for new weights and classifications.

Long-Term Care Hospital (LTCH) DRGs

Long-term care hospitals are a very important patient care setting in North Dakota. They fill the needed services for many very ill and severely injured patients. The projected payment cut resulting form reweighting – 1.4 percent – in combination with the payment cut resulting from the recent LTCH PPS final rule for 2007 – 7.1 percent – will cause substantial volatility for our LTCH providers. This volatility will eventually restrict access for patients needing long-term acute care services. This will mean a total of an 8.5 percent cut in one year. The LTCHs will not have a 7.8 percent Medicare margin as MedPAC projected in 2006. The MedPAC projection does not include the impact of the "25% Rule" and the new reductions associated with the LTCH short-stay outlier policy.

CMS should focus on developing further patient and facility criteria for LTCHs to ensure that patients who are clinically suitable continue to have access to the LTCH setting. In North Dakota our LTCHs are appropriately admitting and maintaining their treatment of patients.

Emergency Medical Treatment and Active Labor Act (EMTALA)

The NDHA supports CMS' proposal allowing qualified medical personnel operating under their scope of practice and defined in the hospital bylaws and included in state law, to certify that a woman is in false labor. This change provides flexible staffing and the needed access in rural communities.

New Technology

Section 503 of the MMA provided new funding for add-on payments for new medical services and technologies with less stringent criteria under the inpatient PPS. This add-on payment and new criteria ensured that the inpatient PPS would better account for expensive drugs, devices and services. Even with the less stringent criteria, CMS

considers only a few technologies a year for add-on payments. Due to the rapid and changing advances in health care, and patient's expectations, the demands are much greater on our hospitals to provide new services and technologies. NDHA is requesting that CMS increases the marginal payment rate to 80 percent rather than 50 percent consistent with the outlier payment methodology. The AHA has previously made this request.

The ability to implement add-on payments for new technologies and services in the future requires that a unique procedure code be created and assigned to recognize new technology. The current ICD-9-CM system will soon be exhausted and needs upgrading. It is imperative to plan for a transition to replace the ICD-9-CM with ICD-10-CM and ICD-10-PCS.

Health Information Technology (IT)

Health IT is a very costly tool that requires both upfront and continued budgeting. Our large health systems in the state anticipate they need to spend approximately $5 million a year for the next five years.

IT needs to be a shared investment between providers, payers and purchaser of health care. Our hospitals recognize it is the right thing to do because it improves patient safety and quality. However, when we surveyed our hospitals, they indicated cost is the greatest barrier to further progress. Perhaps CMS could support the adoption of health IT through a payment adjustment funded with new money. Another alternative for assisting our hospitals with the cost is the possibility of loan guarantees or grant funds.

The NDHA is not in favor of including health IT in the Medicare conditions of participation (COP) for hospitals. The COPs address basic, essential infrastructure needed to ensure patient safety and must be clearly understood. If IT is to be successfully implemented it requires careful planning and many changes to work processes.

The NDHA appreciates the opportunity to submit our comments to CMS on these proposed rules. We encourage you to engage the AHA in ongoing discussion in the planning process. Moving forward requires thoughtful well-planned change.

Sincerely,

Arnold R. Thomas
President

Methodist The Methodist Hospital

213

Ronald G. Girotto
President
Chief Executive Officer

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Mark McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Mailstop C4-26-05
7500 Security Blvd
Baltimore MD 21244-1850

Re: CMS 1488-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

I appreciate the opportunity to comment on the proposed changes to the Medicare inpatient PPS system published in Federal Register on April 25, 2006. The Methodist Hospital is a large academic medical center hospital located in the Texas Medical Center, Houston, Texas; with Centers of Excellence in Cardiovascular Services, Oncology and Neurosciences. We also have three community hospitals located in Baytown, Texas; Sugar Land, Texas; and northwest Houston.

We join with others in the hospital and academic medical center community in supporting meaningful improvement in Medicare's inpatient PPS system however we have grave reservations about the proposed methodologies. In the limited time we have had to analyze the data and comment we have identified several areas of concern that merit a delay in implementation of the proposed changes and further study by CMS to better understand the full impact to both hospitals and patients.

HSRV Weights:

We are concerned that the methodology underlying the proposed changes to the DRG weights is significantly flawed and has not been adequately validated to ensure that the new system will rest on a sound foundation. Given the volume of data and magnitude of potential adverse impact, there should be sufficient opportunity for analysis and comment from the hospital industry before the new changes take effect. We urge that the implementation of a new system be delayed at least one year in order to give more time for the industry to work with CMS to be certain that any new system is based on sound assumptions, accurate data and clear objectives.

The impact of the changes will be profound for many hospitals. We serve a varied patient population from the uninsured patients seeking primary medical care through the Emergency Departments of our hospitals to tertiary care patients seeking the highest levels of technological advances in medicine in the Texas Medical Center. Our preliminary analysis indicates we could lose $5 million, which would adversely impact our finances and ability to deliver the high level and quality of care to our patients provided at this time.

The intent of the revised weights was to improve cost margin consistency particularly for specialty hospitals. The Methodist Hospital is not a specialty hospital but rather a hospital that provides a comprehensive range of services. Use of data that is three to five years old, charge compression, and DRG payments that are the same or lower than the current cost of medical devices impair the ability of general hospitals to sustain themselves economically. Patients may have limited access to lifesaving technology if hospitals cannot even cover the cost. We do not believe the intent was to adversely impact general hospitals to the great degree indicated in our analysis. It is therefore incumbent on CMS to insure that the new system is as technically correct as possible, which is why we believe a delay in implementation is warranted. We also recommend that changes be phased in over a three year period to provide time for hospitals to absorb the impact of the changes gradually rather than abruptly.

With regard to the proposal for Consolidated Severity-Adjusted DRGs, there appears to be a serious shortcoming particularly harmful to academic medical centers. CMS has imposed restrictions to nine patient diagnoses and six procedures for input to the "grouper" for purposes of DRG assignment. It appears that payments using this arbitrary limit would be understated on Medicare claims. Also skewing of severity levels downward occurs within the most complex patient populations such as those seen in academic medical centers, causing a disproportionately large negative financial impact. The resulting underpayments to our organization could amount to millions of dollars beyond the $5 million that was cited earlier. We believe this is contradictory to CMS' intent to more accurately reflect patient complexity in the reimbursement system. We would strongly advocate that the number of diagnoses and procedures used for DRG assignment be expanded to the maximum feasible number.

We also believe that there should be a reconsideration of implementing changes in two stages (once in FY07 for the HSRV weights and then again in FY08 for the Severity-adjusted DRGs), rather than simultaneously. The two year implementation process will cause two sets of revenue shifts. It seems more complicated than necessary to force hospitals to change financial projections twice over a two year period, when the total net effect of all changes could be absorbed in a single implementation process incorporating all changes. The one year delay suggested above would provide time for corrections and validation and allow for simultaneous implementation of all changes.

Resident Time in Patient-Related Activities:
The proposed rule also offers a clarification on time spent by residents in didactic activities. The proposed rule lists didactic activities occurring at hospital sites such as journal clubs, classroom lectures and seminars as examples of time that should be excluded in calculating the resident FTE for Indirect Medical Education payments. In this clarification, CMS also lists the same activities that occur in a non-hospital setting as excludable for Direct Graduate Medical Education. However, "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty" are an essential element of a medical education that only then results in patient care. [The quotation is from the September 24, 1999 letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins expressing the Agency's position supporting these activities].

These didactic activities that CMS proposes to exclude for payment are an integral part of the resident learning experience centered on the delivery of patient care, and there is no residency experience occurring at the hospital that is not related to patient care activities. We therefore strongly urge CMS to rescind the clarification regarding the exclusion of didactic time for IME and GME.

Industry Collaboration
Finally, let me reiterate our support for changes that can truly achieve a more balanced and equitable inpatient reimbursement system. Given time and the opportunity for thoughtful analysis and open communication with CMS on goals, designing systems, validating the results, and implementing changes gradually, I believe the hospital community will support an improved reimbursement system. The AHA, AAMC and Federation of American Hospitals conducted an analysis that incorporates both cost and charge inflation, which makes the threshold calculation more accurate and reliable. We urge you to review and give serious consideration to the methodology, as described in more detail in the AHA's comment letter.

Sincerely,

Ronald G. Girotto
President and CEO

RGG/cjb

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CATHOLIC HEALTH INITIATIVES

Memorial
Health Care System
MEMORIAL HOSPITAL

June 8, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Comment Period FY 07 IPPS Proposed Rule
Memorial Health Care System #44-0091

Memorial Health Care System urges CMS to delay the current proposal to overhaul the DRG system with a return to the current methodology, until the proposed methodologies and underlying cost data can be improved to ensure the accuracy of payments. Memorial Health Care System urges this delay based on several reasons:

Estimated, not Actual, Costs—CMS proposes to base payments on "costs". However, the "cost" for a particular category of patients is not an approximation of the actual price the hospital pays for the items and services required to treat the patients, but rather a rough approximation of costs. To calculate the cost estimates for Fiscal Year 2007 payments, CMS will use hospital claims data from Fiscal year 2005, and hospital cost reports from fiscal year 2003. The cost reports provide the actual costs and the actual charges for all patients (non-Medicare and Medicare patients). However, the cost centers contain products with low costs and high costs. Since hospitals have varying mark-ups, the cost estimations generally underestimate the value of high price items and overestimate the value of low-cost items as illustrated below:

Impact of Assuming Uniform Mark-Up in Estimating Costs – A Hypothetical Example

	Costs	Mark-Up	Charges After Mark-Up	Average Mark-Up for Department	Estimated Costs Based on Average Mark-Up
Medically Advanced Technologies	**$25,000**	200.0%	$50,000	266.7%	**$18,750**
Other Supplies	**$5**	400.0%	$20	266.7%	**$8**

Ten National Cost Groups and Calculation Error--The proposed changes would further distort the estimation of accurate costs by combining multiple costs centers on hospital cost reports into ten CMS-designated cost centers. In the proposed payment system, CMS would calculate ten national average cost-to-charge ratios (CCRs) for each of the designated cost centers. In making the national level calculations, however, the ratios were not weighted by each hospital's Medicare charges. This mathematical error would allow very small hospitals to have just as much impact on the national cost-to-charge ratios as larger hospitals. In addition, hospitals with low mark-ups (high CCRs) would have just as large an impact as hospitals with high mark-ups (low CCRs). If these methodological flaws are corrected, it would produce very different DRG weights and hospital impacts than those published in the proposed rule. CMS should allow adequate time for commenters to analyze these errors, the resulting DRG changes, and hospital impacts before finalizing the regulation.

Lags, Mismatched, and Missing Data-- Moving from charge-based payment weights to cost-based payment weights would introduce additional lags in the data used to calculate rates. The mismatch between the time period for the hospital claims and the hospital cost reports further distorts the calculations. For FY 2007 rates, CMS would use FY 2005 hospital claims. By contrast, cost reports for the calculations would be for periods ending in FY 2003. Many of the new technologies that will be available in FY 2007 will not be included in the claims data nor the cost report data used to calculate payments. Finally, early modeling results suggest that CMS data trimming method excluded 260 large hospitals with high room and board mark-ups (accounting for 25% of routine room and board charges) from the national cost center calculations.

Variation in Hospital Reporting– Since the implementation of the inpatient payment system, the validity of the cost reporting data has increasingly diminished. In any given time period, the data may be unreported or the cost report may be "unsettled" for a significant portion of hospitals. Approximately 15% of cost reports are audited.

Reforming Medicare's inpatient payment system to provide more accurate rates for hospitals is a laudable goal. But the current proposed rule is deeply flawed. An initial review of the proposed rule has uncovered a number of technical errors or questionable technical decisions. Two of them—the decision to remove 260 large hospitals accounting for 25% of routine room and board charges, and improper weighting of the data used to develop the national cost-to-charge ratios—have a major impact on a number of key DRGs . Replacing the existing system with the one currently proposed by CMS would create even greater opportunities for inaccurate payments. The limited time to review and adjust such a fundamental change raises the possibility of extremely negative impacts on hospitals, patients, physicians, and other key stakeholders.

Again, Memorial Health Care System urges CMS to delay the current proposal to overhaul the DRG system with a return to the current methodology, until the proposed methodologies and underlying cost data can be improved to ensure the accuracy of payments.

Sincerely,

Ruth W. Brinkley

Ruth W. Brinkley
President/CEO

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ASTS
American Society of Transplant Surgeons

AMERICAN SOCIETY OF TRANSPLANTATION
AST

June 9, 2006

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates, CMS 1488-P

Dear Dr. McClellan:

The American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) are pleased to have this opportunity to comment on the proposed inpatient prospective payment rule for FY 2007, as published in the April 25, 2006 Federal Register.

ASTS is an organization comprised of over 1000 transplant surgeons, physicians and scientists dedicated to excellence in transplantation surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

AST is an organization of more than 2,600 transplant professionals dedicated to research, education, advocacy and patient care in transplantation with a goal to offer a forum for the exchange of knowledge, scientific information and expertise in the field of transplantation.

While our organizations commend CMS for its efforts to make the prospective payment system for inpatient hospital services more equitable and more accurate, we have serious concerns regarding the proposed changes both with respect to the methodology for calculating DRG weights and with respect to the implementation of the new consolidated

APR-DRG system. Given the magnitude of the proposed changes and the complexity of the proposal, we urge CMS to delay implementation of the proposed changes until at least FY 2008.

I. Implementation of Hospital Specific Relative Values (HSRVs)

A. HSRVs for Transplants

CMS has proposed new DRG weights based on hospital costs rather than on hospital charges. Under the new methodology, the hospital-specific relative values (HSRVs) derive DRG weights from hospital cost report data and would replace the current system of developing DRG weights based on hospital charges. We do not disagree with the change from a charge-based to a cost-based approach in principle and believe it may, if properly implemented, result in more equitable and accurate DRG payments. However, there appear to be a number of problems in the methodology as well as errors in the data calculations which need to be corrected before the changes can be implemented.

Most seriously, it has come to our attention, and CMS has confirmed, that all of the transplant DRG weights published in the proposed rule are incorrect because organ acquisition costs, which are paid on a pass-through basis, were not properly backed out of the calculation. Consequently, the DRG weights for transplant services are overstated--although we do not know by how much. Moreover, CMS has informed us that it does not plan to publish a correction until the final rule. As a result, our organizations are unable to assess the impact of the proposed changes on payment for transplant services and therefore cannot effectively comment on the proposal.

For purposes of estimating the effect on transplant services, we have attempted to develop revised DRG weights which back out organ acquisition costs. If our estimates are correct, it appears that all of the transplant DRGs (with only one exception) would decrease – some significantly. The effect of these reductions is exacerbated by the increase in the outlier threshold. Given the fact that the proposed rule appears to have potentially serious negative financial implications for transplant centers, it is all the more crucial that transplant centers be provided with the information they need to determine the extent of that impact, in order to comment appropriately and to plan accordingly. Since the new DRG weights have not been provided, CMS should defer implementation of the transplant HSRV weights.

B. General Concerns with HSRVs

We are also concerned with the overall accuracy of the proposed methodology for calculating DRG weights. If there are errors in the transplant DRGs, we suspect there may be other errors affecting other DRGs. In addition, the proposed methodology depends, to a large extent, on the reliability of hospital cost report data and, in particular, the internal assignment of costs to specific cost centers. However, since hospital cost reports are no longer the basis for hospital reimbursement (with only minor exceptions)

and have not been for many years, there has been little incentive for hospitals to accurately allocate costs. Consequently, there may be serious quality problems with the data used to develop the HSRVs.

Moreover, CMS is proposing to implement an entirely new set of DRGs—perhaps as soon as 2008 or even earlier. Consequently, the DRG weights published in the proposed rule likely would be effective only for FY 2007, after which CMS will need to calculate DRG weights for an entirely new set of DRGs—DRGs that are very different from the existing ones. It would be much more reasonable, and less disruptive to hospital and Medicare program operations, for all of the proposed DRG changes to be implemented at the same time: It simply is not reasonable to expect hospitals to make such drastic changes by FY 2007 and then again as soon as FY 2008. This is especially true since, if the two sets of changes are implemented in separate years, institutions may see big jumps in payment in one year followed by significant drops the following year (or vice versa), creating havoc in hospital operations.

Recommendation: We urge CMS to defer implementation of the HSRV DRG weights until FY 2008, at the earliest. The hospital community must have an opportunity to fully understand the proposal and its impact on hospital payment. In addition, a longer time frame from proposed to final rule will allow for more constructive comments which, in turn, will give CMS an opportunity to make refinements and revisions to its proposal. We do not believe changes of this magnitude, which call for a fundamental overhaul of the current DRG system, should be implemented in haste and before affected entities have had a reasonable opportunity to study the proposal and to evaluate its ramifications. Postponing implementation of the HSRVs until 2008 or later and combining it with implementation of the consolidated APR-DRGs would be a much more rational transition strategy.

II. Adoption of Consolidated APR-DRGs

We support the agency's effort to develop DRGs that more accurately take into account severity of illness. Certainly in the area of transplantation patient severity can vary enormously. Unfortunately, current reimbursement for the more complex patients is inadequate even when the outlier threshold is reached, since outlier payments generally do not compensate for the enormous costs associated with caring for the sickest transplant patients. [1] For example, as discussed in more detail below, a study at a Medicare certified liver transplant center revealed that 19% of cases fell in the Medicare outlier gap.[2] Moreover, for those patients who exceeded the outlier threshold, revenues still failed to cover hospital costs.

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[1] The economics of transplantation and the importance of DRG payments that cover hospital costs is discussed in detail in Abecassis M, *Financial Outcomes in Transplantation – A Provider's Perspective*, Am. J. Tr. 2006; 6:1257-1267.

[2] Axelrod DA, et al., *The Economic Impact of MELD on Liver Transplant Centers,* Am. J. Tr. 2005;5:2297-2301. (Attached)

Therefore, we support, in principle, the effort to more accurately recognize severity of illness as a factor for determining payment. However, we have a number of concerns with the consolidated APR-DRGs for transplant services.

A. Methodology for Assignment of APR-DRGs

Our first concern is that CMS has not made available the 3M algorithm used in assigning cases to the consolidated APR-DRGs. We have reviewed the information on the 3M website and have tested the program with a number of hypothetical cases. The resulting DRG assignments, especially for combined transplants, are disturbing in a number of respects, as described more fully below. However, because the actual logic of the program has not been made public, it is difficult if not impossible to determine the nature of the clinical errors or inconsistencies. This lack of transparency is extremely troubling and is inconsistent with the requirements of agency rulemaking under the Administrative Procedure Act. Therefore, we urge CMS to refrain from moving forward with the consolidated APR-DRGs until it is in a position to provide the public with access to the 3M algorithm or whatever other DRG grouper it intends to use.

Moreover, we have serious concerns about the accuracy of the 3M algorithm as it applies to transplant services. We conducted four tests on the 3M website using diagnosis and procedure codes for patients who had received combined liver/kidney transplants. One case was assigned to SOI level 2 which is the lowest level liver transplant DRG. Two were assigned to SOI level 3 and one to SOI level 4. We believe the algorithm failed to recognize and account for the increased costs and complexity associated with combined liver/kidney transplants. In one case, a patient with a 46 day LOS was only assigned to SOI level 3.

We also believe there are serious problems with the 3M algorithm for assigning combined liver/intestinal transplants to the consolidated APR-DRGs. We tested two cases performed at a large Midwestern transplant center using actual diagnostic and procedure codes from patients who underwent the combined procedure. Both cases were assigned to the liver transplant DRG for SOI levels 1 and 2 – the lowest level. Again, we believe this reflects a serious problem with the clinical inputs used to assign transplant cases to the consolidated APR-DRGs.

B. Lung Transplants

There is no separate APR-DRG for lung transplants. Currently, lung transplants alone are assigned to CMS DRG 495 with a weight of 8.5736. Under the consolidated APR-DRGs, lung transplants would be assigned to DRGs 4-6 which describe heart and combined heart/lung transplants with weights ranging from 6.0823 to 21.1486 depending on severity of illness. Lung transplants have an average length of stay (LOS) of 14.2 days (geometric mean); heart and heart/lung transplants have an average LOS of 22.2 days. We have analyzed the effect of assigning DRG 495 cases from the most recent MedPAR

data to the consolidated APR-DRGs. That analysis shows that payment for lung transplant cases would increase by 31%.

We question the wisdom of assigning lung transplants to the same DRG as heart and heart/lung transplants given the much lower average LOS for lung transplants. The lower hospital inpatient costs associated with lung transplants alone would dilute the cost data used to determine the weights for the heart and heart/lung transplant DRG and result in an inappropriate decrease in the weights assigned to that DRG.

We believe the current CMS DRGs, which separate lung transplants alone from heart or combined heart/lung transplants, will result in more equitable and accurate payment for these procedures.

Recommendation: DRGs for lung transplantation alone should be created within the consolidated APR-DRGs system.

C. Heart Transplants and LVADs

In the FY 2005 IPPS rule, CMS modified DRG 103 (heart and heart/lung transplants) to include insertion of implantable left ventricular assist devices (LVADs). Previously, this procedure (procedure code 37.66) had been assigned to DRG 525 which describes heart assist system implants generally. The reason for reassignment was that insertion of implantable LVADs were associated with significantly higher inpatient costs and stays that were three times longer than other heart assist procedures. Overall, CMS determined that the costs of these procedures were more similar to the costs and length of stay associated with heart transplants. (See August 11, 2004 Federal Register at 48929.) Our organizations supported this change and we continue to believe that the higher costs associated with this procedure justify grouping it with heart and heart/lung transplants and not with other heart assist procedures.

However, the consolidated APR-DRGs for heart transplants do not include insertion of implantable LVADs. Rather, this procedure would appear to match most closely with consolidated APR-DRGs 207, 208 or 209 which describe cardiac defibrillator and/or heart assist implants. The weights for consolidated APR-DRG 207-209 range from 3.8849 to 5.482 for SOI Levels 1- 3 respectively. The weights for the heart transplant consolidated APR DRGs range from 6.0823 to 21.1486. Thus, even if insertion of an implantable LVAD were assigned to the highest heart assist implant DRG (DRG 209), the DRG payment would still be well below the lowest level heart transplant APR-DRG. Based on this, it is apparent that insertion of implantable LVADs (procedure 37.66) will be significantly undercompensated under the consolidated APR-DRGs. CMS already determined, in 2004, that hospital inpatient costs for this procedure were on a par with those of heart transplants and were considerably higher than costs of other heart assist procedures. Implementation of the consolidated APR-DRGs would effectively reverse this determination.

Recommendation: The heart and heart/lung transplant consolidated APR DRGs 4-6 should be revised to include insertion of implantable LVADs.

D. Combined Kidney/Pancreas Transplants

The current CMS DRGs include a separate DRG for combined kidney/pancreas transplants (DRG 512). The consolidated APR DRGs do not include a separate DRG for this procedure and combined kidney/pancreas transplants would be assigned to the pancreas DRG. Patients receiving double organ transplants are generally much sicker and have longer lengths of stay than patients receiving only a single organ. The proposed DRG weights for FY 2007 for pancreas and pancreas/kidney transplants reflect this. CMS has proposed a weight of 9.9384 for the combined procedure; the weight for pancreas alone is considerably less – 6.5546. Although we recognize that these weights are incorrect because they improperly include organ acquisition costs, we believe the relativity of the codes is generally accurate and demonstrate that hospital costs for combined kidney/pancreas transplants are considerably higher than pancreas transplants alone.

Nor do we believe the 3 SOI levels for pancreas transplants will take care of the problem. If combined procedures were automatically assigned to a level 3 SOI this might be sufficient. However, we did a number of test cases using the 3M program made available on the website, using actual patient diagnoses and procedure codes of patients who had received kidney/pancreas transplants. Two of these cases were assigned to SOI level 2 and 1 to SOI level 3 within the pancreas APR-DRG; none were assigned to SOI level 4. Further, our analysis of MedPAR data shows that the majority of kidney/transplant cases now assigned to DRG 512 (260 of 512) would be assigned to the lowest level pancreas transplant DRG. We believe this suggests a problem with the 3M algorithm; however, without access to the program we cannot identify exactly what the problem is.

Recommendation: The consolidated APR-DRGs should include DRGs for combined kidney/pancreas transplants.

E. Combined Liver/Kidney Transplants

Liver and liver/kidney transplants are assigned to a single DRG for liver transplants, both under the current CMS DRGs and the consolidated APR-DRGs. We believe a separate DRG is needed to address the significantly higher costs associated with combined liver/kidney transplants. We raised this issue in the FY 2006 proposed IPPS rule. CMS acknowledged that the costs for a liver-kidney transplant were significantly higher and lengths of stay were considerably longer than those associated with liver transplants. Specifically, FY 2004 MedPAR data showed average charges for liver/kidney transplants of $237,759 and average LOS of 21.3 days compared with $165,314 for liver transplantation. (See August 12, 2005 Federal Register at 47286) However, CMS determined that there were too small a number of cases (79 out of 959) to justify creation of a new DRG.

With respect to the relatively small number of cases, we note that with the February 2002 implementation of the model end stage liver disease (MELD) system to prioritize patients, there has been a substantial increase in the number of patients receiving liver/kidney transplants. [3] This is due, in large part, to the fact that high creatinine levels affect the MELD score more than other variables. Thus, many of the patients who are priority candidates for liver transplants also have impaired kidney function. In a study at one large transplant center, liver/kidney transplants were 6% (n=5) of the total number of liver transplants prior to implementation of the MELD system but 17% (n=22) post-MELD.[4] That same study found that hospital costs for inpatient stays involving combined liver/kidney transplants were 124% higher than liver transplants alone and the average LOS was 144% longer.

Further, outlier payments are generally inadequate. In the study referred to above, 19% of liver/kidney cases fell in the outlier gap and 44% achieved outlier status. However, the transplant center calculated that its average per case loss for outlier cases was over $17,000 per liver/kidney transplant. Those that fell in the outlier gap resulted in a loss of over $19,000.

We believe hospital inpatient costs and LOS associated with a liver/kidney transplant are sufficiently higher than those of a liver transplant alone as to justify the creation of a separate DRG. Further, although we recognize that the new consolidated APR-DRGs are designed to more adequately reflect severity of illness, the liver transplant DRG is still calibrated based largely on hospital costs for liver transplants alone and, as CMS has acknowledged, the costs of the combined procedure are significantly higher.

Recommendation: CMS should create a separate DRG for liver/kidney transplants.

F. Combined liver/intestinal transplants

For the same reasons as articulated above with respect to combined liver/kidney transplants, we believe it may be appropriate to establish a separate DRG for combined liver/intestinal transplants. We presented this issue to CMS in the FY 2006 proposed rule, and, although the agency agreed that the costs of the combined procedure were significantly higher than a liver transplant alone, CMS determined that a separate DRG was not required because the MedPAR data showed only one case in 2004. We urge CMS to review the most recent MedPAR data to see if the number of cases has increased to the point where a separate DRG might be appropriate. We note that OPTN data shows 36 cases reported in 2005.

Recommendation: CMS should review MedPAR data and consider creating a separate DRG for liver/intestinal transplants.

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[3] OPTN data shows 246 cases in 2003, 279 in 2004 and 337 in 2005.
[4] Axelrod DA, et al., supra.

G. Islet Cell Transplants

Islet transplants are classified into DRG 315 ("other kidney and urinary tract procedures"). In our comments on the FY 2006 IPPS rule, we asked that CMS consider assigning islet cell transplants to the pancreas transplant DRG. The agency declined to do this but did agree to review MedPAR data as it became more complete to determine whether DRG 315 is the most appropriate DRG for this procedure. We continue to believe that the DRG assignment is inappropriate and that the pancreas transplant DRG would be more appropriate.

Recommendation: CMS should review the cases in DRG 315 and compare the average charges and LOS for islet cell transplants compared to other cases in that DRG to determine whether these procedures are properly assigned.

III. Conclusion

The agency has proposed fundamental changes to the existing DRG system. While we agree with CMS' objective of increasing the accuracy and fairness of the DRG payments, we believe there are a number of problems with the proposed rule that need to be addressed before it can be implemented. Therefore, we urge that implementation of both the HSRV weights and the consolidated APR-DRGs be deferred at least until FY 2008.

Sincerely yours,

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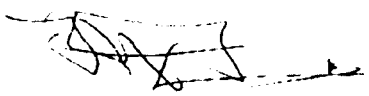

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Attachment 2.15

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The Economic Impact of MELD on Liver Transplant Centers

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Adoption of the model for end stage liver disease (MELD) system prioritized patients awaiting liver transplant (LT) by severity of illness including progressive renal dysfunction. Unfortunately, current reimbursement for LT is not adjusted by severity of illness or need for simultaneous liver-kidney transplantation (LKT). This study examines hospital cost and reimbursement for LT and LKT to determine the effect of MELD on transplant center (TC) financial outcomes given current reimbursement practices as well as DRG outlier threshold limits. LT was performed for 86 adults prior to and 127 following the implementation of MELD. Between the eras, there was a substantial increase in the average laboratory MELD score (17.1 to 20.7 $p = 0.004$) and percentage of LKTs performed (5.8% to 17.3% $p = 0.01$). Increasing MELD score was associated with higher costs ($4309 per MELD point $p < 0.001$) and decreasing TC net income ($1512 per MELD point $p < 0.001$). In patients not achieving the Medicare outlier status, predicted net loss was $17 700 for high-MELD patients and $19 133 for those needing LKT. In conclusion, contractual reimbursement agreements that are not indexed by severity of disease may not reflect the increased costs resulting from the MELD system. Even with outlier thresholds, Medicare reimbursement is inadequate resulting in a net loss for the TC.

Key words: Disease severity, financial outcomes in transplantation, health economics, liver transplantation, MELD

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Introduction

The adoption of a 'sickest patient first' strategy for organ allocation for deceased donor liver transplantation (LT) has resulted in a profound shift in the liver transplant population. While adoption of the model for end stage liver disease (MELD) score to prioritize patients in February 2002 has led to a reduction in mortality, particularly among patients with the highest MELD score, its impact on post-transplant survival is less clear.(1) Furthermore, the increasing complexity and acuity of patients undergoing transplantation is likely to have a significant impact on hospital resource utilization and financial outcomes of the nation's transplant centers (TC).

Two groups of patients have been particularly favored by the current organ allocation system. Under the MELD system, patients with progressive renal impairment receive a very high priority and appear to constitute an increasing proportion of the patients undergoing transplantation. Previous investigations have demonstrated a significant relationship between the degree of renal impairment and the cost of transplant (2). Thus, these patients are likely to have a profound effect on TC economics. Furthermore, an increasing number of these patients require a simultaneous liver-kidney transplant (LKT) that is currently reimbursed by Medicare under the same DRG as liver transplant alone (3).

The second group of patients who have benefited from the MELD score are patients to whom MELD scores are assigned based on exceptions to the MELD system, such as patients with hepatocellular carcinoma (HCC). It is important to differentiate between patients whose calculated MELD scores reflect hepatic decompensation and those who received MELD exceptions. The latter receive MELD point and upgrade to facilitate early transplant, whereas the former are desperately ill, often with multi-organ failure. In order to assess the financial impact of the increased acuity of illness associated with a high MELD score while controlling for secular trends in the cost of care, the cost of LT/LKT in patients with high calculated MELD scores can be compared to those with high-assigned MELD scores, but low calculated scores.

In this investigation, the clinical and financial records for 213 consecutive liver transplant recipients at a single TC spanning the implementation of MELD were assessed to

examine the impact of the new organ allocation system on the cost of transplantation in the context of current contractual reimbursement agreements and determine the impact of MELD on the profitability of the TC.

Materials and Methods

Patient population

Clinical and demographic data for all adult patients (n = 229) undergoing liver transplantation (n = 233) from January 2000 to December 2003 at a single institution were examined. This analysis included whole organ transplants from a deceased donor (DDLT), split liver transplants (SLT) including both segmental and lobe splits and adult-to-adult live donor liver transplants (ALDLT). A combined liver-kidney transplant (LKT) was performed if the renal failure was thought to be irreversible. Alternatively, patients with renal insufficiency were maintained on dialysis through the perioperative period until adequate return of renal function. Patients undergoing transplant for fulminant hepatic failure (n = 11) or undergoing a combined LT and coronary artery bypass grafting procedure (n = 5) were excluded from this analysis resulting in 213 transplant patients (216 LTs) for analysis.

MELD

MELD score was calculated using the last laboratory data available prior to transplant for all patients, including patients who were transplanted in the pre-MELD era. For patients on dialysis, a creatinine level of 4.0 was assigned and used to calculate the MELD score. The calculated MELD score was used in all patients. For patients who had been assigned a MELD score upgrade on the basis of a MELD exception granted by the Regional Review Board, the calculated MELD score was used to determine the severity of liver disease.

Cost data

Financial records were extracted from the hospital cost accounting system for the hospital stay in which the transplant occurred. For the small number of patients who were retransplanted during the same hospital stay (n = 3) due to primary nonfunction or hepatic artery thrombosis, all costs were assigned to the first transplant. The cost of care was determined using the full allocated cost of care (fixed and variable components) net of organ acquisition cost. Net income reflects the actual difference between allocated cost and hospital revenue. Given the short time period of this analysis, cost data were not adjusted for inflation.

Medicare gap analysis

Using existing Medicare fee schedules for DRG 480 (liver transplant), all cases, regardless of payer, were examined to determine the expected reimbursement under Medicare. For cases in which costs exceeded the outlier threshold, expected reimbursement was calculated using data from the current (2004) Medicare cost report. The outlier payment gap was defined as the amount between reimbursement for DRG 480 and the payment threshold that triggers outlier reimbursement.

Data analysis

Continuous and categorical variables were compared using Student's *t*-test and chi squared analysis as appropriate. Multivariate linear regression was used to assess the independent affect of demographic and clinical variables. A p-value <0.05 was considered significant. Patient outcome at 1 year was assessed using a chi-squared test. All analyses were conducted using Stata 8.0 (Stata Corporation College Station, TX).

Human subjects review

This project was approved by the Northwestern University Institutional Review Board.

Table 1: Patient demographics and transplant results

	Pre-MELD	Post-MELD	p-Value
N	86	127	
Age (years)	50.8 ± 9	53.0 ± 10	0.13
Male (%)	72	68	0.49
DX of HCC	15%	31%	0.009
DX of Hep C	39%	42%	0.07
Average MELD	17.1	20.7	0.004
With MELD >15 (%)	59	67	0.35
Total LOS (days)	16.1 ± 18	12.1 ± 15	0.08
Pre-TXP LOS, MELD <15	1.6 ± 5	0.3 ± 1	0.09
Pre-TXP LOS, MELD >15	7.3 ± 14	4.1 ± 9	0.11
1-year patient survival	85%	91%	0.20

Table 2: Procedures performed prior to and following the implementation of MELD

	Pre-MELD	Post- MELD	p-Value
Liver transplant alone, N (%)	81 (94)	105 (83)	0.01
Deceased donor	62 (76%)	71 (67%)	0.18
Live donor	13 (16%)	23 (22%)	0.32
Split liver	6 (7%)	11 (10%)	0.47
Liver-kidney transplant, N (%)	5 (6)	22 (17)	0.01

Results

Liver transplantation was performed for 86 patients prior to and 127 patients following the implementation of the MELD system of organ allocation in February 2002. Patient characteristics including age, gender and the incidence of hepatitis C were similar across the period of analysis (Table 1). There was a significant increase in the number of patients transplanted for HCC (31% vs. 15% p = 0.009) as a result of the MELD upgrade accorded to these patients. Overall, there was a 21% increase in mean calculated MELD score between patients transplanted before and after the MELD system (17.1 vs. 20.7 p = 0.004). Among patients receiving a whole organ DDLT (excluding live donor and split liver transplants), the average calculated MELD score increased by 28% (17.8 to 22.8 p < 0.001). Overall patient survival was comparable between eras (p = 0.20)

As a result of the emphasis placed on renal dysfunction in the MELD score, there was a significant increase in the number of LKTs after the implementation of MELD (Table 2). In the pre-MELD era, LKT represented 6% of transplants, which increased to 17% in the post-MELD era (p = 0.01). There was also a trend toward a reduction in the number of whole organ DDLT accompanied by an increased use of live donor and split liver transplant in the post-MELD era.

The increasing severity of illness, as reflected in the higher MELD scores, was associated with dramatically higher costs of care and reduced margins for the TC. When compared to patients with low calculated MELD scores, patients with MELD scores greater than 15 had total

Table 3: Impact of MELD score on resource utilization for liver transplantation

	Relative cost of high (>15) versus low (≤15) MELD LT	p-Value
Total cost	49% increase	<0.001
Room and board	135% increase	<0.001
Operating room	11% increase	0.09
Pharmacy	87% increase	0.02
Laboratory	100% increase	<0.001
Radiology	92% increase	0.007
Supplies	40% increase	0.06
Overall LOS*	108% increase	<0.001
Pre-TXP LOS*	489% increase	<0.001
Net income	114% decrease	0.02

MELD = model for end Stage liver disease; LT = liver transplant. *Increase in days in the hospital.

inpatient costs that were 49% higher ($p < 0.001$; Table 3). The major cost drivers for the increased cost of high MELD patients include higher room and board costs, as well as increased use of laboratory, radiology and pharmacy services (Table 3). High MELD patients were associate with a significant increase in overall length of stay (16.9 vs. 8.1 days $p < 0.001$) as well as longer pre-transplant hospitalization (5.3 vs. 0.9 days $p < 0.001$). Despite the significant increase in resources needed to care for high MELD patients, hospital revenues increased by only 24%. Consequently, average net income was 114% less in high MELD patients ($p = 0.02$), resulting in a net loss for the TC.

Univariate analysis revealed that MELD score, diagnosis of HCC, diagnosis of hepatitis C and living donor liver transplant ($p = 0.02$) were significantly correlated with the cost of liver transplant (Table 4). However, in the multivariate analysis only the MELD score was found to correlate with cost, demonstrating an increase of $4309 per MELD point. Neither donor type nor diagnosis remained significant after adjustment for MELD score. Univariate analysis revealed that a diagnosis of HCC, MELD score and LRD transplant were all significantly associated with TC income. However, in the multivariate analysis, only MELD score was associated with decreasing TC net income ($1512 reduction per MELD point $p = 0.002$).

The disparity between cost and revenue was particularly profound for patients who required LKT (Table 5). When compared with patients undergoing liver transplant alone, LKT patients did not differ based on age or gender. The overall LOS following LKT was markedly longer than for LT alone (28.4 days vs. 11.6 days $p < 0.001$). This difference was largely the result of a more complex pre-transplant course, characterized by pre-transplant LOS which was significantly longer (14.3 vs. 2.2. $p < 0.001$) As a result, the mean cost of LKT was 124% higher than for LT and revenues were often inadequate resulting in a net loss for the TC. Compared to LT alone, LKT was associated with a 388% reduction in net income.

Table 5: Differential in resource utilization for liver-kidney transplant versus liver transplant

	Ratio of LKT to LT alone (%)	p-Value
Total cost	124 increase	<0.001
Net income	388 decrease	0.004
LOS (days)	144 increase	<0.001
Pre-TXP LOS	550 increase	<0.001

LKT = liver-kidney transplant; LT = liver transplant; LOS = length of stay.

An additional analysis was conducted to assess the impact of current Medicare reimbursement policy on TCs. Overall, Medicare was the primary payer for 16% of patients undergoing LT/LKT. Among high MELD patients, 25% met outlier thresholds under current Medicare guidelines, while an additional 19% fell in the gap in which costs exceed reimbursement but fail to qualify for outlier payment. For high MELD patients undergoing liver transplant alone, patients achieving outlier status resulted in a predicted let loss for the TC of $17 000 while those in the gap had a predicted net loss of $17 700. Under current Medicare reimbursement schedules, LKT are reimbursed as liver transplant alone. In LK cases achieving outlier status, the predicted loss per patient under current Medicare guidelines was $17 037. However, among LKT cases falling in the gap the loss was $19 133 per case.

Discussion

The implementation of the MELD system of organ allocation has resulted in a shift in liver transplant recipients to patients with higher MELD scores and increased

Table 4: Univariate and multivariate analysis of cost drivers

Variable	Cost Univariate	p-Value	Multivariate	p-Value	Net income Univariate	p-Value	Multivariate	p-Value
Age (per year)	−271	0.64			−532	0.21		
HCC	−43 895	0.001			24 313	0.02		
Hep C	−22 291	0.05			8768	0.33		
MELD (per patient)	4309	<0.001	4309	<0.001	− 1512	0.002	−1512	0.002
Split	−2689	0.89			− 11 170	0.49		
LRD	−35 432	0.02			25 640	0.03		
Pre-MELD	−8102	0.47			−2839	0.75		

Variables are reported in dollar change in cost and net income associated with the variable of interest.

severity of illness. Patients with high MELD scores have longer hospital stays and, thus, incur higher hospital costs. Hospital revenues, however, are frequently either tied to Medicare DRG 480 or are reimbursed on a case rate-based reimbursement that is not indexed to severity of illness. In either situation, outlier payments are meant to provide a safety net for high cost cases, but often result in payments that are either at the margin or below cost. This results in significant reductions in net income, and may lead to a net loss for TC. This disparity is particularly significant in patients undergoing LKT.

The objective of the MELD system is to transplant the patients with the highest likelihood of dying without receiving a transplant. Recent analysis of the MELD system has demonstrated a significant reduction in wait-list mortality among adult and pediatric recipients (>2 year old) (1). Among adults listed for transplant, there was a reduction in the deaths/1000 patient-years from 910 to 743. Despite the increased severity of illness in patients undergoing transplantation, overall patient and graft survival have improved in the post-MELD era (4). Even for patients with high MELD scores, the outcome of transplant is often favorable. Although MELD scores are a relatively poor predictor of long-term outcome, in patients with scores greater than 24, there is a only 7% reduction in 5-year survival when compared to scores less than 10 (5). Conversely, those patients with low calculated MELDs who are awarded upgrade points for HCC are likely to benefit significantly from early transplant.

While transplantation of patients with high MELD scores has been shown to be of substantial clinical benefit (6), this shift in the transplant population will, predictably, increase the cost of transplantation. Prior to the implementation of MELD, improvements in clinical care and reduction in hospital stay had led a reduction in the cost of care. From 1993 to 1998, the average cost of liver transplantation performed in the Medicare population decreased from $201 677 to $143 363 (7). In the pre-MELD era, analyses of the cost of liver transplantation have identified several recipient factors that were associated with high costs. In a multicenter analysis, Showstack and colleagues demonstrated increased costs associated with older donor age, older recipient age, alcoholic liver disease, Child-Pugh class C cirrhosis and hospitalized patients. (8) Markman and colleagues identified several additional variables in their large single center study including donor sodium level, recipient creatinine and recipient ventilator requirement pretransplant. (2) Thus, it is the patients most likely to be prioritized under the MELD system who can be expected to have the highest costs associated with liver transplantation. The cost of care is likely to be further increased by the increased reliance on older and marginal donors (e.g. nonheart beating DDLT), both of which have been associated with higher costs, and longer lengths of stay.

While reimbursement varies considerably depending upon contractual negotiations between TC and third-party payers, many follow the current Medicare practice of case rate-based reimbursement that is not adjusted for severity of illness. Current practice does allow for some reimbursement for true outliers. Outlier protection typically consists of a stepwise or incremental payment methodology whereby cases at the margin will receive no additional reimbursement or payment until a certain outlier threshold is met. Thus for patients who exceed this threshold, payment in addition to the case rate will be made to the TC based on a percentage of charges, whereas for those patients who fail to meet the threshold, the TC receives no additional payment. Unfortunately, a significant percentage of high MELD patients (19%) fell in the Medicare outlier gap between hospital cost and the outlier provision threshold. Even among those patients (25%) who exceed this threshold, revenues frequently failed to cover hospital costs. For LKTs, this problem is particularly severe with 19% falling in the outlier gap and 44% achieving outlier status. Outlier payments were often inadequate resulting in a calculated average per case loss of over $17 000 per LKT, while those in the gap resulted in a loss of more than $19 000.

This study is limited in its general applicability because of the use of a single center's cost accounting information. Changes in clinical practice may reflect local practice and as well as the known variations in MELD score at transplantation, which occur between regions. (9) However, multiple studies have documented the relationship between increasing severity of illness and the cost of liver transplant. Thus, the conclusion that the MELD allocation system is likely to increase liver transplant costs is likely to be robust. With regard to reimbursement, by utilizing current Medicare guidelines in addition to actual TC experience to assess the impact of current reimbursement policies, including outlier threshold costs, on TC profitability our findings should be generalizable at least to this population nationwide.

In conclusion, the shift in the allocation policy for liver transplantation has resulted in the transplantation of patients with higher acuity of illness who incur significantly higher costs. The change to the MELD system has led to higher costs for LT and will negatively impact TC profitability unless current reimbursement policies are changed. A modified reimbursement policy to a system indexed by severity of illness is needed to protect TCs from financial losses due to the MELD policy. Specifically, a new DRG is needed for LKT, which reflects the significant increase in costs associated with this procedure. Finally, TCs should consider case rate reimbursement contracts with third-party payers that account for the higher costs incurred by the TC as a result of allocation policies that favor transplantation for the sickest patients first.

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Mount Clemens General Hospital

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June 9, 2006

Centers for Medicare and Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850

To whom it may Concern:

I have been chosen by my organization to respond to your invitation for comments relative to " Proposed Changes to the Hospital Inpatient Prospective Payment Systems", specifically concerning the **X- STOP Interspinous Process Decompression System.**

Dr. Mark Goldberger a, neurosurgeon at Mount Clemens General Hospital has used the **X Stop** technology four times this year. The patient ages ranged fifty- two to seventy – five years old. All four patients were experiencing moderate to severe spinal stenosis , refractory to continued conservative treatment and interfering with normal ambulation and activities of daily living. Prior to the development of this technology, the only surgical option would have been a spinal fusion.

All four patients underwent the operative procedure and were discharged the following day. Spinal fusion inpatient stays are from 4-5 days dependent on postoperative complications, ability to ambulate, and pain control. All four had operative / anesthesia time of less than 2 hours as opposed to the 4-6 hours of operative time for a spinal fusion. All four patients had good pain control using only oral pain medications as opposed to the use after spinal fusion surgery of multiple doses of intravenous narcotics. All four patients were ambulating on postoperative day one without problem and were discharged without complications.

The challenge for hospitals will be the ability to provide this type of service when the reimbursement for the entire surgery and stay (including therapy) is less than the cost of the device alone. This may prevent future use of the device and lead to some patients electing to have the more expensive and risk inherent spinal fusion procedure.

Please consider the technical add on payment for this procedure.

Maureen Kennedy

Maureen Kennedy, RN, BSN, MBA
Director, Orthopedic Service Line

UPMC | University of Pittsburgh Medical Center

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June 9, 2006

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via: UPS Delivery

ATTENTION: CMS-1488-P

RE: CMS-1488-P
Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Dear Sir or Madam:

On behalf of the University of 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 (71 FR 23995-24472, 4/25/2006) "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."

Listed below is a brief summary of the UPMC position and concerns regarding the major provisions of the FY2007 proposed rule, with more detailed responses in the subsequent pages.

I. "HSRV Weights"

While UPMC supports the concept of basing relative DRG weights on costs instead of charges, we cannot support the FY 2007 proposed rule as written. As set forth in detail in this memorandum we are concerned that the alternative weighting methodology used by CMS may contain developmental flaws. We urge CMS to postpone implementation of a new weighting process for 1 year, to implement a new weighting process only in conjunction with the simultaneous adoption of a severity adjusted DRG system, and to phase-in these major payment refinements over a three (or more) year period.

II. "DRGs: Severity of Illness"

UPMC supports CMS efforts in the development of a severity adjusted DRG payment system for fiscal year (FY) 2008 but believes the CMS proposed process, as written, is moving too quickly. The severity adjusted system as proposed has potential but it needs to account for both severity and complexity, since both affect the ultimate cost of care. In addition, hospitals have not been given adequate tools, time or appropriate information to evaluate the proposal in order to provide meaningful comments or alternatives. We also do not support its proposed implementation at a different time than the proposed HSRV Weights, as it needlessly decreases payments to teaching and large urban providers when implemented separately. We urge CMS to correct the proposed consolidated severity adjusted DRG payment process by adding complexity adjustments in addition to severity adjustments. We again urge CMS to postpone the implementation of both the severity of illness and new weighting process for at least one year until all the processes and methodologies can be appropriately corrected, evaluated and tested for accuracy. We also believe that changes of this magnitude and complexity should not be rushed, and that a three (or more) year phase-in is necessary for both CMS staff and hospital staffs to acquire the necessary understanding of the process.

III. Coding and CMI Adjustment of 2 Percent

UPMC urges CMS to withdraw its proposal to create a national case mix index adjustment of minus 2 percent for severity coding creep since we do not believe this can be accurately measured. Instead we favor the one year delay and a three (or more) year phase-in of any new payment system. We also favor more national training sessions be established and held to better educate the CMS and hospital staffs on the final new payment process.

IV. "Hospital Quality Data"

UPMC urges CMS to drop its proposed retroactive reporting "requirement" for 11 eleven expanded quality measures with a start date of January 1, 2006 and a due date of August 15, 2006. We do not believe that due dates for required quality data should be set prior to the publication of the final rule (anticipated around mid August) or prior to the effective date of the final rule. While we can understand CMS's desire to have older data we suggest that retroactive requests for data should be on a voluntary basis only and not subject non-complying providers to financial penalties. Hospitals need sufficient time to gather data for reporting and since JCAHO does not currently require the data collection on all these core measures the retrospective reporting creates a burden on hospitals.

V. "Value-Based Purchasing"

While UPMC is a leader in using health information technology (HIT), and encourages and agrees with using HIT to provide better quality service, we are

concerned that the costs and staff resources needed to put this in place for rural and small community hospitals could be burdensome and as such believe this should remain voluntary. We suggest that CMS continue to participate in, or encourage more operational studies on the potential benefits and costs associated with these types of initiatives, for provider's consideration. Mandatory use of HIT initiatives, however, should not be pursued as it may result in unintended consequences across all providers.

VI. "Operating Payment Rates – Outlier Payment Thresholds"

CMS is proposing to set the fixed-loss outlier threshold for federal fiscal year (FFY) 2007 to be equal to the DRG payment plus any IME and DSH payments, and any additional payments for new technology, plus $25,530. The threshold for FFY 2006 was equal to the DRG payment plus any IME and DSH payments, and new technology payments, plus $23,600. An increase in the threshold for FFY 2007 appears questionable considering that outlier payments for the past two years were less than the target of 5.1 percent of operating payments. We urge CMS to reevaluate this proposal, and to consider a fixed-loss threshold of approximately $22,000 which we believe would be more appropriate.

VII. "Resident Time in Patient Activities"

We strongly urge CMS to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. This proposed position is in stark contrast to the Agency's position as recently as 1999 which allowed these activities as "related to patient care". We support this 1999 interpretation and the AAMC position that recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

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.

Comment Reference "HSRV Weights"

Refinement of the Relative Weight Calculation (Page 24007)

Background: With the rapid expansion of specialty hospitals, CMS has become concerned that specialty hospitals are concentrating on the most lucrative procedures and are treating the healthiest and best-insured patients, leaving the community hospitals to take care of the poorest and sickest patient services which are less profitable. As a result CMS is trying to improve some of the inaccuracies of the current payment system which results in the system paying too much for some DRG's

relative to others and too much for patients with relatively less severe conditions. Three recommendations that CMS is working to implement include:

- Refining the current DRG's to more fully capture differences in severity of illness among patients (Proposed for FY 2008)
- Basing the DRG relative weights on the estimated cost of providing care rather than on charges (Proposed for FY 2007)
- Basing the weights on the national average of hospitals' relative values in each DRG (Proposed for FY 2007)

Two of these recommendations are included in CMS planned rule on hospital-specific relative value (HSRV) weight refinement.

Proposed Rule: CMS has proposed to change its method of developing Diagnostic Related Groups (DRGs) weights from the current relative weights based on the national charges of each DRG, to relative values based on hospital-specific relative values and national cost to charge ratios. CMS believes this approach removes the bias in the current weights caused by the hospital practice of applying different markups to different ancillary service cost centers, which may artificially increase select DRGs such as cardiology.

Response: While we agree with Medicare's goal of improving the payment accuracy of the inpatient prospective payment system we cannot confirm the accuracy of the alternative weighting methodology described by CMS in this proposed rule. Therefore for the reasons listed below we urge CMS to postpone implementation of the new weighting methodology until a better understanding of the entire process can be understood by the hospital community.

First, the weighting methodology process described by Medicare does not address whether provider subscripted ancillary cost centers, were included in the CMS national cost center ratios. We believe many larger teaching facilities have utilized cost center subscript lines to handle some of their more specialized ancillary departments and the preamble text does not clearly indicate whether these lines were incorporated into the ancillary national costs. For example, in one of our largest facilities the cost report line 41.0 "Radiology-Diagnostic" has subscript lines for 41.01 Scanner Service and 41.02 Ultrasound. This teaching facility had more than 20 different subscript ancillary departments, and if those costs were excluded they could artificially decrease the ancillary scaling factors.

Second, due to the complexities of the "Recalibration of DRG Weights" proposed by CMS a clear understanding of the accuracy of the proposed new cost weighting methodology was not possible. For instance, in the six steps described by CMS in the proposed rule it did not appear that CMS took into account the provider DRG volumes in arriving at the proposed average cost weights. A small provider with low service volumes could have equal

weighting as a large provider with high service volumes, when determining the hospital specific relative values (HSRVs). We would urge CMS to supplement the text of these proposed rules with possible "free" downloadable excel files (on the Web) containing examples of the calculations and detail files of the recalibrated data files by provider. This might help eliminate much of the confusion that text alone created. Without proper volume weightings we do not believe accurate average cost weightings are possible. As such we cannot support this complex and confusing process, over that which was historically applied by CMS, without more time and details.

Third, the process utilized by CMS in developing these proposed new DRG weights utilized data from different fiscal years (2005 MedPAR data with FY 2003 cost data). It is not clear whether the application of different fiscal year data elements creates any distortion in the estimated cost and weighting process.

Fourth, while CMS indicates that their proposed process achieved similar results with less work, we saw no detailed comparisons of the two different approaches. The MedPAC process used each hospitals cost-to-charge ratios for all cost centers, while CMS used national cost center charge ratios and hospital specific charge relative weights with only 8 ancillary and two routine cost centers. At this time it is unclear how CMS defines similar, and whether the two different approaches resulted in computation results that are comparable or substantially different.

Fifth, as CMS indicates on Table L (page 24025) – "Payment Impact of Hospital-Specific Cost Weights and Consolidated Severity-Adjusted DRGs by Hospital Category" the implementation of planned cost weight changes without the final refined severity adjusted DRGs causes large unnecessary payment decreases to large urban and major teaching providers in FY 2007, then receives a positive adjustment in FY 2008 when the severity adjusted DRGs are implemented. We believe the adoption of both provisions should occur simultaneously, after further refinement and study, so that unnecessary payment shifting does not occur.

In Summary – For the five reasons noted above, we do not support this proposed recalibration of DRG Weights for FY 2007 given our concerns regarding methodology and information availability. We recommend that a new cost weighting process not be adopted in FY 2007 and that CMS or 3M provide extensive training sessions on the entire process and provide free data files, by provider, to the hospital facilities. In addition, we believe that it is critical that the change in DRG cost weighting not be performed without the simultaneous implementation of severity refined DRGs, since it creates unnecessary payment shifting for large urban and teaching providers when implemented separately. We urge CMS to withdraw its proposed weighting methodology change for FY 2007 and to

carefully re-evaluate that methodology with the further refinements planned for the severity-adjusted DRGs over the next year. At that time we believe the whole plan should be phased in over a three (or more) year period so providers and clinical staffs can be educated and trained on this major reform process.

Comment Reference "DRGs: Severity of Illness" Page 24011

Refinement of DRGs Based on Severity of Illness

Background: One of the major changes planned in the refinement of the DRG system is the implementation of a severity-adjusted payment system to recognize the higher costs incurred by the more severely ill patients. To accomplish this CMS considered the "All Payer Refined" DRG system (APR DRG) developed by 3M and used by the State of Maryland. This system utilized 314 APR DRGs with four subclasses of severity for each DRG and two error DRGs, resulting in 1,258 DRGs. This APR DRG model requires the determination of severity of illness and risk of mortality for each secondary diagnosis as well. The determination of the final severity of illness level requires a three phase process with 18 different steps. Since the APR DRG system was developed as an "ALL payer" system with many services having little or no Medicare utilization, CMS proposed a consolidated version of the APR DRG process, called the "Consolidated Severity-Adjusted" DRGs. The CMS "consolidated severity-adjusted DRG model consolidated 1,258 APR DRGs into 861 consolidated severity-adjusted DRGs. The result is a severity adjusted DRG model that is significantly different from our current DRG system.

Proposed Rule: CMS is proposing to implement its consolidated severity-adjusted DRG system in fiscal year (FY) 2008 or earlier and is asking for comments on whether there are potential alternatives that might more effectively recognize severity of illness.

Response: While we applaud CMS's efforts in working to develop a more refined DRG payment system that takes into consideration the differences in the severity of the patient, we believe the entire process is moving too quickly. The proposed consolidated severity-adjusted DRG system for FY 2008 does not address both "complexity" and "severity" issues. CMS modeled this system off the 3M "All Patient Refined DRG" system (APR DRG), which also recognizes patient severity but not necessarily complexity. We believe the final payment methodology product must address both. As CMS suggested "complexity" might be determined using technology and other factors. However, at this time hospitals do not have adequate or sufficient information to evaluate the "consolidated severity-adjusted DRGs" without data files and "grouper" software. We again urge CMS to delay implementation of both the change in DRG weighting methodology from charge based to cost based as well as the consolidated severity-adjusted DRGs for a 1 year period and then begin a three (or more) year phase-in of the entire process. During this initial period we would urge CMS to provide national training sessions on both of these revisions and urge CMS to

release free of charge their data files so that providers can gain a better understanding of the process and its financial implications. A payment methodology change of this magnitude cannot be implemented in two months, and possibly not within a year unless there are massive training sessions and tools available for hospital staffs (clinical, coding. billing, financial) and physicians to gain a better understanding of the entire process. With more knowledge and understanding of the entire process better suggestions for system improvements could also be presented.

Changes to CMI from a New DRG System of 2 % (page 24019)

Proposed Rule: CMS is asking for comments on their belief that the adoption of the consolidated severity-adjusted DRG system would create a risk of increased payment levels of as much as 2 percent due to increased documentation and coding issues. As such CMS is considering an offset adjustment to the national average base payment amounts to budget neutralize this documentation and coding creep.

Response: We do not support a documentation and coding case-mix index (CMI) adjustment to the national rates after the implementation of the consolidated severity-adjusted DRG system. We believe this would be an arbitrary percentage assumption that could not be accurately measured. We also believe that if CMS delays the adoption of a new consolidated severity-adjusted DRG system and its proposed associated shift from a "charge" to "cost" based DRG weighting system by 1 year before beginning a three (or more) year phase-in of a new consolidated severity-adjusted DRG system the additional time could be used for staff and physician training to minimize coding and documentation errors. We again believe that CMS would need to take an active role in offering national training sessions for the various types of staff affected by this methodology change and with this type of training support the coding errors could be kept at a minimum, making this a mute issue.

Comment Reference – "Hospital Quality Data" (Pages 24091 and 24093 – 24094))

New Procedures for Hospital Reporting of Quality Data

Proposed Rule: CMS is proposing to implement a 2.0 percentage point reduction on the payment update beginning FY 2007 for hospitals that do not comply with the reporting requirements for quality data. In addition CMS has expanded the 10 quality measures to 21. For the FY 2007 update CMS will require hospitals to complete and return a written form on which they pledge to submit data on the following set of expanded quality measures (anticipated 21 clinical quality measures), starting with discharges that occur in CY 2006. These expanded quality measures are the HQA-released measures that the 2005 IOM report recommended we use as expanded ``starter'' measures for payments beginning with FY 2007. Hospitals will be required to submit data on the expanded measures to the QIO Clinical Warehouse beginning with discharges that occur in the first calendar quarter of 2006 (January through

March discharges). The deadline for hospitals to submit their data for first quarter 2006 is August 15, 2006. CMS also states that even with the use of "sampling" there will be no anticipated "significant additional burden on hospitals regarding the starter set of 10 quality measures or the anticipated 21 clinical quality measures because all JCAHO-accredited hospitals are currently required to adhere to these sampling requirements in acute myocardial infarction, heart failure, pneumonia, and surgical infection prevention for accreditation and core measure reporting purposes."

Response: We can not support the proposed FY 2007 procedures for "required" retroactive reporting of expanded hospital quality data, as written, for several reasons. First, we believe the retroactive start date of January 1, 2006 and the due date of August 15, 2006 are both problematic since the final IPPS payment rules may not be published by the 15th of August. Next, even if the final rules are published by August 12, 2006 many providers may not have enough time to accurately compile all the data necessary by the reporting due date of August 15. Finally CMS would penalize providers not meeting this retroactive reporting requirement with a 2.0 percent payment loss for services, even though the data requested is for services rendered 9 months prior to the effective date of the final IPPS rules. Final rules once published will have an effective date of October 1, 2006.

We also do not agree with the statement that there will be no anticipated significant additional burden on hospitals in relation to sampling. CMS states that for FY 2007, hospitals must submit a random sample or complete population of cases for each of three topics (acute myocardial infarction, heart failure, and pneumonia). CMS continues in the "no burden" paragraph to only address sampling (as opposed to the overall burden) and to include all 21 proposed measures that include acute myocardial infarction, heart failure, pneumonia and surgical infection prevention. JCAHO currently only requires data collection and submission on three of the Core Measures. Though sampling is a feature that allows you to collect clinical data on a smaller select patient population, there is still an extreme burden on hospitals to make arrangements to retrospectively collect data on an additional Core Measure, for example, additional staff, staff training, assurance of staff accuracy, and time and additional cost for vendor preparation. Vendor utilization requires first quarter data submission by June 30, 2006 for their submission to the Clinical Data Warehouse by August 15, 2006. In addition, this also adversely affects the existing time constraints on current data collection and submission.

We urge CMS to reconsider this proposal and make the "required" start date for reporting of expanded quality measures October 1, 2006 with a due date of January 15, 2006. (Or a starting date no earlier than July 1, 2006 with a reporting date of November 15, 2006.) We believe that all quality data start requests or due dates earlier than 60 days after publication of the final rule should be on a "voluntary" basis with no annual payment penalties attached for non compliance.

Comment Reference - "Value-Based Purchasing" (Page 24095)

Promoting Effective Use of Health Information Technology

Proposed Rule: CMS is seeking comments on their statutory authority to encourage the adoption and use of Health Information Technology (HIT). CMS is also seeking comments on the appropriate role of HIT in any value-based purchasing program, beyond the intrinsic incentives of the IPPS, to provide efficient care, encourage the avoidance of unnecessary costs, and increase quality of care. In addition they are seeking comments on promotion of the use of effective HIT through hospital conditions of participation, perhaps by adding a requirement that hospitals use HIT that is compliant with and certified in its use of the HIT standards adopted by the Secretary.

Response: Implementation of Health Information Technology (HIT) in hospitals may contribute to improved processes and coordination of patient care, as well as improved reporting of health information to CMS and other agencies; however, adoption of HIT should be a voluntary decision based on available resources of each facility, and should not be a condition for participation in the Program. The potential addition of electronic medical records and bar coding technology could result in significant costs for rural and community hospitals, as well as unintended consequences across all providers. We would encourage CMS to pursue further studies on this issue, supporting provider's voluntary adoption of HIT.

Comment Reference - "Operating Payment Rates"

Outlier Payment Thresholds (Page 24149)

Proposed Rule: The proposed rule would increase the fixed–loss cost outlier threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus $ $25,530. The federal fiscal year (FFY) 2006 fixed-loss cost outlier threshold was $23,600.

Response: The (FFY) 2007 proposed cost threshold is 8.2 percent higher than the level in FFY 2006. Outlier payments are funded through a 5.1 percent reduction in the PPS standardized payment amount. Consequently, CMS sets the outlier cost threshold at a level it believes will result in outlier payments that equal 5.1 percent of total DRG payments. However, CMS estimates that the actual outlier payments for FY 2006 represented only 4.71 percent of total DRG payments and 4.1 percent in FY 2005. While we realize that CMS makes every effort to estimate these outlier payments as accurately as possible, and to periodically refine their methodology, the outlier percentage points were .39 and 1.0 percent lower than the required 5.1 percent.

Since the outlier threshold was still too high during the last two fiscal years, and resulted in total outlier payments that were less than the target of 5.1 percent, we believe your current outlier payment projections will also be understated. As such we

urge you to reduce your FFY 2006 proposed outlier threshold by this average error of 13.6 percent. This would result in a suggested outlier threshold of $22,000.

Our error percentages and suggested outlier threshold computations are shown below:

FFY 2006 Error = (5.1% - 4.71 = 0.39%) / 5.1% = 7.6%
FFY 2005 Error = (5.1% - 4.10 = 1.00%) / 5.1% = 19.60%
Average Error = (7.6% + 19.6%) / 2 = 13.6%

Suggested Outlier Threshold = $25,530 * (100.0 – 13.6 = 86.4%) = $22,058 rounded to $22,000

Comment Reference - "FTE Resident Count and Documentation"

Resident Time Spent in Non-patient Care Activities as Part of Approved Residency Programs (page 24114)

Policy Clarification: CMS has issued a clarifying statement that resident time spent in didactic activities such as journal clubs or classroom lectures may not be counted in the hospital's GME or IME FTE resident count for non-hospital site training. They also indicate that didactic training activities performed in the hospital cannot be counted in the hospital IME count. CMS bases this clarification on the premise that "time spent by residents in other activities in the non-hospital site that do not involve the care and treatment of particular patients, such as didactic or scholarly activities, is not allowable for direct GME and IME payment purposes."

> For GME training in non-hospital sites CMS references: (SSA 1886(h)(4)(E)) "*shall provide that only time spent in activities relating to patient care shall be counted* and that all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting."
>
> For IME payment purposes CMS states "all the time spent by an intern or resident in patient care activities under an approved medical residency program at an entity in a non-hospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting".

Response: We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care" The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic

activities that must be excluded when determining the full time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school.

The proposed rule position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins].

We support the Agency's 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. Everything that a resident physician learns as part of an approved residency training program is built upon a delivery of patient care and the resident physician's educational development into a practitioner. We urge CMS to withdraw its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Conclusion

We appreciate the opportunity to submit these comments on your proposed changes to the Acute Care Hospital Inpatient Prospective Payment System for fiscal year 2007 and request that our concerns be considered before any final rules are published.

If you have any questions regarding our comments please contact Paul Stimmel, at (412) 647-8695.

Sincerely,

Edward T. Karlovich
Chief Financial Officer
Academic and Community Hospitals

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Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Inpatient Prospective Payment Systems and FY 2007 Rates regarding "Geographic Reclassifications – Urban Group Hospital Reclassifications" (File Code CMS-1488-P)

Dear Sir or Madam:

The purpose of this letter is to comment on the FFY 2007 proposed Inpatient Prospective Payment System (IPPS) regulation regarding geographic wage index reclassifications and urban group hospital reclassifications.

Pinecrest Rehabilitation Hospital is a 90 bed acute rehab facility located in Palm Beach County Florida. 80 percent of our patient population consists of Medicare beneficiaries and adequate Medicare reimbursement is critical to our continuing ability to meet their needs.

In 2004, when the FFY 2005 proposed IPPS regulation regarding geographic wage index reclassifications and urban group hospital reclassifications was published, Palm Beach County hospitals had, for the first time, qualified for the opportunity to reclassify for wage index purposes. Palm Beach County hospitals qualified in part because the FFY 2005 proposed rule allowed Metropolitan Divisions within a CBSA to qualify for an urban group reclassification. Based on the FFY 2005 proposed regulation, we joined with all other Palm Beach County hospitals and applied for the urban group reclassification. However, the final FFY 2005 IPPS regulation revised the proposed criteria and eliminated the ability for Metropolitan Divisions within a CBSA to qualify for an urban group reclassification.

We subsequently learned, however, from CMS through the FFY 2007 IPPS proposed regulation that the intent of the urban group reclassification was, and is, "to allow hospitals located in counties that are in the same CBSA (in the case of Metropolitan Divisions) as the area to which they seek redesignation to be considered to have met the proximity requirement We agree with CMS on the point above and agree with CMS on the following two points; that "the proximity standard for group reclassifications is intended to allow all of a county's hospitals to reclassify to an adjacent area where there is sufficient economic integrations that there can be an expectation that both areas are competing in a similar labor market area," and that "we believe there is sufficient economic integration between Metropolitan Divisions within a CBSA that urban county reclassifications within a CBSA or a CSA should be permitted."

We thank CMS for recognizing the economic integration between Metropolitan Divisions within a CBSA and request that CMS, at a minimum, adopt the FFY 2007 IPPS proposed urban group reclassification eligibility criteria [Sec. 412.234(a)(3)] as proposed, without modification.

However, we do believe, based on the CMS comments quoted above from the FFY 2007 IPPS proposed regulation, that the hospitals of Palm Beach County should have been allowed to qualify for an urban group reclassification beginning in FFY 2006 had the final FFY 2005 IPPS regulations correctly recognized the economic integration between Metropolitan Divisions within a CBSA (as CMS had done in the FFY 2005 proposed regulation and now again recognizes in the FFY 2007 proposed regulation).

Therefore, we respectfully request that CMS, in the final FFY 2007 IPPS regulation, make the FY 2007 proximity criteria effective for urban group reclassifications beginning on October 1, 2006 (as opposed to October 1, 2007) IF the urban area:

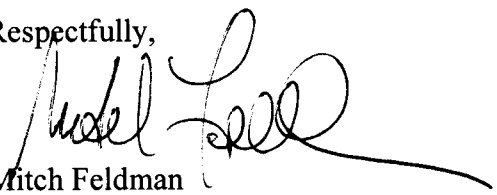
- Filed an application for urban group reclassification by September 1, 2004 for reclassification beginning on October 1, 2005;
- Met all of the non–proximity urban group reclassification criteria published in the FFY 2005 final regulation;
- Had the application denied only because the urban area did not meet the flawed FFY 2005 proximity criteria;
- Would have had the application approved had the FFY 2007 proposed proximity criterion been the criterion in the FFY 2005 final regulation;
- Meets the proximity and non-proximity criteria described in the FFY 2007 IPPS proposed regulation; and
- Files an application for urban group reclassification by September 1, 2006.

Based on the aforementioned information we request that CMS incorporate the proposed revision, as written above, in the FFY 2007 final IPPS regulation. We believe the requested revision is critical to the financial stability of the hospitals located in the West Palm Beach Metropolitan Division and should take effect, for payment purposes, for all hospitals in the West Palm Beach Metropolitan Division beginning October 1, 2006 rather than delaying until October 1, 2007. If granted

this revision will allow the urban group reclassification to take effect one year sooner than otherwise currently proposed, though a year later than the date which we would have otherwise qualified (October 1, 2005) had the final FFY 2005 regulation properly recognized the intent of the economic integration criteria.

We appreciate your consideration of this comment to the FFY 2007 proposed IPPS regulation.

Respectfully,



Mitch Feldman
Chief Executive Officer
Pinecrest Rehabilitation Hospital

219

Palm Beach
HEALTH NETWORK

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June 12, 2006 Overnight Mail Tracking No: 16537455152

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Inpatient Prospective Payment Systems and FY 2007 Rates regarding "Geographic Reclassifications – Urban Group Hospital Reclassifications" (File Code CMS-1488-P)

Dear Sir or Madam:

The purpose of this letter is to comment on the FFY 2007 proposed Inpatient Prospective Payment System (IPPS) regulation regarding geographic wage index reclassifications and urban group hospital reclassifications.

Delray Medical Center is a 403 bed institute located in Palm Beach County Florida. 65 percent of our patient population consists of Medicare beneficiaries and adequate Medicare reimbursement is critical to our continuing ability to meet their needs.

In 2004, when the FFY 2005 proposed IPPS regulation regarding geographic wage index reclassifications and urban group hospital reclassifications was published, Palm Beach County hospitals had, for the first time, qualified for the opportunity to reclassify for wage index purposes. Palm Beach County hospitals qualified in part because the FFY 2005 proposed rule allowed Metropolitan Divisions within a CBSA to qualify for an urban group reclassification. Based on the FFY 2005 proposed regulation, we joined with all other Palm Beach County hospitals and applied for the urban group reclassification. However, the final FFY 2005 IPPS regulation revised the proposed criteria and eliminated the ability for Metropolitan Divisions within a CBSA to qualify for an urban group reclassification.

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- Files an application for urban group reclassification by September 1, 2006.

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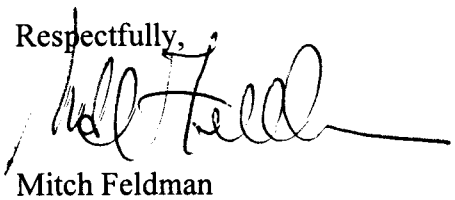
this revision will allow the urban group reclassification to take effect one year sooner than otherwise currently proposed, though a year later than the date which we would have otherwise qualified (October 1, 2005) had the final FFY 2005 regulation properly recognized the intent of the economic integration criteria.

We appreciate your consideration of this comment to the FFY 2007 proposed IPPS regulation.

Respectfully,



Mitch Feldman
Chief Executive Officer
Delray Medical Center

Jewish Hospital &
St. Mary's HealthCare

220

June 12, 2006

Mark McClellan, M. D., Ph. D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P. O. Box 80111
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. McClellan:

On behalf of Jewish Hospital and St. Mary's Healthcare (JHSMH) we appreciate the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed fiscal year (FY) 2007 inpatient prospective payment system (PPS). JHSMH's various healthcare facilities are located in the Louisville, KY MSA. Medicare comprises approximately 50% of our inpatient business across our facilities and as such these rules have a substantial impact on the financial performance of our organization. While the proposed rule has many provisions, we would like to comment specifically on the following issues:

DRG Relative Weights

The proposed rule would revise the methodologies used to calculate the relative weights of the Diagnosis Related Groups (DRGs) used to determine Medicare inpatient hospital services payment. The proposal would replace charge-based weights with a modified version of cost-based weights using hospital-specific relative values (HSRVs). The Centers for Medicare and Medicaid Services (CMS) also proposes a major revision to the DRG classification system to account for patient severity.

Adoption of the proposed DRG weight changes and proposed severity adjustments would result in the biggest change to the hospital inpatient prospective payment system (IPPS) since its inception. These changes would significantly redistribute payments among the DRGs and among hospitals.

We urge CMS to delay these changes, undertake more in-depth analyses of their impact, and evaluate alternative methodologies for improving the DRG system.

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HSRV Weights

- **Cost Reports**-The cost report is not a good rate setting tool nor does it have reliable information regarding DRG costs.
- **Charge Compression**-The manner in which costs are derived from charges assumes that higher cost devices are marked up to the same extent as low-cost items. Mark up policies for supplies is different around the country. Charge compression is occurring and has been an industry standard for many years. Charge compression is the markup of higher cost items at a lower rate then lower cost items. This is especially relevant when it comes to the large cardiac and orthopedic implants such as defibrillators, spinal fusion, heart valves, ventricular assist devices, hip and knee implants. These items fall under the Medical/Surgical Supply Category which has numerous small items with large markups.
- **Cost Data-**The new proposed DRG weights would be based on cost data that are 3-5 years old. Clinical practice has changed in many areas, especially cardiology, over the last two years.
- **Centers of Excellence-**The proposed changes are particularly significant for large volume hospitals and will have an impact on Centers of Excellence, which could impede beneficiary access to high quality services.
- **Distortion of Costs-**The proposed methodology would distort the accuracy of cost estimates by combining multiple cost centers on hospital cost reports into ten CMS-designated cost centers. In its recommendations to move to a cost-based relative weight methodology, the Medicare Payment Advisory Commission (MedPAC) suggested application of hospital-specific data to weight DRGs on estimated hospital-specific costs using individual claims data.

JHSMH believes CMS should either completely abandon these HSRV changes or at a minimum consider phasing these changes in over a number of years. Hospitals negatively impacted by these changes should have adequate time to plan for future spending cuts. JHSMH urges CMS to undertake more in-depth analysis of the impact of these changes and evaluate alternative methodologies for improving the DRG system.

Physician-Owned, Limited Service Hospitals

JHSMH urges CMS to continue the suspension of issuing new provider numbers to physician-owned, limited-service hospitals. CMS's strategic plan should first be completed and Congress should have an opportunity to consider CMS' final report on physician-owned hospitals.

Hospital Quality Data

JHSMH supports expansion of the number of measures to be reported for the Annual Hospital Payment Update. This expansion follows the recommendation of the Institute of Medicine.

However, we do have a concern with the timing of the final regulation and the requirement to begin the expanded reporting with January 1, 2006 discharges.

Hospitals are currently abstracting information for quality reporting for the January – March 2006 period with a closing date of mid-July. For those hospitals that have been collecting the "starter set" of 10 quality measures and have not begun abstracting the additional 11 measures, this retroactive requirement may pose an undue monetary and administration burden.

By the time the final rule is published, these hospitals may not have time to go back retrospectively and still meet the data submission deadlines for that period, especially if they need to have their vendor contracts amended to allow for the addition of an entire core measure set. These hospitals may also have difficulty retroactively collecting the second quarter information.

JHSMH recommends that CMS start the reporting period for the expanded quality measures with services provided on or after July 1, 2006.

Graduate Medical Education (GME) Payments

JHSMH urges CMS to rescind the "clarification" in the proposed rule which excludes medical resident time spent in didactic activities in the calculation of Medicare DGME and IME payments. We believe it would be very difficult to separate out time spent for these activities. Additionally, JHSMH urges CMS to recognize the integral nature of these activities to the patient care experience of residents during their residency programs.

DRGs: Severity of Illness

CMS has proposed a new classification system to reflect severity of illness among patients beginning in FY 2008 or earlier. CMS has proposed adoption of CMS-developed Consolidated Severity-Adjusted DRGs (CS-DRGs) rather than the widely applied All Patients Refined DRG system endorsed by MedPAC. Additional information and further analysis is needed to determine whether the CMS-proposed system, or another classification system, would result in an improved hospital payment system.

Until hospitals have a final GROUPER that can accurately assign the new CS-DRGs, it is difficult to calculate the impact. While we have surrogate methods of calculating the impact, GROUPERs used to calculate payments have changed in the past and minor changes can cause major changes in reimbursement.

We anticipate that for some hospitals the reimbursement changes resulting from new severity adjustments would adjust payments in the opposite direction from reimbursement changes

resulting from new cost-based DRG weights. For other hospitals, both changes could be positive or both negative.

We are concerned about the impact of making two major payment changes in two successive years. We are also concerned about the ability of hospitals to adapt to these major changes in PPS in the short time frame proposed.

If the need for and best approach for changing the patient classification system is clearly demonstrated, CMS should simultaneously implement the DRG weight changes and new classification system to provide greater stability and predictability in hospital payments. These changes should not be implemented before FY 2008. A three-year phase-in period with "stop loss" protections should be provided to ensure that redistribution of hospital payments is not unduly disruptive to negatively impacted hospitals.

JHSMH recommends further analysis by CMS to determine if the proposed CS-DRGs, or an alternative patient severity classification approach, would result in more accurate payments. If CMS believes a patient severisty classification exists along with a new DRG weighting system we believe the changes should be implemented at the same time. A three-year phase-in with "stop loss" protections should be allowed to provide greater stability and predictability in hospital payments. A new patient classification system should not be implemented before FY 2008.

Wage Index Budget Neutrality

JHSMH urges CMS to apply a positive budget neutrality adjustment in FY 2007 to compensate for underpayments related to the elimination of CAH data. The elimination of CAH data from the wage index file has resulted in an overstated national average hourly wage (NAHW). This artificial increase is included in the negative budget neutrality adjustment that consequently reduces payment, resulting in the national inpatient PPS operating payments being understated.

Thank you for the opportunity to comment on this proposed regulation.

Sincerely,

D. Gregory Dorris
Vice President Finance/Revenue Cycle

cc: Mark Carter, Senior Vice President and Chief Financial Officer/Administrative Services Officer

Wellington Regional
Medical Center

Kevin DiLallo
CEO/Managing Director

100 SOLUCIENT TOP HOSPITALS

June 12, 2006

Overnight Mail Tracking No: 8542 7955 3204

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Inpatient Prospective Payment Systems and FY 2007 Rates regarding "Geographic Reclassifications – Urban Group Hospital Reclassifications" (File Code CMS-1488-P)

Dear Sir or Madam:

The purpose of this letter is to comment on the FFY 2007 proposed Inpatient Prospective Payment System (IPPS) regulation regarding geographic wage index reclassifications and urban group hospital reclassifications.

Wellington Regional Medical Center is a 143 bed for-profit hospital located in Palm Beach County Florida. 26 percent of our patient population consists of Medicare beneficiaries and adequate Medicare reimbursement is critical to our continuing ability to meet their needs.

In 2004, when the FFY 2005 proposed IPPS regulation regarding geographic wage index reclassifications and urban group hospital reclassifications was published, Palm Beach County hospitals had, for the first time, qualified for the opportunity to reclassify for wage index purposes. Palm Beach County hospitals qualified in part because the FFY 2005 proposed rule allowed Metropolitan Divisions within a CBSA to qualify for an urban group reclassification. Based on the FFY 2005 proposed regulation, we joined with all other Palm Beach County hospitals and applied for the urban group reclassification. However, the final FFY 2005 IPPS regulation revised the proposed criteria and eliminated the ability for Metropolitan Divisions within a CBSA to qualify for an urban group reclassification.

We subsequently learned, however, from CMS through the FFY 2007 IPPS proposed regulation that the intent of the urban group reclassification was, and is, "to allow hospitals located in counties that are in the same CBSA (in the case of Metropolitan Divisions) as the area to which they seek redesignation to be considered to have met the proximity requirement We agree with CMS on the point above and agree with CMS on the following two points; that "the proximity standard for group reclassifications is intended to allow all of a county's hospitals to reclassify to an adjacent area where there is sufficient economic integrations that there can be an expectation that both areas are competing in a similar labor market area," and that "we believe there is sufficient economic integration between Metropolitan Divisions within a CBSA that urban county reclassifications within a CBSA or a CSA should be permitted."

We thank CMS for recognizing the economic integration between Metropolitan Divisions within a CBSA and request that CMS, at a minimum, adopt the FFY 2007 IPPS proposed urban group reclassification eligibility criteria [Sec. 412.234(a)(3)] as proposed, without modification. However, we do believe, based on the CMS comments quoted above from the FFY 2007 IPPS proposed regulation, that the hospitals of Palm Beach County should have been allowed to qualify for an urban group reclassification beginning in FFY 2006 had the final FFY 2005 IPPS regulations correctly recognized the economic integration between Metropolitan Divisions within a CBSA (as CMS had done in the FFY 2005 proposed regulation and now again recognizes in the FFY 2007 proposed regulation).

Therefore, we respectfully request that CMS, in the final FFY 2007 IPPS regulation, make the FY 2007 proximity criteria effective for urban group reclassifications beginning on October 1, 2006 (as opposed to October 1, 2007) IF the urban area:

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We appreciate your consideration of this comment to the FFY 2007 proposed IPPS regulation.

Respectfully,

Kevin DiLallo, C.E.O.
Wellington Regional Medical Center

KD/ph

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222

June 8, 2006 Overnight

Mail Tracking No: 1Z395 813 221007 7834

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Inpatient Prospective Payment Systems and FY 2007 Rates regarding "Geographic Reclassifications – Urban Group Hospital Reclassifications" (File Code CMS-1488-P)

Dear Sir or Madam:

The purpose of this letter is to comment on the FFY 2007 proposed Inpatient Prospective Payment System (IPPS) regulation regarding geographic wage index reclassifications and urban group hospital reclassifications.

Our facility is a 175 bed for-profit hospital located in Palm Beach County Florida. Twenty three percent of our patient population consists of Medicare beneficiaries and adequate Medicare reimbursement is critical to our continuing ability to meet their needs.

In 2004, when the FFY 2005 proposed IPPS regulation regarding geographic wage index reclassifications and urban group hospital reclassifications was published, Palm Beach County hospitals had, for the first time, qualified for the opportunity to reclassify for wage index purposes. Palm Beach County hospitals qualified in part because the FFY 2005 proposed rule allowed Metropolitan Divisions within a CBSA to qualify for an urban group reclassification. Based on the FFY 2005 proposed regulation, we joined with all other Palm Beach County hospitals and applied for the urban group reclassification. However, the final FFY 2005 IPPS regulation revised the proposed criteria and eliminated the ability for Metropolitan Divisions within a CBSA to qualify for an urban group reclassification.

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Therefore, we respectfully request that the HHS Secretary in the final FFY 2007 IPPS regulation, utilize his broad authority to make an exception to the assignment of wage index value for hospitals in Palm Beach County for Federal Fiscal Year (FFY) 2007 to Broward County as if they had been granted a reclassification based on the application submitted in 2004. The following criteria could be utilized: .T

- Filed an application for urban group reclassification by September 1, 2004 for reclassification beginning on October 1, 2005;
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We appreciate your consideration of this comment to the FFY 2007 proposed IPPS regulation.

Respectfully,

Robert Preato
Chief Financial Officer

Abbott

1399 New York Avenue, NW
Suite 200
Washington, DC 20005

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f 202 783 6631

223

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1488-P -- Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates

Dear Dr. McClellan:

Abbott welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare hospital inpatient prospective payment system ("IPPS") proposed rule for fiscal year ("FY") 2007 (the "Proposed Rule").

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies. The company employs 65,000 people and markets its products in more than 130 countries. In the hospital inpatient setting, Abbott offers a broad line of vascular products and technologies for interventional procedures, including coronary and endovascular stents, guide wires, catheters and balloons, and innovative vessel closure devices. Abbott also has coronary drug-eluting stents in development. In addition, Abbott offers a broad range of spine surgery technologies. An important focus of our work in spinal technology is in minimally invasive devices and techniques for spinal surgery, which can decrease patient discomfort and shorten the length of a hospital stay following a procedure.

As a leading medical device manufacturer, we seek to ensure that Medicare policies promote beneficiary access to high-quality health care and advanced medical technologies. In this letter Abbott would like to highlight a number of

areas of particular importance to the patients we serve in the hospital setting. Our comments and recommendations will focus on the issues of (1) cost-based weights, (2) severity of illness adjustments to DRGs and (3) payment for carotid stenting.

I. Summary of Abbott Recommendations

CMS has proposed two major reforms related to diagnosis related groups ("DRGs"): (1) basing the relative weights assigned to DRGs on estimated hospital costs (referred to as hospital-specific relative value cost center or HSRVcc weights) rather than charges and (2) modifying the DRG system to account for patient severity of illness.

CMS denies the request by Abbott and others to (1) create a new DRG(s) for carotid stenting, or (2) assign all carotid stenting cases paid under DRGs 533 (Extracranial Vascular Procedures with C/C) and 534 (Extracranial Vascular Procedures w/o C/C) to DRG 533 on an interim basis for FY 2007.

Cost-Based Weights (HSRVcc weights)

- Abbott shares CMS's goal of providing accurate payment for Medicare hospital inpatient procedures. However, we recommend alternative approaches to refining the inpatient payment methodology that we believe avoid certain methodological problems inherent in the HSRVcc proposal, enhance payment accuracy, and preserve beneficiary access to advanced medical technologies, including interventional cardiology procedures.

- If CMS moves to a cost-based weight system, we urge CMS to defer adoption until FY 2008 so that appropriate refinements can be developed and so the new system can be implemented at the same time as severity of illness adjusted DRGs, as the Medicare Payment Advisory Commission ("MedPAC") has recommended. During FY 2007, we recommend that CMS continue to base payments on charge-based weights.

- We recommend that if CMS adopts a cost-based weight system in FY 2008, it should consider a system modeled on the one used in the hospital outpatient department. We believe that modification of the hospital outpatient payment methodology for use in the hospital inpatient setting, coupled with refinements to the cost reporting system, presents a viable payment option that could address the needs of patients.

- In addition, if CMS moves from a charge-based to a cost-based payment system, we believe that it will be crucial for CMS to adopt reforms to make the cost reporting process more timely, reliable, and accurate in capturing hospital costs, including costs associated with advanced medical technology. Specifically, we recommend that CMS establish an external advisory panel to develop recommendations to improve the cost reporting system and address charge compression.

- We encourage CMS to phase in any cost-based weight system over a five-year period to monitor the impact of the payment adjustments on patient access to care. To prevent a disproportionate adverse impact on individual procedures and patients, CMS should impose a 5 percent limitation on the decrease in payment a particular DRG can experience in one year.

Severity of Illness Adjustments

- Abbott agrees with CMS that adjustments to the DRG system to better account for the severity of illness associated with individual patient cases could result in more accurate payments. However, we believe that any severity of illness adjustments should accommodate complex advanced technology procedures, incorporate recent refinements in the current DRG structure, and include a procedure for the initial assignment of new technology procedures to DRGs.

- We recommend that CMS defer adoption of severity of illness adjustments until FY 2008 in order to develop refinements that are based on the current DRG system and that account for the

resources associated with complex procedures and advanced technology. The refined system also should include a specific process and criteria for assigning new technology procedures to appropriate DRGs.

- We encourage CMS to monitor actual changes in coding and documentation practices associated with implementation of inpatient payment reforms to determine if any base payment adjustments are needed, rather than adjust payments in anticipation of such changes.

Carotid Artery Stents

- Abbott recommends that CMS assign all carotid stenting cases paid under the DRG 533/534 pair to DRG 533 on an interim basis for FY 2007, since the average charges for a carotid stent case in DRG 534 are much closer to the average charges for DRG 533 according to the CMS analysis of 2005 MedPAR data. If CMS proceeds with implementation of severity-adjusted DRGs in FY 2008, we urge the agency to create a new DRG for carotid stenting as part of this system. These payment changes are needed to assure adequate payment to hospitals for performing the procedure and to support patient access.

- Addressing payment for carotid stenting through a temporary DRG assignment is preferable to deferring action until the adoption of severity of illness adjusted DRGs, because the proposed severity of illness system currently does not have a mechanism to account for the cost of technology in establishing payment.

II. Detailed Comments

A. Proposals for Revisions to the IPPS Payment Methodology

1. Overview

CMS is proposing two major reforms to the hospital inpatient payment system: (1) basing the relative weights assigned to diagnosis related groups (DRGs) on estimated hospital costs rather than charges, and (2) modifying the DRG system to account for the severity of illness of patient cases. CMS is considering phasing in these reforms separately, with implementation of the cost-based DRG weights in FY 2007 and the patient severity adjustments in FY 2008, although CMS reserves the right to implement both components as soon as FY 2007.

We share CMS's goal of improving the accuracy of Medicare payments for hospital inpatient procedures. However, as discussed below, we are concerned that certain methodological problems in the cost-based weight proposal could result in inaccurate and inadequate payment rates. Likewise, in the case of severity-adjusted DRGs, we want to ensure that any refined system accounts for the cost of complex cases involving advanced technologies. Specific alternatives for CMS's consideration are presented in our comments.

Given the magnitude of the proposed changes, the limited time available for detailed analysis and development of policy recommendations during the 60-day comment period, and the potentially significant impact on hospitals and patients, we urge CMS to defer adoption of any major payment system changes until FY 2008. We are confident, however, that working together we can develop refinements to inpatient payment policy for FY 2008 that improve patient care while ensuring equitable and appropriate payments.

2. Hospital-Specific Relative Value Cost Center (HSRVcc) Weights

CMS proposes to change the basis for the relative weights assigned to DRGs from hospital charges to estimated hospital costs, effective October 1, 2006. CMS refers to this cost-based weighting system as the hospital-specific relative value cost center, or HSRVcc, methodology. CMS is proposing to base HSRVcc weights on national average CCRs in 10 cost center categories, subject to various adjustments. Although there has been limited time to examine this new methodology, we offer the following observations.

Redistribution of Medicare Spending. CMS anticipates that adoption of the HSRVcc weights would result in a significant redistribution of Medicare spending, dramatically decreasing payment for many surgical DRGs while increasing payment for medical DRGs. For instance, the HSRVcc methodology would result in a 20-33% percent reduction in national average payment for interventional cardiology procedures – a magnitude of change that could jeopardize Medicare beneficiary access to therapies like drug-eluting stents. By reducing payment disproportionately for high-technology surgical DRGs, adoption of HSRVcc weights could provide hospitals with insufficient reimbursement to support the use of advanced technologies that allow patients to recover faster with fewer complications and better clinical outcomes, and that potentially reduce overall medical and social costs. Instead, the HSRVcc methodology would reward low-tech, longer-stay hospital treatments. In addition, the sharp payment cuts potentially could discourage community hospital investment in cardiovascular facilities, especially in rural areas.

Methodological Problems. There are a number of significant methodological problems associated with the proposed HSRVcc weights, including the following:

- In calculating the cost-to-charge ratios, CMS excluded data from 260 large hospitals accounting for 25 percent of routine room and board charges. In addition, the national CCRs are unweighted and as a result do not account for varying amounts of aggregate charges across hospitals. According to an analysis by Chris Hogan of Direct Research, these two technical problems alone are a major reason for the wide swings in DRG weights under the cost-based weight proposal that potentially could disrupt patient care. These methodological problems have a particularly large impact on payment rates for a number of cardiovascular DRGs. For instance, if the problems were corrected, the impact of the HSRVcc changes on DRG 558 (Percutaneous cardiovascular procedure with drug-eluting stent without major cardiovascular diagnosis) would be an 18 percent rather than a 32 percent reduction. Likewise, the impact on DRG 557 (Percutaneous cardiovascular procedure with drug-eluting stent with major cardiovascular diagnosis) would be a 12 percent

rather than a 23 percent reduction. Correction of these methodological problems would result in more accurate payment rates and help to protect patient access to advanced medical technologies.

- The proposed methodology would introduce significant time lags in the data used to calculate payment rates. For example, FY 2007 rates would be based on claims from FY 2005 and cost reports from FY 2003 and FY 2004. The older cost report data does not reflect newer technologies that will be available to patients in FY 2007. Thus, the relative weights and resulting payments would not accurately capture actual hospital costs.

- Hospitals have considerable discretion in determining how to report revenues and expenditures on their cost reports. The Prospective Payment Assessment Commission and other researchers have found that this results in an overstatement of routine and special care costs and an understatement of ancillary costs on hospital cost reports. For instance, a study completed for the Commission in 1993 found that routine and special care costs were overstated by 12.6 percent, while the ancillary costs were understated by 4.9 percent. Such variances in reporting practices could further skew cost-based weights and lead to underpayment for procedures with high ancillary costs.

- Settled cost reporting data is not always promptly available for every hospital. Moreover, only a small percentage of hospital cost reports are audited annually. This raises additional questions about the validity and timeliness of the pool of cost data on which CMS intends to rely.

- CMS proposes classifying all hospital costs into one of 10 cost centers, with only one cost center for all "Supplies and Equipment." However, there is a substantial amount of research demonstrating that hospitals do not apply the same mark-up percentage to set charge levels for all items, and that the mark-up percentage is lower for high-cost, advanced-technology items than for low-cost items such as surgical supplies. Under CMS's proposal, very different products with very different costs and

markup levels would be consolidated, resulting in compressed values for higher-cost, low-markup items and inflated values for lower-cost, high-markup items. Charge compression results in inadequate payment rates for advanced technology procedures, which could affect patient access to such therapies.

- The HSRV method of standardizing hospital charges, as opposed to the traditional standardization methodology used by CMS, does not recognize legitimate differences in hospital-specific cost structures, and would penalize hospitals with higher cost structures that reflect the use of advanced technologies and medical services.

Abbott Recommendations

In light of the potential impact on quality of care and patient access to advanced technologies, serious methodological problems, and limited time to evaluate alternative systems, we recommend that CMS not adopt the proposed HSRVcc weights in 2007. During FY 2007, we recommend that CMS continue to base payments on charge-based weights.

We agree with MedPAC that cost-based weights should not be implemented prior to adjustments to account for patient severity of illness. In an April 19, 2006 letter to CMS, MedPAC stresses that "(i)t is important to correct for differences in patients' severity concurrently with the corrections for charging distortions. Adopting all of the policies we recommended would create the most accurate payments and prevent hospitals from facing unjustified shifts in their payments that may occur under partial adoption of the payment reforms." As discussed below, we support implementation of severity adjustments, but CMS needs additional time to develop a mechanism to ensure that severity adjustments appropriately address complex care, particularly for patients using advanced medical technology. We recommend that if CMS proceeds with implementation of cost-based weights and severity adjusted DRGs, it should implement both changes in FY 2008. A delay in implementation will permit CMS, hospitals and the medical technology community to work collaboratively to refine the approach to

address the methodological issues noted and best serve the needs of Medicare beneficiaries.

We believe that CMS should consider alternatives to the HSRVcc weights that avoid the methodological problems inherent in the HSRVcc weight system and that offer more accurate payment to hospitals for advanced patient care. For example, we recommend that if CMS adopts a cost-based weight system in FY 2008, it should consider a system modeled on an existing proven cost-based weight methodology, such as the one used in the hospital outpatient department. We believe that adaptation of the hospital outpatient payment methodology for use in the hospital inpatient setting, coupled with modifications to the cost reporting system, presents a viable payment alternative. Such an approach would avoid the methodological problems and sharp cuts in payment for technology procedures associated with the CMS HSRVcc cost-based weight proposal. In addition, it would seem logical to apply the same cost-based payment methodology to all hospital inpatient and outpatient procedures instead of applying two different methodologies. We urge CMS to work over the next year to refine a payment approach based on the outpatient cost-based weight methodology.

In addition, if CMS implements a cost-based weight payment system, it will be essential to implement measures to improve the cost reporting system, upon which the cost-based weight methodology is based, and to address the distortions to the payment system that result from charge compression. Specifically, we recommend that CMS establish an advisory panel comprised of representatives from government, hospitals, and the medical technology community to recommend specific reforms to make the cost reporting process more timely, reliable, and accurate in capturing hospital costs, including costs associated with advanced medical technology. We suggest that the panel be established by September 1, 2006 and make initial recommendations by the first quarter of 2007.

With regard to the timeline for implementation, CMS solicits comments on whether to provide a transition to the HSRVcc weights. We believe that if CMS decides to implement any major DRG weighting reforms, a phase-in period is necessary to allow hospitals to adapt gradually to payment changes and to allow CMS to monitor the impact of the

payment adjustments on patient access to care prior to full implementation. A gradual phase-in also would allow CMS to identify and correct any additional methodology problems that are identified as the changes are implemented.

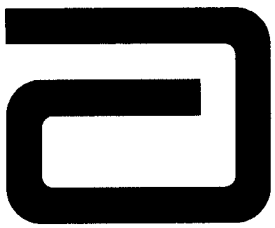
Thus, we recommend a five-year phase-in period for implementation of any cost-based weighting system. To ensure that the new weighting methodology does not disproportionately affect individual procedures and patients, CMS should impose a 5 percent limitation on the decrease in payment a particular DRG can experience in one year regardless of the length of the transition period.

3. DRGs: Severity of Illness

The second payment methodology reform in the Proposed Rule would adjust relative weights to more accurately reflect severity of illness among patients. Specifically, CMS proposes to replace the 526 current DRGs with approximately 861 DRGs adjusted for patient severity of illness. These 861 DRGs are based on 3M's All Patient Refined Diagnosis Related Group System ("APR DRG").

We agree that adjustments to the DRG system to better account for patient severity of illness could result in more accurate payments. However, we recommend modifications to the specific severity of illness adjusted DRG system proposed by CMS.

CMS is proposing to increase the number of DRGs. Yet in some cases, the proposed changes do not reflect improvements in DRG structure implemented by CMS to reflect the complexity of certain surgical procedures. For example, the proposed severity-adjusted DRGs do not include a DRG for combined anterior and posterior spinal fusion procedures. Combined anterior and posterior spinal fusion cases currently fall under DRG 496, which now has a relative weight of 6.09. Under the Proposed Rule, it appears that these cases would group to four possible consolidated DRGs (425, 462, 423, and 424) that have an average relative weight of only 2.823. This would result in significant underpayment for these cases and could threaten patient access to this advanced procedure.

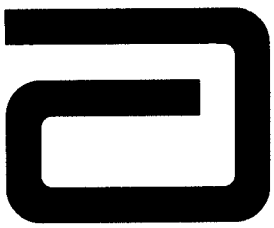


In addition, some of the proposed severity-adjusted DRGs actually would be less precise than current DRGs. For instance, the proposed DRGs for percutaneous cardiovascular procedures are less specific than the current DRG structure, which differentiates payment for cases involving drug-eluting stents and also those involving major cardiovascular diagnoses. In such cases, the proposed system would not as accurately reflect hospital resource use.

In addition, as CMS itself points out, the APR DRG system on which the CMS consolidated severity-adjusted DRG methodology is based does not accommodate the accurate assignment of payment for complex patient cases involving the use of medical technology but not necessarily greater severity of illness. For instance, CMS notes that patients receiving coronary stents may not be severely ill, although they need complex care. In such cases, relying exclusively on the patient's severity of illness to determine payment would not result in an accurate picture of the complexity and resources associated with the patient's care and would undercompensate hospitals for performing technologically complex procedures that improve patient outcomes.

CMS states that under the severity-adjusted DRG system, "requests for new Base DRGs formed on the use of a specific technology may be difficult to accommodate." We are concerned that no mechanism appears to exist for assigning new technology procedures to an appropriately paying DRG.

Lastly, CMS suggests that adoption of consolidated severity-adjusted DRGs potentially could result in increased aggregate levels of payment as a result of improved hospital documentation and coding. In order to assure budget neutrality, CMS is proposing to decrease payment levels in advance to offset the potential higher aggregate payment that could result from improved coding and documentation. Implementing such payment offsets in advance is problematic given the difficulty of accurately predicting the impact of severity-adjusted DRGs on hospital coding practices. Such coding and documentation changes may or may not actually occur.

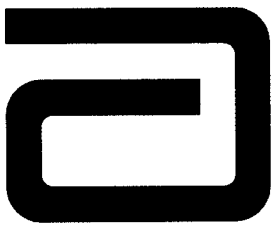


Abbott Recommendations

CMS states that it believes "a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system." We concur. Such methodologies undoubtedly could be developed with additional time to analyze the data on which the Proposed Rule was based and to model alternative severity adjustment options. One potential alternative would be to overlay severity adjustments on the current DRG structure, i.e., split the current DRGs as appropriate to reflect the severity of cases within the DRG. This would have the advantage of building upon the improvements that have been made in the DRG structure in recent years to account for new technologies. However, there is insufficient time during the 60-day comment period to perform a comprehensive analysis of this model and make detailed recommendations. We therefore recommend that CMS to work with the hospital and medical technology community in anticipation of the proposed FY 2008 Proposed Rule to study modifications to the proposed severity-adjusted DRG system and alternative systems that would account for the resources associated with complex advanced technology procedures.

We believe that a process should be established for the initial assignment of new procedures to DRGs, including criteria for assignment, data requirements, and specific timelines. In a related matter, CMS is requesting comments on how potential criteria for recognizing increased complexity in the structure of the DRG system should interact with current provisions related to new technology add-on payment. We believe that this issue would be most constructively considered when CMS advances specific proposals to recognize complexity and to assign new procedures to an appropriate DRG. We recommend that CMS also work with stakeholders to develop recommendations for the establishment of a detailed procedure for assigning new technologies to appropriate DRGs and determining the interaction between the severity-adjusted DRG system and new technology add-on payment.

CMS should not decrease base payments in advance to offset the potential higher aggregate payment that could result from improved



coding and documentation. Instead, we believe CMS should monitor coding changes in the first 1-2 years of implementation, and make any adjustments based on actual data.

In sum, given the importance of recognizing and adequately compensating hospitals for complex medical care involving advanced technology, we recommend that CMS modify its approach to severity of illness adjusted DRGs to assure that the system accommodates complex advanced technology procedures, incorporates recent refinements in DRG structure and includes a specific process and criteria for assigning adequate payment for new technology procedures. We urge CMS to work with stakeholders to study modifications to the proposed system and alternative systems to achieve these objectives.

B. DRGs: Carotid Artery Stents

In the Proposed Rule, CMS denies the request by Abbott and others to (1) create a new DRG(s) for carotid stenting, or (2) assign all carotid stenting cases paid under DRGs 533 (Extracranial Vascular Procedures with C/C) and 534 (Extracranial Vascular Procedures w/o C/C) to DRG 533 on an interim basis for FY 2007. Instead, CMS proposes continuing to pay for carotid stenting procedures under DRGs 533 and 534, which would result in payment decreases of 2-3 percent. As discussed below, a CMS analysis of Medicare Provider Analysis and Review File ("MedPAR") charge data demonstrates that hospital inpatient payment for carotid stenting remains inadequate. The proposed payment reductions for these two DRGs would only widen the gap between hospital costs and Medicare payment.

By way of background, stroke is a leading cause of death and disability for Medicare beneficiaries. Carotid stenting provides an alternative less invasive treatment option for beneficiaries at risk of stroke but who are not good candidates for surgery (carotid endarterectomy) due to anatomical complications and/or co-morbid conditions. The FDA has approved two Abbott carotid stent systems for use in the population at high risk for surgery, and the FDA is expected to approve additional manufacturers' carotid stent systems in 2006. CMS has recognized the value of carotid stenting by expanding coverage for the procedure for the Medicare population in 2004 and again in 2005.

Adequate payment for carotid stenting is essential to assure that patients at high risk for endarterectomy have access to this therapy. Due to the inadequacy of the current and proposed Medicare payment rates, however, hospitals could be reluctant to provide this therapy because of the negative financial impact on the hospital departmental budget. It would appear that CMS's coverage decisions recognizing the value of carotid stents also could be undermined if Medicare hospital payment remains inadequate.

Under the Proposed Rule, Medicare reimbursement for DRGs 533 and 534 would both be reduced as follows:

DRG	Descriptor	2006 National Average Payment	Proposed 2007 National Average Payment
533	Extracranial Vascular Procedures with C/C	$8,123	$7,916
534	Extracranial Vascular Procedures w/o C/C	$5,256	$5,132

Charge data presented by CMS in the Proposed Rule clearly shows that carotid stenting cases are underpaid in both DRG 533 and DRG 534. Specifically, a CMS analysis of the 2005 MedPAR data found that the average charges for the carotid stent cases were higher by $6,968 in DRG 533 and $7,804 in DRG 534, even though the average length of stay ("LOS") was slightly shorter for the carotid stenting cases than for all other cases in DRGs 533 and 534. The average charge for a carotid stent case in DRG 534 is $25,000, much closer to the average charges for DRG 533 ($26,376) than the average charges for DRG 534 ($17,196), as illustrated by the following table included the proposed rule:

DRG	Number of Cases	Average Length of Stay (Days)	Average Charges ($)
DRG 533 -- All cases	44,031	3.65	26,376
DRG 533 with codes 00.61 (perc. angioplasty or atherectomy of precerebral) & 00.63 (insertion of stent)	2,400	2.94	33,344
DRG 533 with code 00.61 and without 00.63	99	5.95	46,591
DRG 534--All cases	40,381	1.72	17,196
DRG 534 with codes 00.61 and 00.63 reported	2,056	1.52	25,000
DRG 534 with code 00.61 and without 00.63	55	2.31	27,895

Although the charge data presented by CMS demonstrates that carotid stenting cases are underpaid in both DRG 533 and 534, CMS suggests that the higher charges associated with carotid stenting may result from higher device mark-ups rather than higher procedure costs. Specifically, CMS observes that most of the cases assigned to these DRGs (carotid endarterectomy) -- unlike carotid stent placements – do not involve a device cost. For this reason, CMS concludes that "the higher average charges and lower length of stay for the cases involving carotid artery stents are likely accounted for by the cost of the device." Yet despite acknowledging that the device "likely" accounts for the higher costs, the agency goes on to speculate that the "hospital's charge markup may also explain the higher charges but lower average length of stay," citing a national average CCR for medical equipment and supplies of approximately 34 percent. However, CMS does not provide any actual evidence that markup -- and not the cost of the device -- accounts for the charges associated with carotid stenting.

Likewise, estimating device markups based on the national average CCR for the category of medical equipment and supplies is inappropriate. This broad category encompasses products with very different markup levels, ranging from higher cost, low-markup devices like stents to lower-cost, high markup medical supplies. In the absence of concrete information about markup levels for carotid stents, we recommend that CMS rely on its standard current methodology of using MedPAR charge data to determine appropriate DRG assignment for carotid stenting.

In addition to questioning whether carotid stenting cases actually are underpaid, CMS is proposing postponing resolution of this issue until the consolidated severity-adjusted DRG system is implemented. However, CMS already has acknowledged that the severity-adjusted DRGs as currently proposed do not adequately capture the costs associated with many medically complex procedures that use advanced medical technology, and that refinements will need to be adopted. Moreover, CMS has given no indication of how those refinements might work, or the time frame for implementation of such refinements. Thus, relying on future severity adjustments is not a viable alternative for addressing the current inadequacy of payment for carotid stenting procedures – especially since CMS already has the authority to modify payment in FY 2007 under the current DRG framework.

Abbott Recommendations

Abbott recommends that CMS assign all carotid artery stenting cases paid under the DRG 533/534 pair to DRG 533 on an interim basis for FY 2007, since the average charges for a carotid stent case in DRG 534 are much closer to the average charges for DRG 533 according to the CMS analysis of 2005 MedPAR data. If CMS proceeds with implementation of severity-adjusted DRGs in FY 2008, we urge the agency to create a new DRG for carotid artery stenting as part of this system. These payment changes are needed to assure adequate payment to hospitals for performing the procedure and to support patient access.

* * * *

We appreciate your attention to our comments and would be pleased to provide additional information or discuss any of these issues in greater detail.

Sincerely,

Barbara J. Calvert

Barbara J. Calvert
Director, Medical Products Reimbursement

cc: Virginia Tobiason Sr. Director, Corporate Reimbursement

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Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850.

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

I am a practicing cardiologist in a sixteen physician group. The members of our practice perform many complex cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. These procedures often include the implantation of medical devices such as stents, pacemakers, and internal defibrillators. Because inpatient procedures are a key component of delivering appropriate cardiac care, I am writing to express my concerns regarding proposed changes in the prospective payment system for inpatient services.

The proposed changes were intended to "level the financial playing field" across all hospitals and across multiple DRG's. The stated mechanism was to base reimbursements on the cost of providing each level and type of service. While this is a laudable goal, we believe that the methodology is severely flawed. The Medicare Payment Advisory Committee (MedPAC) recommended that CMS revise the DRG system, but CMS has chosen not to follow their recommendation on methodology in favor of a more "administratively feasible" set of calculations. The result is deep and disproportionate cuts in reimbursement for cardiovascular services that swing the pendulum much too far in the opposite direction. In some cases the reimbursement for cardiovascular procedures will be less than the purchase cost of the materials and devices used to perform those procedures.

Ironically, these changes take us back to a "cost plus" accounting methodology that the DRG system was designed to eliminate. Review of the changes clearly demonstrates this is predominately targeted at a single specialty which cares for the number one killer of Americans: cardiac disease.

Several aspects of the methodologies used to generate the proposal that we feel are inappropriate include:

1. Use of cost reporting data that is inherently inaccurate because it has received little attention from the participating institutions since implementation of the current DRG system in the 1980's.

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2. Flawed method of cost estimation: the proposed 10 cost centers contain products with low costs and high costs. Since hospitals have varying mark-ups, the cost estimations generally underestimate the value of high price items and overestimate the value of low-cost items.
3. Using cost data from 2003 to calculate DRG weighting for 2007. In a rapidly advancing and technology intensive field such as cardiovascular disease, many of the new technologies that will be available in FY 2007 will not be included in the claims data nor the cost report data used to calculate payments.
4. Exclusion of 260 large tertiary care hospitals from the data set used to perform the calculations.

The obvious cost constraints resulting from these reductions in hospital payment will limit patient access to cardiac care, which treats the number one killer in America today - heart disease. As hospitals ask physicians to scale back their number of procedures, due to financial uncertainties, patient access will surely be impacted. As Dr. McClellan recently stated in testimony before the Senate Finance Committee, "how Medicare pays for medical services can significantly impact quality and medical costs for our beneficiaries and our overall health care system." To make such sweeping policy changes with no formal study of the potential for unintended consequences on quality of and access to care would be a serious misstep in public policy.

I respectfully request that CMS return to the current charge-based methodology for the coming fiscal year and work with stakeholders to improve hospital cost reporting processes before any transition to cost-based weights.

Thank you for your consideration.

Sincerely,

Richard C. Slagle, M.D.

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DELAWARE VALLEY HEALTHCARE COUNCIL
of The Hospital & Healthsystem Association of Pennsylvania

Submitted Electronically, Temporary Comment Number: 84527

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; (71 Federal Register 23995), April 25, 2006.

Dear Dr. McClellan:

On behalf of the Delaware Valley Healthcare Council of HAP (DVHC) which represents more than of the more than 150 member hospitals, health systems and other health related organizations in Southeastern Pennsylvania, Southern New Jersey and Delaware, I am writing to convey our views on the proposed rule "Medicare Program; Proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." The proposed rule for the Medicare Prospective Payment System (IPPS) includes some of the most significant changes to the Medicare payment system since the program's implementation in 1983. It has been extremely challenging to evaluate the potential impact of the proposed rule given the magnitude of the proposed changes, the lack of clarity with regard to the methodologies that would be used for various aspects of the payment system, inaccuracies in the published data and the lack of data that will be used for the occupational mix adjustment. Nevertheless we have worked closely with the American Hospital Association (AHA), the Hospital and Health System Association of Pennsylvania (HAP) and the Association of American Medical Colleges (AAMC) in analyzing the potential impact of the proposed rule on the hospitals in the Delaware Valley and in preparing these comments for you.

We believe that in order to ensure continued access to high quality health care for Medicare beneficiaries in the Delaware Valley adequate hospital payments under the Medicare IPPS are critical. Furthermore, the Medicare payment system needs to be one that is predictable and stable so that hospitals can plan effectively for the future. It is important that the Medicare prospective payment system be one that allows providers to reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions. The proposed system seems to be one that is potentially volatile as we discovered that the financial impact for hospitals in Southeastern PA. could range from a potential 70.8 percent

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increase in payments to a 4.9 percent decrease in payments. We are concerned that the rule proposes to implement too many changes, too fast, and does not allow adequate time to fully understand the impact and implications of these changes for facilities over time. Even though DVHC supports the CMS in working toward meaningful improvement to the Medicare IPPS we think that revisions to the system need to be implemented if and only if there has been an opportunity to validate the methodology to confirm that it will not produce huge variations in payments from one year to the next. We have concerns that CMS' current proposal is too narrowly focused on the immediate future without a clear plan and mechanism for developing a payment model that would reward excellence, improve quality and provide safer care.

Our comments primarily focus on seven specific aspects of the proposed regulation: 1) Diagnosis Related Group (DRG) Relative Weights and Severity of Illness; 2) Long-term Acute Care Hospital DRGs; 3) Hospital Quality Data; 4) Outlier Threshold; 5) FTE Resident Count and Documentation; 6) Wage Index Budget Neutrality and Labor-related share; and 7) Other future concepts such as value based purchasing and health information technology. The Delaware Valley Healthcare Council (DVHC) requests that the Centers for Medicare and Medicaid Services (CMS) modify the proposed rule to ensure that inpatient facilities receive adequate reimbursement for their services as follows:

DRG Weights and Severity of Illness

The greatest variance in Medicare IPPS payments when comparing estimated FY 2006 with estimated FY 2007 comes from the impact of the Diagnostic Related Group weights. The DVHC shares a common goal with CMS in 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. However, more time is needed to understand the significant proposed policy changes, which according to an analysis conducted by the AHA would redistribute from $1.4 to $1.7 billion within the inpatient system. While DVHC and HAP support a move to cost-based weights, there are flaws in the CMS proposed methodology, modeling, and technical data used for refining the DRG payment system. Furthermore, analysis shows the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payment. And the validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is uncertain. We caution the CMS about moving forward without the time to validate and make necessary adjustments to the proposed methodology to ensure that it does not create instability in the Medicare inpatient reimbursement system. Therefore, **DVHC in concert with the AHA and HAP requests a one-year delay in the implementation of changes to the DRG payment system to address vagaries in the analyses and to correct identified flaws before implementation.**

In addition, DHVC believes that more work must be done to assess the need and most appropriate approach for changing the patient classification system. The DVHC agrees with the position of the AHA and HAP that **the need for a new classification system is still unclear and we cannot support movement to a new classification system at this time because the best approach to changing the patient classification system has not been concretely and objectively demonstrated.** Much more work understanding the variation

within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes. Thus, **DVHC agrees with HAP and the AHA's support of a simultaneous implementation of the DRG weight changes and new classification system in the event that CMS decides to adopt any changes to weights and classifications.**

Regardless of whether or not CMS agrees to delay the implementation of changes to the DRG payment system, we think that it is imperative that CMS provide a three-year transition for changes to the DRG payment system such as those in the proposed rule because of the magnitude of the potential change in reimbursement. Hospitals will need time to adjust to a revised system that could significantly impact their Medicare reimbursement. **It will be important for CMS to phase in a system for change to the DRG payments to hold the hospitals harmless and allow time for appropriate adjustment. The DVHC recommends a three-year transition period for implementation of a new DRG payment system.**

Specifically, we concur with HAP's recommendation that CMS provide a three-year transition with a blend of old DRG weights and new DRG weights. In the first year, hospitals would be paid based on an average of DRG weights: 75 percent of the old weights; 25 percent of the new weights. The second year would be 50 percent of each, and the third year would be 25 percent of the old weights and 75 percent of the new weights. Another method of transition is dampening the reduction of DRGs with significant decrease in relative weights similar to the dampening of APC weights in the outpatient PPS. Dampening could be more feasible - especially if a significant change to the classification system is made - because it does not require CMS to calculate using two different systems.

We further believe that a stop loss should be instituted as part of this transition. This would be similar to the approach currently used under the inpatient psychiatric PPS whereby no hospitals can receive less than 70 percent of what they would otherwise have been paid under the old system. In combination with the DRG blend or dampening, this would result in less significant losses in the first year than in the last year of the transition. To avoid having to run all claims under both DRG weights, CMS could establish a payment-to-cost ratio for each hospital in FY 2006 and use that as a base against which to compare payments under the new system.

Long-term Care Hospital (LTCH) DRGs

The AHA and DVHC are very concerned about the proposed re-weighting of the long-term care hospital (LTCH) DRGs for FY 2007. The projected payment cut resulting from the re-weighting – 1.4 percent – in combination with the payment cut resulting from the recent LTCH PPS final rule for 2007 – 7.1 percent – will cause substantial volatility for LTCH providers, and ultimately restrict access for patients needing long-term acute care services. It would be

extremely difficult for any provider group to withstand an 8.5 percent cut in one year. By pursuing these changes, CMS is misinterpreting MedPAC's estimate of 2006 Medicare margins for LTCHs and creating an extremely unstable regulatory environment for LTCHs. MedPAC projected a 7.8 percent Medicare margin for LTCHs in 2006 and recommended no market basket update for FY 2007. However, this MedPAC projection does not include two major policy changes that also decrease Medicare margins for LTCHs: the projection excludes the impact of the "25% Rule" limiting payments to co-located LTCHs and the new reductions associated with the LTCH short-stay outlier policy. Therefore, CMS goes too far with this proposal to reduce Medicare payments even further.

Given these considerations, we urge CMS to forgo the proposed 1.4 percent cut and instead implement the re-weighting in a budget-neutral manner. This would appropriately redistribute allocated funds among the payment categories to reflect current costs and omit the inappropriate modification of total payments due to unrelated considerations. It is irrational to treat the LTCH PPS differently than other Medicare payment systems by failing to re-weight the LTCH PPS in a budget-neutral manner.

At this time, CMS should focus on developing further patient and facility criteria for LTCHs to ensure that patients who are clinically suitable continue to have access to the LTCH setting. The DVHC along with the AHA strongly supports CMS' pursuit of a scientific foundation for these expanded criteria and are eager to review the recommendations currently under development by CMS' contractor the Research Triangle Institute.

Hospital Quality Data

CMS has proposed increasing the current reporting requirement from 10 to 21 quality measures. Hospitals must submit data on all 21 measures to the CMS data warehouse in order to qualify for the annual payment update (APU) for FY 2007. Reporting of the expanded quality measures is proposed to begin with January 1, 2006 discharges and 1st quarter data must be submitted to the CMS by August 15. If not submitted by this date hospitals' market basket update will be reduced by 2%. Preparation and submission of new data elements is a complex process and hospitals employ data vendors, hence, conforming to new data requirements is not as simple as turning on a switch as this data is not readily available to all hospitals. The retroactive nature of the proposal presents a reporting burden and hospitals would be required to spend additional resources without guarantee that the data would be accurate. Expenditure of time and resources with no guarantee of achieving accurate data is not desirable for CMS or hospitals. **DVHC recommends that submission of the new quality measures be prospective and begin with discharges after October 1, 2006.**

Chart Validation

It is important that the addition of new quality measures be constructed with accurate data. Since the primary basis for the publication of quality data is to serve as a tool for beneficiaries, providers and CMS to assess hospital performance, it is critical that the need for accurate data is balanced by consideration of administrative burden and cost to hospitals.

AHA has communicated with CMS problems associated with the proposed chart validation process that are beyond the control of hospitals and a penalty should not be assessed for problems not caused by the hospital. Any reduction in a hospital's Annual Payment Update (APU) is a grave concern and hospitals must be afforded a reasonable process to correct challenged data. **DVHC recommends that CMS institute a case-by-case reconsideration process for any hospital that is subject to a proposed APU reduction as result of chart validation. Also, we recommend that the expanded measures not be included in the formal validation process until after one full year of reporting of the additional measures.**

Reconsideration Process

CMS has indicated that hospitals that do not meet the APU requirements for the applicable fiscal year may appeal this determination to the Provider Reimbursement Review Board and that any such requests for FY 2007 must be made by no later than November 1, 2006. Further, CMS is seeking public comment on the need for a more structured reconsideration process for FY 2008 and subsequent year appeals. Moving the effective date to discharges after July 1, 2006 can avoid many appeals that would result from a retrospective submission date and CMS should not require these data appeals to be held with the Provider Reimbursement Review Board. To do so will overwhelm the current PRRB review process and grind all appeals to a halt.

The DVHC recommends that CMS establish a separate process for reconsideration that requires supportable and reasonable evidence for the start up year. Process could require written notification by a senior officer that details the reasons for the reconsideration request (e.g., vendor transmission failures; charts sent to the CDAC were misplaced or lost). The Quality Improvement Organizations have considerable experience with this type of data and can more effectively conduct this review function, as it is consistent with the QIP's quality improvement efforts.

Development of Future Measures

The DRA requires the expansion to other quality measures. The types of measures that CMS has indicated may be added include: the HCAHPS® patient perception of care survey findings; structure measures as detailed in the recent Institute of Medicine report *Performance Measurement: Accelerating Improvement;* and outcome measures, specifically 30-day mortality for acute myocardial infarction and heart failure patients. **The DVHC recommends that CMS should consider measures used by HQA for public reporting.**

Hospital-specific patient outcomes reports have been publicly available in Pennsylvania for over 20 years and these hospital performance reports cover over 30-based code conditions and 19 DRGs. Based on the 20 years of experience, Pennsylvania hospitals do not believe that use of a 30-day risk-adjusted mortality for acute myocardial infarction and heart failure patients represents the best outcome measures for use as overall quality indicator. **CMS should delay implementation of such measures and continue collaboration with the Hospital Quality Alliance partners to identify outcome measures that better reflect the quality of hospital care.**

CMS states that HCAHPS® results will be considered as part of a future measure expansion. HCAHPS® offer an opportunity to incorporate patient satisfaction measures but like any new measurement tool there must be an implementation schedule that provides for sufficient time for hospitals to become familiar with data submission and how to use as a feedback tool. Such an approach allows for development of more accurate data.

Outlier Threshold

Year after year, the hospital community is in the position of having to argue against the CMS plan to increase the outlier threshold. Once again the DVHC strongly opposes CMS' proposed 8.2% increase in the outlier threshold and urges CMS to establish an appropriate outlier threshold to ensure satisfactory payments for outlier cases. The purpose of providing extra payments for cases with unusually high costs that are determined to be outliers is both to limit the hospitals' financial risk from extreme costs and to remove any financial disincentive for treating Medicare patients with especially serious conditions. We believe that an increase in the outlier threshold from $23,600 to $25,530 as proposed in the rule for FY 2007, will make it even more difficult for hospitals to qualify for outlier payments and will put them at greater risk when treating extraordinary cases. Furthermore, CMS has continued to under spend the 5.1% that is set-aside for outliers. It is estimated that in FY 2005 CMS under spent the funds set aside for outliers by an estimated $1.15 billion and spent only 3.5 percent, or $1.3 billion less that the funds withheld in 2004. Given that CMS did not even spend the entire pool of funds set aside in 2006 with an outlier threshold of $23,600, we recommend that the outlier threshold be lowered not increased. According to an analysis conducted by the AHA, CMS underspent the funds set aside for outliers by an estimated $3 billion over FYs 2004, 2005 and 2006. This is a real cut in payments to hospitals that cannot be recouped. If CMS leaves the threshold at $25,530, rather than dropping it to $24,000 as recommended by the AHA, we believe that CMS will again significantly underspend by over $300 million. It is critical that hospitals receive special payments to cover the extremely high-costs associated with extraordinary cases. **We urge CMS to guarantee that hospitals receive the full 5.1 percent of payments that will be withheld from base inpatient payments by lowering the outlier threshold.**

FTE Resident Count and Documentation

The DVHC represents four Academic Medical Centers in the Philadelphia area and we have concerns about the negative impact that the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments would have on these medical educational programs. In the proposed rule, CMS indicated that "with respect to training in non-hospital settings, the time that residents spend in non-patient care activities as part of an approved program, including didactic activities, cannot be included in a hospital's direct GME or IME FTE resident count." The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a

physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care". The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner. We believe that the position that CMS is proposing to take on this issue is one of interpretation and we strongly disagree with it. The statutory requirement is payment for "activities relating to patient care" and we assert that participation in journals, conferences, workshops etc. as part of a training program, are all "patient care related activities" and therefore should be included in the GME and the IME. **Therefore we strongly urge CMS to rescind the proposal to exclude medical resident time spent in didactic activities from the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.**

Wage Index Budget Neutrality

CMS eliminates the Critical Access Hospital (CAH) data from the wage index file it uses to compute the national average hourly wage (NAHW). For FY 2007, 1,191 CAHs representing approximately 24 percent of all inpatient PPS hospitals (as of FY 2000) – 55 percent of all rural hospitals in FY 2000 – have been eliminated from the file. Because CAHs have lower average hourly wages (AHWs) than the average PPS hospital, the elimination of this data results in an overstated NAHW. While the NAHW has been increasing, the systematic withdrawal of low-wage hospitals has artificially inflated the NAHW to some extent. This artificial increase is included in the negative budget neutrality adjustment that consequently reduces payment, resulting in the national inpatient PPS operating payments being understated by an estimated $1.52 billion over five years (2003-2007).

Recently, the DVHC analyzed the impact of excluding the approximately 1,200 Critical Access Hospitals (CAHs) from the wage index file. The results of this analysis indicated that the National Average Hourly Wage for FFY 2007 is overstated by .707% since these small lower paying hospitals have been deleted from the wage index file. This results in an understatement of the various wage indexes throughout the country. For hospitals in the Philadelphia CBSA, any overstatement of the National Average Wage translates into a decreased wage index and ultimately lowers Medicare reimbursement.

MedPAC has previously recommended that the CAH data be included in the wage index file. We think that CMS should follow the MedPAC recommendation and **therefore we ask CMS to use estimated CAH data to include in the FFY 2007 wage index file to compute the National Average Hourly wage.** A Medicare occupational mix factor of 1.0000 could be assigned to these hospitals for purposes of the wage index calculation. In addition, we suggest that CMS obtain wage index data from CAHs and subject the data to the same rigorous intermediary review as is done for Medicare IPPS hospitals and to include the CAH data in future wage index calculations at least in determining the National Average Hourly Wage.

Lastly, in order to rectify the situation that has resulted in underpayments to hospitals based on the removal of the CAH wage index data from the wage index files from FFY 2003-2006, **we concur with the AHA recommendation that CMS should apply a positive budget neutrality adjustment in FY 2007 to compensate for the previous underpayments.**

Labor Share

Last year, DVHC communicated to CMS that the reduction of the labor-related share from 71.1 percent to 69.7 percent was problematic for hospitals in the Philadelphia Core Based Statistical Area (CBSA). According to the proposed rule, the labor related share would remain at the 69.7 percent that was implemented in FY 2006. This continuation of the reduced labor related share has a negative financial impact for hospitals in our region that are under severe financial stress. **We recommend that CMS return to the previously established labor share of 71.1 percent for hospitals with a wage index greater than one.**

Other Future Concepts

Health Information Technology (HIT)
In the proposed rule, the CMS considers the role of interoperable health information technology (HIT) systems in increasing the quality of hospital services while avoiding unnecessary costs. CMS requested comments on the following:

- statutory authority to encourage the adoption and the use of HIT;
- the appropriate role of HIT in any value-based purchasing program, beyond the intrinsic incentives of the IPPS, to provide efficient care, encourage the avoidance of unnecessary costs, and increase quality of care; and
- the promotion of the use of effective HIT through hospital conditions of participation, perhaps by adding a requirement that hospitals use HIT that is compliant with and certified in its use of the HIT standards adopted by the Secretary of Health and Human Services.

The DVHC strongly believes that HIT is a very important tool for improving the safety and quality of health care, and our members are committed to adopting HIT as part of their quality improvement strategies. They also view HIT as a public good that requires a shared investment between the providers and purchasers of care. However, HIT is a very costly tool, requiring both upfront and ongoing spending. The proposed rule highlights the anticipated benefits of HIT as laid out by the RAND Corporation. However, it overlooks another of the study's major findings – that the financial benefits of IT investments accrue more to the payers and purchasers of care than the hospitals and health systems that pay for them.[1]

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[1] R. Hillestad, J. Bigelow, A. Bower, F. Girosi, R. Meili, R. Scoville, and R. Taylor. "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs," *Health Affairs*, September 1, 2005; 24(5): 1103 - 1117.

Simply put, our members have not seen financial returns greater than the costs of implementing clinical IT systems, particularly in the short term. They adopt clinical IT because it is the right thing to do for improving patient safety and quality of care, not because it saves them money. Thus, while IT may be a "normal cost of doing business," it systematically raises those costs. **Given that they reap many of the financial benefits of IT, the DVHC agrees with the AHA that the payers and purchasers of care should share in the costs of HIT.**

Conditions of Participation

DVHC in collaboration with the AHA concluded that it does not make any sense to have the use of HIT as a part of the hospital conditions of participation (COP). The COPs address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, the commercial HIT applications available do not always meet hospitals' needs. The evidence on HIT does not yet support this level of requirement and would amount to an unfunded mandate.

Value-Based Purchasing

Plan for Implementing Hospital Value-Based Purchasing in FY 2009

In its proposed rule, CMS describes several of its efforts over the past several years to improve the quality and efficiency of care delivered to Medicare beneficiaries in America's hospitals. Reference is made to CMS' participation in the Hospital Quality Alliance as a strategy to encourage hospital accountability by making comparative information about hospital performance publicly available and the testing of innovative approaches to improving quality through pilot project such as the Premier Hospital Quality Incentive Demonstration. Pennsylvania hospitals have actively participated in both projects. CMS requested comment on the various components of such a plan (measure development and refinement; data infrastructure; development of incentive methods; and public reporting.

In absence of a specific proposal, meaningful comments cannot be presented. **DVHC recommends that CMS further review the Premier Hospital Quality Incentive Demonstration pilot project, and work with stakeholder groups to propose and model several alternative methods that can be published for a meaningful public review and comment.**

Health IT can play a role in reducing the burden of quality reporting. Presently, electronic health records (EHRs) and other clinical IT systems do not automatically generate quality measures. Most hospitals still require special calculations – including expensive manual chart abstraction and use of third-party contractors – to submit quality data. CMS could advance the quality agenda by investing in the development of algorithms for the calculation of the quality measures it wants reported from EHRs and encouraging vendors to include them in their products.

Rather than including health IT in a value-based purchasing program, **CMS could support adoption of health IT through a payment adjustment funded with new money.** It seems as though at this time a Medicare payment adjustment would be a good mechanism for CMS to employ to provide an incentive for HIT as opposed to it being a hospital condition of performance or one of the pay for performance quality measures. We have concerns about the fact that hospitals are at varying degrees of implementation of HIT and there is a capital expenditure involved.

Thank you for the opportunity to express our views on this important regulation as it will greatly impact on hospital services received by Medicare beneficiaries in the Philadelphia area as well as other parts of the Commonwealth and the nation. We want to emphasize that although we support many of the proposed rule's provisions, we have serious concerns about the proposed changes to the DRG weights and classifications. We urge CMS to consider a one-year delay in implementation to allow the hospital community the opportunity to work with CMS on the development of a predictable, stable system of Medicare reimbursement for the future. Furthermore if significant changes to the DRG payment system are ultimately adopted, there must be a three- year transition period. If you or your staff needs further clarification of our views, please do not hesitate to contact me at (215) 575-3737 or Pamela Clarke, DVHC's Vice President of Managed Care at (215) 575-3755.

Sincerely,

Andrew Wigglesworth

Andrew Wigglesworth
President

NALTH

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June 9, 2006

VIA EXPRESS MAIL

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates" Proposed Rule Published at 71 *Fed. Reg.* 23,995 *et seq.* (April 25, 2006)

Dear Dr. McClellan:

The National Association of Long Term Hospitals ("NALTH") welcomes the opportunity to submit these comments on proposed rules published on April 25, 2006 at 71 *Fed. Reg.*, 23,995 *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 who receive services in long-term care hospitals ("LTCHs") throughout the nation. In this connection, NALTH has completed the first multi-site outcome study of patients who failed weaning from ventilators in acute care hospitals and, therefore, were admitted to LTCHs. NALTH recently completed the development and independent validation of LTCH-specific admission, continued stay and discharge criteria. 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 Untied States and publicly-owned LTCHs.

I. Introduction

The following comments concern proposals to revise LTCH-PPS weights for FY 2007, as well as revisions to the regulation which establish restrictions on the operations of hospitals-within-hospitals (HwH) which are grandfathered from provisions of the so-call "hospital-within-hospital rule" by 42 C.F.R §412.22(f). For the following reasons, we recommend the Secretary exercise the broad discretion which he has asserted in previous rulemaking to establish LTCH-DRG weights for FY 2007 in a budget-neutral manner. We have examined how LTCH-DRG weights would be affected if they were established on a cost basis using the Hospital-Specific Relative Value cost center ("HSRVcc") DRG weights, which are proposed for IPPS hospitals[1]. We have found this method of establishing weights would result in a positive increase in payment of +1.5%. This effectively would offset the proposed negative -1.4% payment reduction from charge-based weights. Also, we are deeply concerned that there may be overlap (a double reduction) between the rationale used to set a zero (0%) percent update for FY 2007 and the proposed -1.4% reduction in weights for FY 2007. Due to these factors, we strongly recommend that CMS exercise its discretion to establish weights for FY 2007 in a budget-neutral manner for LTCHs.

We also have examined closely how HwHs grandfathered by 42 C.F.R. §412.22(f) have been affected by current restrictions on their ability to change hospital operations after September 30, 2003. We endorse the proposed revisions to this rule. Moreover, it is now apparent that this rule unnecessarily interferes with the ability of these hospitals to provide medically-necessary services to patients. We, therefore recommend additional revisions to the rule. In doing so, we mindful of the policy concerns articulated in the preamble to the rule concerning grandfathered HwHs and have endeavored to accommodate those concerns within our recommendations for revisions to the rule.

Finally, 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 dual annual rulemaking process. A 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. This second rulemaking revises LTCH-DRG weights and also makes changes to LTCH-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 prospective system of payment. This problem is

[1] We understand that hospitals subject to IPPS and representative trade organizations are submitting comments concerning the accuracy of weights derived from the HSRVcc methodology. We look forward to reviewing the Secretary's assessment of these comments.

complicated further because the two rulemakings are interrelated. It is not reasonable to expect the provider community to comment on the reasonableness 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. Accordingly, we request that, commencing with FY 2008, routine annual adjustments to the LTCH-PPS occur 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 established cycle for the establishment of LTCH-PPS weights. We further suggest that, in the first year only (*i.e.* 2008), CMS establish a three-month (from July to September) and twelve month (from October to October) update factor.

I. LTCH-DRGs - Proposed FY 2007 Weights

A. Payment Inadequacy

We agree with the statement contained in repeated rulemakings for prospective payment systems, which is reiterated in the preamble to this proposed rule, that the objective of the annual revision to LTCH-DRG weights is to account adequately for each LTCH's case-mix in order to assure a fair distribution of payments, which account for variations in cost and adequately pay for patient resource use. *See e.g.* 71 *Fed. Reg.* 24,052. We think it is both important and appropriate for the Secretary to assess the proposal to recalibrate weights for LTCHs for FY 2007 in the context of other changes the Secretary has made to the LTCH-PPS, in rulemaking which recently was finalized on May 12, 2006 (*see* 71 *Fed. Reg.* 27,797 *et. seq.*). These payment changes are projected by the Secretary to reduce payments by -3.7% due to the adoption of changes to the short-stay policy. This final rule also recaptures another 3.6% in payments, made because of improved DRG coding in FY 2004, by providing for a zero (0%) percent update factor for FY 2007.[2] The proposed LTCH-PPS weights for FY 2007 would impose another negative -1.4% payment reduction. Thus, the combined reduction in LTCH payments, as estimated by the Secretary, is -8.7% for FY 2007. We are concerned that, under the currently proposed IPPS rule, there will be a disproportionate reduction in weights for the highest patient volume and highest weight LTCH-DRGs. For example, LTCH-DRGs related to the treatment of patients with wounds (LTCH-DRGs 263-265 and 439-440) would decrease between -4% to -11%. LTCH-DRGs related to respiratory patients (LTCH-DRGs 76, 87 and 475) would decrease by -5% to -7%. At our request, the Lewin Group has simulated LTCH industry-wide margins which would result from both the final LTCH-PPS rule and the currently proposed change in weights. The Lewin Group simulated FY 2007 LTCH industry-wide Medicare margins in a manner which is consistent with the methods used by MedPAC and CMS to simulate margins.[3] These results are presented below for the LTCH-PPS final rule, as well as

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[2] The preamble to the final LTCH-PPS FY 2007 rule describes this reduction in payments as being "meant to reduce current [FY 2007] payments to account for the increase payments that occurred in FY 2004 that resulted from . . . 'case mix' creep in that year." 71 *Fed. Reg.* 27,822 (May 12, 2006).

[3] Margins were calculated as the difference between Medicare payments and providers' costs as a percentage of Medicare payments.

further payment reductions which would result from the proposed change in LTCH-DRG weights and the proposed change in IPPS weights effective October 1st for short-stay outlier cases.

LTCH Margins and Percentiles

			2007 Rule, with 2006 DRG Weights						2007 Rule, with 2007 DRG Weights					
Grouping	Number of Hospitals	Number of Discharges	Payment Per Case	Average Margin	Percent Negative	Percentiles 25th	50th	75th	Payment Per Case	Average Margin	Percent Negative	Percentiles 25th	50th*	75th
All Long-Term Hospitals	323	123667	$32,100	1.25%	46.7%	-6.72%	1.27%	8.95%	$31,739	0.21%	48.6%	-7.88%	0.20%	8.03%
Ownership Status														
Non-Profit	78	27372	$31,386	-1.91%	56.4%	-9.51%	-3.04%	6.97%	$31,133	-2.71%	56.4%	-10.22%	-3.67%	6.02%
Profit	235	94034	$32,355	2.83%	41.7%	-5.82%	2.67%	10.06%	$31,959	1.70%	44.3%	-6.68%	1.44%	8.36%
Public	10	2261	$30,141	-26.35%	90.0%	-32.79%	-15.99%	-4.74%	$29,908	-26.49%	90.0%	-25.79%	-17.45%	-4.77%

*We project that under the proposed rule, fifty percent (50%) of all LTCHs would have margins at or below 0.20% or essentially zero.

It is clear from the above that, under the 2007 proposed LTCH-DRG weights, LTCH industry-wide margins will approximate zero percent (0%)[4]. Our conclusions are entirely consistent with an estimate contained in MedPAC's March 2006 report to Congress that FY 2006 LTCH margins are projected to be a positive +7.8%[5]. For this same period, NALTH, with the assistance of the Lewin Group, estimated that LTCH margins for FY 2006 would be approximately 8.0%. Accordingly, we are in essential agreement with MedPAC. The FY 2007 total payment reductions of 8.7%, as detailed in the previous paragraph, are consistent with the Lewin Group's more recent analysis (set forth in the chart above) that, with the adoption of the proposed FY 2007 LTCH-DRG weights, LTCH industry-wide margins will be approximately zero. This level of payment is insufficient for hospitals to update their facilities, replace equipment and competitively attract and retain the labor necessary to provide patient care. We believe that no defensible case can be made to the contrary and that these low and unacceptable hospital margins should be one factor that points the Secretary toward establishing LTCH-DRG weights in a budget-neutral manner for FY 2007. In providing a zero percent (0%) update for FY 2007, the Secretary measured LTCH margins based on FY 2004 data which were stated to be 12.7%. *See* 71 *Fed. Reg.* 27,820 (May 12, 2006). This rationale is inapposite and does not account for the substantial payment reduction experienced by the LTCH industry since that time.

B. Adequacy of Charge-Based Weights

Charge-Based weights vs. HSRVcc LTCH-DRG Weights

CMS currently calculates LTCH-DRG weights using a Hospital-Specific Relative Value method based on charges for most LTCH Medicare cases by aggregating charges

[4] We have not accounted for further reductions which will result from a further phase-in of the 25% rule (42 C.F.R. §412.534) in FY 2007.
[5] *See* MedPAC March 2006 Report to Congress: Medicare Payment Policy, Chapter 4C-5, Table 4C-6, page 218.

for most LTCHs[6] paid under the LTCH-PPS and determining the average charge by DRG. Until this year, the Secretary used this same charge-based method of revising DRG weights for hospitals subject to the IPPS. This year, for hospitals subject to the IPPS, the Secretary has proposed to establish DRG weights on a cost and not on a charge basis by using the so-called HSRVcc methodology, since "the charge-based relative weight methodology... has introduced bias into the weights due to differential markups for ancillary services among the DRGs." 71 *Fed. Reg.* 24,007 (April 25, 2006). In the preamble to the proposed IPPS rule, the Secretary stated his own observation that a cost-based HSRVcc method of establishing DRG weights may be reasonable and accurate. While this year's initiative to establish cost-based weights for hospitals subject to the IPPS is directed at charge-related issues identified as occurring in physician-owned specialty hospitals, the Secretary has stated that, even in the absence of these concerns, he would be interested in exploring refinements to the current charge-based methodology to "improve the accuracy of the payment rates." Id. at 24,006. In light of this proposal, NALTH has determined how LTCH-DRG payments would be affected if weights were established under the same HSRVcc system which is proposed for hospitals subject to payment under IPPS. The study, which is detailed in this section of NALTH's comments, shows that the HSRVcc method of determining weights would result in a positive +1.5 percent increase in payments to LTCHs as compared to the traditional charge-based system of establishing LTCH-DRG weights, which resulted in a -1.4% reduction in payments from the 2006 weights. Otherwise stated, the HSRVcc method essentially would restore the negative -1.4% payment reduction contained in the proposed rule. NALTH is not proposing to change the method to determine LTCH-DRG weights at this time. We are presenting our analysis of HSRVcc-based weights as a basis for the conclusion that there can be reasonable differences as to what is the most accurate method to establish weights under prospective systems of reimbursement. In light of the demonstrated differences in the outcomes of the charge-based system used for LTCHs and the cost-based HSRVcc system which the Secretary has found may improve the accuracy of DRG weights, we believe it is reasonable for the Secretary to adjust LTCH-DRG weights this year on a budget-neutral basis.

To simulate the HSRVcc methodology, the Lewin Group used the methods set out and explained in the preamble to the proposed rule at 71 *Fed. Reg.* 24,006 through 24,011 (April 25, 2006). Claims data were taken from the FY 2004 MedPAR file, which includes discharges occurring between October 1, 2003 and September 30, 2004. Discharges for Medicare beneficiaries enrolled in a Medicare+Choice managed care plan were excluded from the analysis. The Medicare cost report data used in the analysis were from FY 2003. Some modifications were made in order to be consistent with the LTCH-PPS. The following steps were used to compute the LTCH-DRG relative weights, (areas where the Lewin Group deviated from the CMS methodology are identified):

1. Clean the claims data - the FY 2004 MedPAR data were edited to exclude claims for hospitals with no cost report data. Claims with total charges or total length of stay less

[6] All-inclusive rate provider LTCHs are excluded from the data used to establish LTCH-DRG weights, since these hospitals do not have a charge structure and are not represented in the MedPAR file.

than or equal to zero were eliminated. Claims that had an amount in the total charge field that differed by more or less than $10 from the sum of charges for routine days, intensive care, pharmacy, special equipment, therapy, operating room, cardiology, laboratory, radiology, and other services were deleted. Hospitals were deleted that were not included in the final LTCH-PPS Impact file. While this claims cleaning varies from the process used by CMS for the IPPS weights, the Lewin Group's observation is that this does not materially affect our results.

2. Group claims data using LTCH-DRGs –FY 2004 MedPAR file was grouped using the LTC-DRG methodology for FY 2006 because only the FY 2006 DRGs are provided on the file and these data were used to develop the FY 2006 DRG weights. The same quintile groupings were applied and assignment method for DRGs with no claims and handling of nonmonotonic LTCH-DRG pairs as defined by CMS for FY 2006. (***This process was not performed by CMS for IPPS***)

3. Remove statistical outliers - the first step in the calculation of the HSRVcc LTCH-DRG relative weights was to remove statistical outlier cases. Statistical outliers were defined as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each proposed LTC-DRG.

4. Remove cases with a length of stay of 7 days or less – consistent with the CMS method for computing LTCH-DRG relative weights, we excluded all discharges with a length of stay of 7 days or less. (***This process was not performed by CMS for IPPS***)

5. Adjust charges for the effects of short-stay outliers (SSO) – in this step in the calculation of the HSRVcc LTCH-DRG relative weights, we adjust each LTCH's charges per discharge for those remaining cases for the effects of short stay outliers. We made this adjustment by counting a short-stay outlier as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the proposed LTC-DRG for non-short-stay outlier cases. (***This adjustment is specific to the LTCH-PPS and was not performed by CMS for IPPS. Under the IPPS HSRVcc method CMS adjusts for transfer cases, which is not relevant under the LTCH-PPS***)

6. Compute HSRVs for each cost center for each discharge – charges were standardized by computing an average charge for each provider for each of 10 proposed cost centers[7]. The average charge was computed by summing the charges for each cost center and dividing by the SSO-adjusted case count for each provider. The cost center charges on each claim were divided by the provider's average charge for the matching cost center across all services. For example, the routine day charges on each individual claim were divided by the average routine day charge for the provider across all services, the intensive care unit charges on the same claim were divided by the average intensive care unit charge for the provider across all services, and so on.

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[7] See Table A – Charge Line Items from the MedPAR included in Cost center Charge Group, 71 *Fed. Reg.* 24,009

*7. **CMI adjust cost center level HSRVs*** – the cost-center level HSRVs were then multiplied by the provider's CMI. This adjustment was made by CMS. They believe that the CMI is a reasonable scale factor to use to further adjust the relative charges to reflect the complexity of cases treated by the provider. A starting CMI of 1.000 was assigned to the cost center for each provider.

*8. **Compute initial cost center level relative weights for each DRG*** – the CMI adjusted HSRVs were summed by DRG. The SSO adjusted case count for each DRG was also summed. Cost center specific relative weights for each DRG were calculated by taking the sum of the CMI-adjusted HSRVs for that DRG and dividing by the SSO-adjusted case count for that DRG. A national average HSRV for each cost center was calculated summing all CMI-adjusted HSRVs in the MedPAR dataset and dividing by the total SSO-adjusted case count. A set of cost center DRG weights were computed by dividing the national average HSRV for each DRG for each cost center by the national average HSRV for that cost center. The result was a set of 10 charge-based relative weights for each DRG. (***CMS uses transfer adjusted cases counts for IPPS instead of SSO-adjusted case counts, which are relevant only for the LTCH-PPS***)

*9. **Perform Iterative process to compute final cost center level relative weights for each DRG*** - the 10 LTC-DRG relative weights are then assigned to each claim, and a new CMI is created for each provider. Then the HSRVs for each cost center on the claim are multiplied by this new CMI and the weights are iterated until the national average CMI for each cost center stops changing between iterations. The result of this step provides a set of 10 charge-based relative weights for each DRG.

*10. **Compute CCRs from the cost reports for each of the 10 cost center groups*** – in order to remove the effects of differential markups within cost centers, we used CMS's NPRM for IPPS methodology to develop national cost center CCRs. Similar to CMS, we used the FY 2003 cost report data and removed all LTCHs that were not included in the LTCH Impact file, all Maryland hospitals, hospitals with cost reports that represented time periods of less than 1 year (365 days). We then created CCRs for each provider for each cost center group while removing any cost center CCRs that were greater than 10 or less than .01. We then took the logs of all cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 1.96 standard deviations of the log of that cost center CCR. ***Figure 1*** shows the national average CCRs.

*11. **Compute national average cost scaling factors*** - the national average CCRs were multiplied by the total unadjusted charges for the matching cost centers in the MedPAR file. The estimated costs were then summed to derive a total cost for all cases across the Nation. The percentage that each cost center was contributing to the overall total costs is calculated by dividing the individual cost center cost by the total.

Figure 1

National LTCH Geometric Mean Cost to Charge Ratios and Cost Scaling Factors

Cost Center	Geometric Mean Cost To Charge Ratio	Cost Scaling Factor
Routine Days	0.659	51.4%
Intensive Days	0.680	4.2%
Drugs Charged to Patient	0.232	12.4%
Supplies and Equipment to Patients	0.253	5.2%
Therapeutic Services	0.251	12.7%
Operating Room	0.591	1.8%
Cardiology	0.418	0.9%
Laboratory	0.323	4.8%
Radiology	0.508	2.7%
Other Services	0.550	3.8%

Source: Lewin Group analysis of FY 2003 Hospital Cost Reports and FY 2004 MedPAR data.

12. Adjust LTC-DRG relative weights to cost by applying cost scaling factors from step 10 - For each DRG, the cost center weights are multiplied by these scaling factors. For example, the routine day weight is multiplied by the routine day scaling factor; the intensive care unit weight is multiplied by the intensive care unit scaling factor, and so on. After the weights are adjusted by the scaling factor, they are summed by DRG to create one final weight for each DRG.

Impact on Medicare Payments to LTCHs

The Lewin Group has estimated that the HSRVcc relative weight method would potentially increase Medicare LTCH payments by $467 (1.5 percent) as compared to the DRG relative weights proposed by CMS for FY 2007. ***Figure 2*** shows the impact of the HSRVcc relative weights by hospital group. The winners and losers show no particular pattern aside from similar gains for voluntary and proprietary hospitals.

Figure 2

Medicare Payments per Case Using the Proposed LTC DRG Weights for 2007 Compared to Weights Computed Using the HSRVcc Methodology (Hospital Group)

Hospital Group	Hospitals	Medicare Discharges	Revenue Per Case Proposed 2007 Weights	Revenue Per Case HSRVcc Weights	Difference Proposed 2007 and HSRVcc Weights
All LTCHs	323	123,667	$31,739	$32,206	$467
Large Urban	166	75,597	$32,920	$33,287	$368
Other Urban	143	44,557	$30,263	$30,829	$566
Rural	14	3,513	$25,046	$26,391	$1,345
Before Oct 1983	15	8,126	$27,398	$28,395	$997
Oct 1983 - Sept 1993	44	22,906	$33,596	$34,066	$470
Oct 1993 - Sept 2002	204	75,014	$31,592	$31,989	$398
After Sept 2002	60	17,621	$31,954	$32,466	$512
Government	10	2,434	$28,671	$30,101	$1,430
Proprietary	233	92,437	$31,971	$32,396	$425
Unknown	11	2,813	$34,029	$34,076	$47
Voluntary	69	25,983	$30,954	$31,523	$569
Under 25 beds	29	4,802	$30,854	$31,623	$769
25-49 beds	160	41,690	$31,753	$31,992	$239
50-74 beds	55	21,667	$32,108	$32,554	$446
75-124 beds	40	20,299	$33,345	$33,813	$468
125-199 beds	25	23,649	$30,089	$31,139	$1,050
200+ beds	12	10,985	$32,070	$32,077	$7
Unknown	2	575	$29,024	$29,072	$48

Source: Lewin Group Analysis

C. The Proposed Rule does not Account for the Interrelationship Between the Annual Reduction of the Update to Reflect Improved Coding and the Perceived Decrease in LTCH-PPS Weights.

The annual LTCH-PPS update process involves an assessment of the portion of the change (increase) in Medicare payments which, in a prior year, was due to "real" increases in case mix intensity and the portion of the change in Medicare payments which resulted from improved coding practices. The latter (*i.e.*, case mix increases due to improved coding) is deemed to constitute an "apparent' but "not real" increase in case mix. Payments related to "apparent" increases in case mix are recovered in a subsequent

year. For example, in the FY 2007 LTCH-PPS rulemaking process, an observed case mix index increase from FY 2003 to FY 2004 of 6.75% was allocated so that 2.75% was deemed to be a "real" case mix change and 4% was deemed to be an "apparent" case mix change. This reduction was based upon a determination by the 3M Corporation that, prior to the initiation of the LTCH-PPS (from FY 2001 to FY 2003 when hospitals were presumed to have had no incentive to change coding practices), case mix increased at an annual rate of 2.75%. The update factor of 3.6% for FY 2007 therefore was eliminated. *See* 71 *Fed. Reg.* 27,820. (May 12, 2006). In this manner, the Secretary has reduced FY 2007 payments to make a retrospective recoupment of reimbursement related to "apparent" increases in case mix (i.e. 4.0%) which occurred in FY 2004. It is significant, with regard to the currently proposed recalibration of LTCH-DRG weights, that the Secretary also noted, in the final LTCH-PPS 2007 rule, an "apparent" increase in case mix index **"results in a case being grouped to a LTC-DRG with a higher weight..."** 71 *Fed. Reg.* 27,819-27,820 (May 12, 2006)(emphasis added). When a case is assigned to a higher weight DRG, its charges are also assigned to that higher weight LTCH-DRG. **By definition, this results in the shifting of cases with lower charges to higher weight LTCH-DRGs.** CMS is using the same rationale it used to provide a zero percent (0%) update in FY 2007 as the basis to reduce FY 2007 TLCH-DRG weights and related payment by -1.4% In this regard, the preamble to the proposed rule states that CMS has "continue[d] to observe that the average proposed LTCH-DRG relative weight decreases due to an **increase of relatively lower charge cases being assigned to LTC-DRG with higher relative weights...**" 71 *Fed. Reg.* 24,413 (April 25, 2006) (emphasis supplied). Thus, it appears there is an overlap (or double accounting) between the elimination of the standard amount for 2007 and CMS' practice of reducing LTCH-DRG weights to account for improved coding.

In connection with this matter, it is noteworthy that, in the FY 2007 LTCH-PPS update rule published on April 25, 2007, the Secretary credited LTCHs with a "real" **increase** in case mix intensity of +2.75% and a mere three weeks later, on May 12, 2007, the Secretary took the opposite position that FY 2007 payment rates should be decreased by a negative -1.4%[8] due to a decrease in case mix weights.

It is important that provider types other than LTCHs also are subject to annual assessments of the effect of coding practices on payments and recovery where appropriate. They are not, however, subject to an additional overlapping reduction due to a decrease in case weights as part of the recalibration process. Inpatient rehabilitation facilities are subject to ongoing rulemaking for FY 2007 which includes a 1.0079% budget neutrality factor in the establishment of IRF weights. The calculation of LTCH-DRG relative weights does not include a budget neutrality adjustment like the one used in

[8] We do understand that the recoupment of 3.6% in payments in the FY 2007 update rule was related to an assessment of case mix index changes related to FY 2004 and that FY 2005 data was used for the purpose of recalibrating FY 2007 LTCH-DRG weights. This mismatch of years does not detract from our observation that there appears to be an overlap in the reductions for "CMI creep" and recalibration of weights. FY 2004 data was used to recalibrate FY 2006 weights, which resulted in a negative -4.2% reduction in payments to LTCHs. FY 2004 data was used a second time to reduce the FY 2007 LTCH update to zero.

the IPPS DRG relative weight calculation method. IPPS incorporates a normalization adjustment that adjusts the DRG relative weights (after recalibration) so there is no change in total IPPS payments due to recalibration. For FY 2007, the normalization adjustment is 1.47462. Thus each DRG weight (after recalibration is done) is increased by 47 percent, which is about 1.7 percent per year since the beginning of IPPS. This adjustment allows for real case mix growth within the IPPS system.

Since the LTCH-PPS system does not include an annual budget neutrality adjustment to DRG weights, the LTCH_DRG weights in effect have been reduced every year since their inception. Thus, CMS' design of the LTCH-PPS does not allow for case mix growth.

It is important that, budget neutrality provisions in other prospective payment systems have operated as an important safeguard in accounting for "real" vs. "apparent" case mix changes. For IRFs and hospitals subject to the IPPS, statutory provisions exist requiring that weights be established in a budget neutral manner. We acknowledge that the same statutory requirement does not exist for LTCHs. Notwithstanding the absence of such a statute, **we strongly** recommend that the Secretary apply a comparable budget neutrality policy for LTCH for the establishment of LTCH-PPS weights for FY 2007. We believe the data set forth above relative to poor LTCH margins and the relationship with recoupment for improved coding, as well as secondary recoupment in the LTCH-DRG recalibration process, warrants the extension of a budget neutrality policy to LTCHs for FY 2007 payments.

II. Hospitals-within-Hospitals Grandfathered Provisions

NALTH appreciates CMS' willingness to revise the grandfathered hospital-within-hospital (HwH) rule as it has caused considerable concern for NALTH member grandfathered HwHs as discussed in this section of these comments. As an initial matter, NALTH notes its concern that the general prohibition contained in 42 C.F.R. § 412.22 (f) that a HwH with grandfathered hospital status may not change its operations and must continue to provide services under the same terms and conditions as existed, at the latest on September 30, 2003 constitutes an overly inflexible standard which should be reviewed with an eye toward prudent revision. NALTH respectively submits that it is not in the best interests of Medicare beneficiaries to retain such broad language in the grandfathered HwH rule. We are also of the view that the Secretary can and should revise the rule, in a manner which does not diminish the policy objectives which are articulated in the preamble to the rule. Grandfathered HwHs must change their operations over time to improve patient care and to offer new programs of care. It is important that CMS make reasonable changes to the rule to harmonize the best interests of Medicare beneficiaries with CMS' payment goals.

The Current Grandfathered Hospital-within-Hospital Rule

Under the current rule, to retain grandfathered status an HwH may not:

- change (increase or decrease) square footage;
- change (increase or decrease) the number of its beds; or
- change its terms and conditions of operations in any way.

CMS has interpreted the above conditions to preclude a grandfathered HwH from making any changes in square footage or bed number that affect Medicare or Medicaid[9] payments.

Proposed Revisions to Grandfathered HwH Rule

In the proposed rate year 2007 update rule for hospitals subject to the inpatient short-term acute hospital prospective payment system (IPPS), CMS has proposed the following limited revisions to the rule governing grandfathered HwHs:

- to allow for increases or decreases in square footage, or decreases only in the number of beds, due to relocation of the hospital (a) to permit construction or renovation necessary to comply with state, federal or local law affecting the physical facility, or (b) because of a catastrophic event, such as a fire, flood, earthquake, or tornado;
- to allow for decreases only in the number of beds or square footage.

NALTH agrees with the above proposals. We request that CMS clarify that if a grandfathered HwH decreases square footage or decreases the number of its beds under the above proposals it may subsequently increase its square footage or its number of beds back to the number of beds and square footage that existed effective September 30, 1995 or September 30, 2003 in the case of a grandfathered HwH that changed the terms and conditions of its operations before October 1, 2003.

CMS' Proposed Changes to the Grandfathered Hospital-within-Hospital Rule at 42 C.F.R. §412.22(f) Need to be Expanded

CMS' stated concern for establishing the HwH regulations and grandfathering rule which are discussed below do not apply to the following services or operations.

a. Outpatient Services

CMS states that its concern in establishing the HwH regulations is "that a HwH's or a satellite facility's 'configuration would result in patient admission, treatment, and discharge patterns that are guided more by attempts to maximize Medicare payments than by patient welfare.'" 71 Fed. Reg. at 24124, citing 69 Fed. Reg. 48916, p. 49191 (August 11, 2004). CMS explains that "'the unregulated linking of an IPPS hospital and a

[9] CMS' introduction of Medicaid payments as a variable in its analysis is not authorized by Section 4417(a) of the BBA and leaves grandfathered HwHs vulnerable to the unpredictable changes in state Medicaid payment policies. We request CMS to clarify that the grandfathered HwH rule does not apply to a hospital's participation in the Medicaid program.

hospital excluded from the IPPS could lead to two Medicare payments for what was essentially one episode of patient care.'" 71 Fed. Reg. at 24124, citing 69 Fed. Reg. at 49191. CMS' concerns apply to inpatient services only. None of its concerns apply to outpatient services. There is no reason for any restrictions imposed by the grandfathering rule to apply to outpatient services when outpatient services are beyond the scope of the HwH regulations, and NALTH requests clarification that grandfathered HwHs are allowed to establish and/or expand on-campus and off-campus provider-based outpatient services without risk of losing their grandfathered status.

b. Expansion of Square Footage

Subsequent to the adoption of Section 412.22(f) there has been a widely documented increase in patients with communicable and infectious diseases since 1995, including the following:

- Vanocomycin – Resistant Enterococci (VRE)
- Methicillin – Resistant Staphylococcus Aureus (MRSA)
- Clostridium Difficile (C-Difficile)

It is necessary to place these patients in private, single-bed isolation rooms for their protection as well as the protection of other hospital patients. In addition, many grandfathered HwHs treat immuno-suppressed cancer patients who require chemotherapy and radiation. Chemotherapy and radiation can each cause significant decreases in blood counts and make the patients susceptible to infection. These cancer patients need to be placed in private rooms for their own protection. In NALTH's view it would be contrary to Medicare principles designed to promote the best interests of beneficiaries not to allow grandfathered HwHs to increase square footage to accommodate the conversion of double rooms to single rooms to treat patients with infectious or communicable diseases or who require immuno-suppressed safeguards. An increase in square footage resulting from a need to create private, single bed isolation rooms for patients would not result in an increase in Medicare payments. Therefore, CMS' concerns are not applicable to these circumstances. Similarly, it is singularly in the best interests of patients to allow an expansion of square footage to permit the conversion of double rooms to single rooms to accommodate other legitimate patient centered requirements in order to, for example, provide renal dialysis services and to accommodate single sex issues related to the placement of patients in hospitals. An expansion of square footage for these reasons does not compromise CMS' policy goals.

c. Expanding Square Footage to Accommodate Ancillary Services

The proposed revisions to the rule preclude grandfathered HwHs from expanding their square footage to provide or expand ancillary services that are necessary for patient care, such as dialysis services, ventilator services, telemetry, hyperbaric services, services to improve wound care, and palliative care programs. As noted above, hospitals require larger rooms to serve dialysis patients. Virtually all grandfathered LTCHs, over time,

must change their operations, including square footage, to initiate or expand patient services and to develop new inpatient clinical programs of care to complement the current standard of care in the medical community. For example, as of September 30, 1995, some grandfathered HwHs did not have a patient demand for telemetry services, but now have patients who require these services. The full scope of services and programs offered by grandfathered HwHs need to be able to evolve to meet the clinical conditions and needs of their patients.

NALTH **strongly recommends** that CMS clarify Section 412.22(f) to affirmatively provide that the rule does not affect a grandfathered HwH's ability to add or discontinue direct patient care services in the same manner as any other hospital may do so and that the scope and amount of these services are not limited to those in service as of September 30, 1995 or September 30, 2003. In this same connection NALTH **strongly recommends**, for the reasons stated above, that CMS revise Section 412.22(f) to allow grandfathered hospitals to reconfigure existing bed capacity from double to single rooms and vice versa as needed which would include authorization to change square footage.

d. Expanding Square Footage to Accommodate Governmental Requirements

There are circumstances where grandfathered HwHs are required to increase square footage to add space in order to comply with governmental requirements of federal, state, or local law. Examples are set forth below:

1. A grandfathered HwH needs to add space for a conference room in which to discuss patient related issues with families in private and to counsel patient families in private.

2. A grandfathered HwH needs to add space so that physicians have a private area to make entries on patients' charts and to dictate notes in patients' records.

The addition of space in both examples above is needed to comply with the privacy requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the regulations promulgated thereunder. 45 C.F.R. Part 160 and Part 164, Subparts A and E.

3. A grandfathered HwH is required to convert a storage area to an exam room to meet revised state law requirements governing hospitals. The hospital now needs to add a storage room to replace the one that had to be converted to an exam room.

4. In order to comply with local law a host hospital constructs an elevator shaft which encroaches on a grandfathered hospital's leased premises. The grandfathered hospital must either expand its current space or relocate within the same hospital. In either case net square footage must increase due to space consideration issues.

Each of the examples listed above is not in any way motivated by or related to increasing a grandfathered HwH's volume of inpatients.

In the preamble to the proposed rule, CMS states that it is proposing changes that would allow for increases or decreases in square footage or decreases in the number of beds "that are needed for specific circumstances beyond the control of the facility." 71 Fed. Reg. 24125. CMS has omitted a number of specific circumstances that are beyond the control of the facility, such as those listed above. There appears to be no reasonable basis for CMS not to allow grandfathered HwHs to accommodate these space requirements. At the very least, the proposed revisions to the grandfathered HwH rule should be expanded to permit a grandfathered HwH to increase square footage or the number of its beds to comply with state, federal or local law affecting the physical facility or to accommodate a change in square footage or bed number that occurred as a result of compliance with state, federal or local law affecting the physical facility. Allowing increases under these circumstances would not implicate CMS' stated policy concerns for the grandfathered HwH rule.

e. Expanding Square Footage to Accommodate Administrative Offices or Non-Patient Care Related Activity

NALTH requests clarification that an increase in square footage to accommodate administrative offices or non-patient care related activity by a grandfathered HwH would not result in loss of grandfathered status, since such an increase would not result in an increase in Medicare payments. Examples are set forth below.

1. A grandfathered HwH needs additional administrative space for computer hardware to convert to electronic medical records and to store its electronic medical records upon conversion.

2. A grandfathered HwH needs to add space for a small conference room in which to discuss employment related issues in private with employees who otherwise share office space with other employees.

3. A grandfathered HwH needs to add space so that staff is able to take their work breaks in a private area that is not used by the public or patients.

In support of the grandfathered rule CMS states that it "did not want to allow these entities to realize additional economic advantages by expansion that would increase their Medicare payments by virtue of their grandfathered status." 71 Fed. Reg. at 24,125. An increase in square footage to accommodate administrative offices or non-patient care related activity would not result in an increase in Medicare payments. Therefore, there is no reason for CMS to impose any restrictions on a grandfathered HwH which seeks to increase its square footage to accommodate administrative offices or to accommodate non-patient care related activity.

Increase in Bed Complement

NALTH recommends that CMS allow grandfathered HwHs a modest increase in beds equivalent to the increase that Congress allowed physician owned specialty hospitals. Section 507 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 placed an 18-month moratorium on the establishment of physician owned specialty hospitals, as defined in Section 1877(h)(7) of the Social Security Act. However, existing specialty hospitals or those under development as of November 18, 2003 were exempt from this moratorium provided certain conditions were met. They were permitted to increase their total number of beds by no more than 5 beds or 50% of the number of beds in the hospital as of November 18, 2003. They also were permitted to adjust their programs of care and operations, for example, to establish isolation rooms, to increase ventilator support, or to reconfigure space for administrative and therapeutic services. This limited ability to expand hospital beds and to change programs of patient care, in the manner prescribed by Congress was reasonable, since it allowed specialty hospitals the flexibility they needed to provide medically necessary care during the moratorium. Grandfathered LTCHs should be afforded the same flexibility under the proposed revisions to the grandfathered HwH rule since so many years have passed since these LTCHs were established.

The above examples of the flexibility afforded to specialty hospitals underscore the need for CMS to address the restrictions that will remain in place by the proposed revisions to the regulation governing grandfathered HwHs. If grandfathered HwHs are not allowed to make changes to their terms and conditions of operation, as described above, then these hospitals, unlike all other hospitals, will be unable to respond to the evolving needs of their patient populations and to changes in medical practice. NALTH believes that such an application of the rule would be inconsistent with the needs and best interests of Medicare beneficiaries. The remaining restrictions imposed under the proposed rule unduly and unfairly restrict the ability of grandfathered HwHs to improve the services they provide to Medicare beneficiaries. These hospitals deserve the same management prerogatives that are available to all other hospitals to improve the inpatient and outpatient services they provide.

NALTH's Recommendations

Section 4417(a) of the Balanced Budget Act of 1997 ("BBA") by its terms was enacted to grandfather long-term care hospitals which existed on or before September 30, 1995 from the Secretary's rules regulating co-located hospitals. We believe that Congress envisioned that grandfathered hospitals would continue to operate as full service hospitals that would be able to accommodate their services, programs and facilities to provide medically necessary care. While we welcome the proposed rules we believe that further modifications of the rule as requested above are prudent, warranted and entirely consistent with Congressional objectives.

Grandfathered HwH Co-Located on the Campus of a Host Hospital Where No Services are Paid for Under the Short-Term Acute Hospital Prospective Payment System

There are some grandfathered HwHs that are not co-located on the same campus or in the same building as short-term acute hospitals subject to payment under the short-term acute hospital prospective payment system. NALTH additionally requests that where a grandfathered HwH is located in the same building or on the same campus as an Inpatient Rehabilitation Facility (IRF) or IRF unit or an Inpatient Psychiatric Facility (IPF) or IPF unit and does not admit any or admits a very small number of patients from a co-located IPPS exempt hospital or unit, that the grandfathered HwH not be subject to the restrictions imposed by the grandfathered HwH rule. We make this request because where a grandfather HwH does not in fact admit patients from a co-located hospital there is no basis whatsoever to retain the restrictions contained in Section 412.22(f) To make this point we note that a long-term care hospital which is located on a provider based campus of another hospital would be considered freestanding if the "host" hospital provided only outpatient services on that campus. CMS' policy concerns are not implicated in cases where an LTCH is not co-located with a short-term acute hospital.

There are some grandfathered HwHs that are located on a host hospital campus which is not the main campus of the host hospital. For example, one NALTH member grandfathered HwH is located on a provider-based campus of its host hospital where the only inpatient activity performed by the host hospital is through an IRF unit located in the same building as the grandfathered HwH. This past year the grandfathered HwH has admitted no patients from the IRF. In 2004 this grandfathered HwH admitted only three (3) patients or less than .009% of its total admissions from the IRF.

In the preamble to the proposed 2007 LTCH rule, in discussing the so-called twenty-five percent (25%) rule applicable to co-located HwHs, CMS indicates that it views the percentage of patients a co-located LTCH admits from its host hospital as indicative of how functionally separate the co-located LTCH is from its host hospital, with a twenty-five percent (25%) threshold being indicative of functional separateness. 71 Fed. Reg. 4697 (January 27, 2006).

> "We are concerned about these situations and in this context, we continue to believe that (*** the extent to which a facility accepts patients from outside sources can be an important indicator of its functions as a separate facility, not merely a unit of another hospital (59 FR 45391)."'

Id. at 4698. In the case of a grandfathered HwH co-located with an IRF or IRF unit or IPF or IPF unit, almost all of the LTCH's admissions would most likely be from sources other than the co-located hospital.

NALTH's Recommendation

NALTH recommends that the grandfathered HwH rule not be applicable to (1) a grandfathered HwH that admits a de minimus percentage such as ten percent (10%) or less[10] of its patients or such other percentage that CMS deems appropriate from the same campus of the host hospital on which it is located, or the same building of the host hospital in which it is located, provided that there are no other buildings on that campus in which the host hospital provides services paid for under the short-term acute hospital prospective payment system or (2) a grandfathered HwH that is co-located in the same building or on the same campus as an IRF or IRF unit or IPF or IPF unit, provided that there are no other buildings on that campus in which the host hospital provides services paid for under the short-term acute hospital prospective payment system.

The Proposed Revisions to the Grandfathered HwH Rule are Inconsistent with the Legislative Intent of Section 4417(a) of the Balanced Budget Act of 1997

It is important that CMS' revisions to the grandfathered HwH rule operate in harmony with the statute that was enacted to protect these LTCHs. Section 4417(a) of the Balanced Budget Act of 1997 ("BBA") (Section 1886(d) (1) (B) of the Social Security Act) provides that a long-term care hospital, established on or before September 30, 1995, shall continue to be classified as a long-term care hospital "notwithstanding that it is located in the same building as, or on the same campus as, another hospital." This law "grandfathered" approximately eighteen LTCHs from the HwH regulations, which first became effective October 1, 1995. The hospitals which have "grandfathered" status were exempted from the regulations because they had characteristics which would have made it difficult for them to comply, such as requirements imposed by state Certificate of Need programs, location in a rural area, common ownership and control by a unit of government, or common ownership by a health care system. These grandfathered HwHs are small, cost effective hospitals that were developed in otherwise underutilized space in the same building as, or on the campus of, existing hospitals. If they had not been grandfathered they would have been forced to engage in excessive capital expenditures and undergo corporate reorganizations in order to meet the regulatory limits imposed on purchasing services and the prohibition against common control of co-located hospitals.

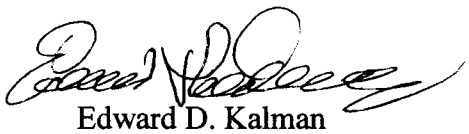
Section 4417(a) of the BBA evidences a broad legislative intention that LTCHs certified to participate in the Medicare program prior to the implementation date of the HwH regulations be grandfathered from the restrictions imposed by those regulations. The only condition to qualify for such grandfathered status is that the LTCH was certified to participate in the Medicare program on or before September 30, 1995. Thus, Congress specifically exempted grandfathered HwHs in existence on or before September 30, 1995 from restrictions imposed on co-located hospitals. NALTH submits that Congress'

[10] NALTH suggests ten percent (10%) or less to reflect a de minimus percentage which is more stringent than the twenty-five percent (25%) rule.

express decision to exempt these LTCHs from the hospital-within-hospital rules should not form a basis for the Secretary to severely restrict the scope of their programs and operations through the grandfathered HwH rule. The grandfathered rule and the proposed revisions to that rule are inconsistent with the statutory provision of Section 4417(a) of the BBA, to the extent they subject grandfathered HwHs to loss of their grandfathered status and disqualification from Medicare and Medicaid participation if they add beds or increase square footage for reasons related to patient care or operations.

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

Sincerely,



Edward D. Kalman
General Counsel

setting and offers the only possibility of a complete and durable response in patients affected by these otherwise fatal cancer disease states. Novartis' goal is to ensure that patients have meaningful access to effective therapies in the context of adequate and appropriate reimbursement to providers. We believe

Rainer Boehm, MD
Senior Vice President &
North American Region Head

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NOVARTIS ONCOLOGY

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June 7, 2006

BY HAND DELIVERY

Mark B. McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 433-G Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: **Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal year 2007 Rates, Notice of Proposed Rulemaking – CMS-1488-P**

Dear Dr. McClellan:

On behalf of Novartis Pharmaceuticals Corporation (Novartis), I appreciate this opportunity to comment on the Centers for Medicare & Medicaid ("CMS's") proposed rule on revisions to the Hospital Inpatient Prospective Payment System (IPPS) for fiscal year 2007 (FY2007), published in the *Federal Register* on April 25, 2006. Novartis is part of the Novartis Group of Companies, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. Of particular relevance to this rulemaking, Novartis manufactures and markets high-dose interleukin-2 (HDIL-2) under the brand name Proleukin®[1]. Proleukin® is approved for the treatment of metastatic renal cell cancer and metastatic melanoma. HD-IL2 therapy is generally delivered in the inpatient setting and offers the only possibility of a complete and durable response in patients affected by these otherwise fatal cancer disease states. Novartis' goal is to ensure that patients have meaningful access to effective therapies in the context of adequate and appropriate reimbursement to providers. We believe that this goal would be adversely affected for patients requiring HD-IL2 therapy if the CSA-DRG system is implemented as proposed. We support CMS's effort to better reflect disease severity in assigning DRGs; however, the proposed CSA-DRG system does not provide adequate reimbursement for medical conditions where the patient's admission status is relatively good but the course of treatment is very complex and resource intensive as is the case with metastatic renal cell cancer and metastatic melanoma treated with HD-IL2. Hospitals providing HD-IL2 in the treatment of the above cancers would face a reduction of approximately 58% if the proposed CSA-DRG system were implemented. We urge CMS not to implement the CSA-DRG system as proposed in either 2007 or 2008 given that it does not take into account the situation where a resource intensive treatment such as HD-IL2 is administered to treat an otherwise fatal condition but where the patient's ambulatory status is relatively good. Instead, we ask CMS to make certain any new classification system take into account the situation described

[1] Novartis acquired Proleukin® as part of its acquisition of Chiron Corporation in April 2006.

immediately above involving the administration of HD-IL2 therapy and allow for procedure code 00.15 to map to a DRG with an appropriate reimbursement. The agency did this in 2003 and doing so again would be an effective way to ensure that hospitals receive adequate reimbursement for HD-IL2 therapy and patients maintain access to this treatment. Our reasons behind this concern are detailed below along with a background of HD-IL2 therapy and previous CMS DRG coding changes with this therapy.

Background of High-Dose IL-2 Therapy and previous coding changes:

High-dose IL-2 therapy was approved by the FDA in 1992 and remains the only therapeutic possibility for a complete and durable response in patients with metastatic renal cell carcinoma and metastatic melanoma. Metastatic renal cell carcinoma and metastatic melanoma occur relatively infrequently, and only a small proportion of patients insured by Medicare are eligible to receive this intensive treatment. In 2004 there were only 559 Medicare claims for HD-IL2 therapy.

It is important to note that as an immunotherapy, high-dose IL-2 therapy differs from conventional chemotherapy in the resources required to administer it. Unlike conventional chemotherapy which is given to patients either on an outpatient basis or through a series of short (i.e. one to three days) inpatient stays, HD-IL2 is a much more intensive intervention that requires administration in an intensive care unit or equivalent setting over five to six days. In addition, HD-IL2 must be given according to a precisely defined protocol, with round-the-clock nursing support available in order to guard patients against certain expected and well-understood adverse events (e.g., metabolic acidosis, acute renal failure, cardiac arrhythmias, respiratory distress syndrome, thrombocytopenia, hyperthyroidism, and psychosis).

Previous Medicare coding changes regarding HD-IL2 therapy:

In 2002 and 2003, the Chiron Corporation, leading medical centers, and the Kidney Foundation worked closely with CMS to address issues related to the coding and reimbursement of HD-IL2. Before October 2003, there was no specific DRG or ICD-9 procedural code assigned to HD-IL2 patient admissions; as a result hospitals received an IPPS reimbursement rate far below the true hospital costs. These stakeholders requested a DRG re-classification based on the resource intensive nature of HD-IL2 in the clinical setting which would make this life saving treatment more available to patients.

In the FY2004 final rule (CMS-1470-F), CMS issued the procedure code 00.15 for high-dose interleukin-2 and re-classified DRG 492 to include high dose interleukin-2 admissions. CMS determined that DRG 492 appropriately reflected the resource intensity of this therapy. Adopting the proposed CSA-DRG payment system would, once again, make administration of high-dose IL-2 financially unfeasible for many medical centers and would deny access to this important therapy.

Summary of Issue

Under the current DRG system, high-dose interleukin-2 (procedure code 00.15) is reimbursed under DRG 492. In the proposed CSA-DRG system, DRG 492 does not exist. Novartis performed an analysis of the 2004 MedPAR files to: 1) determine to which CSA-DRGs claims with procedure code 00.15 would map: and, 2) estimate the impact that the proposed system would have on high-dose IL-2 reimbursement.

In the 2004 MedPAR files, there were 559 Medicare claims with procedure code 00.15. In the proposed CSA-DRG system, 48% of these 559 claims would map to CSA-DRG 736 (Chemotherapy SOI 2) and 28% would map to CSA-DRG 737 (Chemotherapy SOI 3). The proposed weights for these two CSA-DRGs are 0.9771 and 2.5486, respectively. Thus the payment (using the current national standardized amounts) for 00.15 in CSA-DRG 736 would be $8,804 which would be a **58% reduction in payment** when compared to the proposed FY 2007 relative weight for DRG 492 of 3.6663.

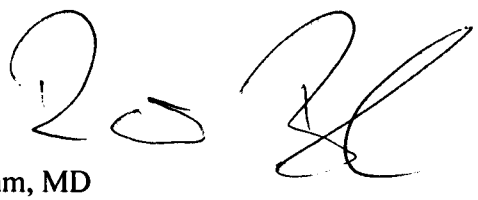
On average, the actual hospital cost of administering high-dose IL-2 is between $20,000 to $25,000 per admission. The base payment rate for DRG 492 in FY2007 is $17,876. An analysis of the actual CMS payment to hospitals billing for 00.15 was approximately $23,000 in 2004 after the base rate was adjusted for hospital-specific factors. A 58% reduction in payments to hospitals administering this therapy would be financially devastating and could lead to the closure of high-dose IL-2 programs, thus denying patients access to this important, life-saving treatment. Under the proposed CSA-DRG system, the "severity of illness" (SOI) is based on the patient's status at admission. In order for a patient to receive high dose IL-2, the patient must have a performance status of 0 to 1 (i.e. ambulatory and in relatively good health). Therefore, it is highly unlikely that a patient admitted for Proleukin would receive an SOI of greater than 2-3. High-dose IL-2 is an intensive medical treatment for cancer and often causes severe side-effects that can be life-threatening. Patients are generally well managed through these side effects, but hospital resources expended are often complex and go far beyond the typical resources used with usual chemotherapy.

Under the current DRG system, high-dose IL-2 therapy (procedure code 00.15) rather than the primary diagnosis code (V58.1) triggers assignment to the DRG. Under the proposed system, the diagnosis at admission triggers DRG assignment , which would not take into account the significant resources required to administer this intensive therapy.

In summary, we urge CMS not to implement the CSA-DRG system as proposed in either 2007 or 2008 given that it does not take into account the situation where a resource intensive treatment such as HD-IL2 is administered to treat an otherwise fatal condition but where the patient's ambulatory status is relatively good. CMS should once again recognize the unique clinical demands and resources involved with administering HD-IL2 and implement an appropriate mechanism to ensure that hospitals are not burdened financially moving forward and that patient access is preserved. Allowing certain procedure codes to map to a DRG with an appropriate reimbursement (as is the current situation with DRG 492 and procedure code 00.15) would be an effective way to ensure hospital receive adequate reimbursement for HD-IL2 therapy.

If you have any questions or require clarification on our concerns, do not hesitate to contact me.

Sincerely,



Rainer Boehm, MD
Sr. Vice President and North American Head
Novartis Oncology

cc: Marc Hartstein
Tom Gustafson
Liz Richter

Spinal Surgery
ASSOCIATES PLC

228

May 31, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: St. Francis Medical – X Stop
P.O. Box 8011
Balitmore, MD 21244-1850

Dear Sir/Madam:

The X Stop treatment for spinal stenosis offers significant benefit to Medicare patients. In the past few months, I've done 7 patients successfully – perhaps 2/3 of the cases were elderly on Medicare. In my orthopedic practice, I have focused primarily on non-surgical conservative treatment, including pain management treatment, physical therapy, NSAIDs, and narcotics. I do not generally refer patients to laminectomy. Perhaps half of my caseload could benefit from X Stop, in my opinion.

Clinically, ¾ of my patients have done well post-treatment. The most dramatic improvement is in leg pain, which tends to dissipate after the procedure. Patients who had difficulty walking prior to X Stop now can walk independently (minus cane), with no leg or back pain. One of my patients had such cramping pain in his legs that he was forced to discontinue hiking, one of his favorite pastimes. Now, he reports being able to walk for one mile pain free, and his pain was gone immediately post-surgery.

For patients of advanced age or with comorbid conditions, like asthma, X Stop offers the advantage or relatively short time in the operating room under local anesthesia.

In my view, X Stop is the safest and most effective treatment option for LSS, a common condition that is becoming a significant health problem with the aging of the U.S. population.

Sincerely,

William Sukovich, M.D.
Spinal Surgery Associates

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ST. ELIZABETH MEDICAL CENTER
Sponsored by The Sisters of St. Francis
2209 Genesee Street • Utica, New York 13501-5999
(315) 798-8100

May 24, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
4/25/2006 Federal Register Pages 23995-24550

Dear Sir or Madam:

I am a member of the Board of Trustees of St. Elizabeth Medical Center. St. Elizabeth is a 201 bed acute care general community hospital located in Utica, New York. It is one of two hospital systems that serve the greater Utica, New York area of Oneida County, New York. Approximately 30% of our admissions and our revenue come to us through our cardiac surgery, angioplasty and catheterization program - the program that will be hurt most by the proposed changes to the CMS regulations on DRG weights.

Management advises that the proposed changes to the Medicare DRGs will threaten the premier service that is provided by St. Elizabeth to our community, the cardiac program. Over ten years ago, after significant community support from the medical, hospital, political and business communities and the general public, the community received New York State approval for a cardiac surgery program that would include angioplasty services. Since this was a community effort, both community hospital systems in the Utica area began collaboration through Mohawk Valley Heart Institute, Inc. to provide cardiac services in a "hospital without walls" concept. 2007 reimbursement reductions proposed by CMS will negatively impact both hospital systems if implemented. It is not likely that CMS's intent is to punish our community hospitals' successful cardiac program that has had exceptional patient outcomes in the community where the majority of our patients reside and which supports many other programs offered by St. Elizabeth. CMS is encouraged to exempt community hospitals such as St. Elizabeth from the onerous impact of the DRG weight reductions. St. Elizabeth has been able to use its cardiac program to support other necessary medical programs in the community like the Area Trauma program and to serve the poor and uninsured.

Management advises that there are technical flaws in the calculation of the cost variances used to determine the proposed reimbursement levels. Most significantly is the use of the 2003 cost reporting period which does not reflect the over 700% increase in costs experienced with the introduction of drug eluting stents in the second half of 2003. Use of a more comparable cost reporting period to 2007 would mean that reimbursement reductions will likely be less onerous when comparing true costs.

We hope that the CMS reimbursement proposals set out in the draft regulations can be eliminated. If they cannot be eliminated, we request that they be at least phased in over a longer period of time so that management can implement changes to our operation to more reasonably anticipate the changes in reimbursement.

Another effect of implementation of the reduced DRG reimbursement to St. Elizabeth will be that St. Elizabeth must look to other payors to fill the void created by Medicare's reductions. This will mean that the commercial payors that we use to provide health insurance to our employees will need to increase their

premium rates to Utica area businesses to cover the increased cost. This shifts the costs of the health dollar away from Medicare and on to the businesses that employ the patients being seen by St. Elizabeth. This effect should not be minimized to the long term financial health of our community and to the State.

We respectfully request that CMS withdraw its proposed DRG payment changes for 2007, but if it is not possible to withdraw those changes, that they be phased in over an extended period of time.

Thank you for your consideration.

Very truly yours,

Steven Williams, M.D.
Trustee

Enclosure – 2 copies of letter
cc: Congressman Sherwood Boehlert
Senator Charles Schumer
Senator Hilary Clinton
Board of Trustees of St. Elizabeth Medical Center

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ST. ELIZABETH MEDICAL CENTER
Sponsored by The Sisters of St. Francis
2209 Genesee Street • Utica, New York 13501-5999
(315) 798-8100

June 5, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
4/25/2006 Federal Register Pages 23995-24550

Dear Sir or Madam:

I am a member of the administrative team at St. Elizabeth Medical Center. St. Elizabeth is a 201 bed acute care general community hospital located in Utica, New York that is sponsored by the Sisters of St. Francis of the Neumann Communities. It is one of two hospital systems that serve the greater Utica New York area of Oneida County, New York. Over 64% of our patients are Medicare and Medicaid patients. Approximately 30% of our admissions and our revenue come to us through our cardiac surgery, angioplasty, electrophysiology and catheterization program - the program that will be hurt most by the proposed changes to the CMS regulations on DRG weights.

I request that the CMS proposed regulations that change the DRGs not be implemented as proposed and that CMS consider other alternatives to address its goals.

St. Elizabeth has a one hundred and forty year history of caring for everyone regardless of ability to pay. To this end, our Medicare and Medicaid patient volumes are, as a percentage of services provided, higher than the majority of hospitals in our region. The $3.8 million reduction in Medicare payments as proposed, coupled with the over $300,000 reductions to proposed by President Bush to Medicare, and New York State's $920,000 Medicaid reductions and trend factor freeze, have the effect of making it difficult to recruit and retain staff in a very competitive compensation environment.

Over the last few years, we have worked very hard to work more efficiently. St. Elizabeth has the highest patient severity case mix adjustment and among the lowest gross length of stay statistics of all the hospitals in the Central New York region. This is a tribute to our fine employees and the dedicated care that they provide to our patients. The reimbursement reductions that St. Elizabeth will receive if the regulations are amended as proposed will make it difficult for the Medical Center to maintain its compensation programs at competitive levels; stifle the staff development and improvement programs that are currently offered; and reduce investments in patient care services and equipment that the Medical

Center has been able to make historically. We believe that our community deserves the best possible care and access to the most effective technology that is available to treat the high demand patients that St. Elizabeth has become known to treat.

As we have reviewed the CMS amendments and how those amendments were computed, we identified a number of concerns and inequities. The most significant issue appears to St. Elizabeth in the use of the 2003 cost reporting period. Using the cost reporting period starting in January 1, 2004 would be more representative of the type of cost being incurred by St. Elizabeth for the 2007 fiscal year. For example, in 2003, before drug-eluting stents were available, the cost per stent at St. Elizabeth was $400. In 2004, when drug-eluting stents were available, the cost per stent at St. Elizabeth was $2,900. With the advent of drug-eluting stents, almost all stents implanted are drug-eluting. St. Elizabeth uses on average, 2 to 3 stents per patient which means that since January 1, 2004, the average cost per patient went from $1,200 per patient to $8,700 per patient. This is an increase in excess of 700%.

Use of this new technology has been the major reason why cardiac surgical procedures and repeat angioplasty procedures have gone down. This has increased the life expectancy of cardiac patients and minimized the invasive surgical procedures that cardiac patients have historically experienced. The cost of the angioplasty and drug-eluting stent surgical procedure costs far less than the cost of a more invasive Coronary Artery Bypass Graph procedure. Additionally, the patient recovery time is faster, increasing patient satisfaction, decreasing mortality, decreasing morbidity and extending life expectancy. In short, the procedures that will see the greatest reductions in Medicare reimbursement, are more efficient and cost effective from a pure dollars and quality of life perspective than the alternatives.

Commentators on the proposed regulations have indicated that the CMS revisions are being driven to some extent by recommendations made by MedPAC. MedPAC's recommendations were being driven by:

1. concerns that specialty hospitals are taking too much profit out of the Medicare program while other services are not being paid at adequate levels;
2. the need to move the reimbursement system away from charge based payments and toward cost based payments; and
3. the need to refine severity adjustments to the payment system.

<u>Specialty Hospitals/Limited Service Hospitals</u>

Although St. Elizabeth has a high percentage of cases that are brought about by the reductions, St. Elizabeth should not be confused as being a specialty/limited service hospital. St. Elizabeth is an acute care, general, community hospital. The margin that is realized through the efficient use of St. Elizabeth's facilities and the hard work of our employees are plowed back into the community's hospital services, some for the benefit of the Medicare population, some for the Medicaid population and the balance for the commercially insured and the uninsured populations. St. Elizabeth's status as a community hospital means that it

provides a full range of services and operates for the benefit of the entire community on a 24/7 basis.

St. Elizabeth Medical Center is an Area Trauma Center. As such it receives more complex cases and a wider variety of cases than specialty or limited use hospitals and most community hospitals. The changes to the regulations as proposed will severely limit St. Elizabeth's ability to address this population at reimbursement levels that are fair and equitable and at levels that will support this needed service in the Community. St. Elizabeth is the only Area Trauma Center between Albany, New York and Syracuse, New York, a distance of approximately 150 miles.

If CMS's intention was to address the specialty or limited service hospitals' use of margin to benefit their physician owners, address it. Do not cast the net unnecessarily wide to encircle community hospitals. We recommend that CMS include in its regulations some hold harmless provision that will provide community hospitals from the unintended consequence of the reductions that are focused more on specialty or limited service hospitals.

Movement Away from Charge Based Reimbursement

It is our understanding that the proposed regulations adopt a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. The change is drastic in that it changes the entire emphasis and understanding of what severity means, as it relates to treatment of patients and reimbursement for patient care.

We understand that there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights. When the drug-eluting stent was approved by the FDA, St. Elizabeth updated its charge master to reflect the significant increase in stent cost from $400 per uncoated stent to $2,900 per drug-eluting stent. We believe that a significant percentage of hospitals nationally did not do this. There is not a significant margin being earned by the hospitals, but rather an exaggerated margin shown on paper because charge masters were not updated to reflect changes in actual costs.

The effect of these reductions will mean that hospitals cannot afford to provide the services to those that need it, but rather will need to limit or ration the service to only the most critical patients. The availability of services will be limited due to cost, since adequate facilities will not be able to be built and maintained to supply the demand. Rationing of healthcare services has not been, to date, a goal of the Medicare program and is not consistent with the mission of St. Elizabeth.

Severity Adjustments to DRGs

Reviewing of the severity adjustments to DRGs is a good thing, but when those are reviewed, appropriate weight and consideration should be provided to severity issues. Over the last few years, St. Elizabeth Medical Center has become very efficient. Its unadjusted case mix length of stay is 5.4 days which is among the lowest in the Central New York region; its occupancy rate of 89.2% which is the highest in that same region; and its case mix is in excess of 2 which is among the highest in Central New York. These impressive statistics are a testament to the hard work that our 1900 employees provide to the sickest patients in our community. Our clinical staff is on the front line in caring for those patients with multiple morbidities and care that treats higher severity conditions. If the changes is inevitable, postponing or phasing the DRG changes to address the addition of the 300+ new DRGs would appear to be a better approach rather than doing part now and part later.

Technical Points

The changes that CMS is proposing are significant. There is significant precedent to have changes of much less significance be phased in over a 5 to 10 year time frame. This will allow current programs to properly plan and develop modifications so that when the change is ultimately implemented, appropriate community planning could have occurred. Community planning can take a number of forms from collaboration to consolidation, among many others. Allowing time for the community to plan will ensure that the medical and surgical services that are being provided are appropriate to meet the community need.

Shifting of the reductions in DRG payments of 903 hospitals to 2,619 hospitals nationally is inequitable and discriminates against those 903 hospitals who must pay for the benefit being received by the 2,619. In New York State the problem is greater in that 30 hospitals will have their reimbursements reduced while 149 hospitals will see their reimbursements increased. Both in New York State and nationally, the very large reduction in payments on a hospital by hospital basis is spread very thinly over the large number of hospitals that will see increased payments under the proposed regulation.

Summary

The payment methodology changes that CMS has proposed would have a severe financial impact on St. Elizabeth, our employees and our community – without accurate data to justify the change. In addition to requiring the potential dismantling of this infrastructure, St. Elizabeth would face the uncertainty of what other changes will be proposed by CMS that will put St. Elizabeth in further financial jeopardy. Access issues will develop as a result of this shift. Finally, use of the 2003 cost report does not ensure an accurate reflection of cost to be used on a going forward basis.

We respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity-adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments. We ask that you reconsider the changes to the regulations

and if elimination of the changes cannot occur, that CMS consider a gradual phase in of the effect of the regulations on hospitals such as St. Elizabeth – acute care general community hospitals.

Thank you for your consideration.

Very truly yours,

Louis Aiello
Vice President, Finance

Enclosure – 2 copies of letter
cc: Congressman Sherwood Boehlert
Senator Charles Schumer
Senator Hilary Clinton
Board of Trustees of St. Elizabeth Medical Center

231-O
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CEDARS-SINAI HEALTH SYSTEM

June 7, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Attention: CMS–1488–P
P.O. Box 8011
Baltimore, MD 21244–1850

Attention: **CMS-1488—P "Resident Time in Patient Activities"**

Dear Administrator McClellan:

Cedars-Sinai Health System welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006).

We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care". The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school.

Furthermore, what is discussed in the didactic session is essential to improving quality patient care and following identified best care practices. Didactics help insure patient care that has been identified by national core measures is carried out to the highest degree.

The proposed rule position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures...and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins].

We support the Agency's 1999 position. The activities cited are an integral and vital component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs, as well as clinical benefits to their patients.

Sincerely,

Thomas M. Priselac
President and CEO

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ORTHOPEDIC
SPECIALISTS

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CMS
Dept of Health & Human Services
ATTN: CMS-1488-P
PO Box 8011
Baltimore, MD 21244-1850

To Whom it may concern,

I am writing this letter in support of a new devise for lumbar stenosis that I use in my practice made by St. Francis Medical Technologies called the X-stop IPD. It is useful because in patients that have failed the appropriate conservative care, it offers a minimally invasive technique that may replace the need for traditional laminectomy in the appropriately selected patient. The procedure can be performed under local anesthetic, which is useful in patients who are high risk for general anesthesia.

I have had anecdotal experience with three patients and have been very happy with the results thus far. Again this does not solve the problem of stenosis all together, but provides an excellent bridge between conservative care and laminectomy or fusion.

Thank you for your time and attention,

N M Patel 6/16/06

Nilesh M Patel, MD

JELSMA AND NAZAR ASSOCIATES
ADULT NEUROSURGERY

Richard K. Jelsma, M.D., FACS
Gregory B. Nazar, M.D., FACS,FRCS
Diplomats of the American Board of Neurological Surgery

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May 15, 2006

CMS
Dept of Health & Human Services
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear CMS,

I am currently a practicing neurosurgeon in Louisville, Kentucky, who has had the opportunity to become exposed to the X STOP Technology offered by St. Francis Medical Technologies. I have reviewed the FDA data as well as I have personally implanted the X STOP procedure on one of my patients with excellent results. The patient had dramatic relief of her bilateral leg pain related to neurogenic claudication from her spinal stenosis. The implantation avoided the patient from having a more invasive surgical procedure and she is very pleased with the results. Currently, I have 3 additional patients who would benefit from the operation. However, I am having trouble obtaining approval for the surgery. The problems of approval pertain not to their insurance but rather to the hospitals that are concerned about the cost of the new technology itself and related reimbursements. This now appears to be the major stumbling block from allowing these patients to benefit from the intervention. There also is no question in my mind that there is an important niche of patients that do benefit from this procedure and for the majority of patients this avoids the need for more aggressive surgical intervention with its associated complications. It does improve the lifestyle of these patients when they are properly selected and when the guidelines for recommended implantation are followed. I would also strongly endorse CMS to do everything possible to allow this procedure to become available for these patients.

Main Office:
410 Audubon Medical Plaza
Louisville KY 40217
Phone: (502) 636-2667
Toll Free: (877) 585-2667
Fax: (502) 636-2668

Bardstown Office:
300 West John Finch, Suite 100
Bardstown KY 40004
Phone: (502) 348-3512
Fax: (502) 348-9075

Baptist Hospital Northeast
1025 Sanibel Way, Suite E
LaGrange KY 40031
Phone: (502) 222-3884
Fax: (502) 222-3453

Please don't hesitate to call should you have any questions or concerns (502) 636-4208.

As always,

Best personal regards,

Gregory B. Nazar, M.D., FACS, FRCS
GBN/jqa
P.S.: I am a private practice neurosurgeon and have no interest or relationship to either X STOP or St. Francis Medical Technologies. My primary purpose of this endorsement is to allow this procedure to become available to my patients.

cc: St. Francis Medical Technologies
CMS Comments
960 Atlantic Avenue
Ste 102
Alameda, CA 94501

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MOUNTAIN STATES
HEALTH ALLIANCE

June 12, 2006

Center for Medicare & Medicaid Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS-1488-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and fiscal year 2007 Rates; Proposed Rule

Dear Sirs:

Mountain States Health Alliance (MSHA), on behalf of our six member hospitals, appreciates the opportunity to submit comments to the Center for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) proposed rule.

The rule proposes the most significant changes in the calculation of diagnostic-related group (DRG) relative weights since 1983 through the creation of a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc). It also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008 or sooner. In addition to these sweeping changes, the rule would update the payment rates, outlier threshold, hospital wage index, quality reporting requirements, and payments for medical education, among other policies.

While MSHA supports many of the rule's provisions, we have serious concerns about the proposed changes to the DRG weights and classifications. More time is needed to understand the significant proposed policy changes, which national organizations estimate will redistribute from $1.4 to $1.7 billion within the inpatient system. In addition to needing the additional time to understand the system, time is also needed in order to fully update and educate internal staff members, Medical Records personnel and physicians on the documentation ramifications and changes necessary to ensure that all diagnoses, procedures and conditions are properly captured to enable accurate DRG

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classification reporting resulting in the continued uninterrupted equitable reimbursement for our member facilities. Given the potential significance on provider operations of applying the new occupational mix adjustment to 100% of the wage index for the first time in FY 2007, providers will need additional time to ascertain, isolate and adjust to that impact alone without the complicating factor of any DRG weight & classification changes added to the mix.

Analysis from national organizations shows the impact of the proposed changes to be highly unstable, with small changes in methodology creating large changes in provider

payments. The validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification is highly uncertain. Moving forward requires thoughtful change with due consideration of the various alternatives available.

Specifically, MSHA supports the following:

- **A One-year Delay:** MSHA supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology.

- **Valid Cost-based Weights:** MSHA supports moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS'proposed HSRVcc method is flawed in many ways.

- **A New Classification System Only if the Need Can Be Demonstrated:** MSHA does not support a new classification system at this time, as the need for a new system is still unclear. Any new system should continue to recognize the provider resources expended in treating any given patient classification. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system is selected or advanced.

- **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and to smooth the volatility created by these two, generally off-setting changes.

- **Three or Four-year Transition:** Any changes should be implemented with an optional three or four-year transition, given the magnitude of payment redistribution across DRGs and providers.

We have enclosed additional detailed comments below that further explain our concerns and recommendations on the proposed DRG weight and classification system changes. MSHA appreciates the opportunity to submit these comments. If you have any questions about our remarks, please feel free to contact me at (423) 431-1017 or eichornmh@msha.com.

Sincerely,

Marvin Eichorn
Senior Vice President/CFO
Mountain States Health Alliance

DRG Reclassifications

In response to payment recommendations from the Medical Payment Advisory Commission (MedPac), CMS proposed the biggest changes to the calculation of DRG relative weights since the creation of the IPPS. These changes would significantly redistribute payments among the DRGs and among hospitals. Specifically, CMS proposes the use of hospital-specific relative values (HSRVs) and a modified version of cost-based weights (rather than charge-based) in fiscal year (FY) 2007. CMS also proposes an alternative patient classification system called consolidated severity adjusted DRGs (CS-DRGs), with implementation likely in FY 2008 (or sooner). **MSHA supports meaningful improvements to Medicare's IPPS and the move to cost-based weights but we believe CMS' proposed method is seriously flawed. Therefore a one year delay is needed to validate CMS corrections and for providers to understand and gauge their potential impact on our finances and operations. Trying to implement this radical change with a shorter time frame at the same time that providers are adjusting to the impact of the occupational mix adjustment being applied to 100% of their wage indices is too much to expect hospitals to adjust to at once.**

HSRVcc Method Concerns

1. **Errors:** While analyzing CMS' proposed rule, national organizations such as the American Hospital Association (AHA) uncovered a series of data errors, inconsistencies across databases and questionable methodological choices. Further analyses to investigate these questions showed that small changes in method lead to large changes in DRG weights, signaling that the proposed changes are highly volatile and unstable.

    - CMS inadvertently included organ acquisition costs in the data used to set weights for DRGs. This error has a material effect on the resulting weight calculation for transplants.
    - CMS was inconsistent in its treatment of certain categories of hospitals between their calculation of the FY 2007 HSRVcc weights and the proposed CS-DRG weights, making it hard to directly compare the results. For example, hospitals in Maryland were included in the FY 2007 MedPar data used for the HSRVcc weight calculation and excluded from the CS-DRG calculation.
    - It is unclear whether the weights published for CS-DRGs included a transfer adjustment.
    - Data cleaning steps used were not always consistent with standard CMS practices (e.g., removal of cases with 0 charges, low volume DRGs, etc.). The mere fact that data cleaning was necessary for these identified

issues also gives rise to the legitimate concern that other non-identified anomalies may in fact also exist in the data.

- The cleaning steps applied to the cost report data were not consistent with the cleaning steps applied to the MedPar claims data, which resulted in different hospitals being included in data sets used for the calculation of the weights and the calculation of the scalers to the weights.

2. **Trimming:** CMS trimmed the cost center CCRs at 1.96 standard deviations from the geometric mean. This skews the CCRs by systematically removing the hospitals with high routine charge mark-ups from the calculation. It also creates a mismatch between the CCRs used and the charges they are applied to, as the hospitals that are trimmed out of the CCRs are still included in the charges that are then reduced to costs and thus determine the cost shares.

3. **Weighting:** CMS also hospital-weighted rather than charge-weighted the calculation of the CCRs which in turn are used to calculate the scaling factors used to convert the charge-based relative weights to "cost". There are several issues associated with this approach:

    - This approach gives equal weighting to each hospital in the national CCR calculation even though hospitals can range in size from fewer than 25 to more than 1,000 beds.
    - This method is inconsistent with the method of averaging used to develop the cost center-specific DRG weights to which the scaling factors are applied. CMS calculated hospital-specific DRG relative weights, but then used a case-weighted average to develop the national value.
    - This hospital-weighted approach results in a 1% to 54% difference versus a charge-weighted approach in the resulting scaling factors used for the conversion to cost.

    The above errors in the calculations over-weight CMS' routine cost shares and under-weight the ancillary cost shares, thus creating erroneously large swings in DRG weights and thus hospital payments as well. CMS' method for weighting and trimming has been estimated by national organizations to redistribute $1.4 billion dollars among hospitals nationally. Charge-weighting the CCRs and trimming them at three standard deviations would reduce this shift to $900 million – a reduction of **half a billion dollars.** This highlights the need for more work to validate each methodological step to understand how it affects payment and to ensure it adds to accuracy.

4. **Failure to Calculate Costs at the Claim Level:** CMS chose to use charges to initially calculate the relative weights at the DRG level and then a national scaler to make the conversion to "cost-based" weights. The national scaler converts the 10 cost center charge-based weights to one national weight using the actual share of costs across departments. CMS maintains that this adjusts for differential mark-ups across hospital departments; however, no validation of this methodological shortcut was provided.

5. **Validation:** As mentioned above, CMS provided no analysis to validate that the proposed changes result in better payment policy. While measuring improved payment accuracy is difficult, the large degree to which the weights fluctuate given methodological changes alone strongly indicates the need for further analysis. CMS should construct a process to test the sensitivity of weights to various methodology assumptions and publicly share the results, including:

    - Compare CMS weights to MedPac's HSRV-cost approach;
    - Compare CMS weights to those developed using standardized costs (as opposed to HSRV);
    - Compare CMS weights to weights calculated by estimating costs at the claims level using the 10 cost center approach;
    - Evaluate alternative methodologies for estimating costs;
    - Compare the stability of weights over time; and
    - Determine whether payment policy is improved.

DRGs: Severity of Illness

MSHA believes that the need for and best approach to changing the patient classification system has not been concretely and objectively demonstrated. More careful analysis is needed, along with **greater access to the specifics of CMS' methodology and the new GROUPER.**

CS-DRG Method Concerns

1. **Lack of Recognition for Resources Expended in Treating Patients:** By CMS' own admission, there is often not a direct correlation between the resources expended by hospitals to effectively treat patients and the severity of illness of the patient. Any new system should continue to take these resources into account.

2. **Validation:** CMS provided no analysis that shows that the proposed changes result in an improved hospital payment system compared to the existing DRG system or APR-DRGs.

3. **Budget Neutrality Adjustment:** CMS suggests in the proposed rule that it would reduce payments to hospitals by instituting a budget neutrality adjustment to offset the fact that case mix may increase because of improved documentation and coding rather than actual changes in acuity. **The DRG IPPS was developed in part to encourage these practices and furthermore the need for such an adjustment has thus far not been demonstrated or quantified. CMS also did not propose an adjustment or even a methodology for determining an adjustment. CMS often initiates such adjustments based on assumptions which are never checked or corrected. An added concern is presented by the data shown in Table L of the proposed rule for one of our large (over 400 beds) teaching facilities. This facility is expected to take a large hit due to both characteristics and to pile on a reduction for budget neutrality amounts to a one-two knockout punch which could have extreme negative operational ramifications for the entire organization. MSHA recommends that CMS hold off on such an adjustment until there is evidence that one is needed and that it could be equitably administered.**

4. **Lack of Availability of the GROUPER:** Without access to the new GROUPER and its' logic, it is virtually impossible for hospitals to thoroughly analyze the system and comment, nor will we providers have any understanding of how and why patients fall into certain CS-DRGs and thus we will not be able to evaluate whether it represents a policy improvement. **We urge CMS to make any new classification system widely available to the public and exclude proprietary logic or software from consideration.**

5. **Too Few Diagnoses and Procedures Considered:** We are concerned that CMS' GROUPER does not use all diagnoses and procedures that affect a patient's severity of illness and/or the resources utilized. **We recommend that the GROUPER consider all diagnoses and procedures.**

Outlier Payments

The rule proposes establishing a fixed-loss cost outlier threshold equal to the inpatient PPS rate for the DRG, including indirect medical education (IME), disproportionate share hospital (DSH), and new technology payments, plus $25,530. While this is not a particularly sizable increase from the FY 2006 payment threshold of $23,600, we remain very concerned that the threshold is too high. According to industry analyses, **actual outlier payments for**

FY 2006 are currently estimated to be 0.47 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments. CMS spent only 3.8 percent or $1.15 billion less than set aside in FY 2005, and only 3.5 percent, or $1.3 billion less than the funds withheld in 2004.

In the rule, CMS proposes to use a one-year average annual rate-of-change in charges per case from the last quarter of 2004, in combination with the first quarter of 2005, to the last quarter of 2005, in combination with the first quarter of 2006, to establish an average rate of increase in charges. This results in a 7.57 percent rate of change over one year, or 15.15 percent over two years.

The American Hospital Association (AHA) has proposed a methodology that incorporates both cost and charge inflation which should make the threshold calculation more accurate and reliable than the use of charge inflation alone. The estimated fixed-loss amount that would result in 5.1 percent outlier payments under this proposed methodology is $24,000. If CMS leaves the threshold at $25,530, rather than dropping it to $24,000, we believe that CMS will again significantly under spend by over $300 million. This is a real cut in payments to hospitals which cannot be recouped even though they were funded by the very providers whose payments would be cut.

Occupational Mix Adjustment

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 requires CMS to 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.

CMS initially stated in the proposed rule that it would again limit the occupational mix adjustment to 10 percent because of concerns regarding the validity of the data and the potential financial impact on hospitals. However, as a result of the decision handed down by the U.S. Court of Appeals for the Second Circuit on April 3 in *Bellevue Hospital Center v. Leavitt*, CMS on May 12 released a proposed rule revising the occupational mix adjustment portion of the FY 2007 inpatient PPS proposed rule. Under the court ruling, CMS must collect new data on the occupational mix of hospital employees and fully adjust the area wage index (AWI) for FY 2007.

Hospitals are required to collect the hours and wages for employees from January 1 through June 30, 2006. Data initially was supposed to be collected by

July 31; however, hospitals are required to submit data by June 1 for the first calendar quarter of the year and by August 31 for the second calendar quarter. Data from the first quarter will be used to adjust the FY 2007 AWI, while data for the full six months will be used to adjust the AWI for FYs 2008 and 2009.

Non-responsive Hospitals. Because data from all hospitals is needed to construct an accurate national average hourly wage, full participation is critical. There is a general sentiment that hospitals that do not participate should not benefit from the participation of others. However, given the rushed collection and general confusion around the interim-collection, we believe that, to the extent possible, **CMS should substitute data from the previous survey for hospitals that did not turn in their data for the first calendar quarter of 2006.**

However, hospitals will have plenty of notice and time to submit data for the second calendar quarter in August. Thus, moving forward CMS should consider a methodology that does not reward hospitals that do not participate. We caution CMS not to simply substitute unfavorable data for these hospitals, as it also will impact other area hospitals that conscientiously reported data. CMS could alternatively substitute the national average hourly wage for non-responsive hospitals in calculating an area's wage index, and then require hospitals that did not turn in data to use something lower than their area's wage index. This would avoid CMS having to create an extensive hospital-specific wage index table and would minimize the effects on the other hospitals in the area. **We urge CMS to construct an application of the occupational mix adjustment that encourages hospitals to report but does not penalize neighboring hospitals.**

Corrections. **We urge CMS to allow hospitals to turn in both calendar quarters of data in August whether for the first time or with corrections.** Again, as this collection has been rushed, the idea is to allow hospitals to improve the data for the FYs 2008 and 2009 adjustment. For hospitals that were previously non-responsive, the submission of the first calendar quarter would remove any penalty.

Comment Timeframe. While we understand that CMS is under severe time pressure due to the timing of the court's decision, we do not believe that the 30-day comment period was sufficient, as hospitals were busy during this time trying to meet the new survey deadline and answering requests for information from the FIs. In addition, we believe it would be appropriate for CMS to take comments on the calculation after the initial results of the survey are tabulated and posted. The results of the survey could be material. **Thus, we urge CMS to publish the occupational mix adjustment changes as an interim-final rule in August with an associated comment period.**

AKIN GUMP
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June 8, 2006

BY HAND DELIVERY

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Attention: CMS – 1488 – P

Re: Comments on April 25, 2006 Notice of Proposed Rulemaking: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
GME: PRA for Merged Hospitals

Dear Administrator McClellan:

We appreciate this opportunity to submit comments on the graduate medical education ("GME") payment provisions of the Centers for Medicare & Medicaid Services' ("CMS's") April 25, 2006 Notice of Proposed Rulemaking, which was published at 71 Fed. Reg. 23,996. We are greatly concerned about the effects of this proposal on our hospital clients and look forward to your response to these comments.

CMS has proposed to establish a new methodology for the determination of Medicare GME payments when hospitals merge. Specifically, it would require the PRAs of merging hospitals to be averaged on an FTE-weighted basis based on the PRAs and FTEs in the merging hospitals' most recently settled Medicare cost reporting periods. CMS describes the proposed method as being based on administrative convenience because the 1984 base year records are over 20 years old and are often no longer accessible.

Significantly, CMS also describes its policy regarding the treatment of mergers prior to the effective date of the new rules. CMS states that Medicare policy has always been to blend the base year PRAs when hospitals merge, weighted by the 1984 FTE count of residents and interns. In that regard, after acknowledging that "the [Medicare Act] does not address how to treat the PRA(s) of teaching hospitals that subsequently merge," CMS cites its November 8, 1990 Questions and Answers on Medicare GME Payments as the sole authority for this assertion.

We respectfully request that CMS reconsider and correct this misstatement of historical Medicare policy. Although this methodology may have often been used for determining the PRA after merger, we understand that the Medicare Program has used a number of different methodologies based upon the facts and circumstances in specific mergers. In light of information supplied by the former Medicare official who authored the 1990 GME Questions and Answers, discussions with a former official from one of Medicare's principal fiscal intermediaries, and the reported inconsistent treatment of other hospital mergers in fiscal periods after the base year PRAs were initially established, we believe that in reality the intermediaries have followed a variety of approaches to the establishment of PRAs in hospital mergers sometimes after consultation with CMS. The Medicare program has applied varying methodologies in years after the initial base period PRAs were established. If CMS were to survey its hospital intermediaries to ascertain their historical treatment of PRAs in mergers, it would recognize that a variety of approaches have been applied in the past based on the providers' facts and circumstances. It would be helpful if the results of a comprehensive survey in this regard could be included in the CMS response to these comments.

CMS's historical GME rules did not provide for the blending of the established PRAs in cases of mergers weighted by either the 1984 FTE counts or more recent FTE counts. Instead, CMS unambiguously prescribed that the base period PRAs, once established and final, would not be changed, except for the annual inflation updates (and certain other factors not at issue), regardless of any post base year operational changes. See, e.g., 54 Fed. Reg. 40,286, 40,302 (Sept. 29, 1989). Therefore, under the current rules, CMS may not even have the authority to do anything but carry forward the PRA assigned to the surviving provider number when hospitals merge.

Moreover, the 1990 GME Questions and Answers are not good evidence of the posited consistent, historical PRA blending policy because they were issued to apply to the *original* determinations of the base period PRAs, and not to redeterminations of PRAs in later years. Once the base period PRAs were established and became final, they were not subject to redetermination because of later operational changes, such as mergers. Additionally, those Questions and Answers were not adopted pursuant to notice and comment rulemaking procedures, and are at odds with the plain language of the rules, which carry forward the original PRAs from year to year.

Both the new payment and the supposed historical methodologies for blending PRAs in mergers would be undesirable if applied to every hospital merger. CMS should instead adopt a rule authorizing it to determine whichever PRAs would be most accurate in light of the merging hospitals' facts and circumstances, such as the expected combined or separate operations of their facilities and programs. In cases where one party to a hospital merger is dominant, the other

hospitals are being acquired by it, and they are being reengineered and restructured to conform their operations to the dominant hospital's operations, the Medicare program should carry forward the survivor's PRAs, as the current rules contemplate.

For instance, this would be especially important in cases where one of the merging hospitals is a children's hospital with a significantly inaccurate PRA. Otherwise, the resulting GME reimbursements would be plainly erroneous for the surviving entity. As CMS knows, numerous problems occurred in establishing the 1984 base period PRAs. Most teaching hospitals had to pursue costly and lengthy appeals to obtain reasonably accurate PRAs. This is especially true with New York State teaching hospitals due to the different Medicare reporting requirements applicable to the 1984 base period under the statewide demonstration project in place at that time. Moreover, children's hospitals often did not fully pursue these appeals because their interest in Medicare GME policy and payments in 1984 was typically insignificant due to exceptionally low Medicare utilizations. CMS's proposed methodology would lead to inaccurate and potentially devastatingly low GME payments when acute care hospitals merge with children's hospitals and, for that reason alone, we respectfully request that CMS should consider revising its methodology to reflect these types of situations and prevent the continuation of inaccurate GME payments to providers.

We also believe that CMS's policy concern in formulating the proposed blending methodology is misplaced. Beyond the foregoing absence of records from 20 years ago, CMS states that this approach is desirable because it minimizes the role Medicare GME payments would have in the choice of the surviving entity in a merger. Nonetheless, reimbursement planning is invariably one factor when providers consider changes of ownership and will plainly remain so under the proposal. The proposal does not really affect planning options because providers in acquisitions of other providers always have the choice of continuing the operations of acquired hospitals in their separate corporations (and separate provider numbers), instead of merging the corporate structures, if they wish not to blend the acquired hospitals' weighted PRAs. Since this planning aspect is unavoidable, CMS should not adopt a less accurate, mandatory "one size fits all" approach to hospital mergers, regardless of the providers' facts and circumstances.

CMS should promulgate a policy that would give it the latitude to handle the calculation of PRAs after mergers in light of the best available data on the merging hospitals and their post-merger operations. This could involve, among other methodologies, the adoption of the dominant and surviving provider's PRA or a blending of PRAs that utilizes a weighted average that takes into account the Medicare utilization of each merging provider.

Finally, whatever methodology CMS adopts, it seems clear that this new policy should be codified in the Medicare rules. Otherwise, it will be difficult for providers who consult the rules to ascertain the actual Medicare policies in this area. Placing these new policies only in the historical rulemaking notices without any reference in the codified rules would make them needlessly obscure and undoubtedly mislead providers and intermediaries in the future.

Once again, thank you for your consideration of our comments on this proposed rulemaking. We look forward to CMS's guidance and response on this important issue.

Sincerely,

John R. Jacob
David B. Palmer

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June 8, 2006

Comment on FY2007 Proposed Rule for Hospital Inpatient Prospective Payment System

DRGs: Severity of Illness

Adjusting the current DRG system for severity of illness involves a certain amount of conflict between meeting the needs of payers (who strive for appropriate reimbursement aligned with costs) and providers (who likewise desire proper payment while receiving fair characterization of their clinical outcomes through recognition of the true severity of their patient population). Hospital charge data, though traditionally used as a proxy for acuity, does not always parallel severity of illness.

For example, extremely ill patients readily fall within cost extremes. Severity within this patient group may be so high that they do not survive long enough to accrue a significant cost of care; while others linger on through protracted hospital stays and generate enormous financial burdens. Yet the pervasive DRG case-mix index has been widely used to both justify clinical outcomes and reimburse hospitals. This dilemma will always require compromise when indices of case assignment are derived from a single classification methodology.

Ideally, weighted case values tied to reimbursement should be purely derived from financially valid cost-utilization data; and weighted case values representing disease severity should be the product of clinically valid morbidity-mortality data. The APR-DRG system attempts to reconcile these two disparate goals by adjusting the resource-based case weight into three additional severity-based weights. The extent to which it meets the demands of both payers and providers is only now emerging in the state of Maryland and has not yet been reported for widespread analysis and review. The proposed consolidation of certain APR-DRGs only diminishes the severity stratification in favor of eliminating marginal reimbursement differences. Combining two or more severity levels is apparently justified on the bases of insignificant differences in cost without recognition of prevailing differences in severity for the affected DRG subpopulations. This appears to be a loss for the provider's severity adjusted design target and a win for the payer's goal of budget neutrality.

The APR Black Box
It is the inherent complexity of both systems, essentially APR-DRG in nature, that renders the process of DRG assignment only practical through utilization of software available solely from one source--the government contracted entity, 3M Health Information Systems.

Aware of the incredibly obscure and obtuse methodology employed by the APR-DRG system and the voluminous tables required to describe its operation, it appears doubtful that no single issue of the Federal Register would ever be capable of publishing it for hospital use. The APR-DRG system is essentially a black box. Even the CMS modification that "consolidates" a number of severity levels and reduces the total number of DRGs to maintain a three-digit designation admittedly does not dare tamper with the proprietary 18-step severity of illness subclassing process buried within 3M's system.

Expanding Severity
CMS for FY 2006 introduced an initial effort to address severity within the existing DRG system by allocating 12 cardiac DRGs for recognition of system-specific CCs identified as Major Cardio-vascular diagnoses. This is a natural and intuitive approach that can be applied similarly to the

remaining MDCs. Rather than use a generalized collection of CCs across all MDCs, system-specific CCs should be identified for each MDC which can be demonstrated to correlate well with both cost and severity-mortality data for a given DRG within each MDC.

Isolating Severity
There needs to be a separation of severity on admission from severity after admission. The current system makes no such distinction within the recognized list of CCs and consequently provides for the potential of rewarding complications in addition to appreciating comorbidities. While the principal diagnosis, critical to the assignment of both MDC and DRG, must be present on admission, no such requirement is imposed on CCs. In the era of hospital performance and quality initiatives, it is alarming to find post-admission and post-operative complications contributing to increased reimbursement--a positive incentive for a negative outcome.

Separating severity levels from relative weights does address both quality and financial concerns by removing the distortion imposed by each factor on the other. Relative weights should be determined primarily by the principal diagnosis and surgical procedure. System specific comorbidities present on admission should contribute to a composite level of severity for each case based on a tiered set of increasingly high-risk diagnoses such as present in the APR-DRG system. The severity level may then secondarily modify the relative weight. This would produce two reportable values for each case: a relative weight for reimbursement and a severity weight for comparative clinical outcomes performance and quality measurements.

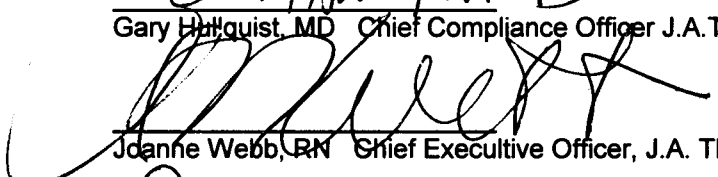
Conclusions

- Whatever severity-modified system is adopted by CMS, the data elements (code-DRG associations) should be released to all providers consistent with past policy.
- CMS should provide public dissemination of the Maryland APR-DRG trial results.
- CMS should provide the health care industry with the list of the other companies they consulted in the analysis of the APR-DRG system beside 3M Health Information Systems.
- We recommend that CMS not change the DRG system (consolidated, APR or otherwise) for FY2007 because of the insufficient time for preparing to make such extensive changes.

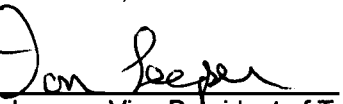
When it does modify the existing system or adopt a new one, CMS should consider the following recommendations:

- each DRG should be provided with separate values for both cost-utilization and severity-outcome parameters
- system-specific comorbidities present on admission should be identified for each MDC which correlate well with both cost and severity data.

Gary Hullquist, MD Chief Compliance Officer J.A.Thomas and Associates, Inc, Smyrna, Georgia



Joanne Webb, RN Chief Executive Officer, J.A. Thomas and Associates, Inc.



Don Leeper, Vice President of Technology/Physician Services, J.A. Thomas and Associates, Inc.

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Aurora Sinai Medical Center

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June 9, 2006

Mark McClellan M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. McClellan,

Aurora Sinai Medical Center wishes to comment on the April 25th Federal Register entitled, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.

In particular, Aurora Sinai Medical Center would like to comment on the changing of the DRG weight calculation from a charge based to a cost based system, removal of offsite non patient care time for Indirect Medical Education reimbursement, the movement to severity adjusted DRG's, the expansion of number of quality measures to report on, and non payment for infections not present at the time of admission.

DRG Reclassification

Aurora Sinai Medical Center takes issue in the re-weighting of the Medicare inpatient DRG's based upon costs rather than billed charges. Our main issues are as follows:

- Not all hospitals have the same cost to charge ratios. In fact, in order to remain competitive, many urban facilities do not mark up expensive surgical supplies such as drug eluding stents and pacemakers, very much at all to keep managed care companies from not authorizing a potentially life saving surgery. These supplies in the CMS calculation are marked up based upon overall department markup, which may not reflect actual supply mark-up.
- Two hundred sixty very large hospitals representing twenty five percent of the total charges were excluded from the cost center cost to charge ratio calculation. However, these hospitals were not exempt from the effects of the DRG weight change, even though the data from their hospital(s) were not included in the calculation of the DRG weights. Large hospitals offer cutting edge technology services such as Cardiology, and Neurosurgery. Excluding these hospitals from the cost to charge ratio calculation does not give an accurate national cost to charge ratio for modeling purposes.
- Hospitals do not consistently group costs in the same manner on the Medicare cost report. This will lead to cost to charge ratio inaccuracies for the calculation of the DRG payments.
- The cost to charge ratio data used in the calculation is based upon cost report information from 2003. Current technology such as drug-eluding stents, and bi-ventricular pacemakers were in its infancy in 2003, and does not accurately reflect the utilization of these services, as it exists today. This leads to inaccuracies in the way these DRG's are proposed to be reimbursed by CMS compared to the actual costs the Hospital incurs for the inpatient stay.

- Cardiology related services will be hit unusually hard in this proposal. As a result of these changes the proposed DRG's for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24%, and pacemakers reduced 12 to 14%. Drug eluding stents cost $3,000 a piece. The average number of stents per patient is 1.65. Cost for drug eluding stents per patient is $4,950. With the average reimbursement for DRG 558 being $7,200, this leaves $2,250 to cover the surgery, all of the other supplies, drugs, and the patient stay of two days. This will not even cover the direct costs much less the overhead it takes to run a hospital. The payment shortfall will have a devastating impact for Cardiology programs across the country, and will potentially cause access problems due to programs not being able to recover the cost of the leading edge technology. This is clearly not the intent of what CMS wanted to do.

With DRG's being a payment system of gains on some DRG's and losses on others, recalculation of the DRG weights based upon costs, will cause a lot more losers than gainers. This could cause hospitals not to invest in expensive life saving treatments due to lack of adequate payment, and therefore inhibit potentially life saving patient care.

Due to the drastic financial effect this has on hospitals, at a minimum this change should be delayed for one year, or be phased in over a four year period of time to allow hospitals to adjust to the new payment.

DRG's: Severity of Illness

Aurora Sinai Medical Center supports CMS's concept of paying claims more accurately by having severity payment levels within each DRG. However, there needs to be a lot more work done before severity DRG's can be implemented.

- More time is needed before implementation for coding staff training.
- The Severity of illness DRG grouper needs to be released to the public so other information system vendors can perform the necessary programming for medical records and business office software systems. Having 3M maintain control of the grouper software limits access by other software vendors to begin reprogramming of the many of computer systems that needs to have the severity adjusted grouper software and are not compatible with the 3M grouper. This needs to happen well before implementation so hospitals can test their systems, and study the impact on their facilities.
- The new version of the UB-92 needs to be released, so the additional ICD-9 codes beyond nine can be accepted by claims processing system. Without this change hospital providers may not get paid accurately under the severity adjusted system.
- ICD-10 codes need to be implemented in order to obtain an accurate patient diagnosis.
- The effect the severity adjusted payment system has on outliers needs to be studied more closely to make the sure payment is accurate for the resources consumed by the patient.

CMS also needs to take the additional time to implement this so their systems operate smoothly and not create accounts receivable problems for the hospitals.

Hospital Quality Data

Aurora Sinai Medical Center supports CMS's effort to expand the number of quality measures hospitals report on in order to receive the full market basket payment increase. However, more time is needed in order for hospitals to implement the expansion. With the final notice not coming out until the beginning of August, and the quarterly data that CMS wants providers to report the expanded data is due on August 15th. That is not enough time for providers to implement the change. Many hospitals

use external vendors to compile and submit the data to CMS. Vendors need adequate time to deal with the programming changes necessary to implement the revised quality measures after the regulation is final. Software testing at the hospital needs to be completed to make sure the data is complete and accurate. Aurora Sinai Medical Center proposes delaying this provision for at least six months to allow for a smooth implementation.

Value Based Purchasing

Aurora Sinai Medical Center is opposed to CMS's recommendation to not pay additional payments for infections acquired while the patient is in the hospital. Hospitals, most of the time, have no control over what the patient complications arise when they are in the hospital. Many visitors who may come to the hospital have drug resistant staph infections, and not even realize it. This can be passed along to the patient quite easily.

Hospital's infection control departments have measures in place to prevent infections as much as they can. However, they cannot possibly control all of the infections all of the time. Hospital's still need to be paid adequately for taking care of the patient, especially the complex hard to treat patient with acquired infections.

FTE Resident Count and Documentation

Aurora Sinai Medical Center remains opposed to CMS's interpretation of Public Law 105-33 requiring only patient care time spent be allowed in the FTE count calculation when the Intern or Resident is training outside of the Hospital.

Interns and residents, in order to obtain proper training must spend significant non-patient care time out of the hospital. Time spent at external seminars, reviewing clinic patient charts, researching patient symptoms for related diseases, virtual learning (practice suturing etc.) and documentation coordination with the physician in their clinic, are just of the few of very important functions the Intern or Resident spends doing activities outside of the hospital. These are very essential roles for the education of future

Residents are bound to train for a maximum of 80 hours per week, so wherever the resident may have down time, they spend their time on these non - direct patient care functions. Without these functions, the training programs cannot exist.

CMS has made a commitment to fund Graduate Medical Education programs. Without adequate funding by CMS for these programs, many programs will not be able to survive and forced to shut down.

Aurora Sinai Medical Center would like to thank CMS for the opportunity to submit our comments on this very important proposed regulation. Should you have any questions, please feel free to call Steve Kowske at 414-647-3429.

Sincerely,

Kevin Jones
Director of Finance

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(2)

BOCA RATON COMMUNITY HOSPITAL

June 7, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Inpatient Prospective Payment Systems and FY 2007 Rates regarding "Geographic Reclassifications – Urban Group Hospital Reclassifications" (File Code CMS-1488-P)

Dear Sir or Madam:

The purpose of this letter is to comment on the FFY 2007 proposed Inpatient Prospective Payment System (IPPS) regulation regarding geographic wage index reclassifications and urban group hospital reclassifications.

Boca Raton Community Hospital is a 394 bed not-for- profit hospital located in Palm Beach County Florida. Approximately 60 percent of our patient population consists of Medicare beneficiaries and adequate Medicare reimbursement is critical to our continuing ability to meet their needs.

In 2004, when the FFY 2005 proposed IPPS regulation regarding geographic wage index reclassifications and urban group hospital reclassifications was published, Palm Beach County hospitals had, for the first time, qualified for the opportunity to reclassify for wage index purposes. Palm Beach County hospitals qualified in part because the FFY 2005 proposed rule allowed Metropolitan Divisions within a CBSA to qualify for an urban group reclassification. Based on the FFY 2005 proposed regulation, we joined with all other Palm Beach County hospitals and applied for the urban group reclassification. However, the final FFY 2005 IPPS regulation revised the proposed criteria and eliminated the ability for Metropolitan Divisions within a CBSA to qualify for an urban group reclassification.

We subsequently learned, however, from CMS through the FFY 2007 IPPS proposed regulation that the intent of the urban group reclassification was, and is, "to allow hospitals located in counties that are in the same CBSA (in the case of Metropolitan Divisions) as the area to which they seek redesignation to be considered to have met the proximity requirement We agree with CMS on the point above and agree with CMS on the following two points; that "the proximity standard for group reclassifications is intended to allow all of a county's hospitals to reclassify to an adjacent area where there is sufficient economic integrations that there can be an expectation that both areas are competing in a similar labor market area," and that "we believe there is sufficient economic integration between Metropolitan Divisions within a CBSA that urban county reclassifications within a CBSA or a CSA should be permitted."

We thank CMS for recognizing the economic integration between Metropolitan Divisions within a CBSA and request that CMS, at a minimum, adopt the FFY 2007 IPPS proposed urban group reclassification eligibility criteria [Sec. 412.234(a)(3)] as proposed, without modification.

However, we do believe, based on the CMS comments quoted above from the FFY 2007 IPPS proposed regulation, that the hospitals of Palm Beach County should have been allowed to qualify for an urban group reclassification beginning in FFY 2006 had the final FFY 2005 IPPS regulations correctly recognized the economic integration between Metropolitan Divisions within a CBSA (as CMS had done in the FFY 2005 proposed regulation and now again recognizes in the FFY 2007 proposed regulation).

Therefore, we respectfully request that CMS, in the final FFY 2007 IPPS regulation, make the FY 2007 proximity criteria effective for urban group reclassifications beginning on October 1, 2006 (as opposed to October 1, 2007) if the urban area:

- Filed an application for urban group reclassification by September 1, 2004 for reclassification beginning on October 1, 2005;
- Met all of the non–proximity urban group reclassification criteria published in the FFY 2005 final regulation;
- Had the application denied only because the urban area did not meet the flawed FFY 2005 proximity criteria;
- Would have had the application approved had the FFY 2007 proposed proximity criterion been the criterion in the FFY 2005 final regulation;
- Meets the proximity and non-proximity criteria described in the FFY 2007 IPPS proposed regulation; and
- Files an application for urban group reclassification by September 1, 2006.

Based on the aforementioned information we request that CMS incorporate the proposed revision, as written above, in the FFY 2007 final IPPS regulation. We believe the requested revision is critical to the financial stability of the hospitals located in the West Palm Beach Metropolitan Division and should take effect, for payment purposes, for all hospitals in the West Palm Beach Metropolitan Division beginning October 1, 2006 rather than delaying until October 1, 2007. If granted this revision will allow the urban group reclassification to take effect one year sooner than otherwise currently proposed, though a year later than the date which we would have otherwise qualified (October 1, 2005) had the final FFY 2005 regulation properly recognized the intent of the economic integration criteria.

We appreciate your consideration of this comment to the FFY 2007 proposed IPPS regulation.

Respectfully,

Kenneth Meinke

Kenneth J. Meinke, CPA
Vice President and Chief Financial Officer

2390
(7

SISTERS OF CHRISTIAN CHARITY
MALLINCKRODT CONVENT
350 BERNARDSVILLE ROAD
MENDHAM, NJ 07945
May 25, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Comments to Proposed Changes to the Hospital IPPS and FY 2007 Rates
Published in the Federal Register on April 25, 2006, regarding:

Geographic Reclassifications –
- Requested Reclassification for Hospitals Located in a Single Hospital MSA Surrounded by Rural Counties

Dear CMS:

The following comments are submitted in support of The Williamsport Hospital & Medical Center relating to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications."

I am a member of the leadership team of sponsoring congregation for Susquehanna Healthy System, which is an affiliate of The Williamsport Hospital & Medical Center. This hospital serves our patients and community very well and very efficiently. They provide many critical services performed by health care workers that are not easy to attract and retain. The ER Department is particularly busy and important to our community, especially when our community hosts the Little League World Series every year.

We offer as many if not more services than our competitors yet they are paid more for their labor costs under the Medicare Program. This is not fair. I think the Medicare Program needs to "level the playing field" otherwise The Williamsport Hospital & Medical Center will not be able to attract and retain the healthcare workers that are so important to our patients - especially the elderly, representing 50% of our inpatients.

Please approve this rule that would allow for more equitable treatment compared to the others hospitals with which we compete. Thank you.

Sincerely,
Sister Joseph Spring, S.C.C.
Sister Joseph Spring, SCC
Provincial Councilor

Transformed by a Eucharistic lifestyle,
we are impelled to give and receive Christ's love, joy, peace and healing for the life of the world.
SCC Mission Statement

CARDIOTHORACIC SURGERY GROUP, S.C.

240

Husam H. Balkhy, M.D. ✧ *Jerold B. Brenowitz, M.D.* ✧ *Robert P. McManus, M.D.*

Christopher D. Stone, M.D. ✧ *Michael Swank, M.D.* ✧ *Curtis C. Quinn, M.D.*

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

CMS -1488 – P

Subject: "New Technology" Add-On payments for New Services and Technologies – C-Port® Distal Anastomosis System

Request for a new technology add-on payment for the C-Port® Distal Anastomotic System

The C-Port® System represents an advance in technology that potentially improves treatment options for Medicare beneficiaries. It can be used in arteries as small as 1mm, which can be difficult for surgeons to sew by hand. The System is a unique and novel means of creating a mechanical, automated, and interrupted bypass anastomosis through a 1mm incision in the target artery. Its use in creating a distal coronary anastomosis does not have clinical precedence and may mitigate some of the negative factors influencing vein graft patency with a hand-sewn anastomosis. Additionally, the C-Port® system potentially improves patient outcomes and procedural reliability by facilitating the creation of a reproducible and compliant, interrupted mechanical anastomosis. There is no other fully-integrated anastomotic system cleared by the FDA for creation of an anastomosis between a blood vessel graft and a target coronary artery.

The System is new and unique from other technologies currently available on the market. The System was recently approved by the FDA on November 10, 2005, meeting the threshold of new defined as being under two to three years old. CMS provided feedback that the C-Port® System was potentially not considered new, as they felt it was similar to staples currently on the market. It is the first and only new technology for the automated creation of a distal coronary anastomosis. Additionally, the performance of the automated mechanical anastomosis procedures comprises additional new steps and preparation in the bypass procedure; both the physician and the OR staff must be trained and proctored to use the equipment, and additional education is required to ensure proper patient selection and outcomes.

St. Mary's Hospital–Seton Tower, 2315 N. Lake Drive–Suite #703, Milwaukee, WI 53211 Phone: (414) 271-5119 Fax: (414) 271-3756
St. Joseph's Hospital–Professional Building, 3070 N. 51st St.–Suite #307, Milwaukee, WI 53210 Phone: (414) 873-7768 Fax: (414) 874-1977
United Hospital System–Professional Building, 6308 8th Ave.–Suite #3040, Kenosha, WI 53143 Phone: (262) 656-2328 Fax: (262) 653-5778

It is clear from the current trend aggressive percutaneous interventions for coronary artery disease has led to later and more urgent referrals for coronary bypass. This results in an older and higher-risk group of patients being operated on. The surgical options for these patients can be limited and the availability of a mechanized reproducible approach for coronary anastomoses would potentially improve outcomes in this very sick group of patients.

I have been using the C-port distal anastomotic device regularly since its FDA approval in Nov 2005, with excellent results. More and more surgeons are getting trained on the use of the device and will be able to offer its benefits to their patients.

Given the excellent patency data seen in clinical trials with the C-port distal anastomotic device I feel that more and more patients should benefit from its use, based on their surgeon's preference and discretion. I strongly recommend that CMS allow surgeons the latitude to make these kinds of operative decisions in the best interest of our patients. In its Proposed Rule CMS recommends an approximate 6% cut in bypass procedures in an attempt to redistribute Medicare payments. This proposed cut, combined with increased resource consumption associated with treating more severely ill bypass Medicare patients, will in itself dramatically limit surgeon's access to needed new bypass technologies. Congress established a process of ensuring adequate payment for new products such as the C-Port® System. For all the reasons listed above, I ask CMS to approve the C-Port® System for a new technology add-on payment for FY2007.

Sincerely,

Husam Balkhy M.D.

241

June 5, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: X Stop interspinous process decompression
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir/Madam:

I am one of the inventors of the X Stop, and I was the principal investigator in the pivotal trial. I strongly urge Medicare to approve the hospital payment add-on for the X Stop, which obviates needless suffering and risk to this patient population. I feel it is a superior treatment and it is as safe as non-surgical treatment alternatives.

In my orthopedic surgery practice, I see about 50 new spinal stenosis patients monthly, two-thirds of whom are Medicare patients. I typically identify about half of these patients who would be appropriate candidates for surgery which consists of laminectomies with or without fusion, or the Xstop., I would estimate that about three-quarters of these patients are candidates for the X Stop procedure.

Clinically, I have found that spinal stenosis responds to activity management and body mechanics. When patients develop disabling pain, it typically manifests during walking or standing, which are optional activities for many older adults. They usually have no symptoms if they remain "bent over" enough or sitting. However, patients who cannot walk or stand are unable to carry out their activities of daily living and often become obese, depressed, and severely out of shape and sickly. This " Burden of the Disease" forces many into major surgery. They often must stop working or take frequent sick days, suffer from insomnia and loss of self-esteem, and cannot continue recreational even low level activities. The interspinous process decompression procedure is the most powerful surgical tool available to provide minimal risk relief of these disabling symptoms and restoring them to acceptable function, and avoiding dangerous, expensive operations that take months to heal.

The X Stop is not a simple procedure, but it is a safe and reliable one for the properly selected patients. It is a great advantage to the patient, the surgeon, and the health care system. It does not preclude any other treatment options, because the spinal anatomy remains intact. So, in the unusual patient who does not respond as well as expected, other options continue to be available.

In my medical center, I've implanted about 150 X Stop devices since 1997, and only four needed to be revised – an outcome that speaks for itself. Certainly, the benefits to patients are far better than for any other spinal procedure we have. Most patients are back to functioning in 1-3 weeks.

Additionally there many highly debilitated patients who cannot tolerate surgical correction with general anesthesia that can safely undergo this procedure without increased risk to life and limb. I am available to answer any questions you may have; please do not hesitate to contact me.

Sincerely,

James F. Zucherman, M.D.

MUNSON MEDICAL CENTER

242-0
(3)

June 6, 2006

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1488-P Medicare Program: Changes to the Inpatient Prospective Payment System and 2006 Rates – April 25, 2006 Federal Register

Dear Dr, McClellan,

As a practicing cardiovascular surgeon at Munson Medical Center in Traverse City, MI, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on Munson's ability to serve patients in our community. Munson Medical Center is a sole community hospital and a rural referral center providing cardiovascular services to over 24 counties in northwest Michigan's lower peninsula. These proposed reductions will likely impact both hospital staffing and product availability for critical procedures which will ultimately be translated into reduced patient access and care.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were "thrown out" of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to "charge compression." The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient's illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

1105 Sixth Street
Traverse City, Michigan
49684-2386
(231) 935-5000
munsonhealthcare.org

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,

R. Glade Smith, M.D.

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Traverse City, Michigan
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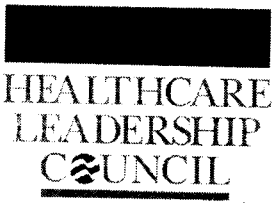
(231) 935-5000
munsonhealthcare.org



June 12, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of the Healthcare Leadership Council (HLC), I am pleased to have the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Fiscal Year 2007 Medicare Inpatient Prospective Payment System (IPPS).

HLC members, the chief executives from all disciplines within the health care system, are committed to constantly improving the affordability, innovation and quality of American health care. Their focus is on a consumer-centered health care system that empowers patients with the information they need to make important health care decisions. Changes that occur to the way health care is delivered should improve the system and ensure that health care operations are seamless.

Restructuring the diagnosis-related group (DRG) system as proposed in the rule would represent the most significant policy change to the IPPS since its inception. Given the complex nature of changing from a charge-based diagnosis-related group (DRG) system to a cost-based system and the magnitude of impact this could have on health care operations, **the Healthcare Leadership Council believes it is important to delay the implementation by one year in order to allow further analysis and refinement of the proposed changes in payment methodology and to ensure the readiness of the new system.**

HLC supports CMS' efforts to develop a system that better reflects the costs to provide services and believes a one year delay will help to ensure that the system that is put in place is the best option for improving the accuracy of payment rates and that the data is available and the systems are in place to be successful. Because there are many stakeholders involved in the process and entire systems will need to be created to implement the new proposals, we believe that additional time is needed so that the implementation is successful.

Thank you for the opportunity to share our comments, and please feel free to contact us as CMS works through the implementation process

Sincerely,

Mary R. Grealy

Mary R. Grealy
President

Healthcare Leadership Council
1001 Pennsylvania Avenue, N.W., Suite 550 South
Washington, D.C. 20004
202/452-8700 • 202/296-9561 • www.hlc.org

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SOUTHCOAST
HOSPITALS GROUP

June 9, 2006

Centers for Medicare & Medicaid Services
U. S. Department of Health and Human Services
Attention: CMS-1488-P
Baltimore, Maryland 21244-1850

Subject: CMS-1488-P
Issue Identifier: Multi-campus Hospitals

To whom it may concern:

I am writing on behalf of Southcoast Hospitals Group to express our opposition to a change proposed by the Centers for Medicare & Medicaid Services (CMS) governing how multi-campus hospitals report their wages when seeking Medicare wage index reclassification.

Southcoast Hospitals Group is a multi-campus hospital in the unusual position of having campuses in different wage index areas. Current CMS regulations provide that for hospitals in such a situation, all wages for all campuses should be combined when applying for wage index reclassification. Now CMS proposes repealing this rule, and requiring multi-campus hospitals to separate the wages at their individual campuses for reporting purposes. We oppose this proposed change.

Southcoast is truly one hospital. It is the product of a full asset merger of three separate hospitals into one. The merger reduced duplicative administrative and overhead expenses in excess of $25 million, thereby reducing unnecessary health care costs for Medicare, Medicaid and all other payors. This is as opposed to the process of creating a hospital system that many other organizations pursue, but does nothing to reduced duplicative costs as they each retain their individual entities. Southcoast is one hospital with one Medicare provider number, not three separate, autonomous hospitals. The demands that would be made by the proposed change would truly be burdensome, necessitating additional time and expense to attribute wages and benefits to each individual campuses. In addition, the wage and benefit programs for the three campuses are the same, which therefore negates any potential benefit from identifying the expenses by site.

For these reasons, we request that CMS not change the current rule. Alternatively, we request that the current rule be extended for five more years. This is important because Southcoast will need to apply for Medicare wage index reclassification in two years. Applying for reclassification requires three years worth of data, but if the rule is changed now, the most we could have is two years worth of data, which means we would not even be able to apply for wage index reclassification. Our desire to be reclassified could never even be weighed on its merits because the lack of available data would make it impossible even to apply for reclassification. We believe this is fundamentally unfair and request that CMS not adopt the proposed rule change.

■ *Uniting for our community*

CHARLTON MEMORIAL HOSPITAL
ST. LUKE'S HOSPITAL
TOBEY HOSPITAL

363 Highland Avenue
Fall River, Massachusetts 02720
Telephone (508) 679-7555

We appreciate the opportunity to submit these comments and welcome any questions you may have about our position on this issue. I can be reached at 508-961-5016.

Sincerely,

William Grigg
Senior Vice President and CFO
Southcoast Hospitals Group

Cc: Ronald Goodspeed MD, President and CEO, Southcoast Hospitals Group

MAYO CLINIC

345

200 First Street SW
Rochester, Minnesota 55905
507-284-2511

June 12, 2006

Centers for Medicare & Medicaid Services
Department of Heath and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: File Code CMS-1488-P

Comments to Proposed Rule 71 FR 23995, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

We appreciate the opportunity to provide comments on the proposed changes to the Inpatient Prospective Payment System (IPPS) that were published in the April 25, 2006 Federal Register.

"HSRV Weights"

We agree with the proposal to refine the current DRG system, by taking into account severity of illness and applying hospital-specific relative values (HSRVs). The proposals suggested in the proposed rule should improve the Inpatient Prospective Payment System's payment accuracy.

While agreeing to the principles described in the rule, we respectfully disagree with the proposed timing of implementing these changes. The proposed changes have been described as the most significant to the inpatient payment system since DRGs were implemented in 1984. The significance and complexity of the proposed changes require adequate time for all stakeholders to analyze the rule, and ensure that potential inadequacies of the proposed methodology are corrected before implementation. The comment letter on this proposed rule submitted by the American Hospital Association (AHA) discusses several concerns and specific errors noted during a review of the CMS databases and methodologies by the Moran Company. Their analysis clearly supports the fact that more time is needed to permit CMS and providers to examine and verify the accuracy of the data.

Some specific concerns expressed in the AHA comment letter include:

1. **Errors:** While analyzing CMS' proposed rule, the AHA uncovered a series of data errors, inconsistencies across databases and questionable methodological choices. Further analyses commissioned by the AHA, the Association of American Medical Colleges and the Federation of American Hospitals and conducted by The Moran Company, Inc. to investigate

these questions showed that small changes in method lead to large changes in DRG weights, signaling that the proposed changes are highly unstable (see attached technical appendix).

For instance, the following inconsistencies were identified:

- CMS inadvertently included organ acquisition costs in the data used to set weights for DRGs. These costs should be excluded. This error has a material effect on the resulting weight calculation for transplants. For example, CMS publishes a weight of 5.5466 for DRG 302 (Kidney Transplant), but with this correction The Moran Company calculates a weight of 3.0102.

- CMS was inconsistent in its treatment of certain categories of hospitals between their calculation of the FY 2007 HSRVcc weights and the proposed CS-DRG weights, making it hard to directly compare the results. For example, hospitals in Maryland were included in the FY 2007 MedPAR data used for the HSRVcc weight calculation and excluded from the CS-DRG calculation.

- The Moran Company used transfer-adjusted charges prior to calculating weights. It was CMS' policy to do this. However, it is unclear whether the weights published for CS-DRGs included this step.

- Data cleaning steps used were not always consistent with standard CMS practices (e.g., removal of cases with 0 charges, low volume DRGs, etc.).

- The cleaning steps applied to the cost report data were not consistent with the cleaning steps applied to the MedPAR claims data, which resulted in different hospitals being included in data sets used for the calculation of the weights and the calculation of the scalers to the weights. For example, hospitals in Maryland and hospitals without cost reports for FY 2003 were excluded from the cost report data used to calculate the scalers and included in the MedPAR file used to calculate the weights.

2. **Trimming:** CMS trimmed the cost center CCRs at 1.96 standard deviations from the geometric mean. We believe that this skews the CCRs, as the hospitals with high routine charge mark-ups are systematically removed from the calculation. This results in the exclusion of 198 hospitals' routine CCRs, accounting for over 26 percent of total routine charges. It also creates a mismatch between the CCRs used and the charges they are applied to, as the hospitals that are trimmed out of the CCRs are still included in the charges that are then reduced to costs and determine the cost shares.

3. **Weighting:** CMS also hospital-weighted rather than charge-weighted the calculation of the CCRs which in turn are used to calculate the scaling factors used to convert the charge-based relative weights to "cost." There are several issues with this approach:

- This approach gives an equal weight to each hospital in the national cost-to-charge ratio calculation even though hospitals can range in size from fewer than 25 to more than 1,000 beds.

- This method is inconsistent with the method of averaging used to develop the cost center-specific DRG weights to which the scaling factors are applied. For this part of the analysis, CMS calculated hospital-specific DRG relative weights, but then used a case-weighted average to develop the national value.

- The hospital-weighted approach results in a 1 percent to 54 percent difference versus a charge-weighted approach in the resulting scaling factors used for the conversion to cost.

The above errors in the calculations over-weight CMS' routine cost shares and under-weight the ancillary cost shares, creating erroneously large swings in DRG weights. Table 1 illustrates how these methodological problems affect the factors used to scale the cost center-specific relative weights. This table shows the impact of trimming the cost center CCRs at 3.0 rather than 1.96 standard deviations from the geometric mean and charge-weighting rather than hospital-weighting the calculation of the national average CCRs that are used in developing the scalers.

Table 1
Impact of Methodological Changes on "Scalers"
Published versus Revised with Methodological Changes

Scaler	CMS Published	Methodological Changes			Percent Change vs. Published
		Trimming Only	Weighting Only	Weighting/ Trimming	
Routine days	0.2881	0.2882	0.2646	0.2490	-14%
Intensive days	0.1919	0.1933	0.1668	0.1636	-15%
Drugs	0.0877	0.0884	0.0939	0.0970	11%
Supplies	0.1150	0.1142	0.1325	0.1383	20%
Therapeutic	0.0384	0.0381	0.0390	0.0388	1%
Operating room	0.0812	0.0838	0.0861	0.0888	9%
Cardiology	0.0241	0.0246	0.0351	0.0371	54%
Laboratory	0.0670	0.0659	0.0681	0.0687	3%
Radiology	0.0427	0.0437	0.0460	0.0474	11%
Other services	0.0639	0.0600	0.0677	0.0712	12%

Source: Moran Company analysis.

These methodological problems have a large impact on the relative weight calculations at the DRG level. Table 2 shows, for key DRGs, how these methodological problems affect the DRG weights and, therefore, hospital payments.

Table 2
DRG Weights with Current Methodology vs. HSRVcc with Various Corrections
High Volume DRGs with Largest Changes in Weights Due to Corrections

				New DRG Weights: Published vs. Corrected			Change vs. Old Weights		
DRG (v24)	DRG Title	Number of discharges	Current Charged-based Weights w/v24 Grouper	CMS Published HSRVcc Weight	HSRVcc w/ Technical Corrections Only	Corrected, Weighted and Trimmed CCRs	DRG Weight Change Current Method vs. Published	DRG Weight Change Current vs. Corrected, Weighted, and Trimmed	Published vs. Corrected, Weighted, and Trimmed
430	PSYCHOSES	74,871	0.8561	1.2316	1.2418	1.1110	87.7%	69.3%	-9.8%
12	DEGENERATIVE NERVOUS SYSTEM DISORDERS	56,042	0.8983	1.0105	1.0099	0.9635	12.5%	7.3%	-4.7%
475	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT	119,513	3.4630	3.8279	3.8366	3.6573	10.5%	5.6%	-4.5%
277	CELLULITIS AGE >17 W CC	118,691	0.8676	1.0015	1.0026	0.9578	15.4%	10.4%	-4.4%
87	PULMONARY EDEMA & RESPIRATORY FAILURE	96,506	1.3854	1.5310	1.5324	1.4699	10.5%	6.1%	-4.0%
320	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W CC	224,491	0.8611	0.9538	0.9544	0.9162	10.8%	6.4%	-3.9%
294	DIABETES AGE >35	97,122	0.7750	0.8642	0.8636	0.8307	11.5%	7.2%	-3.9%
296	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W CC	246,948	0.8213	0.9041	0.9042	0.8701	10.1%	5.9%	-3.8%
79	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W CC	159,894	1.5939	1.7331	1.7359	1.6880	8.7%	4.6%	-3.8%
243	MEDICAL BACK PROBLEMS	100,498	0.7888	0.8680	0.8693	0.8363	10.0%	6.0%	-3.7%
554	OTHER VASCULAR PROCEDURES W CC W/O MAJOR CV DX	77,003	2.0890	1.9483	1.9560	2.0085	-6.7%	-3.9%	3.1%
110	MAJOR CARDIOVASCULAR PROCEDURES W CC	57,436	3.8616	3.6419	3.6558	3.7563	-5.7%	-2.7%	3.1%
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG	119,991	1.4508	1.1670	1.1732	1.2380	-19.6%	-14.7%	6.1%
544	MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY	444,118	1.9514	1.8941	1.9047	2.0147	-2.9%	3.2%	6.4%
551	PERMANENT CARDIAC PACEMAKER IMPL W MAJ CV DX OR AICD LEAD OR GNRTR	53,717	3.0391	2.6339	2.6481	2.8453	-13.3%	-6.4%	8.0%
552	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT W/O MAJOR CV DX	81,744	2.0837	1.7670	1.7771	1.9468	-15.2%	-6.6%	10.2%
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG	91,848	1.1117	0.7862	0.7913	0.8717	-29.3%	-21.6%	10.9%
557	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W MAJOR CV DX	123,550	2.8755	2.1323	2.1499	2.4236	-25.8%	-15.7%	13.7%
515	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH	58,009	5.2691	4.1471	4.1795	4.7999	-21.1%	-8.7%	15.7%
558	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W/O MAJ CV DX	191,677	2.1920	1.4299	1.4456	1.7238	-34.8%	-21.4%	20.6%

Source: Moran Company analysis of FY 2007 proposed inpatient PPS rule. Uses FY 2005 MedPAR.
Notes: High volume DRGs defined as over 50,000 cases. Those included in the table were those with the greatest absolute change in weight moving from the CMS published DRG weight to the DRG weight calculated by trimming CCRs at 3.0 standard deviations, using weighted CCRs, and correcting for technical errors.

These changes have a material impact on hospital payment. CMS' method for weighting and trimming redistributes $1.4 billion dollars among hospitals. Charge-weighting the CCRs and trimming them at three standard deviations would reduce the shift in dollars to $900 million – a reduction of ***half a billion dollars***, or 33 percent. This highlights the need for more work to validate each methodological step to understand how it affects payment and ensure it adds to "accuracy."

4. **Failure to Calculate Costs at the Claim Level:** CMS chose to use *charges* to initially calculate the relative weights at the DRG level and then a national scaler to make the conversion to "cost-based" weights. The national scaler converts the 10 cost center charge-based weights to one national weight using the actual share of costs across departments. CMS maintains that this adjusts for differential mark-ups across hospital departments. In contrast, MedPAC estimated *costs* at the claim level to calculate relative weights. CMS provided no validation of the methodological shortcut they propose.

5. **Cost Centers:** CMS aggregates charges into 10 cost centers for each DRG, then applies a cost-center level CCR (derived from the cost reports) to charge figures (from claims data). But because hospitals often report charges on the cost reports differently than charges on the

claims, the cost-center level CCRs are calculated based on a different set of charges than the charges to which the CCRs are later applied. We believe this may materially distort the DRG weights and needs to be thoughtfully considered and accounted for in any methodology. If CMS is going to move to cost-based weights, regardless of the methodology, hospitals will need time to align their mapping of cost centers into departments or cost categories for purposes of cost reporting with that of claims reporting.

6. **Validation:** As mentioned above, CMS provided no analysis to validate that the proposed changes result in better payment policy. While measuring improved payment accuracy is difficult, the large degree to which the weights fluctuate given methodological changes alone indicates the need for further analysis and study. CMS should construct a process to test the sensitivity of weights to various methodological assumptions and publicly share the result, including:

    - Compare CMS weights to MedPAC's HSRV-cost approach;
    - Compare CMS weights to an approach using standardized costs (as opposed to HSRV);
    - Compare CMS weights to weights calculated by estimating costs at the claims level using the 10 cost center approach;
    - Evaluate alternative methodologies for estimating costs (e.g., method used by New York state's Medicaid program);
    - Compare stability of weights over time; and
    - Determine whether payment policy is improved.

Assessment of "payment accuracy" conducted by The Moran Company as well as The Health Economics and Outcomes Research Institute (THEORI), a division of the Greater New York Hospital Association, finds the CMS HSRVcc approach to be not at all, to marginally better, than the current system. Fixing the major methodological flaws yields minimal improvement, according to THEORI. CMS' HSRVcc approach actually creates new areas of care where systematic incentives for specialization could occur. This analysis raises significant questions about CMS' approach and further analysis should be conducted before any changes to the current charge-based methodology are made. These analyses will help determine the most effective and administratively feasible approach for a shift to cost-based weights.

We recommend postponing the implementation of the HSRV weighting method, publishing the proposed changes in a separate Federal Register issuance, and providing an extended period of time for comments related to this significant change.

A second reason for delaying implementation is that in the FY 2006 final rule CMS discussed that several cardiovascular DRGs requiring stent insertion were not paid appropriately because the DRGs

reflect charges for only one stent. Nationally, it is recognized that on average, multiple stents are used during procedures. However, those costs are not recognized by the current DRG weight calculation process. The FY 2006 Final Rule described that data would be available for the FY 2008 rule that would adequately reflect the charges/costs of the DRGs. Postponing the implementation of the HSRVs will allow time for CMS to adequately determine the costs of the DRGs that are most impacted by this proposal.

Additionally, we recommend that CMS implement all proposed payment corrections simultaneously. Each proposed change is designed to increase the payment accuracy of the system. However, each change corrects different inadequacies in the current system, and a correction of one inadequacy (implementing HSRVs) will actually magnify the inaccurate payment impacts of the remaining inadequacy (non-severity adjusted DRGs) at a facility level. Table K (72 FR 24024), reports that implementation of both proposals will have a relatively small redistribution of reimbursement on most non-specialty hospitals. However, implementing only the refinement of the current DRG weights to HSRVs will result in a material redistribution of reimbursement from urban to rural hospitals. Although the individual change addresses a specific inadequacy of the current payment system, the change implemented individually will result in aggregate payments at the facility level being less accurate than the current weighting methodology for most non-specialty hospitals. We recommend that the application of HSRVs be delayed until the implementation of severity adjusted DRGs. Recognizing the burden in analyzing the APR-DRG (i.e. CS-DRG) proposal on CMS, and agreeing with the discussion regarding the burden of implementation on Providers, we recommend that both proposals be implemented no earlier than FY 2008 and only after adequate time is made available for analysis and comment.

The impacts on cardiovascular and transplant departments and hospitals are significant. We suggest a three year phase-in of the proposals to limit the negative impact to hospitals, and provide time to adjust their practice to the new reimbursement environment.

We believe the proposal for implementing the APR-DRGs (CS-DRGs) represents a significant change to the current DRG payment system. The significant impact requires that all details be set out in a separate Federal Register issuance for public review and comment. Details of the system are not provided and the need for the new system is not explained. While preliminary relative CS-DRG weights were published on the CMS website, they were not included in the April 25, 2006 Federal Register for review as part of this proposed rule.

CMS should provide an explanation of the GROUPER criteria used to categorize discharges into each of the specific CS-DRGs. In this regard, the proprietary nature of the proposed CS-DRG grouper is a major concern. The AHA comment letter clarifies that without the GROUPER logic it is virtually impossible for providers to thoroughly analyze the system and provide substantive comments to CMS. We believe the public has a right to see and understand the details behind the new payment system.

As AHA commented, we also are concerned that CMS' GROUPER does not use all diagnoses and procedures that affect a patient's severity of illness and/or the resources utilized. The current DRG GROUPER only considers nine diagnoses and up to six procedures. Hospitals submit claims to CMS in an electronic format. The HIPAA compliant electronic transaction 837i

standard allows up to 25 diagnoses and 25 procedures. Many fiscal intermediaries are ignoring or omitting the additional codes submitted by hospital providers since these additional diagnoses and procedures are not needed by the GROUPER to assign a DRG.

Capturing all diagnoses and procedures meeting the definitions of reportable secondary diagnoses and procedures will provide a more complete picture of patient complexity. As CMS considers methodologies for refining the patient classification system, the number of secondary diagnoses may be an important factor in determining differences in patient characteristics. This is particularly true of patients with many chronic illnesses that add to the complexity of treating them.

We agree with the Association of American Medical Colleges' (AAMC) comment describing concerns that the APR-DRG proposal reflects patient severity but does not adequately recognize service complexity. We also are interested that CMS address this issue, and explain how the proposed change will account for service complexity.

We also wish to comment on the discussion regarding a budget neutral adjustment to offset the potential improved coding and documentation of Providers that may lead to higher payments when the severity adjusted DRGs are implemented. The calculated relative weights of the severity adjusted DRGs is the determined average resources (costs) for an average length of stay. Creating an artificial adjustment to lower that payment will result in hospitals receiving less reimbursement than the cost of providing services. We recognize the importance of any changes remaining budget neutral, however the proposed rule does not provide any statistical evidence that the case mix index will increase. It could be argued that lack of experience in the new system will cause payments to be less than appropriate for the first few years of the new system. We suggest waiting until data is available that supports an artificial increase in the case mix index before implementing a budget neutral adjustment.

"Hospital Quality Data"

Although many hospitals have been collecting the quality data on the full 21 measures as defined by Public Law 109 sections 1886(b)(3)(B)(viii)(III) and (IV), the hospitals have only been reporting the quality data for the "starter set" of 10 quality measures used since 2003. We believe that it would be an unnecessary burden to require hospitals to retro-actively report the additional 11 measures back to the first quarter of 2006. We recommend that the reporting requirement for the additional 11 measures be revised to the beginning of the fiscal year 2007.

"Value Based Purchasing"

We support hospital value-based purchasing based on evidence-based quality measures but believe that it is premature to attempt to tie payments to an "efficiency" measure. There is currently no common definition of efficiency of care in the hospital setting. Is only hospital care included or is the full spectrum of care including physician services to be included? What time period is measured? Additional analysis is needed to define efficient care before it can be incorporated into a payment model.

We recognize CMS' requirement to identify at least two conditions leading to Hospital Acquired Infections (HAIs) that develop during the patient stay. We recommend CMS consider the following, when determining the two conditions:

The Hospital Acquired Infections chosen should be standard, preventable, familiar, and comparable between institutions. We suggest 1) Surgical Site Infection (SSI) and 2) CVC associated bacteremias as two conditions that meet these criteria. These infections are already being developed for comparison across the country. Conversely, ventilator associated pneumonia is not a good choice. Surveillance is labor intensive and diagnosis is difficult and unreliable.

The conditions chosen must not be conditions normally present at admission and subsequently identified through hospital tests. For example, many cases of asymptomatic bacteremias are undocumented upon admission. These patients have a culture done only after catheterization. The organisms are *community* acquired not *hospital* acquired, even though the infection is discovered after admission to the hospital.

Very sick patients or very complex operations are a predictor of higher rates of HAI. The conditions chosen should not penalize hospitals providing higher risk patients care, and should not discourage innovation or high risk procedures when they are appropriate. We recommend that CMS identify HAIs that are common across both community and tertiary hospitals.

We also recommend that CMS include experts in the field of Infection Prevention and Control, when developing the actual payment mechanism for FY 2008. The Hospital Epidemiologists of America (SHEA), Association of Practitioners of Infection Control (APIC), National Quality Forum (NQF), CDC, AHA, AMA, and others should provide input for any HAI project. This is a very complex undertaking and deserves all the thought that can be afforded it.

We recommend that CMS provide detailed instruction on identifying and documenting infections. Criteria for infections must be consistent, and in sufficient detail to assure a diagnosis of a HAI. Infection Control professionals for all institutions are required to fill in the gaps in the definitions resulting in difficulty comparing data across institutions. We recommend that CMS address this issue before implementing this proposed change. The National Quality Forum is one group that can help define the method for identifying HAIs.

We also agree with AHA's comment 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. Therefore, we suggest that by utilizing the SCIP program as the basis for responding to the congressional mandate, CMS could choose not to penalize a hospital if, despite their best efforts, an infection occurs. For example, if a hospital's performance on the SCIP surgical wound infection prevention measures show that it reliably performs the necessary infection prevention steps all or nearly all of the time, CMS might not make any change to the current payment system for that hospital.

"Occupational Mix"

The change to inclusion of 100 percent of the occupational mix adjustment should have been communicated in the Federal Register as it is an integral part of the 2007 DRG payments. The April 25, 2006 Federal Register discussed only the 10 percent adjustment. This change should be postponed until communicated as part of the CMS administrative rule making process, rather than incorporated without formal notice.

"Resident Time in Non Patient Care Activities"

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (DGME) is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

At Mayo, such activities are considered an integral component of patient care. All such conferences are patient oriented, and discuss actual patients in the context of the discussion. Decisions related to specific patients are commonly made based on the content of the discussion at the conferences.

To reiterate, we urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

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Thank you for the opportunity to comment on this proposed rule and for consideration of our comments. If you have any questions, please contact Chris Tholen at 507-284-0940 or me at 507-284-4627.

Very truly yours,

Ronald W. Grousky
Director, Medicare Strategy Unit

RWG:rpv

L/dept/sal/rwg/ltr/IP Proposed Rule Comment Letter – 2007

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June 6, 2006

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

RE: Medicare Program; Proposed Changes to the Inpatient Prospective Payment Systems and FY 2007 Rates regarding "Geographic Reclassifications – Urban Group Hospital Reclassifications" (File Code CMS-1488-P)

Dear Sir or Madam:

The purpose of this letter is to comment on the FFY 2007 proposed Inpatient Prospective Payment System (IPPS) regulation regarding geographic wage index reclassifications and urban group hospital reclassifications.

North Ridge Medical Center is a 332 bed for profit hospital located in Broward County Florida. Forty Five percent (45%) of our patient population consists of Medicare beneficiaries and adequate Medicare reimbursement is critical to our continuing ability to meet their needs.

In 2004, when the FFY 2005 proposed IPPS regulation regarding geographic wage index reclassifications and urban group hospital reclassifications was published, Palm Beach County hospitals had, for the first time, qualified for the opportunity to reclassify for wage index purposes. Palm Beach County hospitals qualified in part because the FFY 2005 proposed rule allowed Metropolitan Divisions within a CBSA to qualify for an urban group reclassification. Based on the FFY 2005 proposed regulation, we joined with all other Palm Beach County hospitals and applied for the urban group reclassification. However, the final FFY 2005 IPPS regulation revised the proposed criteria and eliminated the ability for Metropolitan Divisions within a CBSA to qualify for an urban group reclassification.

Tenet

We subsequently learned, however, from CMS through the FFY 2007 IPPS proposed regulation that the intent of the urban group reclassification was, and is, "to allow hospitals located in counties that are in the same CBSA (in the case of Metropolitan Divisions) as the area to which they seek redesignation to be considered to have met the proximity requirement We agree with CMS on the point above and agree with CMS on the following two points; that "the proximity standard for group reclassifications is intended to allow all of a county's hospitals to reclassify to an adjacent area where there is sufficient economic integrations that there can be an expectation that both areas are competing in a similar labor market area," and that "we believe there is sufficient economic integration between Metropolitan Divisions within a CBSA that urban county reclassifications within a CBSA or a CSA should be permitted."

We thank CMS for recognizing the economic integration between Metropolitan Divisions within a CBSA and request that CMS, at a minimum, adopt the FFY 2007 IPPS proposed urban group reclassification eligibility criteria [Sec. 412.234(a)(3)] as proposed, without modification.

However, we do believe, based on the CMS comments quoted above from the FFY 2007 IPPS proposed regulation, that the hospitals of Palm Beach County should have been allowed to qualify for an urban group reclassification beginning in FFY 2006 had the final FFY 2005 IPPS regulations correctly recognized the economic integration between Metropolitan Divisions within a CBSA (as CMS had done in the FFY 2005 proposed regulation and now again recognizes in the FFY 2007 proposed regulation).

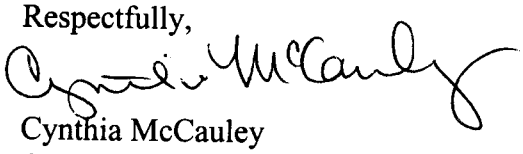
Therefore, we respectfully request that CMS, in the final FFY 2007 IPPS regulation, make the FY 2007 proximity criteria effective for urban group reclassifications beginning on October 1, 2006 (as opposed to October 1, 2007) IF the urban area:

- Filed an application for urban group reclassification by September 1, 2004 for reclassification beginning on October 1, 2005;
- Met all of the non–proximity urban group reclassification criteria published in the FFY 2005 final regulation;
- Had the application denied only because the urban area did not meet the flawed FFY 2005 proximity criteria;
- Would have had the application approved had the FFY 2007 proposed proximity criterion been the criterion in the FFY 2005 final regulation;
- Meets the proximity and non-proximity criteria described in the FFY 2007 IPPS proposed regulation; and
- Files an application for urban group reclassification by September 1, 2006.

Based on the aforementioned information we request that CMS incorporate the proposed revision, as written above, in the FFY 2007 final IPPS regulation. We believe the requested revision is critical to the financial stability of the hospitals located in the West Palm Beach Metropolitan Division and should take effect, for payment purposes, for all hospitals in the West Palm Beach Metropolitan Division beginning October 1, 2006 rather than delaying until October 1, 2007. If granted this revision will allow the urban group reclassification to take effect one year sooner than otherwise currently proposed, though a year later than the date which we would have otherwise qualified (October 1, 2005) had the final FFY 2005 regulation properly recognized the intent of the economic integration criteria.

We appreciate your consideration of this comment to the FFY 2007 proposed IPPS regulation.

Respectfully,



Cynthia McCauley
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LONG BEACH COMMUNITY NETWORK, LTD. (PHYSICIAN-HOSPITAL ORGANIZATION)

TEACHING CAMPUS OF THE NEW YORK COLLEGE OF OSTEOPATHIC MEDICINE AND THE NEW YORK COLLEGE OF PODIATRIC MEDICINE

June 9, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Ladies and Gentlemen:

I write in support of CMS proposed changes to the inpatient DRG weighting and grouping methodologies. As many have observed, including MedPAC, the current methodology creates higher-than-average profitability among the surgical DRGs while providing inadequate reimbursement for the medical DRGs. Over the course of years this imbalance has tended to destabilize community hospitals while encouraging the creation of proprietary specialty hospitals.

The CMS proposed changes should be implemented without delay to rectify the current imbalance and help stabilize the many community hospitals in the country that have suffered under the current formula. While others argue that the CMS proposal may not be the best formula and, therefore, ought to be delayed to allow for further study and refinement, I believe the methodology should be adopted immediately and CMS continue to study the methodology and adopt adjustments in the future as may be warranted. To delay implementation would only aggravate the current inequities in the system and further weaken the nations community hospitals.

On behalf of Long Beach Medical Center I thank you for addressing this important issue.

Yours truly,

Douglas L. Melzer
Chief Executive Officer

DLM:gam

248

Avera
Sacred Heart Hospital

We're Caring for Life

501 Summit
Yankton, SD 57078-3899
(605) 668-8000

www.averasacredheart.com

June 7, 2006

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore MD 21244-1850

RE: Medicare Program; Proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; 71 *Fed. Reg.* 23,996 *et seq.* (Apr. 25, 2006); CMS-1488-P

Dear CMS Representative:

Avera Sacred Heart Hospital is a Sole Community Hospital and a Rural Referral Center that provides comprehensive acute health care services to rural areas of Southeastern South Dakota and Northeastern Nebraska. It includes a service area of 80,000 residents in ASHH's seven county service area. Avera Sacred Heart Hospital provides access to health care for these residents because more intense services are not available in the hospitals in ASHH's geographic referral area. For example, each of the hospitals within a 35 mile radius of ASHH are either Critical Access Hospitals or a specialty hospital. Most of the hospitals do not have many services critical for the area, for example, obstetrics services, emergency services with physician coverage, intensive care services, and dialysis services. The Sole Community Hospital designation has enabled ASHH to provide services such as these on a 24/7 basis for residents many who travel more than sixty miles one way for emergency health care. A definition of "like hospitals" is not an adequate means of identifying the care provided within these hospitals compared to ASHH.

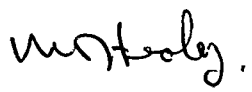
Avera Sacred Heart Hospital requests that the Centers for Medicare and Medicaid Services consider any proposed changes be only for future Sole Community Hospital applicants. ASHH's ability to provide the necessary critical access to health care for thousands in rural communities has been dependent upon maintaining the Sole Community Hospital status.

Avera Sacred Heart Hospital requests that the Centers for Medicare and Medicaid Services consider retaining the Sole Community Hospital designation for existing facilities if the Medicare case mix index exceeds those hospitals within the original designated radius (for Avera

Sacred Heart Hospital it was 25 miles) required to be designated as a Sole Community Hospital and that the volume threshold is met for any "like hospitals" within the original designated radius.

Your consideration to our comments is appreciated. Should you have any questions, please do not hesitate to contact us at 605-668-8321.

Sincerely,



Michael T. Healy
Vice President/Finance

MTH/amk

cc: Pamela Rezac

CARDIAC SOLUTIONS

JOSEPH A. CAPLAN, M.D., F.A.C.C

VISHAL B. PATEL, M.D., F.A.C.C.

MANOJ RAWAL, M.D.

GABOR S. JILLY, M.D., F.A.C.C.

CHRISTOPHER G. MACKEY, D.O.

249-0

(4)

June 06, 2006

Centers for Medicare and Medicaid Services
Department of Health Human Services
Attn: CMS-1488P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir:

We are a group of five cardiologists in practice now for few years and we practice in an environment, which is essentially in a retired senior community. We are very heavily medicare based environment. We also have a fair amount of medicare HMOs as our insurance providers.

We do understand that CMS is planning a significant cut in reimbursement for cardiac devices. Given the environment in which we practice as well as the increases in office costs, due to fixed overheads as well as inflationary adjustments, we think that it is going to be fairly hard for a lot of us to practice in this environment with planned cuts to come in. As mentioned, we are fairly heavily senior citizen based practice with a fair need of cardiac devices and with the oncoming changes, it is possible that a couple of our cardiologists would be forced to retire. Hence, it is our sincere request that these proposals need to be very seriously looked at and readjusted in our opinion, to actually give us a fair increase according to the inflation that affects the rest of the country.

Thank you very much.

Sincerely yours,

Gabor S. Jilly, M.D., F.A.C.C.

UNREVIEWED UNLESS SIGNED BY PHYSICIAN

VP/STA/ROS/161704_003

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250

June 7, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8011
Baltimore, MD 21244-1850

RE: CMS-1488-P; Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2007 Rates

Commenting on: General Comments; HSRV Weights

Dear Dr. McClellan:

I am an electrophysiologist in Cincinnati, Ohio and practice in a cardiology group of 12 physicians (Comprehensive Cardiology Consultants). Medicare patients are an important part of my practice, and the inpatient hospital payment system can affect how I am able to treat them.

I'd like to share my concerns with you regarding the proposed inpatient rule for FY2007. I believe if these changes are implemented, it could have a negative effect on some hospitals, and ultimately could impact the patients that I treat.

As such, I urge CMS to allow time for further study of the proposals but in the meantime continue with the current charge-based system.

Payment rates should accurately reflect the cost of services provided. Inaccurate rates could limit hospitals' capabilities to perform services, and thus limit patient access to some therapies. The current proposal, if implemented, could have unintended and inappropriate consequences.

- **Questions have been raised about CMS's proposed rate-setting methodology.** At a high level, some of these issues include CMS's use of data that are 3–5 years old to calculate the payment rates; technical mistakes such as counting a small hospital equal to a large hospital in calculations; throwing out a quarter of the hospitals' routine day charges in calculating cost-to-charge ratios; as well as

questionable technical assumptions that can alter the estimated impact on payments. Charge compression, a major issue for high-value, high-technology devices, also continues to be a problem and is not properly addressed in the proposal.

- **The current proposed DRG payment rates are in some cases the same or lower than the purchase price for ICDs and CRT-Ds.** Proposed rates for ICD and CRT-D procedures are sometimes below the device acquisition cost, not allowing hospitals payment for operating procedures, supplies, and personnel. For example, DRG 515, where a majority of ICD implants fall, was paid at a base of $28,441 in 2006; for 2007 Medicare is proposing a sharp decrease in payment of 23%, down to $22,015—one of the biggest percentage decreases any DRG faces this year.

Poor economics mean hospitals have to make difficult decisions when it comes to using leading-edge, high-technology solutions for their patients

- If this change is implemented, hospitals could find themselves with limited capabilities to offer their patients some advanced and technologically-driven therapies, particularly for certain cardiovascular therapies such as implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy with defibrillator (CRT-D) therapy.

- **This could result in hospitals altering normal treatment patterns, restricting technology selection, and limiting patient access in order to avoid extraordinary financial losses.** As a result, patients may not receive the already underutilized lifesaving ICD and CRT-D therapies because hospitals are not receiving payment that recognizes the full cost of the services provided.

- **Hospitals cannot sustain themselves economically when inaccurate payments do not cover the cost of supplies, equipment, staff, and medical devices.**

- **ICD and CRT-D therapies are the standards of care** as recognized by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) practice guidelines for many patients. It is important to set payment rates that allow for physicians to provide the right care at the right time for the right patient.

Conclusion

Sweeping decisions of this nature need thorough analysis, stakeholder input, and time and consideration prior to being implemented. Additionally, intended and unintended consequences need to be carefully examined prior to making major changes to a stable environment that could adversely affect hospitals, physicians, and most importantly, patients.

To ensure continued access to high quality care for Medicare beneficiaries, appropriate payment under the prospective payment system is critical. **As such, I reiterate my**

request that CMS allow time for further study of the proposals but in the mean time continue with the current charge-based system.

We appreciate CMS's efforts to improve the inpatient payment system, and agree that it is our mutual goal to improve the lives of Medicare beneficiaries. We all must work together with diligence and dedication to address these complex issues.

Sincerely,

Sheldon L. Brownstein, M.D.
3141 Brinton Trail
Cincinnati,Ohio 45241
(513) 861-5555
sSLBEPS@AOL.COM

cc: Senator Mike De Wine

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June 5th, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

As manager of the Cardiac Cath Lab Department at Innovis Health, I have concerns regarding the proposed cuts in CMS payment for Cardiology DRG's. I will try to explain some of the reasons for my concerns in the following letter.

First, the majority of the patient population we serve is older than 65. This makes payment from Medicare the basis of our operating dollar. Without at least trying to break even on our expenses, we would not be able to continue operating.

Second, we are a major center for even "smaller facilities" to transfer their patients needing specialty care. This specialty care being Cardiology. Our surrounding area is very rural in location and does not have the population base that the large metropolitan centers in other areas of the country have; though we still need to provide this Cardiology care. This makes the impact of payment for Medicare patients receiving Cardiology treatment, more prominent and important.

Next, because of our smaller hospital size; we do not have the same buying power for purchase of the needed technology that being Drug Eluting Stents and Implantable Cardiac Defibrillators (ICD's). We do negotiate aggressively for prices on products we use but are also limited by volume. We are unable to take advantage of the "Walmart" theory used in corporate America.

These technologies have been proven to be best treatment for patients and proven to decrease the rehospitalization potential for these patients. That also decreases the Medicare dollars required to treat these patients. With the movement toward less surgical procedures, the use of interventional

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technologies permit less hospitalization time and quicker recovery for patients. Are we as a society willing and ethically able to compromise this treatment for our senior citizens?

Heart Disease is the #1 condition afflicting all Americans and becomes more prevalent as we age. We cannot compromise the care we give these patients and make treatment based on what we will get paid for the procedure.

Based on 2005 volume, this is the number of patients that will be affected by proposed changes.

- 1542 Diagnostic Coronary Angiograms
- 437 Coronary Interventions
- 217 new Device Implants- Permanent Pacemakers, ICD's, Biventricular pacemakers.

The proposal to move to a Cost-based payment system needs further study and examination before such a change is implemented. Please continue the current system until any changes are thoroughly studied.

Sincerely,

Deb Schneibel RN

Deb Schneibel, RN
Manager Cardiac Cath Services
Innovis Health
3000 32nd Ave. SW
Fargo, N.D. 58103

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OVERLAKE Hospital Medical Center
Medical excellence every day™

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June 1, 2006

Department of Health and Human Services
Attention: CMS -1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Comment on CMS proposed rule regarding "HSRVcc Weights"

Overlake Hospital Medical Center agrees that moving to the HSRVcc calculated weight system with severity adjusted weights will ensure a more accurate distribution of payments among acute care hospitals, and encourage the long term development and investment in both Medical and Surgical programs. However, the dramatic decrease in payment caused by proposed weight changes in specific areas, in particular the Cardiac DRGs, will cause an undue burden on facilities that provide a higher percentage than the national average in these services. Since this impact is so significant in the Cardiac area, and the severity based system will not be implemented simultaneously, we recommend transitioning the FY2007 DRG weights based on 25% HSRVcc weights and 75% charge based weights.

Most of the dramatic decrease in weights is from two cardiac services, Implantation of Drug-Eluting Stents (DES) and Cardiac Defibrillator Implants. For Cardiac DES we estimate a loss of $4,300 – $4,500 per case in reimbursement, and on Defibrillator Implants a loss of $8,000 – $12,000 per case in reimbursement, depending on the DRG category. This results in over a $3 million annualized reduction to reimbursement from Medicare for our hospital. Since hospitals will find it difficult to demand similar decreases from device/supply vendors, hospitals, not vendors, will have to absorb the majority of this negative impact. Hospitals with large cardiac programs will be unable to absorb this significant loss in reimbursement in such a short time period if the proposed rule goes into affect as written. Implementing a transition period would allow the DRG system to be improved and remove the advantage of specialty hospitals without undermining the financial well being of hospitals with large Cardiac programs.

Fully implementing the cost-based system before implementing the Severity based DRG system will cause large swings in hospital payments from Medicare FY07, only to be reversed in many cases in the following fiscal year once severity adjustments are implemented. Based on our internal analysis, most of the loss from the HSRVcc weights would be reversed under the consolidated Severity based DRG system. Similar results were noted in the Proposed Rule and by MedPac, stating that the HSRVcc drop in DRG weights for certain hospitals will be offset by changes in case mix in the severity based system. The Severity based DRG system improves the reimbursement in high severity cases that most hospitals with large cardiac populations treat. Implementing only the HSRVcc method would cause certain hospitals to suffer needlessly for a year, only to have the loss reversed the

following year. A 25% implementation to cost based weights the first year would reduce this disruption to payments.

Our request is that CMS implement a 25% HSRVcc and 75% charge based DRG weights for FY07, and continue to transition in the cost based weights each year. If the Severity Based Consolidated DRGs are implemented before the transition is complete, we recommend switching to 100% HSRVcc weights with the Severity based DRGs. Once CMS implements the Severity Based Consolidated DRGs, the transition period will no longer be necessary as the effect on reimbursement will be somewhat mitigated.

Thank you for considering our comments to the proposed rule change. If you have any questions about our comments, feel free to contact me at (425) 688-5355 or at gary.mclaughlin@overlakehospital.org.

Sincerely,

GMcLaughlin

Gary McLaughlin
Chief Financial Officer

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Deaconess Hospital

June 5, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Docket Number: CMS-1488-P

Dear Dr. McClellan:

I am writing as a healthcare administrator of Deaconess Hospital, Inc., an acute care nonprofit hospital in southern Indiana. We provide care for a population of almost 900,000 residents of southern Indiana, western Kentucky and southern Illinois.

As a regional tertiary referral hospital we have had a longstanding tradition of being a leader in cardiovascular care and providing many firsts to the tri-state in this service. We have been named as a top 100 heart program. Our cardiovascular program brought open heart surgery to the region in the late 1970s and over the last 30 years has provided the latest in technology and procedures. We are on course to this year perform more than 550 open heart surgical procedures and more than 900 percutaneous coronary intervention (PCI) procedures. Our Electrophysiology program assesses patients for the clinical indicators that place them and risk for sudden death, and provides life saving device implants.

As a hospital, we have more than 4,000 inpatient discharges each year categorized as a cardiovascular DRG. Of our cardiovascular inpatients, 70 percent of them are Medicare beneficiaries. In partnership with our cardiologist, we offer more than 22 rural cardiovascular clinics, where our cardiologists travel to small rural hospitals bringing cardiovascular services to communities that otherwise do not have access to this specialty care.

I appreciate the considerable effort of you and your staff in the development and improvement of the inpatient prospective payment system (IPPS) and recognize that there is need to evolve the system to reflect the current landscape within the medical field. I appreciate that there are significant complex matters in gathering accurate cost data, and that that data serves at the basis of payment systems such as the proposed IPPS.

CMS Proposed Changes

As I understand the current situation, CMS is proposing to make significant changes to IPPS, in a response to what seems to be primarily based upon the MedPAC report. While the work of MedPAC was to address the "specialty hospital" situation, this resulting change in reimbursement is targeted at all hospitals, and particularly those that provide significant tertiary referral cardiovascular care. Tertiary referral hospitals see more procedure based cardiovascular patients – those financially targeted the most by the CMS changes.

There are two significant areas of concern with the proposed IPPS. First, the proposal incorporates an estimated "cost-based" system, rather than a charge-based system for determining the payment weights for each patient category in 2007. Second, the proposal seeks to change the way of identifying the variation in patients' severity of illness that would be implemented in 2008, or potentially 2007. Each change is significant and in previous years would be considered a major modification to the payment system. Changing both at one time is unprecedented.

CMS proposes to base payments on "cost". In many ways this can be looked upon as a positive change and is consistent with how private insurers handle costs associated with technology. However, the primary difference between CMS's proposed methodology and private insurers is the timing of cost data. Private insures are utilizing data in real-time and are paying actual invoice cost for technology used in the care of patients. In CMS's proposal, the "cost" for a particular category of patients is not an approximation of the actual price the hospital pays for the items and services required to treat patients, rather it is a rough approximation of costs.

To calculate the cost estimates for Fiscal Year 2007 payments, CMS proposes to utilize hospital claims data from Fiscal Year 2005 and hospital cost reports from Fiscal Year 2003. The cost reports provide the actual cost and the actual charges for all patients (non-Medicare and Medicare patients). The use of any data from Fiscal Year 2003 fails to account for current technology costs, particularly drug-eluting stents and bi-ventricular pacemakers/defibrillators. These devices today are the mainstay of any cardiovascular program across the nation and represent a clinical standard of cardiovascular care in any community. As this stands, the estimates on cost that CMS will use to put forth its rates in 2007 will necessarily be incorrect and will inadequately compensate hospitals for the care of Medicare patients.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by approximately 10 percent. Application of hospital specific values to the

current DRG system would result in an overall average decrease of approximately 6 percent to surgical DRGs, while increasing medical DRGs by 6 percent. In addition, technology intensive DRGs will be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24–34 percent, ICD implants will be reduced 22–24 percent and pacemakers will be reduced 12–14 percent severely impacting these services.

These proposed reductions to cardiac services are severe and are not rooted in any type of realistic mechanism for assessing costs to provide treatment. While it is appropriate to pursue a better understanding of actual cost to treat cardiac patients, and such efforts must be made with the intention of producing accurate information – the end result may well be an alteration in the existing infrastructure for cardiac services reimbursement. However, the existing proposal simply cannot be implemented in its current form, as the impact for cardiac programs across the country will be grave and may potentially limit patient access to leading edge technology (because hospitals will not be able to adequately recover their acquisition costs). I do not believe that this is what CMS intends to achieve with this proposal.

Given the situation described, delaying the implementation of any changes to cardiac services reimbursement until such time as accurate and appropriate information regarding cost to treat and manage patients with cardiovascular diseases can be compiled is the only prudent approach that can be taken.

Cardiovascular disease is our nation's number one killer, and residents of Evansville, Indiana and the tri-state we serve have a higher rate than the nation of dying from this disease. These changes are very real to our hospital cardiovascular program and will significantly impact our financial ability to provide the level of services our community has become accustomed to receiving from us.

I realize that this is an extremely complex issue, that CMS is committed to ensuring adequate reimbursement for all clinical services and desires to ensure that hospitals remain able to provide access to high quality cardiovascular care involving cutting edge technologies in all settings of care. I appreciate your consideration of this matter.

Sincerely,

Becky Malotte

Becky Malotte, RN, MSN
Executive Director Heart Services
Deaconess Health System
600 Mary Street
Evansville, IN 47747

SHORE MEMORIAL
HOSPITAL

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June 8, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Cost-Based Weights: Outlier Threshold

Gentlemen:

Shore Memorial Hospital appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services proposal to adopt Hospital Specific Relative Value (HRSV) weights for all Diagnosis Related Groups (DRG).

The use of Hospital specific information to determine the cost of providing inpatient care and development of Medicare payment weights is a significant improvement over the current system where DRG weights are based upon charges. Shore Memorial Hospital believes this will result in more appropriate Medicare payments and we support this initiative.

Sincerely,

James T. Foley
Vice President of Finance/CFO

Mile Bluff
Medical Center

1050 Division Street
Mauston, Wisconsin 53948

Phone (608) 847-6161
TDD (608) 847-5422

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

June 7th, 2006

Reference: CMS-1488-P; FY07 IPPS NPRM, *Federal Register* April 25, 2006.

Dear Administrator McClellan:

Mile Bluff Medical Center in Mauston, Wisconsin appreciates the opportunity to comment on the proposed rule implementing changes to the hospital inpatient prospective payment systems for fiscal year 2007, published in the April 25, 2006 *Federal Register*. We appreciate your ongoing commitment to rural hospitals and hope that you understand and appreciate our position on the proposed rules.

The proposed rule is exceedingly complex, implementing among the most significant changes to hospital payments since the inception of the program. In summary:

- **We support CMS's efforts to finally move the system to one that is consistent with the agency's original intent. The change is long overdue, and we oppose any delay.**

- **The CSA DRG changes are significant, burdensome, and the lack of a complete impact analysis has denied hospitals the opportunity for appropriate review and comment. It is premature to implement the CSA DRG change for FY07.**

Our detailed comments are as follows:

HSRV Weights

CMS proposes to make major changes to the calculation of DRG relative weights by using hospital-specific relative values and a modified version of costs instead of charges (HSRVcc). There has been a longstanding bias in the PPS system that skews DRG weights upwards for services performed mostly at larger urban facilities, such as teaching hospitals. Up until now, the calculation of DRG relative weights has been done by using hospital charges as a proxy for hospital costs. There may or may not be a good correlation between individual hospital charges and costs, so using charges as a basis for DRG weights is not an appropriate way to determine resource utilization based on underlying costs. RWHC supports the effort to restructure DRG weights based on cost in order to remedy this longstanding inappropriate determination of resource consumption.

Furthermore, we are all well served by remembering that the original intent of the prospective payment system was to base DRG reimbursement on costs, not charges. **We support CMS's efforts to finally move the system to one that is consistent with the agency's original intent. The change is long overdue, and we oppose any delay.**

DRGs: Severity of Illness

Mile Bluff Medical Center has serious concerns about the proposal to use consolidated severity adjusted (CSA) DRGs. According to CMS's analysis, this proposal will lower payments to rural hospitals by 3.1 percent. When combined with the HSRVcc proposal, rural hospitals see a net cut of 0.4 percent. (Table L, *Federal Register* p. 24025.) The effect for small hospitals is even more damaging, with cuts of 5.2 percent under the CSA DRG proposal, and a net reduction of 1.3 percent from both proposals. This payment reduction will have a serious affect on rural hospitals ability to continue providing care and will restrict access to care in rural communities.

We note that have been several analyses done outside of CMS that attempt to replicate CMS's work while correcting for various technical flaws. These analyses find the same trend for rural hospitals, but in different orders of magnitude. For example, the Moran Company's analysis addressed several technical flaws in the data, and subsequently found that rural hospitals would see a net cut of 1.2 percent under the combined HSRVcc and CSA DRG proposals. Clearly the impact analysis is highly sensitive to changes in methodology, which raises the concern that the impact of the final rule will vary widely from the proposed rule, while providing no further opportunity for comment.

Furthermore, we point out that Section 1102(b) of the Social Security Act requires a regulatory impact analysis that describes the impact on small rural hospitals, including a description and estimate of the number of small entities that will be affected, and a description of steps the agency took to minimize the economic impact. This required impact analysis is lacking for the CSA DRG proposal.

Mile Bluff Medical Center is also very concerned about the use of a proprietary system (3M Health Information Systems) to implement public policy. Under the current system, there is adequate information publicly available to replicate various aspects of the derivation of DRGs and the assignment of specific cases to a particular DRG. This degree of transparency is missing in the proposed system. There is the very real possibility of changes in public policy being brought about through changes made in a proprietary system, In addition, there is a financial burden that rural hospitals will incur if they must implement this CSA DRG system. If the new 3M Health Information Systems grouper is not in the public domain it will likely come at a high cost, given that it only available from 3M Health Information Systems or through a contract with a vendor that has a contract with 3M Health Information Systems. This cost will be borne disproportionately by rural hospitals like ours.

Therefore, Mile Bluff Medical Center strongly advises against implementation of the CSA DRG for FY07 given the fact that (1) hospitals have not have opportunity to review and comment on a full impact analysis of the CSA DRG proposal; (2) small rural hospitals have not had the opportunity to review and comment on the 1102(b) impact analysis required by statute; (3) the data are highly sensitive to changes in methodology, which means the impact analysis provided in the NPRM will be somewhat moot if CMS changes its methodology; and (4) implementation of this proposal will impose large financial and administrative burdens on small hospitals. **The CSA DRG changes are significant, burdensome, and the lack of a complete impact analysis has denied hospitals the opportunity for appropriate review and comment. It is premature to implement the CSA DRG change for FY07.**

Mile Bluff Medical Center appreciates the opportunity to submit these comments on the proposed rule. Please do not hesitate to contact Charlie Button, Chief Financial Officer at 608-847-6161 if you have any questions about these comments.

Sincerely,

James M. O'Keefe
President/CEO

256

VASCULAR SURGERY ASSOCIATES, P.A.
MICHAEL J. BEEZLEY, M.D., F.A.C.S.
RICHARD C. ARNSPIGER II, M.D., F.A.C.S.
DANIEL P. CONNELLY, M.D., F.A.C.S.
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SUITE 5
9501 STATE AVENUE
KANSAS CITY, KANSAS 66111

SUITE 350
20375 WEST 151ST STREET
OLATHE, KANSAS 66061

May 25, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I received this letter suggesting that I communicate my concerns about this proposed rule change before the 12th of June.

Actually, as a Vascular Surgeon I am very much in support of this rule change. Cardiologists across the country are doing way too many non-indicated, non-necessary, procedures just because "lesions are there to stent".

I wholeheartedly agree with greatly reducing their reimbursement for stent procedures especially in the peripheral/vascular realm. I also would suggest to CMS that pre-approval be required before any stenting procedure on an elective basis.

If you have any questions concerning my thoughts please feel free to call.

Sincerely,

Michael J. Beezley, M.D.
Vascular Surgeon
MJB/ysr

Attach 256

Medtronic

Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403 USA

tel 707.566.1166
fax 707.566.1296

Scott R. Ward
Sr. Vice President and
President

May 16, 2006

Dear Dr. Beezley,

On April 12, 2006, CMS released its proposed hospital inpatient payment rule for FY07. The rule recommends significant changes to the DRG methodology that move funds away from cardiology services, including proven, cost-effective therapies like implantable cardioverter defibrillators (ICDs) and drug eluting stents, and into other hospital services. CMS' proposed methodology changes are intended to address concerns about the growth in physician-owned specialty hospitals but will affect all hospitals providing cardiology services – not just specialty hospitals. I am writing to you today to encourage you to communicate your concerns about this proposed rule to CMS, and also very importantly to your government representatives before June 12, the end of the official comment period.

A summary of the CMS Proposal is attached for your review but I can assure you that there are some significant methodological problems with the proposed rule. First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by almost 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14%.

CMS-25

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Centers for Medicare & Medicaid Service
Department of Health & Human Service
Attention: CMS - 11488- P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007/Rates. 4/25/06 Federal Register pages 23995-24550

After studying the impact on my community I am very concerned about the unintended negative impact. To better understand how significant the impact is I need to explain how cardiology services are organized in Utica, NY. In the mid 1990's all three Utica hospitals collaborated to form the Mohawk Valley Heart Institute (MVHI), which is a New York State article 28 hospital corporation with its own operating certificate. MVHI holds the certificate of need to perform interventional cardiology and cardiac surgery. The agreement to make this happen at that time was to consolidate all obstetrical services at St. Luke's Hospital and all interventional cardiac services at St. Elizabeth Medical Center. In 2001, Faxton Hospital and St. Luke's Hospital merged. Today, MVHI is wholly owned by the two competing hospital systems in Utica, Faxton-St. Luke's Healthcare (FSLHC) and St. Elizabeth Medical Center (SEMC). Any profits generated by the cardiology services are shared by these two not for profit community hospitals. New York State has recognized MVHI as a model program for cardiology services.

The impact to MVHI if the changes are implemented is catastrophic. At St Elizabeth Medical Center there will be about $3,500,000 less revenue (6% decline). About 43.5% of discharges at SEMC are cardiac. At Faxton-St. Luke's healthcare, because of the corresponding increase in medical DRGs, there will be an estimated increase in $3,000,000 revenue. So, the impact will be to cause one of the collaborators to have a wind fall while the other suffers greatly. Our community has created a cardiac specialty hospital for the purpose of providing high quality care and not duplicating resources. How can the community justify keeping MVHI when the financial impact rewards one institution and penalizes the other?

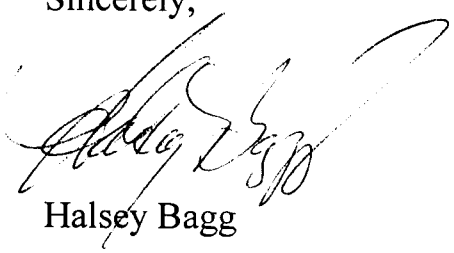
Since one of the purposes of changing the DRG reimbursement system is to restrict the growth of for profit specialty hospitals, especially cardiac, MVHI

has also become a target of this effort. Rather than change reimbursement for cardiac DRGs as the method of impacting these for profit cardiac specialty hospitals, why not propose a specific tax on these for profit specialty hospitals, or even better not allow them to exist. Wouldn't that be a more direct way of resolving this issue?

The reimbursement of hospitals should be tied to the health care needs of our country. Heart disease is still the major reason for death from disease in America. How can we justify decreasing resources for this disease when the needs are so great?

I believe that a not for profit entity such as the Mohawk Valley Heart Institute should somehow be held harmless from this proposed change.

Sincerely,



Halsey Bagg

Director Cardiology Services
St. Elizabeth Medical Center

Co-Coordinator
Mohawk Valley Heart Institute

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CATHOLIC HEALTH INITIATIVES

St. Joseph Regional Health Network

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1488-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

St. Joseph Medical Center appreciates the opportunity to comment on the proposed rule (CMS-1488-P) that would change the Hospital Inpatient Prospective Payment System (IPPS) and Fiscal Year 2007 Rates. Founded by the Sisters of St. Francis of Philadelphia congregation and now part of Catholic Health Initiatives, St. Joseph Medical Center has served the City of Reading, Pennsylvania and Berks County community for over 134 years. We offer not only acute and surgical services to our community of approximately 400,000, but have developed an innovative ambulatory, extended care and health training academy campus in the inner city that some have claimed will be the future model for urban health delivery in the future.

The proposed rule would revise the methodologies used to calculate the relative weights of the Diagnosis Related Groups (DRGs) used to determine Medicare inpatient hospital services payment. The proposal would replace charge-based weights with a modified version of cost-based weights using hospital-specific relative values (HSRVs). The Centers for Medicare and Medicaid Services (CMS) also proposes a major revision to the DRG classification system to account for patient severity.

Adoption of the proposed DRG weight changes and proposed severity adjustments would result in the biggest change to the hospital inpatient prospective payment system since its inception. These changes would significantly redistribute payments among the DRGs and among hospitals.

We support improving DRG payments to more accurately reflect resources used in caring for Medicare patients, but it is not clear that the proposed DRG weight changes or new patient classification system will result in a more accurate hospital payment system. Impact estimates at the DRG and hospital level are extremely sensitive to methodological variations. Implementation in FY 2007 would be premature. For example, at this early examination of the new IPPS result on St. Joseph Medical Center, we have estimated a negative financial result of approximately $700,000 annualized. In addition, there has been no time to analyze resource and investment impact of the new IPPS system on changes that will need to occur in our operating systems to appropriately comply with the new IPPS. **We urge CMS to delay these changes, undertake more in-depth analyses of their impact, and evaluate alternative methodologies for improving the DRG system.** In addition, the following identifies our specific concerns relative to each component of the new IPPS:

HRSV Weights

We support a move to cost-based weights but have several concerns about the adequacy and validity of the proposed methodology. More work is needed to determine the best way to create cost-based weights. If changes are made to DRG weights, those changes should be phased in over three years with "stop loss" protections to allow significantly impacted hospitals time to prepare for payment changes.

In particular, **CMS should further analyze and evaluate the impact of:**

- **Use of 2004 Data** – CMS uses claims data taken from the FY 2004 MedPAR file in its methodology. Clinical practice has changed in many areas, especially cardiology, over the past two years. The data used may not reflect current clinical practice. CMS may need to make specific changes to specific DRGs to reflect the change in clinical practice. For example, interventional cardiology DRGs do not reflect the cost of current clinical practice.

- **Variation in Markups** – The CMS methodology assumes a uniform hospital markup, but markups vary from product to product.

- **Distortion of Costs** – The proposed methodology would distort the accuracy of cost estimates by combining multiple cost centers on hospital cost reports into ten CMS-designated cost center. CMS would then determine ten national average cost-to-charge ratios for each of the designated costs centers but the ratios would not be weighted by each hospital's Medicare charges. This would allow very small hospitals to have just as much of an impact on the national cost-to-charge ratios as larger hospitals.

- **Access to Centers of Excellence** – The proposed changes are particularly significant for large volume hospitals and may have a negative impact on Centers of Excellence, which could impede beneficiary access to high quality services.

We recommend delaying until at least FY 2008 the proposed cost-based DRG weights. CMS should undertake a more thorough analysis, including parallel pilot testing, of the proposed changes to identify any unintended consequences. If DRG weight changes are implemented, they should be phased in over three years with "stop loss" protections.

DRGs: Severity of Illness

CMS has proposed a new classification system to reflect severity of illness among patients beginning in FY 2008 or earlier. CMS has proposed adoption of CMS-developed Consolidated Severity-Adjusted DRGs (CS-DRGs) rather than the widely applied All Patients Refined DRG system endorsed by MedPAC. Additional information and further analysis is needed to determine whether the CMS-proposed system, or another classification system, would result in an improved hospital payment system.

Until hospitals have a final GROUPER that can accurately assign the new CS-DRGs, it is difficult to calculate the impact. While we have surrogate methods of calculating the impact, GROUPERs used to calculate payments have changed in the past and minor changes can cause major changes in reimbursement.

We are concerned about the impact of making two major payment changes in two successive years. We are also concerned about the ability of hospitals to adapt to these major changes in PPS in the short time frame proposed.

If the need for and best approach for changing the patient classification system is clearly demonstrated, CMS should simultaneously implement the DRG weight changes and new classification system to provide greater stability and predictability in hospital payments. These changes should not be implemented before FY 2008. A three-year phase-in period with "stop loss" protections should be provided to ensure that redistribution of hospital payments is not unduly disruptive to negatively impacted hospitals.

We recommend further analysis by CMS to determine if the proposed CS-DRGs, or an alternative patient severity classification approach, would result in more accurate payments. If the effectiveness of, and need for, a new patient classification system is demonstrated, CMS should implement the new DRG system at the same time as the DRG weight changes. A three-year phase-in with "stop loss" protections should be allowed to provide greater stability and predictability in hospital payments. A new patient classification system should not be implemented before FY 2008.

Physician-Owned, Limited Service Hospitals

The DRG changes proposed by CMS seek to address the proliferation of physician-owned, limited service hospitals in response to recommendations from the Medicare Payment Advisory Commission. However, we do not believe that payment changes alone will remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving low-income patients, practice similar forms of selection for outpatient services and drive up utilization for services. Indeed, the IPPS inherently may create financial incentives for some surgical procedures, further skewing – not leveling – the "playing field" between physician owned limited service hospitals and not-for-profit community hospitals. We strongly urge CMS to rigorously examine the investment structures of physician-owned, limited-service hospitals. We also urge CMS to continue the suspension of issuing new provider numbers to physician-owned, limited-service hospitals until the CMS strategic plan has been developed and Congress has had an opportunity to consider CMS' final report on physician-owned, limited service hospitals.

Hospital Quality Data

We support expansion of the number of measures to be reported for the Annual Hospital Payment Update. This expansion follows the recommendation of the Institute of Medicine. However, we do have a concern with the timing of the final regulation and the requirement to begin the expanded reporting with January 1, 2006 discharges.

Hospitals are currently abstracting information for quality reporting for the January – March 2006 period with a closing date of mid-July. For those hospitals that have been collecting the "starter set" of 10 quality measures and have not begun abstracting the additional 11 measures, this retroactive requirement may pose an undue monetary and administration burden.

By the time the final rule is published, these hospitals may not have time to go back retrospectively and still meet the data submission deadlines for that period, especially if they need to have their vendor contracts amended to allow for the addition of an entire core measure set. These hospitals may also have difficulty retroactively collecting the second quarter information.

We recommend that CMS start the reporting period for the expanded quality measures with services provided on or after July 1, 2006.

Value-Based Purchasing

The Deficit Reduction Act of 2005 requires the Secretary to identify by October 1, 2007 at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through application of evidence-

based guidelines. For discharges occurring on or after October 1, 2008, hospitals would not receive additional payment for cases in which one of the selected conditions was not present on admission. CMS seeks input on which conditions and which evidence-based guidelines should be selected.

The proposed rule discusses hospital acquired infections as a complication that could trigger higher payments and an area for consideration. Our concern with the selection of hospital acquired infections as a condition for denying additional payment is that the codes currently used in billing data do not accurately distinguish hospital-acquired infections from community-acquired infections.

Even surgical site infections, which should intuitively be accurately identified through administrative data, have proven to be grossly in error when compared to data collected and reviewed by infection control practitioners using Centers for Disease Control and National Infection Surveillance System definitions.

Instead of hospital acquired infections, CMS may want to consider hospital falls with injury and pressure ulcers not present on admission as two conditions that are potentially preventable through use of evidence-based practices.

In any case, we believe that administrative data should not be the sole decider. Just as there is additional data gleaned from records for the core quality measures, we believe that the adverse outcome concept can only be adequately gauged by reviewing the actual record to ensure that the event is accurately captured, and that the appropriate preventive measures were, or were not, followed. Only then would it be reasonable to base reimbursement on the occurrence.

We recommend that CMS select two "preventable" conditions for additional payment denial that can be most accurately identified as not present upon admission through billing data. Once identified, patient records should be reviewed to determine whether appropriate preventive measures were followed before denying additional payment for the condition.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

John R. Morahan
President/CEO

Lahey CLINIC

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Lynn Malloy Stofer
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June 9, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Lahey Clinic is a 303 bed acute care hospital and outpatient clinic located in the greater Boston marketplace where approximately 3,000 patients are seen daily. As a major health care provider in our area, Lahey performs a wide array of cardiovascular procedures and, therefore, implants medical devices on a significant number of Medicare beneficiaries in the inpatient setting. In fact, cardiology services are a "Center Of Excellence" at Lahey Clinic, where we have invested heavily in talent (people), equipment and space and continue to experience emerging opportunities for growth. More than 42,000 patients annually seek cardiac care at Lahey Clinic. Because inpatient services are a key component of what we provide, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while

increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases. As a result, technology costs could be underpaid.

The payment methodology changes that CMS has proposed would have a severe financial impact on Lahey Clinic – without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs where the proposed payment level is often significantly less than our hospital's actual cost to deliver the service.

The reduction in payment for cardiology services would also have a severe impact on the infrastructure that we have built over the years to treat the number one killer in America today - heart disease. In addition the potential dismantling of the infrastructure, we now face the uncertainty of knowing that next year, or any other year, CMS could decide to under-fund a different service that Lahey might develop to meet patient needs. Obviously, if forced to scale back or not develop service capacity due to payment swings and financial uncertainties, patient access could be negatively affected.

I respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by Lahey Clinic can be appropriately reflected in the DRG payments.

Thanking you for your consideration, I am

Sincerely,

Lynn Malloy Stofer
Senior Vice President, Clinical Services
Lahey Clinic
31 Mall Road
Burlington, MA

LMS/gdc

American Organization of Nurse Executives

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June 12, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services (CMS)
P.O. Box 8011
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

I am writing to you on behalf of the over 5,000 members of the American Organization of Nurse Executives (AONE) who as Registered Professional Nurses provide executive nursing leadership in America's hospitals and in the health systems field.

As a professional nursing organization directly involved with the day-to-day operations and delivery of patient care, we appreciate this opportunity to comment on CMS' proposed Diagnosis Related Groups (DRG) changes in the inpatient prospective payment system rule: RE CMS-**1488-P Medicare Program: Proposed Changes to the Hospital Prospective Payment Systems for Fiscal Year 2007 Rates**. Our interest in this proposal lies in the opportunity it presents to directly factor nursing into the DRG system. It also provides an opportunity to further validate research on the economic relationship of nursing care costs to staffing, education, quality and patient outcomes.

The CMS stated goal is to align future hospital payment with actual cost expenditures; however under the current system it is not possible to calculate the true cost or impact of nursing care. Under the original conceptualization of the DRG System, arguments were made to create a separate cost center for nursing; however, the final design subsumed these costs in what has evolved as room and board room costs. Since the design of the DRG system, nursing research has evolved to show the critical relationship between nursing education, the hours of professional nursing care, and patient outcomes. If the overall intent of CMS is to change the current prospective payment system to reflect the cost of care and accommodate varying levels of acuity, the contributions of nursing must be directly reflected in whatever system is developed and implemented.
As a practitioner, you are aware of the tremendous changes that have occurred in our nation's hospitals and the impact of this change on nursing chare intensity.

This change is most evident in the complexity of the patient mix and the nursing skill and intensity that must be employed to effectively manage patients and save lives. In this context, we view the CMS proposal to develop a new patient classification system as an opportunity to begin a dialogue to examine and understand the true cost of nursing and its relationship to hospital costs. As CMS works to refine the classification system, nursing intensity should be considered along with diagnoses, procedures and other hospital resources as a factor that can distinguish new categories for patient classification. It is our hope that you will view our request as a call for action to bring a full and complete understanding to the complex world of hospital costs and provide recognition to the critical component of nursing care.

Thank you for the opportunity to comment. You may direct questions or comments concerning our remarks to me or Jo Ann Webb, senior director for federal relations and policy at (202) 626-2321 or jwebb@aha.org

Sincerely,

Kathleen D Sanford, RN, DBA, FACHE

Kathleen D. Sanford, RN, MA, DBA, FACHE
President

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Holy Name Hospital

Member
NewYork-Presbyterian Healthcare System
Affiliate: Columbia University College of Physicians & Surgeons

718 Teaneck Road | Teaneck, New Jersey 07666
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June 5, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Cost-Based Weights: Outlier Threshold

Gentlemen:

Holy Name Hospital appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services proposal to adopt Hospital Specific Relative Value (HRSV) weights for all Diagnosis Related Groups (DRG).

The use of Hospital specific information to determine the cost of providing inpatient care and development of Medicare payment weights is a significant improvement over the current system where DRG weights are based upon charges. Holy Name Hospital believes this will result in more appropriate Medicare payments.

Sincerely,

Marcello Guarneri
Director, Budget and Reimbursement
Financial Services

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June 12, 2006

Secretary Michael O. Leavitt
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates: 1) Overarching Comments; 2) Hospital Quality Data; 3) Value-Based Purchasing; and 4) Health Care Information Transparency Initiative

Dear Secretary Leavitt:

Thank you for the opportunity to comment of the proposed changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates. We applaud your efforts to promote and foster increased transparency and we believe that Medicare should lead the way to promoting a market that recognizes and rewards high-quality, efficient, and patient-centered care. First, let us offer some overarching comments for your consideration before providing more granular feedback on three sections of the proposed rules that address hospital quality data, value-based purchasing, and the health care information transparency initiative.

OVERARCHING COMMENTS

Assess provider performance using robust measures: Medicare should evaluate the performance of each health care provider that bills Medicare, using nationally-endorsed, scientifically-valid, risk-adjusted, and regularly-updated measures that address:

- Clinical quality (safe, timely, and effective care);
- Efficiency (prices and resource use over time);
- Equity (gender, race, ethnicity);
- Patient experience; and
- Structure or systems (e.g., use of quality-enhancing information technology).

Recommended Actions

o Provide substantial funding to support development of consumer-relevant measures that fill existing gaps (especially efficiency and equity). Developing measures is a public good that requires significant financing from the public sector. Because of the lack of well-specified and endorsed measures that meet consumers and purchasers' needs, measure developers and their funders should be guided by the following considerations:

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- Reasonably scientifically acceptable. Consumers and purchasers want measures to be scientifically sound, but do not want the pursuit of perfection to delay the availability of good and useful information.
- Feasible to implement. Rapid reporting necessitates measures are constructed and specified so that the data needed is currently available or can be collected with limited reporting burden.
- Relevant to consumers and purchasers. The needs of consumers and purchasers for important and actionable information must drive the development of measures.
- Reflect the continuum of care/care coordination from a patient's perspective. Measures should address the extent to which comprehensive, patient-centered care is delivered, often by multiple providers.
- Provide core operating support for the National Quality Forum (NQF) to ensure ongoing, independent consensus process for the review, endorsement, and updating of measures so as to enable the availability comparative information and the reduction of provider reporting burden.

Collect and report information that will enable informed decision making and provider selection. Medicare should provide the public with the information on the aspects of provider performance described above. Doing so, will allow: 1) consumers to make informed decisions about their health care; 2) insurers and purchasers to make value-based contracting decisions and use differential payments as incentives; and 3) providers' improvement efforts to be supported with better information.

Recommended Actions

- Release physician-identifiable Medicare claims data (fully protecting patient privacy), to allow for better quality and efficiency performance reporting.
- Continue to allow private-sector organizations to download granular provider performance information from the Compare websites.
- Augment hospital claims data with additional clinical data elements to better understand patient acuity.

Implement financial incentives that are sensitive to the provision of high-quality, efficient, patient-centered care: Medicare should phase in a system that differentially pays providers based on nationally standardized measures.

Recommended Actions

- Continue to rapidly expand the number and type of measures that hospitals must report to obtain annual payment update.
- Medicare payments must be sensitive to provider performance and create financial incentives to provide quality care.
- Incentives should take into account performance on quality, efficiency, and patient experience.
- Provider incentives should be budget-neutral and based on a combination of improvement and meeting thresholds.

Now let us offer specific comments on the proposed changes to the three sections that address hospital quality data, value-based purchasing, and the health care information transparency initiative.

SECTION: HOSPITAL QUALITY DATA

Reporting of Hospital Quality Data for Annual Hospital Payment Update
Fiscal Year 2007: We support CMS' recommendation to reduce the FY 2007 annual hospital payment update by 2% for any hospital that does not submit data on 21 measures (8 heart attack, 4 heart failure, 7 pneumonia, 2 surgical infection prevention) for patients discharged starting January 1, 2006 through December 31, 2006.

Fiscal Year 2008: CMS must do far more than merely "exploring the feasibility of adopting additional measures for FY 2008 update, including HCAHPS." There should be a **substantial** expansion of measures for hospitals to obtain the FY 2008 annual update. We strong urge that CMS adopt the measures identified in the Institute of Medicine's *Performance Measurement: Accelerating Improvement*, i.e., Hospital-CAHPS and three structural measures (computerized provide order entry, intensive care staffing with intensivists, and evidence-based hospital referral) as well as consider and adopt a number of other NQF-endorsed measures, for example:
Outcomes
- 30-day heart failure mortality
- 30-day heart attack mortality
- Failure to rescue

Complications
- Urinary catheter-associated infection rate
- Central line-associated blood stream infection rate
- Ventilator associated pneumonia rate

Clinical
- Surgery patients with recommended venous thromboembolism prophylaxis ordered
- Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 hour prior to surgery to 24 hours after surgery.

Electronic Medical Records (p. 343-344)
Health information technology (HIT) – which includes software applications for care management (EMR, EHR, practice management systems, registries) – has the potential to dramatically improve the quality and efficiency of health care, however implementation has been slow. The Secretary should ensure that the data necessary for quality measurement are captured by using conditions of participation that require hospitals to implement HIT/software applications that:
- Comply with interoperability standards;
- Enable standardized quality, performance, and efficiency measurement are a routine by-product of their use. [NOTE: Adapted from AQA Data Sharing and Aggregation Subgroup on HIT: www.ambulatoryqualityalliance.org/files/PrinciplesforHITandMeasAgg-May06.doc]
- Are designed to enable the merger of their data with others for the purpose of facilitating the production of standardized quality, performance, and efficiency

information. [NOTE: Adapted from AQA Data Sharing and Aggregation Subgroup on HIT]

Further, the Secretary should tie the annually hospital payment update to the reporting of hospitals' progress toward CPOE implementation (see previous comments under Hospital Quality Data for Annual Payment Update).

Until HIT becomes wide-spread the Secretary can enable much more robust hospital performance reporting by requiring hospitals to report the following data elements on both paper and electronic claims:

- A unique physician identifier for each coded procedure;
- Capture the referring/ordering physician for each coded procedure;
- Vital signs (heart rate, blood pressure, temperature, and respiratory rate) recorded at presentation;
- Key lab values (BUN, hematocrit, platelets, WBC, sodium, potassium, and creatinine) if obtained at the time of admission, excluding hospitalizations for psychiatric, obstetrical and newborn services;
- Do Not Resuscitate order present (including date and time), if recorded during first 24 hours of patient presenting; and
- Time of day of admission, discharge, and each procedure.

SECTION: VALUE-BASED PURCHASING (p. 344 – 367)

Plan for Implement Hospital Value-Based Purchasing Beginning with FY 2009

As CMS works to develop a plan to implement hospital value-based purchasing beginning in FY 2009, the following issues must be addressed: (a) the ongoing development, selection, and modification process for hospital quality and efficiency measures; (b) the reporting, collection, and validation of data; (c) the structure of payment adjustments; and (d) the disclosure of hospital performance information.

Measure development and refinement (p.350-353)

- As noted in our overarching comments, the development of consumer relevant measures is critical and the Secretary should provide substantial funding to support development of consumer-relevant measures that fill existing gaps (especially efficiency and equity). Developing measures is a public good that requires significant financing from the public sector. Because of the lack of well-specified and endorsed measures that meet consumers and purchasers' needs, measure developers and their funders should be guided by the following considerations:
  - Reasonably scientifically acceptable. Consumers and purchasers want measures to be scientifically sound, but do not want the pursuit of perfection to delay the availability of good and useful information.
  - Feasible to implement. Rapid reporting necessitates measures are constructed and specified so that the data needed is currently available or can be collected with limited reporting burden.
  - Relevant to consumers and purchasers. The needs of consumers and purchasers for important and actionable information must drive the development of measures.
  - Reflect the continuum of care/care coordination from a patient's perspective. Measures should address the extent to which comprehensive, patient-centered care is delivered, often by multiple providers.

- Provide core operating support for the NQF to ensure ongoing, independent consensus process for the review, endorsement, and updating of measures so as to enable the availability comparative information and the reduction of provider reporting burden.

Incentive Methodology (p. 357-367)

- *Incentive Structure*: Incentives should be based on a combination of improvement and meeting quality thresholds based on standard measures adhering to the consumer-purchaser disclosure project guidelines. Our experience with incentives programs indicates that basing the incentives on attaining specific quality-based thresholds allows hospitals (including those serving disenfranchised populations or unique communities) to focus their efforts on the highest-yield improvements. Because of the evidence that performance dramatically varies within hospitals, incentives should be available and calculated at both the service-line level (for clinical areas) and hospital-wide (e.g. for HCHAPS). In the private sector, The Leapfrog Group designed the Leapfrog Hospital Rewards Program to reward both *top performers* and *performance improvers*. The goal is to provide incentives for hospitals to improve continuously and to sustain that improvement once it is achieved. Because the LHRP measures a hospital's performance relative to the performance of other hospitals, even top performers will need to improve continually in order to maintain their status. This use of relative performance to determine which hospitals earn rewards and the level of those rewards was advanced by the current CMS-Premier Hospital Quality Incentive Demonstration. As reported, this Demonstration has experienced quality improvement among participating hospitals on care processes that help ensure better outcomes. As Medicare moves to a permanent use of incentives for quality, setting both baseline thresholds of performance and a relative ranking system will help all hospitals make improvements appropriate to their current level of performance.
- *Level of Incentive*: The share of payment tied to performance should be substantial, though what constitutes "substantial" will differ from one provider to another, i.e., the same percentage may not be appropriate for both hospitals and physicians. The overall proportion of CMS payments dependent on incentives should grow significantly and could eventually reach a level so that 10% or more of total Medicare payments is sensitive to performance. CMS should set and revise the appropriate level using the information that continues to develop from its demonstration projects and private-sector efforts. Initially, we believe that the performance incentive for hospitals should be on the same order of magnitude as the 2% incentive for the FY07 annual market basket update. In addition to financial rewards, there are two other types of incentives CMS can employ: the potential for increased market share and public recognition. For example, The Leapfrog Group designed the Leapfrog Hospital Rewards Program to increase the patient volume at better hospitals through consumer education and benefit design that encourages patients to seek out the best hospitals. This patient shift creates savings for the purchaser, better care for patients, and incentives in the marketplace for hospital improvement. This phenomenon can be supported by ongoing consumer testing of Hospital Compare and making sure that it displays hospital performance information that is as current as possible. We strongly support the current CMS efforts to increase quality and cost transparency. The Leapfrog Group employer members agree that **public** awareness of hospital quality is a powerful motivator for performance improvement. A powerful example was the significant improvement in nursing home quality that was demonstrated in AHRQ's National Healthcare Quality Report between

2003 and 2004, following when CMS began publicly releasing nursing home quality data.

- *Source of Incentive*: Providing additional funding to finance performance incentives is an unrealistic option given the current economic pressures faced by CMS. As a result, value based purchasing initiatives should be budget neutral. The Leapfrog Hospital Rewards Program is an example of how to accomplish budget neutral incentives. Rewards paid out are based on a share of the savings which accrue in the market due to hospital improvement. If there are no savings, no rewards are paid. This design helps ensure implementers' ability to fund bonus payments is sustainable over time. The dollar amount of hospital rewards is not set in advance, though the methodology by which rewards will be calculated is known by hospitals in advance. As rewards are based on the savings generated by hospital performance, the amount of rewards will vary from one period to the next. While this "shared savings" model is more easily implemented when hospitals earn per-diem reimbursement, The Leapfrog Group, with assistance from private sector stakeholders and CMS, is currently devising a similar methodology for DRG-based reimbursement. Leapfrog's incentive structure design for DRGs adheres to the principles of using measured quality and efficiency performance to create budget neutral incentives for hospital performance. The Leapfrog Group would be eager to continue to share its ideas in this area with CMS as appropriate.

Public Reporting (p. 362)

CMS should further stimulate public reporting to increase the transparency and meaningfulness of health care performance information by taking the following actions:

- Continue to allow private-sector organizations to download granular provider performance information from the Compare websites.
- Support further research and consumer testing around the development and display of measure composites, including how different tiers of composite score could be constructed, e.g., an total score combining clinical quality, patient experience, and efficiency; overall score on those three respective domains, and a composite by service line (diabetes, cardiac care, etc.).
- While improving the utility of the CMS Compare websites through using composites and rank ordering providers by performance, CMS should maintain the ability for consumers to "drill down" to a granular level of performance detail.

Beyond these suggested actions, we would call your attention to the Principles for Public Reporting of Health Care Information that were developed and endorsed by the members of the Ambulatory Care Quality Alliance as an additional useful reference. These Principles can be found at:
http://www.ambulatoryqualityalliance.org/files/ConsumerPrinciplesMay06.doc

Hospital Acquired Infections (p. 363)

Given the tremendous toll – both human and financial – caused by hospital-acquired infections, the Secretary should go much further than the statutory minimum of identifying "at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines." The Secretary should work with those states that currently collect Present on Admission (e.g., California and Pennsylvania) to determine all those conditions that meet the above criteria and select a substantial portion of them for which hospitals would not receive additional payments.

With the requirement for hospitals to submit the secondary diagnoses that are present on admission for discharges after October 1, 2007, we anticipate much more robust hospital outcomes reporting due to the increased ability to differentiate co-morbidities from complications.

Promoting Effective Use of HIT (p. 364)
Health information technology (HIT) – which includes software applications for care management (EMR, EHR, practice management systems, registries) – has the potential to dramatically improve the quality and efficiency of health care, however implementation has been slow. The Secretary can spur HIT adoption and ensure that the data necessary for quality measures are captured by using conditions of participation that require hospitals to implement HIT/software applications that:

- Comply with interoperability standards;
- Enable standardized quality, performance, and efficiency measurement are a routine by-product of their use. [NOTE: Adapted from AQA Data Sharing and Aggregation Subgroup on HIT: www.ambulatoryqualityalliance.org/files/PrinciplesforHITandMeasAgg-May06.doc]
- Are designed to enable the merger of their data with others for the purpose of facilitating the production of standardized quality, performance, and efficiency information. [NOTE: Adapted from AQA Data Sharing and Aggregation Subgroup on HIT]

Further, the Secretary should tie the annually hospital payment update to the reporting of hospitals' progress toward CPOE implementation (see previous comments under Hospital Quality Data for Annual Payment Update).

Until HIT becomes wide-spread the Secretary can enable much more robust hospital performance reporting by requiring hospitals to report the following data elements on both paper and electronic claims:

- A unique physician identifier for each coded procedure;
- Capture the referring/ordering physician for each coded procedure;
- Vital signs (heart rate, blood pressure, temperature, and respiratory rate) recorded at presentation;
- Key lab values (BUN, hematocrit, platelets, WBC, sodium, potassium, and creatinine) if obtained at the time of admission, excluding hospitalizations for psychiatric, obstetrical and newborn services;
- Do Not Resuscitate order present (including date and time), if recorded during first 24 hours of patient presenting; and
- Time of day of admission, discharge, and each procedure.

SECTION: HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE (p. 447)
As the Department builds upon its current transparency efforts, we would encourage the Secretary to increase both the scope and breadth of consumer-friendly cost and quality information by employing the following strategies:

Support the development, endorsement, and updating of performance measures

- Provide substantial funding to support development of consumer-relevant measures that fill existing gaps (especially efficiency and equity). Developing measures is a public good that requires significant financing from the public sector. Currently,

because of the lack of well-specified and endorsed measures that meet consumers and purchasers' needs, measure developers must be encouraged to create measures that are:

- o Reasonably scientifically acceptable. Consumers and purchasers want measures to be scientifically sound, but do not want the pursuit of perfection to delay the availability of good and useful information.
- o Feasible to implement. Rapid reporting necessitates measures are constructed and specified so that the data needed is currently available or can be collected with limited reporting burden.
- o Relevant to consumers and purchasers. The needs of consumers and purchasers for important and actionable information must drive the development of measures.
- o Reflect the continuum of care/care coordination from a patient's perspective. Measures should address the comprehensive, patient-centered care that may be delivered by multiple providers.

• Provide core operating support for the National Quality Forum to ensure ongoing, independent consensus process for the review, endorsement, and updating of measures so as to enable the availability comparative information and the reduction of provider reporting burden.

<u>Increase the breadth and scope of performance information available to the public</u>

• Release physician-identifiable Medicare claims data (fully protecting patient privacy), to allow for better quality and efficiency performance reporting.

• Continue to allow private-sector organizations to download granular provider performance information from the Compare websites.

• Release the risk-adjusted DRG rates for every hospital (and rates for physicians), by region in easily accessible formats.

• Develop BOTH total costs of episodes AND total estimated beneficiary out-of-pocket for episodes of care (with estimates for beneficiaries with and without Medigap supplemental coverage). This release should include contextual and background information.

• Present price information in a manner that reflects the following principles:

• **Linked directly to Quality measures** (outcomes, patient experience, compliance with evidence-based medicine). Whenever possible price information should be directly linked to quality information to facilitate total value consideration by the consumer. When it cannot be, there should be context and background (including that "more expensive" does not mean better)

• **Understandable**: Information should be "transmissible", that is, it can be communicated from one consumer to another and must recognize that different consumer audiences will have different information seeking and comprehension skills.

• **Actionable**: Information should include relevant comparisons of providers based on quality and cost; link to a consumer being able to select a particular option; and should provide context and background on how to not just compare price of providers/treatments selected, but information on potentially relevant alternatives.

• **Accessible**: Should be available on-line with no barriers and designed for ease of use.

• **Relevant to consumers' circumstances** (health and coverage status): Information should be as specific as possible to an individual or family's health coverage and health status (including potentially a discrete condition OR considering a combination of conditions).

- **Predictive (accurate)**: Information should predict likely expense accurately and/or have clear explanation of the reason for range of cost variation.

CMS/HHS should consider using either voluntary or regulatory/contracting mechanisms to further enhance transparency of quality and cost information by:

- Releasing physician-identifiable Medicare claims data (fully protecting patient privacy), to allow for better quality and efficiency performance reporting.
- Establishing conditions of participation for hospitals that require posting of prices and/or policies regarding discounts and other payment options for uninsured patients. For insured individuals, health plans will be the primary vehicle for this information but disclosure is an important issue for equity reason, though true transparency and informed consumer decision-making will require actionable tools.
- The Administration through its various contracting mechanisms with health plans (via OPM or Medicare), should ensure they are providing tools for enrollees to make informed choices, considering both quality and costs.
- Requiring hospitals to augment claims form with additional clinical data elements. Accurately assessing provider performance would be greatly enhanced if the severity of the patient could be captured off of administrative claims data. The public reporting of quality and cost information would benefit greatly from claims data richer detail. Adding the following data elements to the inpatient paper and electronic claim form would enable much more robust hospital outcomes reporting:
  - A unique physician identifier for each coded procedure;
  - Capture the referring/ordering physician for each coded procedure;
  - Vital signs (heart rate, blood pressure, temperature, and respiratory rate) recorded at presentation;
  - Key lab values (BUN, hematocrit, platelets, WBC, sodium, potassium, and creatinine) if obtained at the time of admission, excluding hospitalizations for psychiatric, obstetrical and newborn services;
  - Do Not Resuscitate order present (including date and time), if recorded during first 24 hours of patient presenting; and
  - Time of day of admission, discharge, and each procedure.

Again, thank you for the opportunity to comment.

Sincerely,

Suzanne A. Delbanco

Suzanne Delbanco, PhD
CEO, The Leapfrog Group

FYI - Reg Staff

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May 31, 2006

Honorable Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Honorable McClellan:

I am writing in response to your request for comments concerning the proposed Medicare Inpatient PPS rule for FY 2007. I understand the final rule will be published by August, with an expected implementation date of October 1, 2006.

As the President of a 60-bed specialty cardiac facility in Milwaukee, Wisconsin, I have grave concerns about this proposal. While I recognize that a major focal point of your proposal deals specifically with cardiac DRGs in an effort to address what you perceive to be inequities in Medicare reimbursement for cardiac services that may favor specialty hospitals, I want to make you aware of several facts that distinguish The Wisconsin Heart Hospital (TWHH) from other for-profit cardiac facilities.

By way of background, TWHH is the only cardiovascular specialty hospital and accredited chest pain center in the Milwaukee area. The 60-bed hospital was designed for the complexities of heart and vascular care. Our services include surgery, diagnostic imaging, emergency department, outpatient care, inpatient care and wellness and preventive medicine programs. The hospital features four cardiac/electrophysiology catheterization labs for immediate cardiac intervention and one peripheral vascular lab with easy access to operating rooms.

The ownership of TWHH is comprised of a mix of a not-for-profit community-based health care system (Wheaton Franciscan Healthcare -- 49%) and physicians and other community investors (51%). In addition, 50% of the members of the TWHH governing board are representatives of Wheaton Franciscan Healthcare. I am confident that the ownership and governing structure of TWHH is unique in the specialty hospital arena. I believe this arrangement positions TWHH as a true asset to the community and as a resource for quality cardiac care with ready access to a broad range of other health care services at our partner facilities.

In addition, TWHH operates a 24-hour, full service emergency department which is staffed by board-certified emergency department physicians. We are a key participant in the County EMS system, and have become a dependable resource for the community in terms of expanded access to emergency care. Last year alone, our emergency department treated approximately 2,200 patients.

Our average patient length of stay for coronary artery bypass surgery is significantly lower than other hospitals, according to the STS Fall 2005 report. The median stay for our patients is 4 days; in 2005, 71.2% of our patients had a length of stay less than 6 days, as compared to other hospitals in the database with 51.7%. Our operative mortality for 2005 was 1.3% versus 2.6% for other hospitals. We would be happy to share other clinical outcomes with you, if necessary.

Finally, TWHH has adopted the same charity care policy as our not-for-profit partner. In fact, the Wheaton charity care policy was recently revised and is considered one of the most generous policies in the area. The simple fact is: TWHH accepts all patients, regardless of ability to pay and can demonstrate this commitment through the applicability of our charity care policy.

With respect to the proposed rule, our financial analysis shows that if implemented as is, TWHH will see Medicare reimbursements decline significantly. While we have not been able to successfully predict how the expansion of DRG classifications will affect our reimbursement, we do know that the case-mix adjustments will result in at least $2.3 million in Medicare reimbursement losses per year. These losses represent 18% of our overall Medicare reimbursement, which comprises approximately 62% of our total payer mix. Clearly, the losses that will result from the proposed rule will have a considerable impact to our bottom line and may affect our ability to continue to provide needed services in both cardiac and emergency care for the community.

I respectfully ask that as you consider the final implementation of this rule, you take into account the vast differences that distinguish TWHH from most other specialty cardiac hospitals. While cutting cardiac DRGs across the board will certainly have a dramatic negative impact on all specialty cardiac facilities, I would contend that not all specialty cardiac facilities are alike. The many noteworthy distinctions that make TWHH unique also address many of the typical criticisms levied at specialty hospitals. I hope that you will take these facts into serious consideration as you look toward final implementation of this rule.

If you have any questions, please feel free to contact me directly at 414 778-7801. I would be happy to provide you with any supporting materials you may require. Thank you for your consideration of this important matter.

Sincerely

Norma J. McCutcheon

Norma McCutcheon
President

cc: Senator Russ Feingold
Senator Herb Kohl
Congressman James Sensenbrenner
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Via Electronic and U.S. Mail

June 9, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
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Washington, DC 20201

File Code CMS-1488-P: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide this **comment letter on payment issues** in the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2007 rates (CMS-1488-P), (hereinafter referred to as "Proposed Rule" or "NPRM"). **AdvaMed is providing a second letter on proposed quality issues.** AdvaMed is the largest medical technology trade association in the world. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed shares CMS's goal of assuring beneficiary access to services, and believes that improving the accuracy of payments will help achieve this goal. AdvaMed supports

movement toward improved accuracy in reimbursement under the inpatient prospective payment system (IPPS), and appreciates that CMS has worked very hard to produce a set of proposed changes that would affect all of IPPS. However, we do not believe that the wholesale changes to the IPPS contained in the Proposed Rule are either the appropriate solution or ready for implementation in FY 2007. AdvaMed supports maintaining the current methodologies for assigning DRG relative weights and determining patient classifications in FY 2007. Regardless of the IPPS changes that CMS ultimately implements or the timeframe in which those changes are implemented, we believe that the following issues are of paramount importance and need to be addressed:

- **The hospital-specific relative value methodology ignores any hospital-level variation that is not explained by the PPS case-mix index, which may include meaningful and valid cost variations. If certain services are provided predominately in hospitals with higher average costs, this method will produce lower DRG weights for these services. If legitimate costs are not recognized, Medicare beneficiaries' access to care may be diminished.**

- **Using 10 cost center groupings within the Hospital Specific Relative Values (HSRVs) to calculate DRG relative weights ignores detailed data in the cost reports that could be used to derive a more accurate set of weights. This will exacerbate many of the more problematic aspects inherent in the use of weights based on estimated costs, including data lags, data omission, and charge compression.**

- **CMS proposes to implement a new severity-adjusted patient classification system in 2008 or earlier. However, the Proposed Rule models the impact of these changes using FY 2004 inpatient claims, instead of the FY 2005 inpatient claims used to model the estimated cost-based DRG weight changes. This discrepancy, and the fact that CMS did not make the new patient classification system software (the "grouper") available when the regulation was released, made it impossible to accurately assess the impact of both changes from tables provided in the Proposed Rule.**

- **When calculating payment weights, CMS did not use standard methods to weight hospital payment data and trim Medicare claims data. CMS omitted data from 238 hospitals, representing 25 percent of routine hospital charges. This omission and failure to apply appropriate weights significantly decreased the payments for technology intensive cases. These methodological flaws need to be evaluated and addressed by CMS prior to the imposition of any cost-based methodology scenario.**

Due to the magnitude of the changes, the lack of complete information to fully assess the proposed changes, and the importance of improving the accuracy of the payment rates,

AdvaMed supports maintaining the current methodologies for assigning DRG relative weights and determining patient classifications in FY 2007.

- **AdvaMed would support implementation of an estimated cost-based weight system in FY 2008, with an appropriate phase-in, analogous to the methodology that is currently used in the outpatient PPS system, as CMS makes changes that would result in improved timeliness and accuracy of the cost report information used to calculate estimated costs and makes a full adjustment for charge compression. To determine methods of improving hospital cost reports, CMS should assemble an expert panel or work group comprising hospital finance experts, prospective payment authorities, hospital charge master personnel and other experts. This group could make timely recommendations on how to refine the cost reports to yield more accurate and timely data that may be used in setting PPS weights. In this letter, AdvaMed is proposing a methodology to address the issue of charge compression when cost-based weights are implemented.**

- **AdvaMed also would support simultaneous implementation of a revised estimated cost methodology and a DRG classification methodology that accounts for patient severity of illness, complexity and patient benefit. These DRG refinements would make allowances for specific DRG assignments that have been previously approved through notice and comment rulemaking. AdvaMed recommends that CMS start with the current DRG system and provide overlays for severity, complexity and patient benefit.**

- **AdvaMed would oppose a two-step implementation, whereby CMS would implement the movement from charge-based weights to estimated cost-based weights in one year followed by wholesale refinement of DRGs based on patient classification reforms in a following year. Making these changes simultaneously would minimize swings in payment rates for many diagnosis-related groups.**

The Proposed Rule seeks to both create and implement the most significant and complex changes in Medicare reimbursement since the IPPS was implemented more than 20 years ago. And, it does so in just one regulatory cycle, providing stakeholders only one 60 day comment period to review the regulation, analyze the methodological changes, and provide input. The details of these complex proposals were neither discussed nor scrutinized in any public forum prior to the release of the Proposed Rule. Nor were the methods used to arrive at these proposals validated by anyone other than CMS.

Upon the release of the Proposed Rule on April 12, 2006, stakeholders, including AdvaMed, began to work diligently to perform the detailed analyses that were necessary to replicate the methodology of the CMS proposals. We acknowledge the enormity of the task that CMS faced in making the recommendations contained in the Proposed Rule.

We applaud CMS for the its ability to complete the new methodologies in time for release in the Proposed Rule, and for releasing the MedPAR data in advance of the Proposed Rule. However, many other necessary pieces of information were not available to enable stakeholders to perform a thorough evaluation of the proposed changes when the Proposed Rule was released.

AdvaMed has exerted intensive efforts to model and assess the impact of these proposals prior to the expiration of the comment period. Nevertheless, we believe that 60 days is insufficient time given the complexity of the changes proposed by CMS. Additionally, we believe that the time between the close of the comment period (June 12) and the August 1, 2006 expected publication of the Final Rule, is insufficient to fully consider, test and implement the significant, substantive changes of the magnitude contained in the Proposed Rule.

The decision to delay implementation of any changes until FY 2008 would allow CMS, hospitals, patients, physicians, device manufacturers and other stakeholders the opportunity to fully assess any proposed changes before these are applied to every Medicare participating hospital and the services provided to Medicare beneficiaries. Assessment of these changes in the current cycle is simply not possible due to the complexity of the changes proposed, the potential overlay with a completely different DRG system, and the lack of available data and sufficient time to do the assessment that is necessary.

I. HSRV Weights, Cost-Based Weights and Cost Reports (*"HSRV Weights"*)

AdvaMed supports the goal of improving accuracy within the IPPS. Before CMS implements an estimated cost-based payment system, it should address a number of significant concerns raised by the use of cost-based weights. Estimated cost-based weights would be derived, in part, from Medicare cost reports, which were not designed for use in a prospective payment system. The cost reports are a vestige of the "reasonable cost" based reimbursement system that was implemented when Medicare began in 1966. When the hospital inpatient prospective payment system was implemented in 1983, hospitals began to be paid a fixed amount based on the patient's diagnosis, rather than incurred costs. Under IPPS, reimbursement became independent of the actual costs incurred, and the cost report no longer played a key role in the reimbursement received by hospitals, with some limited exceptions for items such as bad debt, graduate medical education, pass-through, or outlier payments.

There are several serious problems in using cost reports to derive estimated costs which are then used to calculate DRG relative weights that should be carefully considered and addressed. These include: 1) the accuracy of the cost-report data and limited auditing; 2) the overall timeliness of the cost report data; 3) the omission of data on new

technologies; 4) comparability of costs reports due to variability in how hospitals allocate costs; and 5) the compression of the weights both across and within cost centers.[1 2 3]

Accuracy of Reporting and Limited Auditing--Under prospective payment systems, providers' payments are not based on their actual incurred costs. Hospitals have little incentive to report accurately and completely for the items and services provided during the patient encounter or length of stay. The cost reports were not designed to establish payment rates for individual services and, as such, do not contain the detailed costs that are necessary to accurately determine estimated costs at the DRG level. Instead, cost reports provide payment, costs, and some reimbursement totals by department or cost center. An analyst must make several assumptions and perform complex calculations before she can translate cost reports into the estimated costs of individual items and services used to determine DRG payments.

CMS and fiscal intermediaries perform limited auditing of cost reports. If DRG weights are based on costs, they will be based on largely un-audited cost reports and, perhaps, extrapolation of average audit findings to un-audited cost reports. According to CMS, approximately 15% of hospital cost reports are audited each year. These audits are limited scope audits that focus primarily on factors that affect Medicare payment, such as bad debt or medical education. Full scope audits are done only rarely. Instead, audits for IPPS providers mostly involve payments for one or more items including DSH, GME, IME, bad debts, and organ acquisition. The fiscal intermediary determines what issue(s) will be audited based on the desk review and experience with the particular provider. Validation audits are not conducted by fiscal intermediaries. If cost reports are to be used to calculate DRGs, additional auditing might be advised. MedPAC estimated that a full scale audit could require 1,000 to 2,000 hours from a fiscal intermediary, as well as additional time and resources from the hospital.[4]

Overall Timeliness of Cost Report Data--The cost report data are old, significantly older than the charge based data currently used to determine payment weights under the IPPS. In the current system, the DRG weights are calculated using claims that are 2 years older than the payment year. Under an estimated cost-based IPPS system, the DRG weights are calculated using cost report data that is 3 to 4 years older than the payment year. The quality of the information is reduced because it is outdated. The use of

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[1] J. Ashby, "The Accuracy of Cost Measures Derived from Medicare Cost Report Data," Intramural Report I-93-01, March 1993; MedPAC, "Sources of Financial Data on Medicare Providers," Report to Congress, June 2004.

[2] Cost-based weights would further exacerbate the problem of "charge compression," which has been observed in the early years of IPPS (when cost-based weights were used) as well as in a number of studies and in the current OPPS. AdvaMed has conducted a study that documents the effects of charge compression using current MedPAR data.

[3] A 1998 study by MedPAC's predecessor, ProPAC noted concerns with cost report data such that "cost report data may, in some cases, produce imprecise DRG weights." ProPAC further noted that the "Secretary [of HHS] should verify the accuracy of cost report data and implement changes as necessary."

[4] MedPAC, op cit., p. 17

estimated cost-based weights requires matching billed charges from over 13 million hospital claims to cost reports for each individual hospital. Under the estimated cost-based system in the Proposed Rule, CMS used hospital claims data from FY 2005, and hospital cost reports from FY 2003. AdvaMed supports an approach that uses the most recent claims data available.

Omission of Data on New Technologies--Inherent lags between the time period covered by the cost reports and the payment year mean that recent important medical technology advances are omitted from the costs, which in turn determine the cost-to-charge ratios that are used to calculate cost-based DRG weights. Data that are three to four years old would exclude many of these technological advances in the calculation of cost-to-charge ratios. The older the data, the greater the omission of new technologies. This will translate into reduced accuracy in DRG weights.

For example, cost-based DRG weights as proposed by CMS could systematically underpay for new technologies because the proposed methodology assumes that hospital ancillary cost-to-charge ratios (CCRs) will not change with the introduction of new technology. The illustrations below demonstrate how a new technology that reduces routine charges by allowing patients to be discharged sooner results in a lower DRG payment under cost-based DRG weights, even under a scenario where total charges are unchanged (due to higher ancillary costs from the new technology). While total charges remain the same after introducing the new technology (resulting in no payment change under the current charge-based method), applying a CCR from an earlier period results in a reduced estimate of costs. Over several years, the ancillary CCR would eventually reflect the new technology; however, the methodology proposed by CMS would reward a hospital that maintains the older treatment with the longer length of stay, due to a higher 'cost-based' payment rate.

Patient Treated with High Concentration of Routine Services and Longer Length of Stay

	Charges
Routine Services (85% CCR)	$15,000
Ancillary Services (34% CCR)	$5,000
Total Charges	$20,000
Estimated Costs Based on Proposed CCR	$14,500

Patient Treated with High Concentration of Ancillary Services (Supplies and Equipment) with Shorter Length of Stay

	Charges
Routine Services (85% CCR)	$5,000
Ancillary Services (34% CCR)	$15,000
Total Charges	$20,000
Estimated Costs Based on Proposed CCR	$9,350

By comparison, the current charge-based system, if continued through FY 2007, would use 2005 hospital claims data to set the IPPS DRG weights. Switching to cost-based weights would entail the use of cost report data from FY 2003 and new technologies that were approved for use subsequent to 2003 would not be reflected in the cost report data. The use of estimated cost-based weights thus induces greater systemic bias against newer technologies by omitting them from the cost report data and the rate calculations.

Comparability of Cost Reports due to Variability in How Hospitals Allocate Costs -- The high degree of variability of hospital cost reports is attributable to several causes, including the allocation of joint costs, such as hospital administration costs, to various revenue generating sectors. This presents a problem for the accurate measurement of other costs such as inpatient, outpatient and skilled nursing costs. Hospitals have a range of options to allocate their overhead costs. Some of the methods of allocation, such as square footage, can result in an over-allocation of costs to secondary services compared to other, core function services. These allocation decisions have a significant impact on the comparability of the cost report data across hospitals.

Compression of Charges Within Cost Centers-- CMS uses hospital cost-to-charge ratios (CCRs) to covert charge data into estimated costs of individual items and services. CMS uses a single CCR for the many items and services in a single department. This process assumes that hospitals apply the same uniform percentage mark-up when setting the charges of each item in the department. Many observers have noted that hospitals do not act this way, but instead use a lower percentage mark-up for high cost items than they use for lower cost items. Hospitals may reduce the mark-ups for higher-cost items to avoid "sticker shock."[5] If hospitals do not use a constant percentage mark-up for items in the department, methodologies that rely on uniform CCRs underestimate the cost of

[5] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106

more expensive items and overestimate the cost of less expensive ones, resulting in a systematic distortion of the estimated costs, and of prospective payment rates.

Recent research showed statistical evidence for this type of charge compression in Medicare claims data.[6] The researcher found a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the fraction of cases with high-cost devices increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the researcher also showed that cases with very high device and supply charges led to a stronger impact on the device and supply CCR. A one-unit increase in the fraction of cases with very high cost devices (device and supply charges over $30,000) was associated with a much larger increase in the average device and supply CCR than was a one-unit change in the fraction of cases with moderate- to high-cost devices (device and supply charges over $20,000), which in turn had a stronger impact than a one-unit change in the lowest measure (device and supply charges exceeding 15,000). These results are consistent with previous analyses demonstrating charge compression in hospitals' billing patterns for high cost devices and drugs.[7]

II. HSRVcc Methodology Exacerbates Problems Inherent in Estimated Cost Based Weights (*"HSRV Weights"*)

AdvaMed does not support the use of the HSRVcc methodology in the Proposed Rule because it exacerbates many of the problems that are otherwise present with the use of estimated cost-based weights. Under HSRVccs, CMS calculates charge-based weights for each hospital at the cost center level. It is important to note that the HSRVcc methodology proposed by CMS differs both from what MedPAC proposed and from how CMS calculates *cost-based* weights for the outpatient prospective payment system. AdvaMed believes that the CMS methodology produces inaccurate and distorted DRG weights due to at least four major deficiencies.

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[6] C. Hogan, Direct Research LLC., March 2005. Significantly, this study was conducted exclusively on Medicare claims data with no use of external data.

[7] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106, GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: http://www.gao.gov/highlights/d04772high.pdf . The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003. The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings, The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

- First, the cost (revenue) centers are collapsed from the full set of at least 37 cost centers into only 10 centers.[8] Although each of the 37 cost centers has a unique cost-to-charge ratio, the CMS grouping methodology employs only 10 cost-to-charge ratios. This approach essentially throws out detail that is available on the cost report and that CMS uses in calculating the outpatient prospective payment system rates. AdvaMed is concerned that CMS disregards information that would increase accuracy and does so as part of an initiative intended to improve accuracy.

- Second, the national cost-to-charge ratio approach eliminates the specificity of cost-to-charge ratios for supplies and equipment in individual hospitals that perform more procedures involving implantable devices. These hospitals in general have higher cost-to-charge ratios for supplies than other hospitals, and using the hospital-specific CCR for supplies and equipment instead of the national CCR better reflects the mix of patients in the hospital and the accompanying costs. [These hospitals still experience charge compression for implantable devices and an adjustment to address this issue (described below) is important in any move to cost-based weights.]

- Third, the HSRVcc methodology proposed by CMS contains two serious mathematical flaws that affect the DRG weights very materially. These problems arise due to the manner in which CMS proposes to implement the HSRVcc methodology. They can be corrected, and the corrected results are illustrated in the table below, or the problems would be removed altogether if CMS abandons the HSRVcc methodology and adopts the methodology used for the outpatient prospective payment system, as AdvaMed recommends. **Fixing these flaws will have a significant impact on hospital-level payments and hospitals that may have assumed that their payments would increase may see reductions.**

[8] CMS's HSRVcc methodology uses two cost centers for routine services (routine days and intensive care services) and eight for ancillary services (drugs, supplies and equipment, therapeutic services, operating room, cardiology, laboratory, radiology, and other services and charges).

The following examples show the dramatic effect that correcting the flaws would have on the weights for selected DRGs.

IMPACT ON SELECTED DRGs OF HSRVcc		CMS	Corrected
558	Percutaneous Cardiovascular Proc W Drug-Eluting Stent W/O Maj Cv Dx	-35%	-21%
557	Percutaneous Cardiovascular Proc W Drug-Eluting Stent W Major Cv Dx	-26%	-15%
125	Circulatory Disorders Except Ami, W Card Cath W/O Complex Diag	-28%	-20%
124	Circulatory Disorders Except Ami, W Card Cath & Complex Diag	-19%	-14%
535	Cardiac Defib Implant W Cardiac Cath W Ami/Hf/Shock	-26%	-16%
536	Cardiac Defib Implant W Cardiac Cath W/O Ami/Hf/Shock	-25%	-13%

The HSRVcc is a complex calculation that begins with calculating charge-based weights for each cost center for each DRG for every hospital. At this stage, CMS has 10 hospital-specific, charge-based weights for each DRG – one such weight for each of the 10 collapsed cost centers. Next, CMS combines these hospital-specific charge-based weights for each cost center for each DRG to get a set of 10 national charge-based weights for each cost center for each DRG. In computing the national weights for each cost center for each DRG, CMS properly weighted each individual hospital number by the hospital's count of cases in the DRG.

Both of the major flaws occur in the final phase of determining the DRG weights. In this stage, CMS is combining the 10 cost center weights to get a single weight for each DRG and simultaneously converting from charge-based to cost-based weights. Both flaws arise as CMS calculates national cost-to-charge ratios to use in converting charges to costs.

Flaw #1: In calculating the national cost-to-charge ratios (CCRs), CMS severely over-trimmed the data and threw out hospital data with CCRs for routine days with a value less than 0.26. These CCRs appear to be real and valid, however. They apply mostly to about 238 very large hospitals that contribute roughly one-quarter of all routine day charges. In dropping these data, CMS is not only throwing out a large amount of valid data, but it is distorting the results by omission of such a significant segment of hospitals with a unique pattern of CCRs. This problem is compounded because CMS retained these hospitals for other steps in calculating the national DRG weights. The table below shows the impact of CMS's trimming.

Trimming of Routine Accommodation Charge Per Day				
CMS CCR trim action	Hospitals	Charges ($ in billions)	Days (in millions)	Charge per Day
Not Trimmed	3133	$ 34.11	39.1	$ 873
Trimmed	238	$ 12.37	3.3	$ 3,723
Total	3371	$ 46.48	42.4	$ 1,097
Source: Direct Research. Ltd. estimate based on 2003 cost reports matched to edited 2005 MedPAR file.				

Flaw #2: In calculating the national CCRs for each of the 10 cost centers, CMS uses the geometric mean of the individual hospital CCRs, after they are erroneously trimmed as discussed above. CMS's calculation of the national CCRs does not account for the volume of charges and costs across hospitals. It is important to note that similar calculations in other CMS prospective payment systems and fee schedules use an appropriate weighting methodology rather than counting each hospital equally. Only with appropriate weighting will the calculated number actually equal the overall national average. In this case, weighting should be based on the aggregate amount of charges in each hospital. Specifically, national CCRs should be calculated using the charge-weighted arithmetic mean. As shown in the table below, the flaw causes a substantial over-estimate of the aggregate national level of costs incurred by prospective payment system hospitals. Routine costs are so overstated by the proposed CMS methodology that total costs compared to total actual payments on the MedPAR file show that hospitals would have lost $23 billion dollars in 2005, or about 29 percent, on care provided to Medicare beneficiaries. We know from MedPAC and CMS reports that this is not true, and that hospitals experienced a small positive margin on inpatient care provided to Medicare beneficiaries. Consistent with this fact, the correct weighting methodology provides an estimated patient care margin of 2.2 percent, as shown below:

	With CMS CCRs[9]	With Charge-Weighted CCRs
▪ Total charges on MedPAR file	$ 315	$ 315
▪ Estimated 2005 costs before charge inflation adjustment	$ 134	$ 107
▪ Estimated 2005 costs after charge inflation adjustment (.92 X previous line)	$ 123	$ 98
▪ Actual 2005 payment on MedPAR	$ 100	$ 100
▪ Estimated 2005 payment-to-cost ratio	0.812	1.022

9 All numbers listed in billions.

The combined impact of the two flaws significantly decreases the payments for technology intensive cases as noted above. AdvaMed strongly urges CMS to fix these problems if it continues to use the HSRVcc methodology, though, as noted above, we recommend an entirely different approach for cost-based weights.

- Fourth, the hospital relative value methodology (HSRV) is unnecessary, compresses the DRG weights, and particularly and unjustifiably cuts payment rates for cardiac care. Under the current standardization methodology, DRG weights are set by determining the average per-case standardized charges or costs in a DRG across all hospitals and dividing that figure by the average per-case standardized charges or costs for all cases in the DRG system. The key is that the weights are based on pooled charges or costs from across all hospitals nationally. This helps to assure appropriate valuation of all services, including services which tend to be highly concentrated in limited centers, such as cardiology services.

  Under hospital specific relative values, rather than pooling charges or costs across hospitals, CMS first creates relative weights from the charges or costs within each hospital for each DRG to get a hospital-specific weight and then averages those hospital-specific weights across all hospitals (using a case-weighted average) to arrive at a single weight for each DRG. In this manner, average charges or costs in a particular DRG are compared with average charges or costs in each hospital rather than with average charges or costs across all hospitals. The hospital-specific relative value (HSRV) methodology reduces the weights for DRGs that are performed predominantly in hospitals with higher average charges or costs. This is true even if the costs are valid and if these hospitals are the only hospitals where the particular services are performed.

  Under the hospital-specific relative value approach, each hospital's data is scaled up or down so that its costs or charges match the level predicted by the hospital's case mix index. All other variation in costs or charges is simply ignored. The hospital-specific approach removes from the data all the hospital-level variation that is not accounted for by case mix. No other hospital-level variation in costs or charges is allowed to affect the calculation of the DRG weights. HSRV contrasts with the current standardization approach which removes from the charge or cost data *only* the hospital-level variation that Medicare will pay for in another part of the payment formula: wage index, indirect teaching and disproportionate share. Under current IPPS, all other hospital-level variation (anything the IPPS does not pay for) is allowed to affect the calculation of the DRG weights.

  The main difference between these two approaches is how you treat charge or cost variation that is not otherwise explained with IPPS payment factors. In the standardization approach, any variation in hospital costs or charges that is not explained with CMS payment factors is allowed to affect the calibration of the DRG weights. The hospital-specific approach, by contrast, ignores any hospital-

> level variation that is not explained by the IPPS case-mix index. The current standardization methodology recognizes that hospital-level variations should not be ignored just because they cannot be explained. In throwing out otherwise unexplained variation in hospital-level costs or charges, the HSRV methodology risks ignoring meaningful and valid cost variations. To the extent that certain services are provided predominantly in hospitals with higher average costs, the HSRV methodology predictably will result in lower DRG weights for these services. If these hospitals' legitimate costs are not recognized, Medicare beneficiaries' access to care for these services could be jeopardized.

AdvaMed strongly believes that HSRV is unnecessary and inappropriate under cost-based weights. If under cost-based weights the cost of care in each DRG has been estimated as accurately as possible, then it is not sound policy to ignore part of what was estimated, as occurs under HSRV. AdvaMed recommends that HSRV be dropped and that costs or charges be standardized using the current methodology. If CMS wishes to remove other sources of cost variation from calculation of the DRG, the standardization process could be expanded to include other factors beyond wage index, indirect teaching and disproportionate share. Such a factor-specific approach would lead to more precise and valid adjustments than the "black box" approach of HSRV.

There are several excellent research studies on the impact of the hospital-specific relative value methodology and, though many of these date from the early 1990's, their findings are remarkably consistent with the impact of HSRV in the Proposed Rule. In general, the HSRV approach tends to lower relative weights for the higher weighted DRGs and reduce the range of DRG weights between the lowest and highest weighted DRGs. Since the inception of the Medicare inpatient prospective payment system, such compression of the DRG weights has been a closely watched issue due to concern that patients might experience reduced access to the higher cost DRGs if compression became a problem and the DRG weights were too low for high cost cases. Finally, considering type of service, research has consistently shown that cardiology services would be hit especially hard by a change to HSRV. In fact, for hospitals that lose under HSRV, they lose more on cardiology services than they lose overall (they make up some of their cardiology losses on other services). Earlier research found that about 83 percent of hospitals losing under HSRV engaged in cardiac surgery compared to 5 percent for other hospitals.

Cardiology services, especially interventional cardiology services, are performed primarily in the type of hospitals that are disadvantaged by the HSRV methodology. Hospitals performing cardiology services tend to mark up their charges for those services less than they mark up their charges for other services. Hospitals performing cardiac surgery charge more than average for typical cases, therefore their charges for the very expensive cardiac cases are down-weighted in calculating the HSRV weights. In addition, surgical cardiac services tend to be higher weighted services and thus are disadvantaged by the compression of the DRG weights that is a hallmark of the HSRV

methodology. These collective effects cause particular disadvantage to cardiac surgery and interventional cardiology services.

Clearly, adopting HSRV is a policy choice with significant implications for hospitals. We seek opportunities to work with CMS to assure that services are paid appropriately and that patient access to these life-saving services and technologies is not diminished. We strongly believe that changes in the Proposed Rule are necessary both to preserve access to care and to continue to encourage the technological innovation and adoption of new technologies that has brought substantial reductions in mortality and morbidity for patients.

III. Charge Compression (*"HSRV Weights"*)

To determine the cost of individual items and services, CMS generally takes hospitals' charges for an individual item or service and converts them to an estimated cost. Specifically, CMS converts charges to costs by "backing out" the average mark-up calculated for each department. Thus, if a department had an average mark-up in which charges averaged twice the department's costs, then a charge of $1,000 would be reduced to a cost of $500.

Basing the estimate of the cost for each item and service on the average mark-up in a particular department implicitly assumes that hospitals apply the same percentage mark-up to set the charge level of each item in the department. Many experts and studies have noted, however, that hospitals generally do not apply a uniform percentage mark-up and that, in fact, the percentage mark-up for high cost items is significantly less than the one used for lower cost items. According to a study commissioned by MedPAC, hospitals may reduce the mark-ups for higher-cost items to avoid "sticker shock."[10] This phenomenon is called charge compression. To the extent that charge compression is present, the current CMS rate-setting methodology underestimates the cost of more expensive items and over-estimates the cost of less expensive ones, resulting in a systematic distortion of prospective payment rates.

Charge compression occurs when items with different markups are combined in the same cost center. The HSRVcc methodology would combine estimated costs into only 10 cost centers nationally, increasing the variation of items placed in a particular cost center. Modeling of the HSRVcc methodology confirms that the degree of charge compression inherent in the use of cost-based weights is exacerbated under the HSRVcc methodology.

To examine further the empirical evidence of charge compression, AdvaMed recently commissioned research to investigate whether Medicare claims data provided statistical evidence of charge compression. The results indicated a strong statistical relationship

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[10] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106

between a hospital's case-mix and the device cost-to-charge ratio (CCR). Specifically, the study found that there is a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the device case-mix increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the research also showed that basing the case-mix index on the percentage of cases with higher device and supply charges led to a stronger impact. A one-unit increase in the fraction of cases with very high cost devices (device and supply charges over $30,000) is associated with a much larger increase in the average device and supply CCR than is a one-unit change in the fraction of cases with moderate- to high-cost devices (device and supply charges over $20,000), which in turn has a stronger impact than a one-unit change in the lowest measure (device and supply charges exceeding 15,000). The results of this research are consistent with previous analyses demonstrating charge compression in hospitals' billing patterns for high cost devices and drugs.[11] It is significant that this study was conducted exclusively on Medicare claims data with no use of external data.[12]

IV. An Alternative Cost-Based Method Should be Used to Calculate Cost-Based Weights and the Detailed Impacts Should be Provided for Public Comment (*"HSRV Weights"*)

AdvaMed supports efforts to improve the accuracy of inpatient hospital payments. The HSRVcc methodology is too complex, omits important data, and results in a systematic bias against the hospitals that provide patients access to many medically advanced technologies. Rather than improving the accuracy of the payments, it further distorts payments by using a distorted estimate of costs. If CMS chooses to move to a cost-based payment system, we recommend a cost-based payment methodology similar to the one used to calculate the hospital outpatient prospective payment rates, with adjustments for both charge compression and biases in the Medicare cost report that lead to over-estimation of routine costs and under-estimation of ancillary costs.

To calculate hospital outpatient prospective payments, CMS matches outpatient hospital claims to Medicare costs reports using hospital-specific cost-to-charge ratios to determine

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[11] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106, GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: http://www.gao.gov/highlights/d04772high.pdf . The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003. The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings, The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

[12] C. Hogan, Direct Research LLC., March 2005

estimated costs for each hospital encounter. These are then combined to determine the payment rates after adjusting for certain factors. While there are several problems associated with the hospital outpatient PPS, the general methodology of adjusting the most recent claims data using hospital specific and department specific cost-to-charge ratios could be used for inpatient hospital payments.

We support using a modified version of the OPPS methodology in determining cost-based relative payment weights for the inpatient setting. Such a methodology would provide an improvement over the proposed HSRVcc methodology in that it would produce estimated costs that would better reflect the variation in costs across hospitals and procedures. At least two modifications are needed in the outpatient methodology. First, as discussed below, CMS must adjust for charge compression. Second, the weight calculation methodology needs to account and adjust appropriately for known biases in the Medicare cost report that lead to over-estimation of hospitals' routine costs and under-estimation of ancillary costs. Further research may be needed on the magnitude of this bias and options to correct for it. The recommended one-year delay allows time for this additional work.

Although evidence of the effect of charge compression is not new, research that could support an adjustment to offset charge compression was not previously available. Research just completed now presents a solution. It takes advantage of the detailed coding of supplies charges by revenue center on Medicare claims data to split the single cost-report CCR into separate CCRs for each supplies sub-category. Five supplies sub-categories are used: general supplies, implantables, sterile supplies, pacemakers (and defibrillators), and all other supplies. The division is based on a strong statistical association between the mix of supplies charges (by revenue center) in a hospital and the overall supplies CCR in a hospital. By pooling the information from all hospitals, research using regression analysis was able to develop one set of CCR adjustments reflecting national average CCRs for each of the five supplies sub-categories. Next, the research applied this national-average set of adjustments to each hospital (combining the adjustments with each hospital's actual supplies CCR), and inserted a "decompressed" estimate of cost on each MedPAR record.

The research found a strong and statistically robust relationship between the mix of charges across supplies sub-categories in a hospital and the hospital's overall average CCR for supplies. Hospitals with a higher share of charges in the pacemaker and implantable device revenue centers (0275, 0278) have higher supplies CCRs. CMS could use the coefficients from a regression model such as this to develop a data-driven adjustment for creating CCRs for sub-categories of supplies. Using the available MedPAR data, only four of the supplies sub-categories have enough charges, on average, to allow such a statistical estimate. The research found, on net after all budget-neutrality adjustments, the average CCRs for the supplies sub-categories which are shown in the table below. The average CCR for all supplies together was 0.33 (top line), but the regression analysis showed substantial variation in CCR by category. The pacemaker

category (which also includes hospital charges for a significant portion of defibrillators) has an estimated CCR of 0.46 (or just slightly more than a 100% average markup). The category of general supplies, by contrast, has an estimated CCR of 0.24 (or just over a 300% average markup).

Estimated Cost-to-Charge Ratios for Supplies Sub-Categories	
Supplies Subcategory	**Net Average CCR After Budget-Neutrality Adjustment**
Supplies, Total	0.33
0270 (general supplies)	0.24
0278 (implantables)	0.43
0272 (sterile supplies)	0.27
0275 (pacemaker (and defibrillator))	0.46
all other supplies	0.29
Source: Direct Research, Ltd. analysis of 2004 5% standard analytic file and hospital cost report data. May 2006.	

The research showed that this variation in CCRs across sub-categories has a significant impact on some DRG weights. Cost-based DRG weights would increase for DRGs with substantial charges in the implantable devices and pacemaker/defibrillator revenue centers.

AdvaMed strongly believes that any change toward cost-based weights, whether accompanied by the hospital relative value methodology or not, must address the distortion caused by charge compression. The recently completed research demonstrates that such an adjustment is possible and provides a solid analytical basis for a specific adjustment.

V. Severity-based DRGs (*"DRGs: Severity of Illness"*)

CMS solicited comments on a consolidated, severity-based DRG system (CS-DRGs) in the Proposed Rule. The CS-DRGs are similar, though not identical, to the All Patient Refined DRGs (APR-DRGs). CMS stated in the Proposed Rule that it was seeking comments on the CS-DRGs as well as alternatives that could be used to capture DRG severity and complexity. CMS also requested comments on a time frame for implementation (FY 2007 or FY 2008) of a severity-based DRG system.

AdvaMed's ability to conduct modeling on the impact of the proposed CS-DRGs was hampered by the fact that there was only limited information available from CMS at the time the Proposed Rule was released. As noted above, CMS did not provide the necessary "grouper" software to analyze the CS-DRG impacts.

In its specialty hospital recommendations last year, MedPAC recommended the use of severity-based DRGs in conjunction with hospital specific weights and cost-based weights. MedPAC examined APR-DRGs and recommended that CMS implement a severity-based DRG system, similar to APR-DRGs, but did not recommend that APR-DRGs be used.

In the Proposed Rule, CMS noted that implementation of APR-DRGs without modification caused several concerns, including the volatility of rates for low-volume procedures and the potential incentives for more thorough coding of severity due to financial incentives provided by severity-based DRGs.

AdvaMed believes that CMS should not implement CS-DRGs or any severity-based DRG system in FY 2007. We support a DRG classification methodology that accounts for patient severity of illness, complexity and patient benefit. These DRG refinements would make allowances for specific DRG assignments that have been previously approved through notice and comment rulemaking. AdvaMed recommends that CMS start with the current DRG system and provide overlays for severity, complexity and patient benefit.

CMS notes in the Proposed Rule that the CS-DRGs do not capture complexity of treatment, but provides no suggested mechanism for doing so in the future. We would like to work with CMS in ensuring that any DRG system that will be used by the Agency will fully recognize complexity and patient benefit. AdvaMed believes that it is essential for any DRG refinements to fully acknowledge these factors.

AdvaMed conducted extensive modeling of one version of severity-based DRGs after MedPAC made its recommendations last year and in November 2005, shared with CMS a number of potential concerns with moving to severity-based DRGs. Included in those concerns were the failure of the severity-based DRGs to recognize newer technologies with an appropriate payment weight and associated payment level. Our analysis of the proposed CS-DRGs reveals that concerns still needs to be addressed. The following examples illustrate several problems with the proposed CS-DRG that call into question the readiness of the proposed severity-based DRG system that fails to recognize such important categorizations.

Improper Classification Under CS-DRGs--Our analysis has revealed that the movement from the current system to CS-DRGs places procedures into inappropriate categories. These mis-categorizations fail to accurately describe accurately the procedure itself, the technology being used, or the resources, complexity or patient benefit of the procedure. Examples are as follows:

- **Current DRGs 118, 551** – In 1997, CMS moved ICD lead and ICD generator/replacement to the pacemaker system with AMI, HF, Shock DRG as justified by average charges (Federal Register, Vol. 62, 45974, August 29, 1997).

Under the CS-DRGs, generator replacement procedures for pacemakers, implantable cardiac defibrillators (ICD), cardiac resynchronization therapy pacemakers (CRT-P) and cardiac resynchronization therapy defibrillators (CRT-D) would be inappropriately categorized together into the same CS-DRGs 243, 244 and 245 (Cardiac pacemaker and defibrillator device replacement with a severity of illness (SOI) levels 1-3) and the ICD lead procedures would map to CS-DRGs 246-248 (Pacemaker & ICD revision). Changing the logic so that ICD generator/replacement map with pacemaker replacements and the ICD lead procedures map with pacemaker and ICD revisions would reverse CMS's 1997 decision without data to justify the change. This, in addition to the fact that there is no variation in the CS-DRGs based upon the type or complexity of the device, would result in a significant penalty to hospitals that treat patients needing implantable defibrillators, which are more complex and resource intensive than pacemakers.

- **Current DRGs 518, 555, 556, 557, & 558** – All of these DRGs would group to CS-DRGs for Percutaneous Cardiovascular Procedures both with and without acute myocardial infarction (CS-DRGs 237-242). DRGs 557 and 558 include drug-eluting stents, and would be placed inappropriately into the same category with bare metal stents.

- **Current DRGs 471, 544 & 545** -- These DRGs for either bilateral or major joint replacement procedures, group to CS-DRGs 414 – 419, which are solely for either hip joint or knee joint replacement. The CS-DRGs thus fail to differentiate between single replacement procedures and revisions, which are more resource intensive and complex. The only distinction made by the CS-DRGs is the distinction based on whether the procedure is performed on a hip or on a knee. Under CS-DRGs, the DRG weight for performing bilateral knee replacement is approximately equal to the payment for one knee replacement.

- **Current DRG 496 (combined anterior/posterior spinal fusion)** -- Based on the CS-DRG descriptions, it does not appear that there is an appropriate CS-DRG crosswalk from current DRG 496. The effect is that combined anterior/posterior spinal fusion procedures, which require two separate incisions and turning the patient over during surgery, get regrouped with all other spinal fusions. This inappropriate categorization ignores the resource intensive nature and greater length of stay associated with this procedure, and is also contrary to CMS policy dating back to the FY 1998 Final IPPS Rule.

- **Current DRGs 110 and 111** – Endovascular aneurysm repair (EVAR), a new generation of surgical services, will experience payment reduction in excess of 12% due to the proposed shift of EVAR into proposed CS-DRGs 234 – 236. EVAR for treatment of Abdominal Aortic Aneurysms (EVAR-AAA) was first approved in late 1999. EVAR for treatment of Thoracic Aortic Aneurysm

(EVAR-TAA) was approved in early 2005. The benefits that this technology offers to patients were reinforced by the implementation of a new "Welcome to Medicare" screening benefit for AAA, enacted under the Deficit Reduction Act of 2005, with implementation effective January 1, 2007, and an award of "New Technology" status for EVAR-TAA in FY 2006. EVAR reduces hospital stays, risk of complications and risk of death resulting from surgery, and is an alternative for many patients where limited or no suitable options were previously available.

Classification of EVAR into CS-DRGs 234 – 236 is inappropriate, and ignores the patient benefit and complexity of these procedures. The CS-DRGs 234 – 236 "Other Vascular Procedures" primarily contain surgeries for peripheral arterial disease – primarily PTA (w, w/o stent) and surgical bypass of the lower limb. This inappropriate classification for EVAR that does not recognize the significant clinical and resource differences (i.e. "complexity") inherent in the treatment of aortic and thoracic aneurysms versus peripheral disease. The disparity of net resource consumption for EVAR versus other procedures in the classification is large, yet would not be recognized under CS-DRG reclassification.

Difficult to Obtain a High Severity Level Absent Adverse Patient Consequences-- Our analysis has also identified concerns regarding the fact that patients may need to suffer adverse consequences in order for the case to be assigned to a higher severity level. While in certain cases this may appropriately reflect the greater use of resources, our analysis uncovered that in some cases it was impossible to obtain a higher severity level unless the patient had a life-threatening complication. We believe that the severity grouping should reflect complexity and patient benefit as well, and should allow for an increased severity/complexity level even without adverse patient consequences. Our examination of this issue led us to review a number of related procedures for arterial repair or occlusion as follows:

- **DRGs 014, 110, 533, 534, 553, 554, and 559** -- When many of the resource intensive procedures within these DRGs are mapped to the proposed CS-DRGs, there are large reductions in payment as virtually none of the procedures map to either of the two highest severity levels. In order to reach the highest severity levels, the patient must have a number of comorbidities that are unrelated to the basic nature of the procedure, such as a severe infection or renal failure.

CS-DRGs Fail to Adequately Recognize Patient Benefit--Our analysis revealed that CS-DRGs appear to be markedly inadequate to recognize patient benefit. One example that demonstrates this deficiency occurs in the context of the use of a more expensive, but longer lasting medical device, such as a hip with hard-bearing or other novel surfaces, that may be dictated by a beneficiary's greater health, activity level and greater potential utility over the individual's lifespan. A subset of today's Medicare patients who undergo total joint replacement are very active and have life expectancy rates that may challenge

some of the older implant designs. Implant longevity has been the focus of significant clinical study and development for this sector of the medical technology industry.

Additionally, implant fixation and range of motion requirements are much more demanding for these patients. Some providers are working to identify patients that are most appropriate to receive these implants based upon such things as family history, overall health and activity level. Unfortunately, the tendency toward better health and higher activity level of these patients would work against them receiving an implant that would be better tailored to their needs, because under the CS-DRGs, such patients would be categorized into the lower level severity. We believe the severity adjustment is flawed because it does not capture resource utilization or the utility of technologies that would be more appropriate for beneficiaries who are more active, healthier, and require a greater range of motion.

Reversal of Recent DRG Refinements--AdvaMed's analysis has revealed that the CS-DRGs, if implemented in FY 2007, would arbitrarily eliminate several important changes to DRGs deemed necessary to encourage promising new technologies. This is illustrated by the following examples:

- **Current DRGs 544 and 545** – In last year's Final Rule, CMS eliminated DRG 209 for primary and revision total hip and knee replacement procedures and replaced it with DRGs 544 (primary total hip and knee replacement) and 545 (revisions hip and knee replacement). CMS also created new and updated existing ICD-9 procedure codes to map to DRG 545 for a more accurate description of the various permutations of potential hip and knee revisions. Under CS-DRGs, revision procedures would map to CS 415 (hips) and 418 (knees) with weights reduced approximately 19 to 20%. Relative weights for bilateral total joint replacement, could likewise decline by as much as 40 to 45%. In the FY 2006 rule, CMS noted that

  > "we examined data in the FY 2004 MedPAR file on the current hip replacement.... as well as the replacements and revisions of knee replacement. . . . We found that revisions were significantly more resource intensive than the original hip and knee replacements."

  It is difficult to understand how CMS can suggest complete reversal of a categorization in FY 2007 that was not only just implemented in FY 2006, but also supported by CMS with the award of additional ICD-9 procedure codes.

- **Current DRGs 110 and 111** – As stated previously, CMS agreed that endovascular aneurysm repair (EVAR) for treatment of Thoracic Aortic Aneurysm (EVAR-TAA) merited the award of a new technology add-on payment in FY 2006. This technology was also made part of the "Welcome to Medicare" screening benefit under the Deficit Reduction Act of 2005, implemented effective

January 1, 2007. Implementation of the CS-DRGs would move these procedures inappropriately to CS-DRGs 234-236 (for more general vascular surgeries), serving to nullify or minimize these recent policy decisions recognizing this technology.

- **Current DRGs 557, 558** – CMS agreed, effective after April 1, 2003, to increased payments for drug-eluting stents. These changes, deemed necessary and appropriate by CMS after careful examination and analysis, would simply be eliminated under movement to CS-DRGs. In 2005, CMS noted that the resource differences between bare metal and drug-eluting stents, stating

  > "We recognize that the resources surrounding bare metal stents and drug-eluting stents differ appreciably and will continue to keep these cases separate..." Federal Reg. Vol. 70, 47294, August 12, 2005.

- **Current DRGs 551-552.** In FY 2006, CMS introduced new severity classifications for a number of cardiovascular DRGs based on the presence major cardiovascular conditions (MCV). CMS stated: "Using the MCV list, we tested our assumption that these conditions described a more severe set of cardiovascular surgery patients. We grouped all the cardiovascular surgery patients within MDC 5 based on the presence or absence of an MCV condition. We found that this split was predictive of significantly increased resource use for nine surgical cardiovascular DRGs."

  Under the proposed CS-DRGs, pacemaker implants would be grouped to CSA-DRGs 228-233 (Permanent Cardiac Pacemaker Implant With & W/O AMI, Heart Failure or Shock), reverting back to classification based on presence or absence of heart failure, AMI, or shock, rather than major cardiovascular condition.

- **Current DRG 103** – In last year's Final Rule, CMS made a significant coding change to account for the use of an external heart assist devices to recover native heart function. Heart assist devices designed for recovery are increasingly used to treat acute heart failure, thus, avoiding the need for heart transplantation. However, patients with recoverable heart conditions may be as ill and utilize as many hospital resources as a heart transplant patient. CMS recognized the need to accurate reimburse for the use of recovery heart assist devices in the FY 2006 Final Rule, and noted that

  > ". . .our data do support that patients having an external heart assist device implanted and removed during the same admission are comparable to in costs and average length of stay to heart transplant and implantable heart assist system patients in DRG 103. . . . we believe that consideration of the comments is best served by recognizing this unique subset of patients,

and making a DRG change that acknowledges the increased resources required for improvement in their care. "

The implementation of CS-DRGs would de-couple external heart assist devices from heart transplantation and regroup them with considerably less costly devices. As a result, reimbursement for external heart assist devices would be reduced significantly and the coverage decision made less than one year ago would be nullified. There has been no clinical data or considered policy justification for this change and it is difficult to understand the rationale for CMS to propose undoing their carefully crafted analysis in less than one year.

AdvaMed is against the elimination of carefully considered DRG reclassifications, performed with stakeholder input and/or pursuant to notice and comment rulemaking -- some as recently as last year -- that would occur if CS-DRGs were to be implemented. We believe that the CS-DRGs are therefore not ready for implementation in FY 2007, and should not be implemented until the problems noted above are addressed fully. Rather than revisiting past policy decisions, AdvaMed believes that CMS should develop and propose a system that establishes severity adjustments for the current DRGs (after eliminating the current CC/no-CC splits), including all of those DRGs that reflect complexity of treatment for some patients. We note that CMS indicated in the Proposed Rule that "a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system." A good first step would be to continue to recognize those technologies that have already been deemed to be worthy of additional consideration under the DRG system.

AdvaMed believes CMS should devote significant additional study to the implementation of any refined or revised DRG system, and seeks opportunities to work with CMS in making revisions to the current DRG system to ensure appropriate recognition for severity, complexity and patient benefit.

VI. DRG Reclassifications

"DRGs: Carotid Artery Stents"

In the Proposed Rule, CMS rejects requests to create a new DRG(s) for carotid stenting or to assign all carotid stenting cases paid under DRGs 533 (Extracranial Vascular Procedures with C/C) and 534 (Extracranial Vascular Procedures w/o C/C) to DRG 533 on an interim basis for FY 2007. Instead, CMS proposes continuing to pay for carotid stenting procedures under DRGs 533 and 534, which would result in payment decreases of 2-3% under the proposed HSRVcc weights.

AdvaMed strongly disagrees with CMS's proposal to keep the current DRG assignments for CAS, as this step would not adequately reflect the resources consumed in the procedure.

Stroke is a leading cause of death and disability for Medicare beneficiaries. Carotid stenting provides an alternative, less invasive treatment option for beneficiaries at risk of stroke but who are not good candidates for surgery. FDA has approved two carotid stent systems for use in the population at high risk for surgery and it is expected that FDA will approve additional manufacturers' carotid stent systems in 2006. CMS has recognized the value of carotid artery stenting by expanding coverage to a subset of the Medicare population that is at high risk for surgery. Adequate payment for carotid stenting is essential to assure that Medicare beneficiaries have access to the therapy.

In the Proposed Rule, CMS includes an analysis of the 2005 MedPAR data which compares the charges and length of stay ("LOS") associated with carotid stenting procedures to the average charges and LOS for all procedures in DRGs 533 and 534. The analysis finds that while the average length of stay was slightly shorter for the carotid stenting cases than for all other cases in DRGs 533 and 534, the average charges for the carotid stent cases were higher by $6,968 in DRG 533 and $7,804 in DRG 534. The average charge for a carotid stent case in DRG 534 is $25,000, much closer to the average charges for DRG 533 ($26,376) than the average charges for DRG 534 ($17,196).

The charge data presented by CMS suggests that carotid stenting cases are underpaid in both DRG 533 and 534. However, CMS suggests that the higher charges associated with carotid stenting may result from higher device mark-ups rather than higher procedure costs. Specifically, CMS observes most of the cases assigned to these DRGs, unlike carotid stent placements, do not involve a device cost. For this reason, CMS concludes that "the higher average charges and lower length of stay for the cases involving carotid artery stents are likely accounted for by the cost of the device." Yet despite acknowledging that the device "likely" accounts for the higher costs, the Agency goes on to speculate that the "hospital's charge markup may also explain the higher charges but lower average length of stay," citing a national average CCR for medical equipment and supplies of approximately 34 percent.

However, CMS does not provide any actual evidence that markup -- and not the cost of the device -- accounts for the charges associated with carotid stenting. Likewise, estimating device markups based on the national average CCR for the category of medical equipment and supplies is inappropriate. This broad category encompasses products with very different markup levels, ranging from higher cost, low-markup devices like stents to lower-cost, high markup medical supplies. As described above in our discussion of the need for an adjustment to address the issue of charge compression, implantable devices typically have lower mark-ups than other supplies and equipment rather than higher mark-ups as suggested by CMS, so the overall charges for carotid stenting are probably deflated relative to other procedures in the DRG. Given our findings above on charge mark-ups for implantable devices, we recommend that CMS rely on its standard current methodology of using MedPAR charge data to determine appropriate DRG assignment for carotid stenting.

In addition to questioning whether carotid stenting cases actually are underpaid, CMS is proposing postponing resolution of this issue until the consolidated severity-adjusted DRG system is implemented. We disagree with this proposal. CMS already has acknowledged that the severity-adjusted DRGs as currently constituted do not adequately capture the costs associated with many medically complex procedures that use advanced medical technology, and that refinements will need to be adopted. CMS has given no indication of how those refinements might work, however, or the time frame for implementation of such refinements. Thus, relying on future severity adjustments is not a viable alternative for addressing the current inadequacy of payment for carotid stenting procedures – especially since CMS already has the authority to modify payment in FY 2007 under the current DRG framework.

AdvaMed urges CMS to create a new DRG or pair of DRGs for carotid artery stenting effective FY 2007.

Alternatively, as an interim solution, we urge CMS to assign all carotid artery stenting cases to DRG 533 for FY 2007, pending further analysis of MedPAR data and the possible future implementation of severity-adjusted DRGs.

This would enhance the DRG groupings in several important ways:

- **Mean standardized charges for DRGs 533 and 534 would be more tightly aligned:** The difference in mean standardized charges for the proposed DRG 533 (all discharges) and the proposed DRG 533 (CAS cases only) is 12% (versus 26% as currently configured);

- **Little or no impact to overall standardized charges for both DRG 533 and DRG 534:** (0% impact to standardized charges for DRG 533 and -3% impact to standardized charges for DRG 534 if proposed changes are implemented);

- **Greater predictability within both DRGs:** standard deviations for DRGs 533 and 534 would be slightly reduced if CAS cases were all grouped to DRG 533; and

- **Clinical criteria for procedures in each DRG are more appropriately aligned,** given that all CAS patients eligible for Medicare coverage are at high risk for surgery due to the presence of a detailed list of complications and comorbidities. By definition, these patients require a higher level of procedural complexity and resource intensity, which justifies all CAS cases being assigned to DRG 533.

"DRGs: Neurostimulators"

Kinetra is an implantable dual array neurostimulator pulse generator used in deep-brain stimulation for the treatment of Parkinson's disease that was approved for a new technology add-on payment beginning in FY 2005. The add-on payment will end at the close of the current fiscal year, but a request was made to reassign the therapy from DRGs 001-002 to DRG 543, a more clinically and cost coherent DRG.

While on average the charges associated with Kinetra procedures are significantly more consistent with the charges in DRG 543 than DRGs 001-002, CMS rejected the proposed reassignment on the basis that it believed the charges associated with the device (and thus the overall procedure) were marked up excessively, and because it wanted to postpone resolution of the issue until the consolidated severity-adjusted DRG system was implemented.

Similar to our comments on the proposed reclassification of carotid stent procedures, we disagree with CMS's statements that mark-ups associated with the Kinetra device are excessive and overstate the total charges of the implant procedure. As described above, we are submitting information in this letter that we believe conclusively finds that hospital charge mark-ups for implantable devices are in fact significantly lower than for other, lower cost supplies and equipment. (Based on this finding, we are submitting a proposal that would make adjustments to correct for the impact of charge compression in the setting of cost-based weights).

We therefore believe that, if anything, the total charges found in MedPAR associated with Kinetra implant procedures may be understated relative to other procedures in DRGs 543, 001, and 002, and that the reassignment of the technology to DRG 543 is fully warranted. Given that we are recommending deferral of the implementation of the consolidated severity DRGs until at least FY 2008, we believe the CS-DRGs should not be a factor in CMS's decision to make DRG reassignments this year. **We strongly encourage CMS to reclassify the Kinetra procedure – determined by CMS to be a significant clinical improvement over previous therapy for Parkinson's disease – to the more appropriate DRG 543.**

VII. New Technology DRGs (*"New Technology"*)

AdvaMed believes that the new technology add-on program is a vital payment mechanism that helps to ensure patient access to new medical services and technologies and to recognize the often higher costs of new technologies more quickly than would otherwise be possible through the underlying DRG system. AdvaMed has worked extensively with both Congress and CMS to create and improve the program so that it most effectively meets the goal of earlier patient access to new medical technologies. AdvaMed and its member companies are committed to continuing to work with CMS to

ensure that the program works as smoothly as possible, and continues into the foreseeable future.

In the Proposed Rule, CMS indicated that it intended to develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments. CMS invited public comment on this issue. AdvaMed believes that the new technology add-on payment is an absolutely essential element of hospital inpatient reimbursement, and that it should be maintained regardless of whether CMS moves toward an estimated cost reimbursement system.

Given the sweeping and complex changes, and uncertainties regarding this year's Proposed Rule, and the potential for a large degree of refinement prior to implementation, AdvaMed supports a robust new technology add-on program that fully recognizes new technologies. At a minimum, we believe that CMS should follow the MMA's report recommendation and raise the new technology add-on payment percentage from 50% to 80% of the difference between the standard DRG payment and the cost of the procedure with the new technology. Doing so would offer some stability and consistency for hospitals providing their patients access to new technologies.

CMS appeared highly non-committal to initial new technology applicants in this year's Proposed Rule. There were three technologies that were proposed for an initial application for the new technology add-on payment, and CMS declined to be definitively positive on any of them. CMS noted that one, C-Port met the threshold criteria, but also noted an FDA finding that the device was 'substantially equivalent' to predicate devices.

In its discussion of NovoSeven, CMS disclosed very little analysis regarding whether the product met the "newness" criterion. It appears that CMS will wait to see if the device gains FDA approval before it engages in definitive analysis. However, as we have pointed out in past comment letters, we believe that CMS should clearly signal its intentions while awaiting additional information. The comment period after the Proposed Rule is released is the last opportunity for many of these technologies to engage in meaningful dialogue with CMS on whether they meet the criteria, and CMS should define its position as thoroughly as possible in the Proposed Rule to allow the best opportunity for input during the comment period. CMS's reluctance to disclose its preliminary views on these new technology applicants hampers discussion during the comment period.

The third new applicant, the X-Stop Interspinous Decompression System, was found by CMS to satisfy both the newness and cost threshold criteria, although CMS expressed concerns regarding whether the device met the substantial clinical improvement criteria. CMS was again non-committal when it offered no preliminary indication on whether it believes X-STOP meets the substantial clinical improvement criterion, and noted that it will await receipt of additional comments before making a decision.

AdvaMed appreciates that CMS took a firm preliminary position on the new technology renewal applicants, and proposed to continue all but one. However, we would like to see CMS be more willing to indicate its preliminary views regarding initial new technology applicants, as this would enhance stakeholder dialog with the Agency on these issues during the comment period.

AdvaMed supports movement toward improved accuracy under the IPPS, so that patients continue to have access to advanced medical technologies. We look forward to working with you and your staff to address the issues discussed in this letter. Please contact us directly if you have any questions or concerns. We thank you for the opportunity to provide comments, and look forward to continuing to work with you on these important issues.

Sincerely,

Ann Marie Lynch

Ann-Marie Lynch
Executive Vice President
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June 7, 2006

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Re: **Comments Regarding Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates (CMS-1488-P)**

Dear Dr. McClellan:

MGI Pharma ("MGI") appreciates the opportunity to comment on the Inpatient Prospective Payment System proposed rule for calendar year 2007 (the "Proposed Rule"). In brief, our comments concern the proposed changes to DRG 543, Craniotomy with Implantation of Chemotherapeutic Agent or Acute Complex CNS Principal Diagnosis. We also request that CMS consider implementing both the revised method for determining DRG weights and the severity-adjusted DRGs together at the same time in 2008 for the following reasons: (1) it is not reasonable to impose or ask hospitals to experience financial losses from implementing the new weights if implementing the severity adjustments would offset some of those losses (2) staggering implementation will cause hospitals to experience unnecessary payment fluctuations, and (3) delaying the proposed changes and implementing the changes simultaneously in 2008 will provide CMS with the needed time to assess, refine, and validate the proposed changes to the hospital-specific relative value cost center ("HSRVCC") weights and severity-adjusted DRGs.

1. Background

MGI is an oncology and acute care focused biopharmaceutical company that acquires, develops, and commercializes proprietary products that address the unmet needs of patients in the United States. Among other life-improving products, MGI manufactures Gliadel® Wafer (polifeprosan 20 with carmustine implant). Gliadel is indicated in newly diagnosed patients with high-grade malignant glioma as an adjunct to surgery and radiation. Gliadel also is indicated in recurrent glioblastoma multiforme patients as an adjunct to surgery. Gliadel provides localized delivery of chemotherapy directly to the site of the tumor and is administered only in the hospital inpatient setting. It currently is reimbursed under DRG 543, Craniotomy with Implantation of Chemotherapeutic Agent or Acute Complex CNS Principal Diagnosis.

2. MGI Supports CMS's Proposed Expansion of DRG 543 but Requests that CMS Keep the Term "Chemotherapeutic Agent" in the DRG Descriptor

MGI supports CMS's proposal to include the Kinetra System within DRG 543. We believe that coverage of the Kinetra System may provide additional treatment options for Medicare patients who are diagnosed with certain types of brain cancer. Equally important is providing fair and adequate payment for Gliadel and, if added, the Kinetra System under DRG 543. Therefore, MGI supports having CMS review and continue to provide appropriate reimbursement for this DRG if expanded.

Currently DRG 543 refers to the "implantation of a chemotherapeutic agent" but under the proposed expansion of the DRG, CMS has recommended retitling the DRG to refer instead to the "implantation of a major device." Gliadel is a pharmaceutical, not a device, and is properly characterized as a chemotherapeutic agent. We are concerned that providers may misinterpret a revision to the title of DRG 543 as excluding Gliadel, although this clearly is not the intent expressed by CMS in the Proposed Rule. The effect of provider confusion could be to restrict beneficiary access to Gliadel, even if the product best meets a patient's needs.

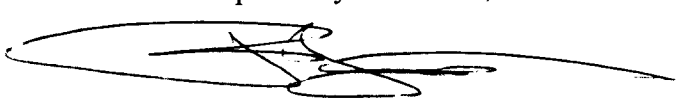
We request that if CMS retitles DRG 543, it continue to include the existing reference in the title to the "Implantation of a Chemotherapeutic Agent." This would result in the new title of DRG 543 being "Craniotomy with Implantation of a Chemotherapeutic Agent or Major Device or Acute Complex CNS Principal Diagnosis. Titling the DRG in this manner will make clear CMS's intent to expand, and not change, the scope of the DRG.

3. MGI Supports Delaying the Implementation of the Changes to the Payment Methodology for Acute Hospital Inpatient Services.

MGI shares BIO's concerns regarding the potentially negative effect on hospitals of CMS's proposed timeline to implement changes to the HSRVCC weights and severity-adjusted DRGs. Given the significance of the proposed changes and complexity of the calculations involved, we urge CMS to delay implementation by at least one year. Such a delay will allow the agency adequate time to assess, refine, and validate the proposals; update claims processing systems; and implement more consistent methods of reporting costs. In addition, we recommend that CMS implement the proposed changes to the HSRVCC weights and severity-adjusted DRGs at the same time as recommended by the Medicare Payment Advisory Commission ("MedPAC") to minimize potential distortions in the payment system.

We appreciate CMS's consideration of our comments. Please contact Jennifer Gruber at 301 698 0318 or jennifer.gruber@mgipharma.com if you have any questions.

Respectfully submitted,



Eric P. Loukas
Senior Vice President, General Counsel and
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June 13, 2006

VIA E-MAIL (http:\\www.cms.hhs.gov/ERulemaking)
Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MC 21244-1850

Re: File Code CMS-1488-P; DRG payments and Outliers

Dear Dr. McClellan:

Our law firm represents the following hospitals and health care systems in the State of North Carolina in connection with these comments: Carolinas Health Care System, Duke University Medical Center, Mission Health, Inc., Moses Cone Health System, North Carolina Baptist Hospital, and WakeMed. We welcome the opportunity to submit comments on Medicare payments made to acute care hospitals for part of an inpatient admission that would be eligible for outlier payments if the beneficiary had been entitled to Medicare for the entire stay.

We believe there has been an oversight in the current Medicare regulations which fails to ensure that hospitals receive reasonable payment for services rendered to Medicare beneficiaries who become entitled to benefits near the end of a lengthy inpatient stay, or who exhaust their benefits during a lengthy inpatient stay. Our comments relate to both DRG payments and outliers since both the hospital's DRG payment and the ability to receive outlier payments are impacted. More specifically, our comments relate to the regulation found at 42 C.F.R. Section 412.42(e).

The concern of our client hospitals about payments under these circumstances may best be understood in the context of an example roughly based upon the facts of a true case involving a client hospital:

> Patient is admitted to Hospital on July 6, 2004. At the time of Patient's admission he is not eligible for Medicare but is eligible for Medicaid. Patient ultimately becomes eligible for Medicare effective October 1, 2004 (nearly three months into his admission). Patient is discharged on October 15, 2004 (just two

> weeks after the effective date of Medicare eligibility). The total charges for Patient's hospital stay are approximately $270,000.00. Unaware of Patient's Medicare eligibility, Hospital billed Medicaid for the entire stay. Under the North Carolina Medicaid DRG prospective payment system Hospital received approximately $134,000.00 as payment for Patient's stay. Several months later the state Medicaid agency establishes that Patient became eligible for Medicare effective October 1, 2004 and issues a recoupment for the full payment made to Hospital. Upon receiving the recoupment notice, Hospital submits a claim to Medicare for Patient's days of entitlement, 10/1/04 through 10/15/04, with charges of approximately $33,000.00. Medicare pays approximately $11,000.00 on the split bill and the Medicaid agency pays Patient's coinsurance and deductible of approximately $800.00. Ultimately, Hospital receives approximately $12,000.00 on $270,000.00 in charges.

A similar result could occur had the patient exhausted benefits during the course of his admission.

Under current regulations Medicare reimburses a hospital only for the patient's entitlement days, yet precludes medical providers from billing the patient (or secondary payor) for pre-Medicare entitlement days or days after benefits have been exhausted. The Medicare payment is frequently insufficient for one or both of the following reasons: First, Medicare bases payment on a DRG applicable only to the days of the patient's entitlement, which in some cases may produce a lower DRG payment because the procedures which would establish a higher DRG payment were performed during a part of the stay when the patient was not entitled to Medicare. Second, Medicare will only make an outlier payment if the charges related to the patient's entitlement days justify a cost outlier payment, even if an outlier payment would be appropriate if the patient had been entitled to Medicare throughout the stay.

To the extent that Medicare pays on a split bill only for the Medicare covered days, and no payment is made for the pre-entitlement days or days after Medicare coverage has been exhausted, hospitals should not be precluded from receiving supplemental payments from the patient or any secondary payors (in most cases Medicaid) for the days which have not been paid for or considered by Medicare. Otherwise, the Medicare payment to the hospital is insufficient to provide reasonable payment for the services rendered to the beneficiary during the entire stay.

Existing regulations recognize the inconsistency and unfairness of Medicare paying only for the patient's days of entitlement and prohibiting a medical provider from pursuing the patient's secondary payor for charges associated with pre-entitlement days or days after benefits have been exhausted. Specifically, 42 C.F.R. § 412.42 and applicable CMS Manual Policy allow hospitals to charge the beneficiary or secondary payor its customary charges for services furnished to the beneficiary on the lesser of the number of outlier days or non-entitlement days. However, when day outliers were phased out by unrelated regulatory changes several years ago, the unintended consequence was elimination of a hospital's ability to receive additional reimbursement for non-covered Medicare days when Medicare's payment would have been greater but for the patient's

qualification for Medicare for only part of the course of the admission. The specific problem is that the 'lesser of' calculations under current 42 C.F.R. Section 412.42(e) is always zero, because Medicare no longer recognizes outlier days.

Our clients have previously raised this issue with CMS through several avenues. Last year, North Carolina Congressman Howard Coble sent a letter to CMS in March, 2005, on behalf of North Carolina hospitals. In addition, upon the suggestion of CMS personnel to North Carolina Senator Richard Burr's staff, the North Carolina Hospital Association also submitted comments related to this issue in connection with last year's Proposed Rule, File Code CMS-1500-P. Although the comments were not addressed in the Final Rule for 2006, Congressman Coble did receive the attached letter from Deputy Administrator Leslie Norwalk Dated December 15, 2005. Despite the reference in her letter that this would be corrected in the Proposed IPPS Rule for Fiscal Year 2007, it does not appear to be addressed therein, though a minor change to§ 412.12 is being proposed.

We again request that CMS immediately rectify this problem and correct appropriate regulations to ensure that hospitals are adequately reimbursed for services rendered to Medicare beneficiaries. This could be accomplished either by allowing hospitals to bill the patient and secondary sources for care not covered by Medicare; i.e. pre-entitlement days, or by basing Medicare payment on the totality of services provided to a Medicare patient, including charges for pre-entitlement days or days after Medicare coverage is exhausted. Hospitals should receive aggregate payment (from Medicare and/or the patient or the patient's secondary payor) for services provided to a Medicare beneficiary which is at least equal to the amount they would have received from Medicare if the patient had been entitled to Medicare throughout the entire stay. It is incongruous for Medicare to limit a hospital's reimbursement to only the applicable DRG for entitlement days if all of the services provided to the patient, and the charges associated with those services, are not taken into account. CMS has recognized the incongruity of the current regulation as evidenced by Deputy Administrator Norwalk's December 15, 2005 letter. We would therefore request that Section 412.12(e) be changed from:

> (e) Services furnished on days when the individual is not entitled to Medicare Part A benefits or has exhausted the available benefits. The hospital may charge the beneficiary its customary charges for noncovered items and services furnished on outlier days (as described in Subpart F of this part) for which payment is denied because the beneficiary is not entitled to Medicare Part A or his or her Medicare Part A benefits are exhausted. (1) If payment is considered for outlier days, the entire stay is reviewed and days up to the number of days in excess of the outlier threshold may be denied on the basis of nonentitlement to Part A or exhaustion of benefits. (2) In applying this rule, the latest days will be denied first.

to the following:

(e) Services furnished on days when the individual is not entitled to Medicare Part A benefits or has exhausted the available benefits. The hospital may charge the beneficiary the lesser of (1) its customary charges for items and services furnished on pre-entitlement days or days after benefits have been exhausted for which payment is denied because the beneficiary is not entitled to Medicare Part A or his or her Medicare Part A benefits are exhausted or (2) the difference between what Medicare paid for the admission and what Medicare would have paid if the patient had been entitled to Medicare for the entire admission.

Thank you for considering our comments. This change would ensure that Medicare only pays for services rendered during a beneficiary's entitlement period and that hospitals are adequately reimbursed for services rendered and protects the patient/beneficiary from liability in excess of the amount Medicare would have paid for the entire stay.

Sincerely,

OTT CONE & REDPATH, P.A.

Wendell H. Ott

Melanie M. Hamilton

MMH:fnt
Attachment
cc: Honorable Richard Burr
Honorable Elizabeth Dole
Honorable Howard Coble
Honorable Walter Holton
Leslie Norwalk, CMS (via e-mail)
Tzvi Hefter, CMS (via e-mail)
Michael Treitel, CMS (via e-mail)
Mike Taylor, CMS, Region IV (via e-mail)
North Carolina Hospital Association
Charlotte Mecklenburg Hospital Authority
Duke University Medical Center
Moses Cone Health System
Mission Health, Inc.
North Carolina Baptist Hospital
WakeMed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Service

Deputy Administrator
Baltimore, MD 21244-1850

DEC 15 2005

The Honorable Howard Coble
House of Representatives
Washington, DC 20515-3306

Dear Mr. Coble:

Thank you for your letters and e-mails regarding Medicare reimbursement policy for inpatient hospital services when a beneficiary becomes eligible for Medicare during an inpatient hospital stay.

As you know, Medicare pays for inpatient hospital services using the hospital inpatient prospective payment system (IPPS). In most cases, Medicare fully compensates the hospital for the services provided to the beneficiary during a stay in an IPPS hospital, even if the beneficiary becomes entitled to Medicare mid-stay. The full IPPS payment is made for each stay during which there is at least one Medicare-payable day of care. If Medicare makes the full IPPS payment, our manuals and regulations do hot permit a hospital to directly bill a beneficiary for services provided on pre-entitlement days, unless the case qualifies for outlier payment.

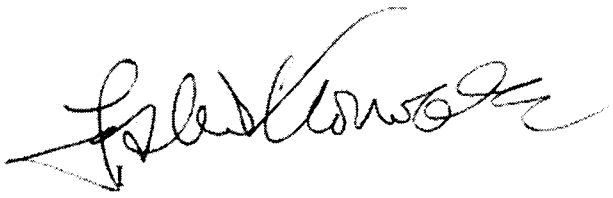
Special rules apply in cases that qualify for outlier payments. Outlier payments are made when a hospital's costs for a particular case exceed its payment plus a threshold amount ($23,600 for fiscal year (FY) 2006). Medicare's outlier payment will equal 80 percent of a hospital's costs for the case above this threshold amount. Our current regulations specify that a hospital may charge the beneficiary its customary charges for non-covered items and services "furnished on outlier days" for which payment is denied because the beneficiary is not entitled to Medicare Part A. Medicare regulations and manuals may be confusing on this point because they refer to "outlier days" which are no longer used in the determination of Medicare inpatient hospital payment. We expect to propose to revise the regulations in the IPPS rule for FY 2007, in order to update the terminology and make clear the application of Medicare's outlier policy to cases where the beneficiary becomes entitled during an inpatient hospital stay.

Until the regulations are updated, we are advising our fiscal intermediaries (FIs) that the application of current Medicare policy requires that charges on pre-entitlement days are treated as non-covered for purposes of calculating outlier payments. In these cases, a hospital would be permitted to charge a beneficiary its customary charges for pre-entitlement days if including those charges in the Medicare payment calculation would result in payment of a cost outlier, subject to the forms of any pre-Medicare insurance.

In order to ensure clarity on this issue, we are currently drafting a national letter that will advise our regions and FIs about how to apply Medicare policy in situations where a beneficiary becomes entitled to Medicare Part A during an inpatient stay.

I appreciate your interest in this important matter.

Sincerely,



Leslie V. Norwalk

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June 7, 2006

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Baltimore, MD 21244-1850

To Whom It May Concern:

The Health Alliance of Greater Cincinnati is an alliance of six acute care hospitals, located in the greater Cincinnati area. Two of the hospitals are located in Northern Kentucky, three in Cincinnati and one hospital in Hamilton, Ohio. One of the Cincinnati hospitals is the University Hospital, which is the safety-net hospital for the greater Cincinnati area.

Our comments are prompted by our concerns over the financial impact of the proposed changes to the Prospective Payment System (PPS) for inpatient operating cost; specifically, the proposed recalibration of DRG weights, the proposed changes to the outlier payment policy and the purported "clarification" that would prohibit hospitals from counting much of the resident time spent in didactic activities when calculating indirect medical education (IME) and direct graduate medical education (DGME) payments. These proposed changes are outlined in the Federal Register/Volume 71, 79/Tuesday, April 25, 2006/Proposed Rules-Page 23996 through 24433.

The proposed rule would increase the fixed-loss cost threshold for outliers from $23,600 to $25,530, an increase of 8.2%. The prospective payment rules mandate that outlier payments be funded through a 5.1% reduction in the PPS standardized payment amount. Based on your own estimates, outlier payments in fiscal year 2005 were approximately 4.1% of the total PPS payments and in fiscal year 2006 you're estimating that outlier payments will reach 4.71% of total payments. Since your policy regarding outlier payments does not allow retroactive increase in payments in any given year, and actual outlier payments have fallen short for three consecutive years of the 5.1% reduction in PPS payments, it's not clear to us why the fixed-loss threshold should again be increased in 2007. Based on the experience of our own six hospitals, outlier payments as a percent of gross PPS payments remain steady at approximately 3.9%.

These numbers suggest that a reduction in the fixed-loss threshold would be more logical. We ask that you re-evaluate your current proposed fixed-loss threshold and lower the threshold to achieve the mandatory 5.1% payment level, or reduce the amount set aside to reduce the PPS funding.

DRG Reclassifications

While we are supportive of CMS attempt to improve the accuracy of the Medicare payment rates for hospital inpatients, we have serious concerns about the proposed approach. Based on internal analysis of the impact of the proposed changes on our six hospitals and re-enforced by third party analysis, we have determined that four of our six hospitals will receive improved reimbursement in the range of $500,000; two of our hospitals, including University Hospital, will be adversely impacted by the proposed rule. Christ Hospital, which treats a large number of cardiovascular cases, is projected to have reduced reimbursement in 2007 of $4.4 million. In focusing on the six highest volume DRG's impacted, i.e. DRG 104, 124, 125, 515, 518 and 557, a detailed analysis of the current and projected cost compared to the current and projected reimbursement produces a reduction in net revenue of $2,850,000 or 22.6%. This analysis would indicate that CMS may have over reached in their attempt to adjust the DRG weights from a charge-base to a cost-base methodology. Our analysis indicates that in these six DRG's the change has resulted in a shift from a net gain of $1,100,000 to a net loss of $1,750,000 for these six specific DRG's. It would appear based on further analysis that the deployment of the adoption of the additional severity weighted DRG's would significantly mitigate this reimbursement change. While we are in full support of the underlying principles driving these proposed changes, we believe that the adoption of the cost-based weights without the deployment of the additional severity weighted DRG's will create in the short-term a significant penalty to all high cardiovascular providers of service. Our principle concern with the changes to the expanded DRG's is a question of the industry's ability to deploy these changes on such short notice. Because of the complexity of the calculations involved in the rebasing we would encourage CMS to move slowly with the implementation of these changes and would recommend that both the rebasing to expense-based weighting determination and the deployment of the additional severity of illness DRG's be postponed until fiscal year 2008. Furthermore, we believe a multiple year phase-in of the change to cost based weighting would allow the industry adequate lead time to adjust capital commitments and other contractual commitments in those service areas that are most adversely affected by the change. This postponement would also give the industry adequate time to evaluate in detail the methodologies and to deploy the needed software to deal with the expanded DRG's.

FTE Resident Count and Documentation

University Hospital receives approximately $30 million in DGME and IME reimbursement. We estimate that our residents spend as much as 14.0% of their time in didactic activities. The

unexpected and unwarranted loss of this revenue would put a significant strain on our already stressed ability to provide services to the underserved in our community.

We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct-graduate medical education (DGME) and indirect medical education (IME) payments. The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care." The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school.

The proposed rule position is in stark contrast to the Agency's position as recently as 1999, at which time the director of acute care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities; such as, educational seminars, classroom lectures ...and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999, Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins].

We support the Agency's 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Thank you for your consideration of these comments.

Sincerely,

R Long

Ronald Long
Executive Vice President & Chief Financial Officer

HEALTHCARE
LEADERSHIP
COUNCIL

June 12, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates - "Value-Based Purchasing"

Dear Dr. McClellan:

The Healthcare Leadership Council (HLC) is a not-for-profit membership organization comprised of chief executives of the nation's leading health care companies and organizations. The HLC is committed to advancing a consumer-centered health care system that values innovation and provides affordable, accessible high-quality health care. A list of HLC's members is attached, along with a statement of HLC's mission.

HLC appreciates the opportunity to provide input to the Centers for Medicare and Medicaid Services (CMS) on section 5001(c) of the Deficit Reduction Act (Pub. L. 109-171) which requires the Secretary to identify, by October1, 2007, at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines. The new law requires that for discharges occurring on or after October 1, 2008, hospitals would not receive additional payment for cases in which one of the selected conditions was not present on admission.

We want to make it clear from the outset that we support efforts to reduce the incidence of hospital acquired infections. HLC is a partner in the Institute for Healthcare Improvement's 100,000 Lives Campaign that aims to enlist thousands of hospitals across the country in a commitment to implementing changes that have proven to improve patient care and prevent avoidable deaths. The program has recommended six targeted interventions:

- Deploy Rapid Response Teams at the first sign of patient decline
- Deliver Reliable, Evidence-Based Care for Acute Myocardial Infarction to prevent deaths from heart attack
- Prevent Adverse Drug Events (ADEs) by implementing medication reconciliation
- Prevent Central Line Infections by implementing a series of interdependent, scientifically grounded steps called the "Central Line Bundle"

Healthcare Leadership Council
[illegible] Pennsylvania Avenue, N.W., Suite 500 South
Washington, D.C. 20004
[illegible] • [illegible] • [illegible]

- Prevent Surgical Site Infections by reliably delivering the correct perioperative care called the "Surgical Site Infection Bundle," and
- Prevent Ventilator-Associated Pneumonia by implementing a series of interdependent, scientifically grounded steps called the "Ventilator Bundle"

By deploying evidence-based guidelines, the hospitals involved in the "100K Lives Campaign" have made significant improvements in the quality of patient care.

Unlike the 100K Lives Campaign, that encourages the adoption of evidence-based guidelines to improve care and reduce the incidence and cost of hospital acquired infections while promoting efficient and effective patient care, the Deficit Reduction Act takes a punitive approach aimed primarily at cost by using DRGs to identify HAIs. Because DRGs were not designed for this purpose, the regulations must carefully consider and avoid unintended consequences. We believe that administrative data (such as diagnosis codes) is unreliable in identifying HAIs. The medical record is imprecise and lacks scientific criteria which can be validated by infection control personnel based on CDC guidelines and definitions. The use of administrative data could significantly overstate HAIs. In addition, population data based solely on DRGs would not allow accurate identification of HAIs, because of confounding variables of age, chronic illness and prescription drug use that may impair immune status. Criteria for identifying the presence of a HAI must be consistent and reliable.

Given these concerns with the current approach, we offer the following recommendations.

1. The primary goal should be quality of care through implementation of evidence-based measures and guidelines and not just eliminating payments associated with hospital acquired infections.
2. The conditions targeted should be preventable, familiar and comparable between institutions based on procedure, patients, and risk.
3. There should be a high likelihood that the condition is a healthcare associated infection to minimize the risk of being undetected upon admission or the potential increased cost of testing for infections upon admission (e.g., surgical site infections).
4. The number of DRGs selected should be narrowed to maximize return and minimize administrative cost. For example, implementing surgical site infection guidelines will benefit all surgeries regardless of which surgeries are targeted for payment adjustments based on the presence of a HAI.
5. In absence of an effective risk adjustment mechanism, the DRGs selected should help minimize other risk factors that may influence the probability of infection. For example, initially CMS may want to target elective or "clean" surgeries only.

The HLC understands and appreciates the difficulty and complexity of the Department's task in drafting these regulations. We offer these comments constructively and in the spirit of promulgating a more effective and workable regulation. The HLC and its members are available if the Department has questions or would like clarification of any of our comments. I may be reached at 202-452-8700.

Respectfully submitted,

Mary R. Grealy
President
Healthcare Leadership Council

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June 12, 2006

VIA ELECTRONIC MAIL
http://www.cms.hhs.gov/eRulemaking

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, Published at 71 F.R. 24,001 (April 25, 2006) CMS-1488-P- Wage Data

Dear Dr. McClellan:

We welcome the opportunity to submit these comments on proposed rules published on April 25, 2006 at 71 F.R. 24001 *et seq.* This firm provides legal services to numerous providers who may be adversely effected by implementation of that portion of the proposed rules that seeks to exclude the wage data of a critical access hospital (CAH) converting to rural hospital status from the computation of the wage index until the converting hospital is an IPPS hospital in both the year in which the survey data is collected (the "base year") and the current rate year (the "rate year"). This aspect of the proposed rule is contrary to the statutory mandate that requires inclusion of all subsection (d) hospitals (those hospitals subject to the prospective payment system) in the wage index calculation and frustrates the purpose of the wage index and the rural floor. It also is inconsistent with the position the Secretary took in determining to remove the wage data of CAHs from the wage index calculation. It has no basis in law or in logic and is antagonistic to the interests of Massachusetts PPS hospitals, many of whom are suffering from a declining and non-representative wage index due to the exclusion of CAHs from the wage index and who would benefit from the immediate inclusion of any converting CAH in the wage index computation.

As you know, Congress mandated the creation of a wage index in 1983 by requiring the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs

of the DRG rates for area differences in hospital wage levels by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. Pub. L. No. 98-21, § 601 (1983) (codified at 42 U.S.C. § 1395ww(d)(3)(E)). In 1987, Congress amended the statute to require the Secretary to update this factor on the basis of an annual survey of the wages and wage-related costs of subsection (d) hospitals. Pub. L. No. 100-203, § 4004. Generally, a hospital's PPS reimbursement is based on the wage index for the geographic area in which it is located. However, Congress also mandated that an urban area's wage index cannot be lower than the wage index applicable to rural areas in that state (the "rural floor"). Pub. L. No. 105-33, § 4410. Congress intended that the rural wage floor benefit urban providers by preventing the wage indexes of urban hospitals from falling below the wage index applicable to rural areas and thereby correct the anomaly of some urban providers being paid less than the average rural hospital in their states.

Prior to October 1, 2003, the Secretary included the wage data of CAHs in the computation of the wage index and the rural floor for various states. It did so because it had no reason to believe that these hospitals did not provide an accurate reflection of the labor market during the relevant period. However, effective October 1, 2003, the Secretary decided to exclude the wage data of CAH from the wage index based on data showing that a substantial negative impact of CAHs on the wage indexes of areas where they were located. Therefore, beginning with the FY 2004 wage index, the Secretary excluded from the wage index the wage data of CAHs "even if the hospital was paid under the IPPS during the cost reporting period used in calculating the wage index." 68 F.R. 45,398, Aug. 1, 2003. The sole reason the Secretary gave for his exclusion of CAHs from the wage index was that he "believe[d] that this change would improve the overall equity of the wage index." Id.

Without regard to the propriety of excluding CAHs from the wage index, the proposed rule preventing the inclusion of the wage data of CAHs in the wage index is inconsistent with the statute and the Secretary's prior practices. Pursuant to the statutory mandate, a CAH that converts to a PPS hospital is a subsection (d) hospital that must be included in the wage index because its wage data reflects the actual wages paid by the hospital and the conditions occurring in the labor market area in which it is located. A CAH that converts to IPPS status is not tantamount to a new hospital that has not filed any wages and hours data on a Medicare cost report; rather, it is a provider that participated in the Medicare program (albeit with a different status) previously and has developed, and in many cases submitted, wages and hours data for the wage index. Because this data is available to the Secretary for the wage index survey and presents an accurate and objective picture of wage conditions in the area that the provider is located, it should be included in the wage index calculation. Indeed, in prior years, the Secretary has recognized the importance of including all available wage data in the wage index calculation:

> We have always maintained, subject to limited expectations [sic], that any hospital that is in operation during the data collection period used to calculate the wage index should be included in the database, since the hospital's data reflects conditions occurring in that labor market area during the period surveyed.

67 F.R. 49,982, 50,023 (Aug. 1, 2002). By excluding the wage data of a CAH that converts to IPPS status for the reason that the hospital was not an IPPS hospital in the year in which the

wage survey was conducted, the Secretary arbitrarily creates a wage index that does not "reflect[] the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level" in violation of the statutory mandate. See 42 U.S.C. § 1395ww(d)(3)(E).

This aspect of the proposed rule also violates the statutory purpose of the wage index and the rural floor. Congress required the wage index to reflect real wage levels and selected a survey format to ensure that a group of providers were included in the wage index calculation. CAHs that have converted to IPPS hospitals are subsection (d) hospitals that Congress intended to be included in the calculation of the wage index. Where actual wage data is available, it defies the statutory purpose of the wage index survey not to use that data. Moreover, to the extent that CAHs form the rural floor in a given state, their wage data is all the more important in carrying out Congressional desire to protect urban hospitals from declining wage indexes. This is particularly true in states subject to an imputed rural floor which, in accordance with Medicare's principles of fairness and accuracy, should be able to avail themselves of a wage index based on the more accurate and representative wage data of a true subsection (d) rural hospital rather than an imputed rural index.

Immediately including converting CAHs in the wage index computation would be consistent with the Secretary's past practice in excluding CAHs from the wage index. As noted above, the Secretary excluded CAHs from the wage index based on their Medicare status in the current rate year. Even hospitals that were IPPS hospitals in the base year (the year the wage data was collected), were excluded from the wage index calculation simply by virtue of their Medicare status in the rate year. In choosing to focus on a provider's Medicare status in the rate year, the Secretary acknowledged the importance of actual conditions in the labor market, despite the time lag in the computation of the wage index.

The Secretary's proposed changes will have a significant adverse impact in Massachusetts should its CAHs choose to convert to IPPS status. In Massachusetts, the imputed rural floor for FY 2006 (1.075) is lower than the actual rural floor that existed prior to the Secretary's exclusion of CAHs from the wage index and lower than the rural floor would be if converting CAHs were included in the wage index in the year of conversion. Massachusetts PPS hospitals would continue to suffer severe reductions in their Medicare payments if they are compelled to wait four years after a CAH converts to PPS status before the Secretary includes the wage data of the converting CAH in the wage index calculation. The proposed changes would, therefore, have a drastic and unwarranted impact on Massachusetts PPS hospitals and would undoubtedly have an injurious impact on their ability to deliver quality care and services.

Thank you for the opportunity to comment on the proposed rules. For the reasons set forth above, these proposed changes to the wage index calculation are arbitrary and should not be implemented. If you or your staff needs further clarification of the views expressed in this submission, please contact either of the undersigned at 617-951-7000.

Respectfully submitted,

Deborah Kantar Gardner and Jeffrey L. Heidt
Ropes & Gray LLP
One International Place
Boston, MA 02110-2624
617-951-7000

June 8, 2006

Centers for Medicare and Medicaid Services
Department for Health and Human Services
Attention: CMS-1488-P
P O Box 8011
Baltimore, MD 21244-1850

RE: CMS-1488-P – Medicare Program: Changes to the Inpatient Prospective Payment System and 2006 Rates – April 25, 2006 Federal Register

To Whom It May Concern:

Munson Medical Center appreciates the opportunity to comment to the Centers of Medicare and Medicaid Services regarding the proposed rule updating the Medicare Inpatient Prospective Payment System for Federal Year 2007, as published in the April 25, 2006, Federal Register.

We believe that the proposed changes would have a significant negative impact access to care in northern Michigan. Munson Medical Center is a sole community hospital and a rural referral center serving many communities in northwest Michigan's lower peninsula. As such, Munson Medical Center provides a full array of health care services, including many specialized services not available at smaller hospitals in the region. These intensive specialized services are those being dramatically impacted by this proposed rule and its changes to DRG weights for cardiovascular services. The DRG weights for cardiac interventional inpatient cases are slated for declines in excess of 25% on average, which is an insurmountable impact to our services in these areas. This will dramatically affect access to care for Medicare beneficiaries in our service areas since we will be unable to cover our costs for this care. Munson Medical Center incurs a loss in serving Medicare patients under the current DRG weighting system. An initial estimate of the impact of the change in DRG weights indicates that the loss of Medicare patients would be increased by approximately $4,000,000. This would have a devastating impact on Munson's Cardiology program, and place its future viability at risk. In light of the unique situation of rural referral centers we ask CMS the following:

1. Recognize the unique impact of the proposed changes on the rural referral center by excluding these hospitals from this change.

2. Delay implementation to allow rural centers such as Munson Medical Center to adequate adjust costs to these dramatically lower reimbursements.

Munson Medical Center would also like to comment on the new sole community hospital self-attestation requirements. We believe that our intermediary has much better data in order to make determinations on whether significant changes occurred which could potentially impact a SCH's designation. Instances of "like hospital" changes, or criteria for determining inpatient case numbers in specific geographic areas are more readily available to our intermediaries. Further, we ask that when adjustments to a SCH's designation become apparent, that the affects of this change be made on a prospectively basis and no penalties be applied on a retroactive approach.

If you have any questions on our comments, please feel free to contact me at (231) 935-6910 or our Reimbursement Manager, Steve Leach at (231) 935-7797.

Sincerely,

Edwin Ness
President and CEO

EAN:kah
cc: Edward Carlson
Doug Deck
Marilyn Litka-Klein, MHA

United States Senate

WASHINGTON, DC 20510

June 7, 2006

Centers for Medicare & Medicaid Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Proposed Hospital Inpatient Prospective Payment Systems and FY07 Rates Published in the Federal Register on April 25, 2006

To Whom It May Concern:

As U.S. Senators representing Pennsylvania, and serving on the Senate Finance and Appropriations Committees, we have been fully engaged and strongly supportive of the efforts of the Susquehanna Health System to obtain a more equitable wage index for the Williamsport Hospital and Medical Center (Williamsport Hospital) in Williamsport Pennsylvania. This wage index disparity is particularly problematic. It was our belief that the issue would have been resolved as part of the Medicare Modernization Act's Section 508 one-time appeal process, but unfortunately that was not the case.

The hospital continues to try to diligently work through the regulatory process, and a productive meeting was held in March of this year with CMS staff, staff from our offices, and executives from Williamsport Hospital, to find a solution. To that end the FY07 Inpatient Prospective Payment System Proposed Rule now presents an opportunity for CMS to fix this problem. Thus, we are submitting the following comments in support of, and on behalf of Williamsport Hospital relating to the section of the FY07 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications." We strongly believe now is the time for CMS to address this problem.

The FY07 Inpatient Prospective Payment System Proposed Rule asked for comments concerning the reclassification for hospitals located in a single hospital MSA surrounded by rural counties. The proposed rule invited comment on three specific questions.

1) **What is the justification for reclassifying a hospital that is receiving a wage index reflecting its own wages?**

   A hospital, such as Williamsport Hospital, that receives a wage index reflecting its own wages is justified in seeking reclassification when its competitors have all been reclassified to and/or are located in an area that receives a wage index reimbursement that is significantly higher than the competitors' own actual wages. The geographic reclassification rules have created an anomaly whereby a reclassified hospital may receive wage index reimbursement above its

own average hourly wage. This additional reimbursement allows the reclassified hospitals to recruit and retain employees, while investing in new technology and services. The hospital receiving the lower wage index that competes with the reclassified hospitals must continually work to try to keep wages as competitive as possible to recruit and retain employees, while struggling to purchase new technology and continue to provide needed services to Medicare beneficiaries.

2) **Why should a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals that have received one form or another of special payment status relating to their rural locations, receive special treatment under the wage index?**

A hospital should receive special treatment under the wage index when it is a single hospital in an urban county surrounded by rural counties, that is within a modest distance of a number of hospitals with whom it competes (in terms of services provided, emergency room visits and case/mix) that have received one form or another of special payment status relating to their rural locations. Under these circumstances, the wage index reclassification rules interfere with a competitive market to the detriment of Medicare beneficiaries. A single hospital in an urban county must offer a broad range of services to meet the needs of the Medicare beneficiaries in its large service area, while competing with hospitals that offer fewer services yet receive increased reimbursement due to their ability to reclassify. This is the type of situation the geographic reclassification process is designed to address but, due to its unique location, a single hospital in an urban county is unable to reclassify through the general reclassification process.

Williamsport Hospital competes for employees with a number of hospitals, but is the only one of these hospitals that does not receive increased reimbursement. Williamsport Hospital has been able to remain viable and continues to compete in the level of services it provides as a result of the efficiencies achieved through its affiliation with Susquehanna Health System in 1994. Now, with few if any additional costs left to cut and its competitors continuing to receive higher wage indexes, Williamsport Hospital is at a competitive disadvantage that will adversely impact the services that the hospital is able to provide the community. Williamsport Hospital needs to be reclassified into the Harrisburg MSA to be able to recruit and retain employees, and maintain its high level of patient care and access. The hospital is no longer able to make up shortfalls through any additional cost reduction efforts because it has already achieved a high level of efficiency.

In rendering decisions on requests for reclassification, the Medicare Geographical Classification Review Board is required to consider information provided by a hospital applicant with respect to the effects of a hospital's geographic classification on access to inpatient hospital services of Medicare beneficiaries. Unless Williamsport Hospital is able to reclassify, there will be a negative impact on access to inpatient hospital services for Medicare

beneficiaries. Accordingly, CMS needs to provide Williamsport Hospital with appropriate regulatory criteria under the wage index regulations, allowing the hospital to reclassify to the area where its competitors are have been reclassified.

3) **Why should a hospital be allowed to reclassify to a labor market area that is further away than other, closer urban labor market areas?**

CMS has stated that geographic reclassification is limited to hospitals that are disadvantaged by their current classification because they compete with hospitals that are "located" (physically located or located by reason of being reclassified) in the geographic area to which they seek reclassification. In addition, CMS has indicated that hospitals seeking reclassification to another area must demonstrate an economic connection to the area to which reclassification is requested. Accordingly, the focus is on competition as demonstrated through an economic connection, not on location per se. Williamsport Hospital has an economic connection to the Harrisburg MSA because that is where Williamsport Hospital's competitors are located and/or have been reclassified. In addition, the Harrisburg MSA represents the relevant market for purposes of (1) wage comparison in the context of employee recruitment and retention; (2) comparability of service delivery needs/capabilities with respect to patient care; and (3) the area with which Williamsport Hospital competes for staff and patients. Accordingly, CMS should permit Williamsport Hospital to reclassify to the Harrisburg MSA even thought it is further away than other, closer urban labor market areas

We hope this brings clarity to the questions CMS has raised and again, we ask you to use the regulatory process to address Williamsport Hospital's legitimate concerns on this isolated situation where reclassification rules do not provide a remedy.

Our staff is ready to convene whatever meetings are necessary if any additional information or clarification is needed.

Sincerely,

Arlen Specter

Rick Santorum

272

PENNSTATE
The Milton S. Hershey Medical Center
The College of Medicine

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5/26/06
~~Date (due by 6/12/06)~~

Centers for Medicare & Medicaid Services
Department of Health & Human Services
7500 Security Blvd
Baltimore, MD 21244-1850

To Whom It May Concern:

This letter is written in reference to file code CMS 1488-P, issue identifier Hospital Quality Data.

On page 24093 of the proposed rules (Section IV.A.2) it is noted "we do not anticipate significant additional burden on hospitals regarding the starter set of 10 quality measures or the anticipated 21 clinical quality measures because all JCAHO accredited hospitals are currently required to adhere to these sampling requirements in AMI, HF, Pneumonia and SIP for accreditation and core measure reporting purposes".

This statement is incorrect. As confirmed in the JCAHO On-going Activities Report: "To date, five core performance measurement sets have been identified for hospitals. These include AMI, HF, pneumonia, SIP and pregnancy and related conditions...Effective January 2004 hospitals are required to select 3 core measure sets to meet accreditation requirements."

As such, we disagree that there is no additional burden to hospitals to meet the anticipated 21 clinical quality measure requirement. It is quite possible for hospitals to have selected only the measurements sets for the current 10 quality measures from AMI, HF and pneumonia and not begun data collection for SIP. This is the case at PSMSHMC.

Our current January thru March 2006 discharge measurement sets are due to our vendor on May 31, 2006 and thus our reviews are completed. The April thru June 2006 discharge measurement sets are due to our vendor on August 31, 2006. Please understand that data collection for Hospital Quality Data is performed by professionals who have other work related responsibilities as well. As noted throughout the proposed, PSMSHMC continues to promote of the use of health information technology but we do still have a partial paper medical record. Thus the burden is multi-level:

- Qualified discharges need to be identified
- Data files for our software need to be developed by our IT department
- Workload feasibility for our current professionals need to be assessed. Overtime is likely.
- The Health Information Services/Medical Records Department needs to assess their workloads to identify the qualified discharge's paper medical records.

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- Our professional abstractors need to be trained, and internal quality checks performed prior to submission.
- Our current electronic medical record information needs to be assessed for data collection feasibility. Forms revision is possible.

And finally, our vendor is charging us $1200 to activate the SIP module. We support the expansion to 21 clinical quality measures but a retroactive requirement, based on inaccurate assumptions, linked to such a significant penalty for non-compliance *and required before the results of the comment period & final rule would be published* was indeed a significant burden and frankly, inconsiderate.

Sincerely,

Carol Houlihan, MHA, RHIA
HIS Manager, Coding & Registries

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Advancing Excellence

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Rec'd 6/9/06

June 8, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Attention ~~CMS-1502-FC~~

Dear Dr. McClellan:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Medicare program proposed rule on the hospital inpatient prospective payment system rulemaking for fiscal year 2007. The nearly 16,000 pathologist members of the CAP represent board-certified pathologists and pathologists-in-training with a shared mission to advocate for high-quality and cost-effective medical care. To protect access by Medicare and other federal health care program beneficiaries to high quality laboratory services, the CAP asks the CMS to instruct hospitals on the proper methodology for reporting and reimbursement for the medical direction, supervision and management of hospital clinical laboratories.

The CAP monitors changes in pathology practice and has become aware of an issue that threatens the quality of clinical pathology services. Pathologists report spending a substantial portion of their practice time on clinical pathology management and administrative services; however, compensation from hospitals for these services is declining. In some cases the amount of compensation has been reduced to de minimis and in others compensation for such services has been terminated. Whether these changes are due to a lack of understanding of cost reporting or refusal to pass along an appropriate portion of their Part A reimbursement, hospitals are reducing or eliminating payment for oversight of the clinical laboratories.

Prior to 1983, many pathologists received direct reimbursement for clinical pathology services under Part B of the Medicare program. In 1983 the Health Care Financing Administration issued regulations under the Tax Equity and Fiscal Responsibility Act of 1982 that required indirect reimbursement on a reasonable cost basis under Part A. When the prospective payment system was introduced later the same year, the weighting of

DRG payment included reimbursement for these services. The value and importance of clinical pathology services that are rendered for the general benefit to hospital patients are being diluted, absent a clear mandate to hospitals to make pass-through payments for clinical pathology services.

Pathologists, in their capacity as medical directors of hospital clinical laboratories, provide valuable, necessary medical services for hospital patients. These services and responsibilities are many and varied, and focus, in large part, on ensuring quality in the laboratory. In fact, many of these duties and responsibilities are mandated by the Clinical Laboratory Improvement Amendments.

Subpart K of CLIA addresses the requirement to maintain quality systems, which requires continuous improvement of a laboratory's performance and services through ongoing monitoring and evaluation. Under Subpart M, the laboratory director is responsible for the overall operation and management of the laboratory and ensuring satisfaction of the quality requirements. Other common duties include supervising laboratory technical personnel; selecting, evaluating and validating test methodologies; supervising the blood bank; and recommending additional diagnostic or therapeutic tests, among many others. For all of these services, pathologists also bear professional liability.

The CAP recognizes and respects the CMS mandate of noninterference under title XVII of the Social Security Act and is not requesting the CMS to determine the nature of the arrangement between pathologists and hospitals or to specify or influence the provisions of any such contractual arrangement. However, we do believe the CMS to have the authority to instruct hospitals of their responsibility for reporting costs and making pass-through payments to pathologists for these necessary medical services.

One of the primary principles of the Medicare program is the assurance that providers will receive reasonable payment for covered services rendered. In determining reasonable payment, the Secretary must account for both direct and indirect costs of providers and services. Part A of the Medicare program established a methodology for hospitals to report both the direct and indirect costs. For providers of these services, including pathologists, reimbursement is to be made as a pass-through payment from the hospitals. However, due to the lack of a specific allocation of the hospital's Part A reimbursement, without a clear mandate from CMS hospitals are disregarding their obligation to pass-through payments for clinical pathology services.

At this time we ask the CMS to reiterate the responsibility of hospitals to reimburse pathologists for their medical direction, supervision and management of the clinical laboratory as a portion of their Part A reimbursement and clarify the methodology for reporting the costs associated therewith. Failure to ensure and maintain a reasonable compensation structure for clinical pathology undermines the quality of laboratory services being provided to Medicare and other federal health care program beneficiaries.

The CAP and its membership applaud CMS' efforts to improve the accuracy of hospital payment systems as part of this proposed rulemaking and remain ready to work with the CMS to achieve high quality and cost-effective clinical pathology services for all program beneficiaries. Any questions regarding the CAP comments should be directed to Donna Meyer, in the CAP Division of Membership and Advocacy, at 202-354-7112 or dmeyer@cap.org.

Sincerely,

Thomas Sodeman MD FCAP

Thomas M. Sodeman, MD, FCAP
President

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HI-DESERT MEDICAL CENTER
Your Partner for Life

June 8, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mailstop: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing today on behalf of Hi-Desert Medical Center. We appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) and occupational mix adjustment proposed rules.

The rule proposes the most significant changes in calculation of diagnosis-related group (DRG) relative weights since 1983 by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc). IT also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008. In addition, the rule would update the payment rates, outlier threshold, hospital wage index, quality reporting requirements, and payments for rural hospitals and medical education, among other policies.

While the AHA supports many of the proposed rule's provisions, we have serious concerns about the proposed changes to the DRG weights and classifications.

The hospital field supports meaningful improvements to Medicare's inpatient PPS. We believe the AHA and CMS share a common goal in 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. However, more time is needed to understand the significant proposed policy changes, which redistribute from $1.4 to $1.7 billion within the inpatient system. Analysis shows the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payment. And the validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is uncertain. Moving forward requires thoughtful change.

Specifically, HDMC supports the following:

- One-year Delay: We support a one year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology.
- Valid Cost-base Weights: We support moving to a DRG-weighting methodology based

on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.

- A New Classification System Only if the Need Can Be Demonstrated: HDMC does not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRG's and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.
- Simultaneous Adoption of Any Changes to Weights and Classifications: If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.
- Three-year Transition: Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.
- Collaborative Approach to Moving Forward: We commit to working with CMS to develop and evaluate alternatives for new weights and classifications.

Thank you for your support. We appreciate the opportunity to submit these comments. If you have any questions, please contact me at (760) 366-6260.

Sincerely,

Keith Mesmer, CEO

University of Connecticut Health Center

VIA EMAIL & CERTIFIED MAIL

June 8, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Dr. McClellan,

UConn Health Center & John Dempsey Hospital (07-0036) welcome this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Inpatient Proposed Rule for 2007 (the Rule) published on April 12, 2006.

Our letter comments on a number of proposals included within the Rule, but we focus primarily on portions specific to the Diagnosis Related Group (DRG) changes and the discontinuation of Section 508 of the Medicare Modernization Act (MMA) of 2003.

Comment 1 "HSRV Weights"

While the Hospital would support meaningful improvement to Medicare's inpatient PPS (Prospective Payment Systems), the changes proposed within the Rule are the most significant changes to the calculation of DRG relative weights since the inception of PPS. The proposed revisions would significantly redistribute current payments among both DRGs and hospitals without sufficient notice for budgetary impact and planning. Additionally, the methodologies proposed contain data errors & inconsistencies, identified by AHA, that we believe would inaccurately represent resource consumption, acuity and true costs:

- CMS was inconsistent in its treatment of certain categories of hospitals between their calculation of the FY 2007 HSRVcc weights and the proposed CS-DRG weights, making it hard to directly compare the results. For example, hospitals in Maryland were included in the FY 2007 MedPAR data used for the HSRVcc weight calculation and excluded from the CS-DRG calculation.
- Data cleaning steps used were not always consistent with standard CMS practices (e.g., removal of cases with 0 charges, low volume DRGs, etc.).
- The cleaning steps applied to the cost report data were not consistent with the cleaning steps applied to the MedPAR claims data, which resulted in different hospitals being included in data sets used for the calculation of the weights and the calculation of the scalers to the weights. For example, hospitals in Maryland and hospitals without cost reports for FY 2003 were excluded from the cost report data used to calculate the scalers and included in the MedPAR file used to

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Farmington, Connecticut 06030

calculate the weights.

- **Trimming:** CMS trimmed the cost center CCRs at 1.96 standard deviations from the geometric mean. We believe that this skews the CCRs, as the hospitals with high routine charge mark-ups are systematically removed from the calculation. This results in the exclusion of 198 hospitals' routine CCRs, accounting for over 26 percent of total routine charges. It also creates a mismatch between the CCRs used and the charges they are applied to, as the hospitals that are trimmed out of the CCRs are still included in the charges that are then reduced to costs and determine the cost shares.
- **Weighting:** CMS also hospital-weighted rather than charge-weighted the calculation of the CCRs which in turn are used to calculate the scaling factors used to convert the charge-based relative weights to "cost." There are several issues with this approach:
    - This approach gives an equal weight to each hospital in the national cost-to-charge ratio calculation even though hospitals can range in size from fewer than 25 to more than 1,000 beds.
    - This method is inconsistent with the method of averaging used to develop the cost center-specific DRG weights to which the scaling factors are applied. For this part of the analysis, CMS calculated hospital-specific DRG relative weights, but then used a case-weighted average to develop the national value.
    - The hospital-weighted approach results in a 1 percent to 54 percent difference versus a charge-weighted approach in the resulting scaling factors used for the conversion to cost.
    - The above errors in the calculations over-weight CMS' routine cost shares and under-weight the ancillary cost shares, creating erroneously large swings in DRG weights.
- Dependent on the structure of each provider, those having a Centralized Supply department will yield different cost to charge ratios than those providers with separate Cardiac Catheterization Labs and Cardiology Clinics who order, pay and keep in inventory their specific supplies. Medicare Cost Reporting processes do not take into account this operational variability.
- Scaling the DRG weights to cost based on historical cost report data is inherently flawed because it ignores costs for new technology not present in that historical cost data. Drug Eluting Stents, for example, were not fully represented in the Cost Reporting Year of 2003. New cardiac ablation and devices for arrhytmias were also not fully represented in the Cost Reporting of prior years. Additionally, Providers with varying year ends will be impacted differently as new technology emerges.
- It appears, after preliminary analyses, that the impact is not stable, with small changes in methods leading to large changes in hospital payment. The CSA DRGs include cardiology service lines that are categorized as both "Medical" (Congestive Heart Failure) and "Surgical" (PTCAs). Medical Centers with a higher prevalence of PTCAs would expect to see a more pronounced reduction in revenue under this methodology, while those Centers with a higher instance of non-invasive Cardiology volumes may see a net increase. Specific to John

Dempsey Hospital, the Cardiology loss would be estimated at approximately $1,000,000.

- DRG weight changes proposed for 2007 have the opposite impact of the HSRV changes proposed for 2008. Financial impacts would swing wildly from year to year. Implementation would make significant "winners and losers" from different hospitals based upon their patient mix. Since the estimated dollars to be redistributed are expected to equate to approximately $1.4 to $1.6 billion, we are asking that the implementation of any system be delayed at least one year for further analysis and transitioned into payment methodologies over a three year phase in period.
- As mentioned above, CMS provided no analysis to validate that the proposed changes result in better payment policy. While measuring improved payment accuracy is difficult, the large degree to which the weights fluctuate given methodological changes alone indicates the need for further analysis and study. CMS should construct a process to test the sensitivity of weights to various methodological assumptions and publicly share the result, including:
    - Compare CMS weights to MedPAC's HSRV-cost approach;
    - Compare CMS weights to an approach using standardized costs (as opposed to HSRV);
    - Compare CMS weights to weights calculated by estimating costs at the claims level using the 10 cost center approach;
    - Evaluate alternative methodologies for estimating costs (e.g., method used by New York state's Medicaid program);
    - Compare stability of weights over time; and
    - Determine whether payment policy is improved.

Comment 2 "DRG: Severity of Illness"

CMS also proposes to move to an entirely new DRG system beginning in FY 2008 *or sooner,* referencing a new patient classification system called Consolidated Severity Adjusted DRGs (CSA-DRGs). Clearly a new system, which increases the DRG choices from 526 DRGs to 861 severity-adjusted DRGs, requires software and programming changes, education, training and staffing revisions. A revision of this magnitude would need a *defined* timeline of implementation with a transitional payment period of at least three (3) years to allow providers to financially and operationally prepare for such an impact. An issue specific to CSA DRGs is the proposed adjustment for what CMS defines as "Case Mix Creep", which is based on the idea that improvements in coding and documentation do not prove increased acuity and should not be paid for as such. The basic premise of DRGs is to reimburse for resource consumption based upon the PPS methodology established. It is the Hospital's position that we have expended the resources, provided the patient services and documented accordingly, therefore any adjustment negating that "work" would be inappropriate. The documentation reflects the resources expended and the acuity of case mix. Proper documentation is both necessary and appropriate and does not produce "Case Mix Creep". The rise in DRG weight would be corollary to increased costs, not a driver, and should be adequately reimbursed as such.

Also, the arbitrary limit of nine diagnoses and six procedures imposed by CMS serves to further understate the severity of illness in all Academic Medical Centers. Specific to John Dempsey Hospital (JDH), if the current limitation on these fields was relaxed, the projected increase in reimbursement would be approximately $400,000 for the very same services. To further subdivide the severity subclasses to the cardiovascular DRG's would significantly increase the complexity of coding necessitating more resource consumption and increase the cost of caring patients with cardiovascular disorders.

CS-DRG METHOD CONCERNS

1. **Validation:** It is unclear whether there is a need for a new patient classification system. More work is needed to assess the proposed system and others that might be considered. As with the HSRVcc proposal, CMS provided no analysis that shows that the proposed changes result in an improved hospital payment system compared to the existing DRG system or APR-DRGs.

   CMS must test the degree to which the variation in costs within cases at the DRG level is reduced under both CS-DRGs and APR-DRGs. Payment classifications that still exhibit a high degree of cost variation should be identified and potentially revised. We suggest comparing the distribution of the coefficient of variation at the DRG level for various grouping approaches.

   For instance, CMS chooses to collapse the tier-four cases within major diagnostic categories (MDCs). It is unclear whether all of the tier-four cases are clinically cohesive enough to be combined and whether consolidation adequately considers variations in resource requirements. CMS also aggressively collapses the DRGs with low Medicare volume such as obstetrics, psychiatric and substance use services without any discussion of the potential ramifications for other payment systems, such as other Medicare PPSs, Medicaid and the private sector that often bases payment off the Medicare inpatient DRG system. CMS believes that a new patient classification system that distinguishes more-sick from less-sick patients will reduce the "cherry picking" of healthy patients, but there may be other, easier ways to accomplish this. For example, CMS embarked on a new way to differentiate patients last year based on the absence or existence of a major cardiovascular diagnosis but did not discuss the possibility of other similar, less disruptive changes to the system as an option in this year's rule.

   Even more fundamentally, today's DRG system was created to distinguish the resource use required among patients. It has been modified over time to reflect changes in clinical practice and technology. The APR-DRG system is based on severity of illness, not necessarily the resource use required. The impact of a move to CS-DRGs – an APR-DRG hybrid – is unclear. But the implications of moving from a resource-based system to a severity-based payment system must be more fully explored and understood.

Comment 3 "DRG Reclassifications "

DRGs: Dual Array Implantable Neurostimulators for Deep Brain Stimulation. We oppose CMS' recommendation to keep the implantation of dual array implantable neurostimulators for deep brain stimulation in DRG 1 (Craniotomy Age >17 with CC) and DRG 2 (Craniotomy Age >17 without CC). CMS should recognize the higher resources associated with this technology.

DRGs: Carotid Artery Stents. We oppose the proposed delay in making any changes to carotid artery stent cases. The higher costs associated with carotid stents should be recognized within the existing DRG system.

DRGs: Cardiac Resynchronization Therapy, Defibrillators (CRT-D). We agree with the proposal to add code 37.74 (Insertion or Replacement of Epicardial Lead [Electrode] into Atrium) to the DRG logic so that all types of defibrillator devices and lead combinations would be included in the following DRGs:

- DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheter);
- DRG 535 (Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock); and

- DRG 536 (Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock).

This change would bring the DRGs into alignment with the change in coding advice to assign code 37.74 in conjunction with implantation of CRT-D defibrillators.

Application of Major Cardiovascular Diagnoses (MCVs) List to Defibrillator DRGs. We oppose the proposal to delay refining defibrillator DRGs based on MCVs. We believe it is appropriate for CMS to apply a clinical severity concept similar to the approach used in FY 2006 to refine cardiac DRGs to an expanded set of DRGs (e.g., defibrillator DRGs) based on the presence or absence of an MCV.

DRGs: Hip and Knee Replacements. For FY 2006, new codes were created to differentiate between new and revised hip and knee replacements. In addition, more specific codes were created to identify the joint components replaced. After publication of the FY 2006 inpatient PPS final rule, a number of commenters advised CMS that the DRG logic for DRG 471 (Bilateral or Multiple Major Joint Procedures of Lower Extremity) included knee and hip procedures that are not bilateral or do not involve multiple major joints. We agree with CMS' proposal to remove the codes from DRG 471 that do not capture bilateral and multiple joint revisions or replacements.

DRGs: Severe Sepsis. We agree that hospitals have found the coding of systemic inflammatory response syndrome (SIRS), sepsis and severe sepsis confusing in the last few years. The classification of these conditions has changed several times during this

period. We also concur that data have not been consistent and that a new DRG for severe sepsis would be inappropriate. However, we recommend that a change be made so patients with severe sepsis associated with respiratory failure requiring mechanical ventilation may be properly recognized. The ICD-9-CM classification instructions require that these patients be coded with the systemic infection as the principal diagnosis. The infection codes do not group to DRG 475 (Respiratory System Diagnosis with Ventilator Support) despite the use of resource-intensive mechanical ventilation (procedure code 96.7). This results in a significant loss of reimbursement for these patients.

Since the change in coding sequencing of these patients, many advisory boards have discussed this issue several times. In addition, several proposals have been submitted to the ICD-9-CM Coordination and Maintenance Committee to allow the sequencing of respiratory failure as the principal diagnosis. To date, no changes have been made. At this point, reverting the sequencing instructions would be confusing to coders and would once again disrupt trend data.

Instead, we recommend considering mechanical ventilation as a pre-MDC DRG on the basis of the procedure code. If this is not possible, we recommend that CMS add systemic infections (038.xx,) as acceptable principal diagnoses for DRG 475 when reported in conjunction with mechanical ventilation or tracheostomy.

Comment 4 "Hospital Redesignations and Reclassifications"

Section 508 of the MMA provided $900 million over three years for a one time geographic reclassification opportunity which expires March 31, 2007 for hospitals which met the specific criteria and wage related tests. John Dempsey Hospital is one of approximately 120 hospitals that qualified for reclassification increasing our reimbursement by approximately $3 million annually. More specifically, the unique circumstances at JDH allowed the Hospital to be assigned their own specific wage index which enables us to recruit and retain the required clinical personnel to meet the specific health care needs of our community.

We believe that the efforts invested now by CMS to revise the existing Prospective Payment System methodology focus on short term solutions and are inconsistent with efforts to develop models that reward excellence, improved quality and safer patient care. A change of this magnitude requires more analysis and input from industry and regulatory resources. It is with this belief that we urge you to reconsider the points raised above and that you delay any further revisions of great magnitude for at least another year's time.

Sincerely,

Steven Strongwater, MD
Associate Dean, Clinical Affairs
Director of Clinical Operations
Hospital Director

Bruce Liang, MD
Chief of Cardiology and Director of
Calhoun Cardiovascular Center

Cc: Senator Christopher Dodd
Representative Nancy Johnson
Senator Joseph Lieberman

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MED EL CORPORATION

June 8, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
PO Box 8011
Baltimore, MD 21244-1850

RE: CMS-1488-P: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY 2007 Rates

Dear Dr. McClellan:

I am writing to submit public comments in response to the proposed regulation indicated above, which governs payment under the Medicare Inpatient Prospective Payment System (IPPS) for FY 2007.

As a long time stakeholder within the cochlear implant industry and strong advocate for Medicare beneficiaries' continued access to the cochlear implant technology, I am deeply concerned by the perpetual cycle of low reimbursement for cochlear implants under the IPPPS (DRG 49). Payment under Medicare for this life altering technology is regarded as "severely inadequate" which has been the case since payment began nearly 20 years ago. Although CMS acknowledged this disparity between payment and cost in the preamble of CMS-1470-P, and agreed to further re-evaluate possible re-classification options for cochlear implants, CMS-1488-P provides no payment increase for cochlear implants which forces hospitals to continue to incur significant financial losses when providing this service.

II. DRG Reclassifications

To mitigate the payment shortfall, cochlear implant procedures (DRG 49, ICD-9-CM 20.96, 20.97, and 20.98), should be re-assigned to DRG 1, Craniotomy Age > 17, W/CC, a more clinically coherent and resource coherent DRG. My recommendation is based on the following:

1) **Clinical Coherence** – Cochlear implant procedures involve surgical removal of part of the skull (temporal bone) via drilling during an approximate 3 hour surgery performed under general anesthesia. This surgery on and inside the skull (craniotomy of the temporal bone) is performed, exposing the cochlea through the facial recess of the mastoid. An electrode array is inserted into the cochlea and the internal receiver/stimulator is secured in a surgically created bony recess behind the ear. Electrical signals can then be transmitted through the skin to the VIII cranial nerve giving the patient the sensation of sound. Similarly,

procedures in DRG 1 involve surgical removal of the skull and implantation of complex devices, including implantation of neurostimulators that deliver electrical signal to the brain. Additionally, the cochlear implant procedure is the ***only*** procedure in DRG 49 that involves implantation of a highly sophisticated medical device. Based on the information above, I believe that the current assignment of the cochlear procedure to DRG 49 is clinically incongruent and therefore should be re-assigned to DRG 1, which includes procedures that involve implantation of highly complex and sophisticated neurostimulators within the skull.

2) **Resource Consumption** – In the preamble of CMS-1470-P, CMS acknowledged the significant charge variance between cochlear implants and other procedures paid under DRG 49 as documented by the charge data contained in the 2003 MedPAR file. Charge data from the 2005 MedPAR file, obtained from an independent source, documents similar findings. An independent analysis of the 2005 MedPAR file shows that of the estimated 2415 discharge cases assigned to DRG 49, only 5 percent represent cochlear implant procedures **AND** the average charge per case was approximately 81% higher than non-cochlear cases ($58,000 vs. $32,000). By contrast, average charges for DRG 1 ($64,572) are more similar to cochlear implant cases. Additionally, mean costs were calculated using the ratio of cost to charge methodology by revenue center and found cochlear implant cases to be 116% higher in cost than non-cochlear cases ($32,800 vs. $14,700). **It is important to note that the hospital acquisition cost alone for the cochlear implant device is greater than $25,000 and therefore payment under DRG 1 is still insufficient.** However, if CMS's FY 2007 proposed payment weight of 1.765 for DRG 49 is adopted, hospitals will continue to incur **significantly higher** losses when performing cochlear implant cases, as compared to non-cochlear cases. Considering the low volume of cochlear implant procedures performed as inpatient, it is believed that the effect on the weight for DRG 1 would be negligible if re-assigned to DRG 1.

As mentioned previously, cochlear implantation represents a highly complex surgical procedure with clinical similarity and resource compatibility to procedures performed under DRG 1. Re-assignment to DRG 1, without regard to complication and co-morbidity, will allow the cochlear implant procedure to be reimbursed more appropriately. Your full consideration in this matter is greatly appreciated.

Sincerely,

Barbara Carter
MED-EL Corporation

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John M. Young
President

June 9, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1488-P
P. O. Box 8011
Baltimore, MD 21244-1850

RE: Comments to Proposed Changes to the Hospital IPPS and FY 2007 Rates Published in the Federal Register on April 25, 2006, regarding:

Geographic Reclassifications –
- Requested Reclassification for Hospitals Located in a Single Hospital MSA Surrounded by Rural Counties

Dear CMS,

The following comments are submitted in support of the Williamsport Hospital and Medical Center relating to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications".

I am a member of the Williamsport Hospital Foundation Board of Directors. Additionally, my wife Sue and I have recently volunteered along with many other community members in a county wide fundraising effort to modernize this fine but aging Williamsport Hospital and Medical Center.

The Williamsport Hospital Medical Center in center city Williamsport is located in the western portion of Lycoming County of PA. Lycoming is the largest geographic county in PA; the size of Rhode Island with a population of 120,000. We are 90 miles north of Harrisburg (Dauphin County) and approximately 90 miles west of Scranton (Lackawanna County).

Our main competitors in providing health care in our area lie in two adjacent counties, namely Union (Evangelical Hospital in Lewisburg) and Montour (Geisinger Medical Center in Danville). All three of these rural counties, Lycoming, Montour, and Union, have low density populations ranging from 97 people per square mile (Lycoming) to 139 for Montour.

These three competing hospitals are fairly close together in terms of distance and travel time by car due to modern roads and low congestion. It's 22 miles from Williamsport Hospital to Evangelical or 25 minutes on Route 15. Hop on Interstate 80 east,near Evangelical Hospital and in 15 miles and in a very short time you can be at Geisinger Medical Center. It's a little harder to get from Williamsport Hospital to Geisinger, but not by much. It is a 35 mile trip that takes 35-45 minutes on Interstate I-180 and Route 54.

According to the U.S. Census Bureau and its' website American Fact Finder, these three rural counties in North Central PA are fairly similar in many ways. Please refer to the following 2000 Census Bureau data;

	Geisinger Medical Center	Evangelical Hospital	Williamsport Hosp. & Med. Ctr.
Population	Montour Cty.	Union Cty.	Lycoming Cty.
Total Population	18,236	41,624	120,044
Median Age	39.8 years	35.8 years	38.4 years
Under 5	5.7%	4.8%	5.5%
Over 65	17.1%	13.4%	16.0%
Density–People/Sq.Mile	139	131	97
Income / Median			
Households	$38,075	$40,336	$34,016
Families	$45,224	$47,538	$41,040
Full Time;			
- Males	$32,478	$31,242	$30,783
- Females	$23,837	$22,010	$21,372
Per Capita Income	$19,302	$17,918	$17,224
Poverty			
Allages	8.7%	8.8%	11.5%
Under 18	11.2%	8.6%	14.5%
Over 65	10.2%	7.0%	7.8%
Families	4.5%	5.1%	7.9%
Minorities			
White	96.7%	90.1%	93.9%
Black	1.0%	6.9%	4.3%
Other Minority	2.3%	3.0%	1.8%
Total Minority	3.3%	9.9%	6.1%
Housing			
Single Family			
Owner Occ. Homes	3,696	7,351	25,502
Median Value	$93,400	$97,800	$86,200
% of Total Population	20.3%	17.7%	21.2%
Travel Time to Work	19.7 min.	20 min.	19.6 min.

Lycoming County, based on the 2000 census data, appears to be trailing its two adjacent neighbors, Montour and Union Counties, in some economic measurements. We believe that is about to change.

Looking retrospectively, Lycoming County's lagging economic statistics has been due in part to Lycoming County being further from Interstate 80 than it's two neighbors, Montour and Union County. The construction of Interstate 80 has proven to be a meaningful economic stimulus to central PA.

The soon-to-be completed divided highway, Route 15 system, from Maryland to New York state and it's connection to the Interstate I-180 bypass through Williamsport is also expected to stimulate accelerated growth within Lycoming County.

Significant economic development activity has in fact already begun in Lycoming County. We believe this will close or eliminate any economic gap with respect to our neighboring counties Montour and Union.

The Williamsport Hospital serves our patients and community very well and efficiently. It's center-city location means that this hospital provides a high degree of charity care within our rural region of PA. This includes providing modern medical care to the minorities of our population; many of who live near this hospital. The Hospital E.R. Department is particularly busy and important to our community, especially during the Little League World Series hosted by Williamsport in late summer each year. Additionally, we operate an ambulance service not mandated by law but by our sense of community commitment. This hospital provides many critical services performed by health care workers that are not easy to attract and retain.

Both Evangelical Hospital and the Geisinger Medical Center have modern facilities, healthy advertising budgets, significant economic reserves, and satellite medical facilities within our county.

We offer as many, if not more, services than these competitors, yet they are paid more for their labor costs under the Medicare Program. The difference in reimbursement is significant. Based on an expected 49% inpatient Medicare load during FY 2007, this reimbursement inequity will cost the Williamsport Hospital nearly $3,500,000 for the upcoming year alone.

All of these three hospitals are essentially in the same labor market. We are paying our staff personnel comparable wages as Evangelical and Geisinger, yet they are somehow judged to be in the Harrisburg labor market. We, unfortunately are not. No representative from the Williamsport Hospital and Medical Center is asking your center to take anything away from our competitors. We are merely asking for a fair chance to compete.

I believe the Medicare program in our area should be equitable for all competitors, otherwise the Williamsport Hospital and Medical Center will not be able to attract and retain the health care workers that are so important to our patients – especially the elderly which in our case represents 50% of our inpatients. The projected $3,500,000 shortfall under existing rules could well be the difference for Williamsport between profit and a loss for the full fiscal year.

THE YOUNG INDUSTRIES INC.

Please approve this rule that would allow for more equitable treatment compared to the two hospitals with which we compete.

Thank you for your consideration.

Sincerely,

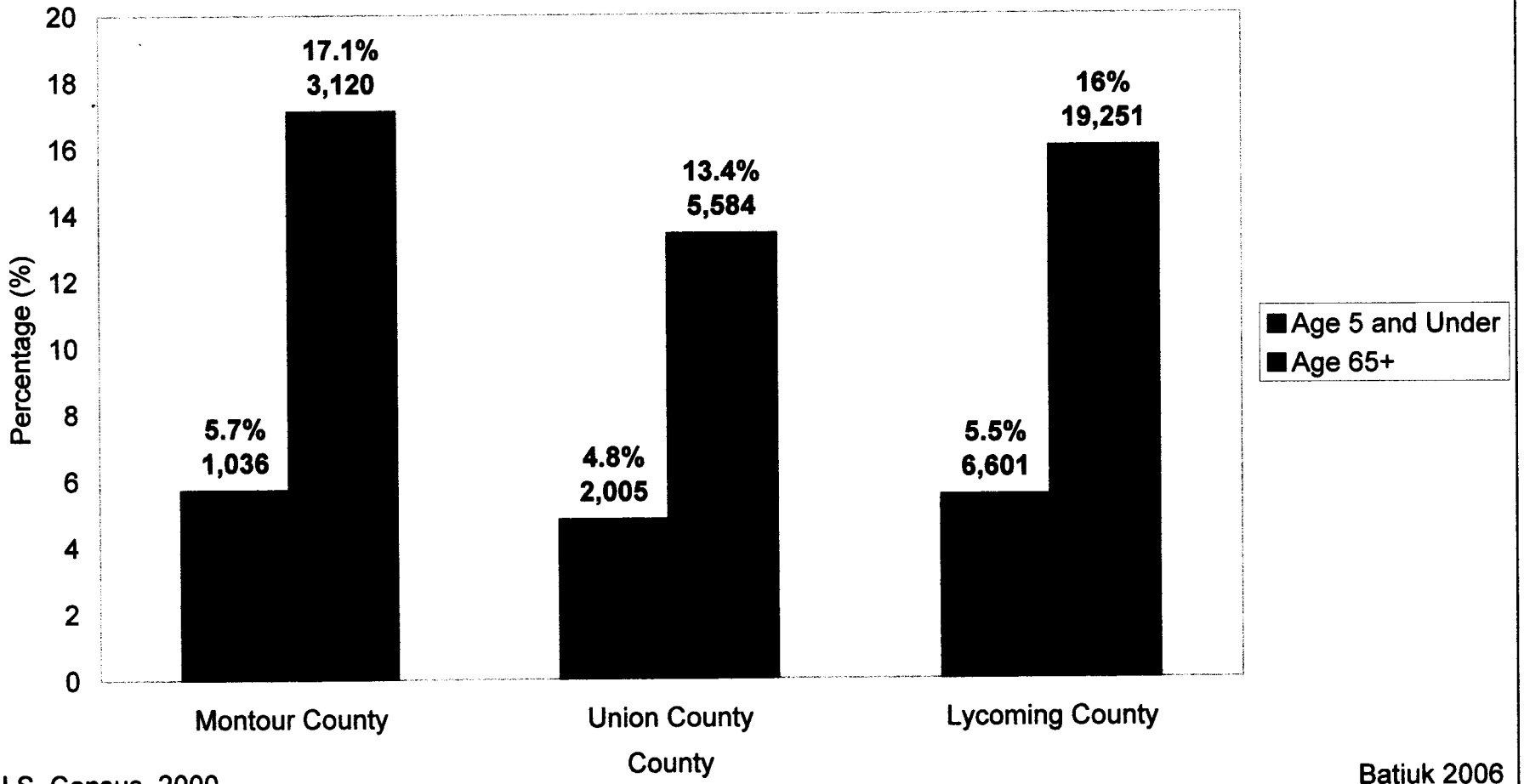
John M. Young
President

JMY/als

Attachments Enclosed:

- 6/8/2006 Lycoming County Planning and Community Development letter to John Young
- Graphs comparing Montour, Union and Lycoming County
  - % of total population under 5 and over 65, by county
  - Median age in three counties
  - % of total population disabled, by county
  - Median household income, by county
  - Individuals & families below poverty level, by county
  - Median value of single family owner-occupied, by county

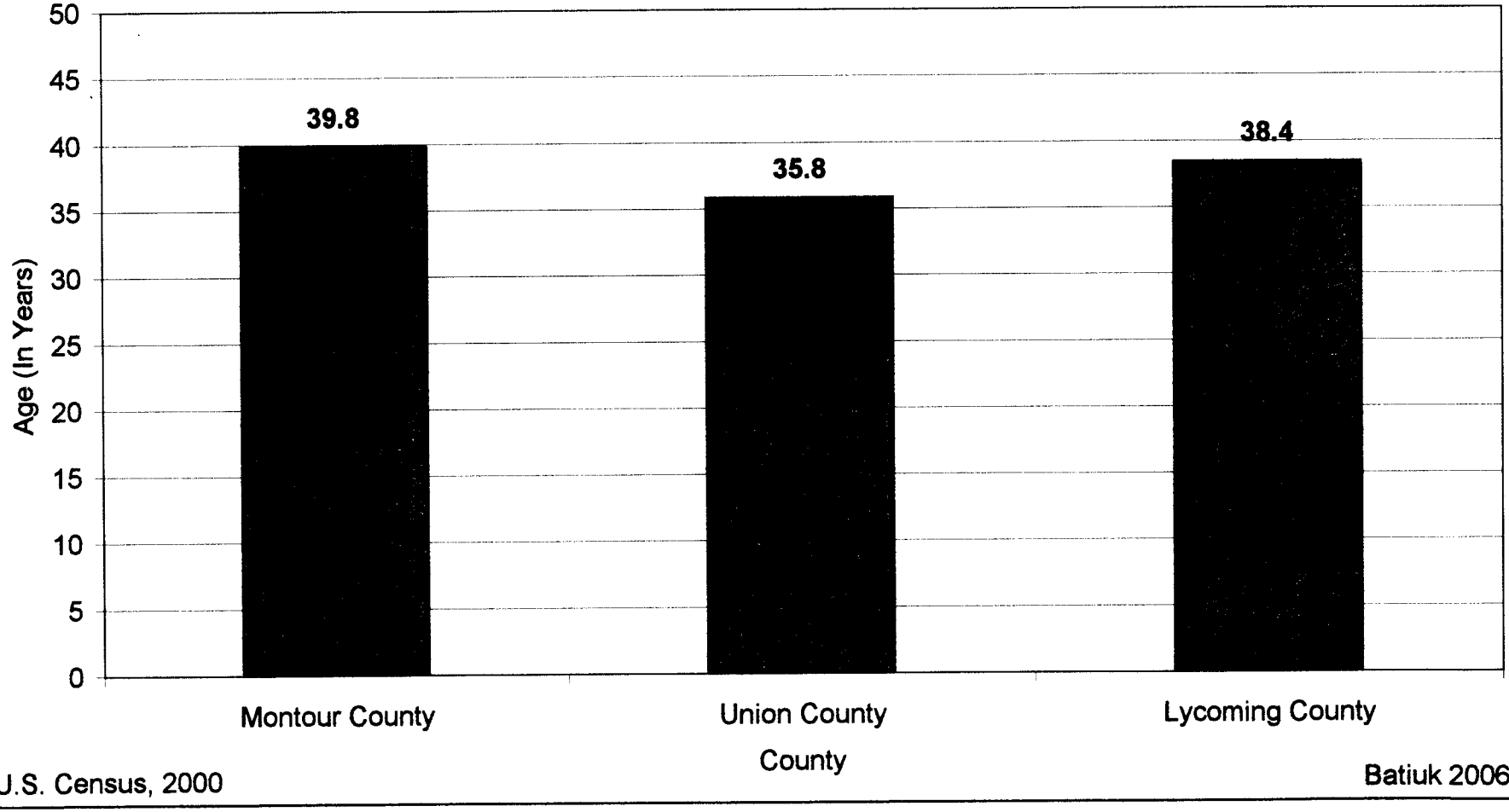
PERCENTAGE OF TOTAL POPULATION UNDER AGE 5 AND OVER AGE 65



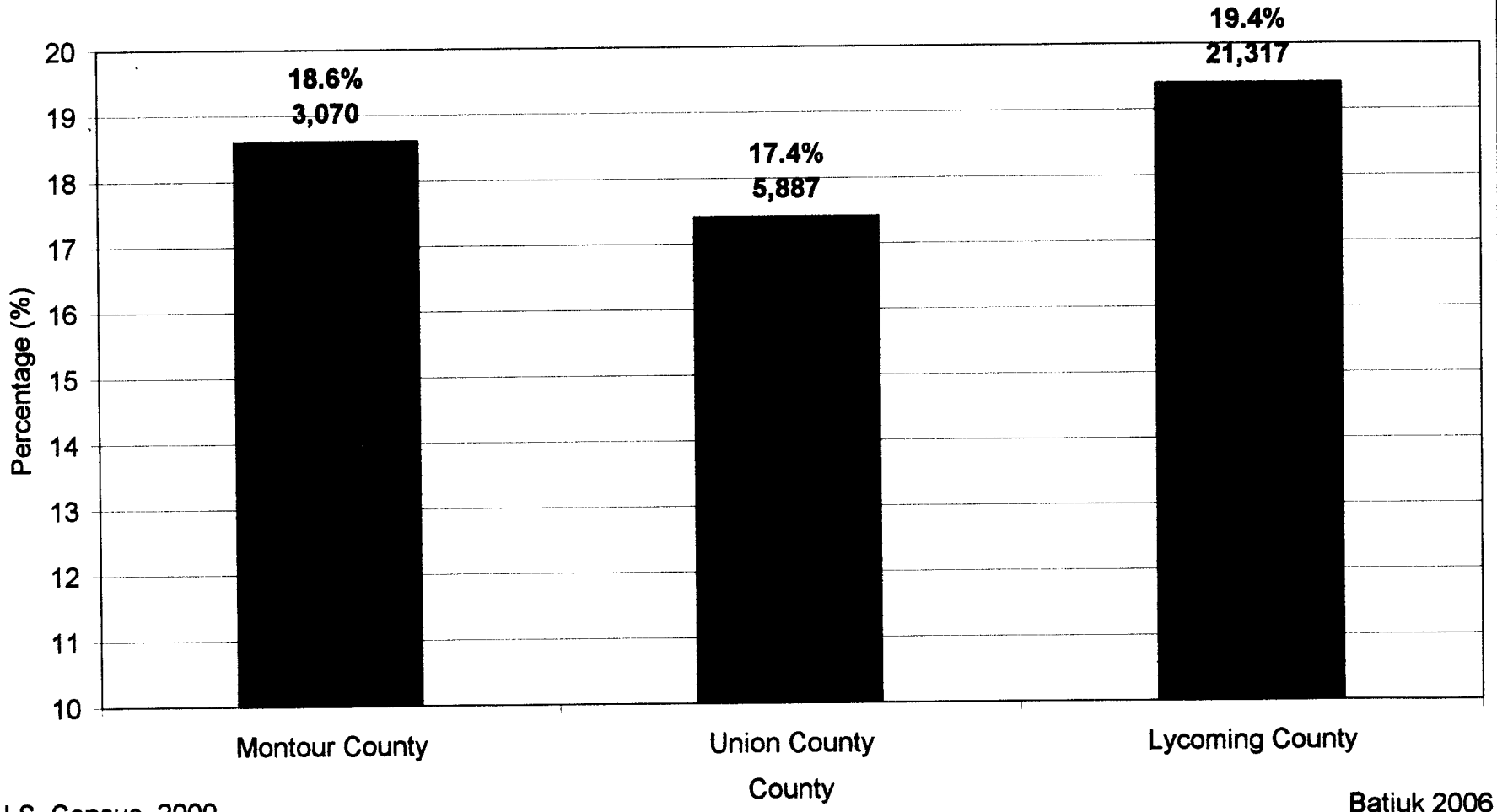
U.S. Census, 2000

Batiuk 2006

MEDIAN AGE OF MONTOUR, UNION, AND LYCOMING COUNTY



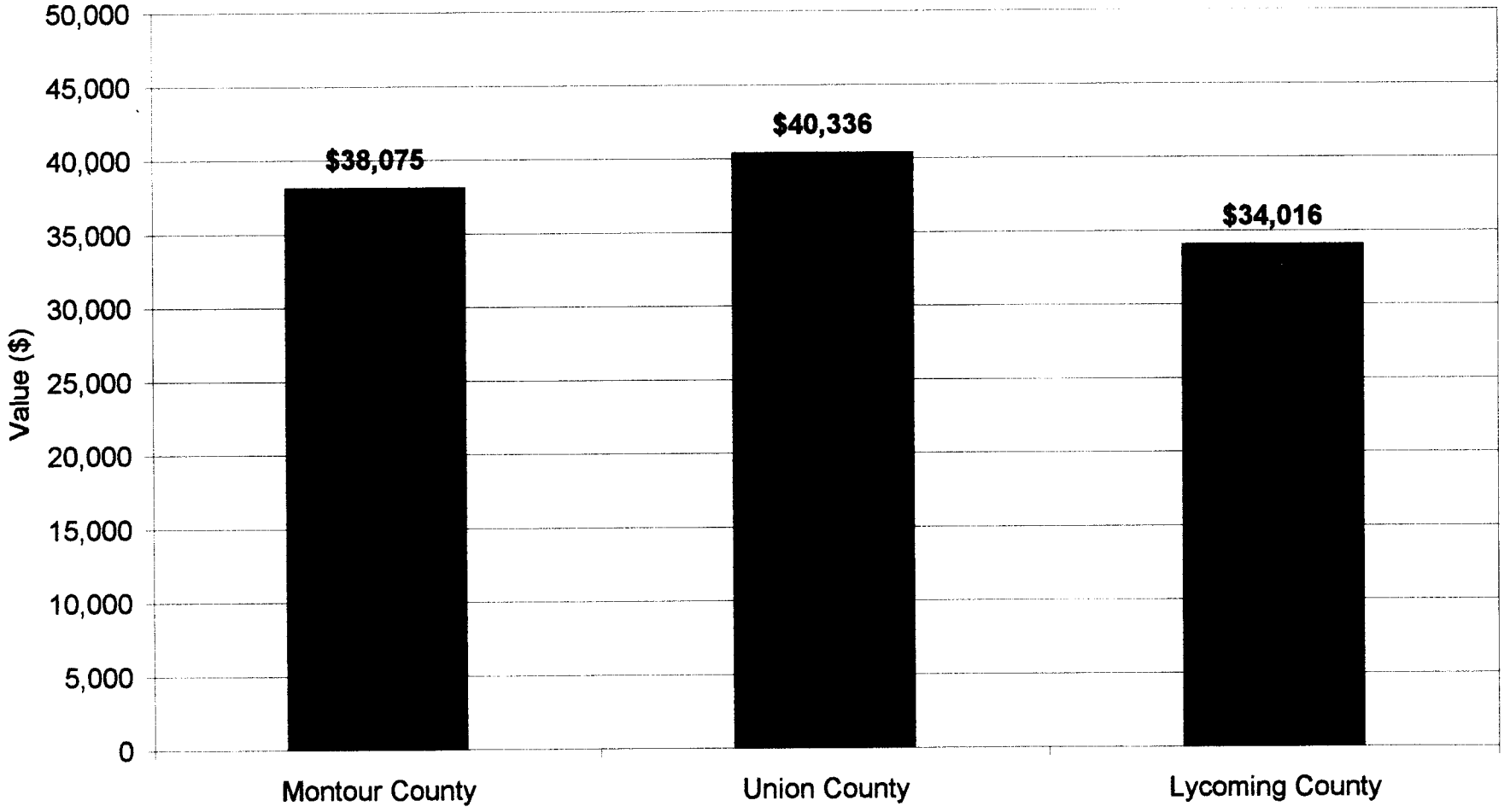
PERCENTAGE OF TOTAL POPULATION (AGE 5 AND OLDER) WHO ARE DISABLED



U.S. Census, 2000

Batiuk 2006

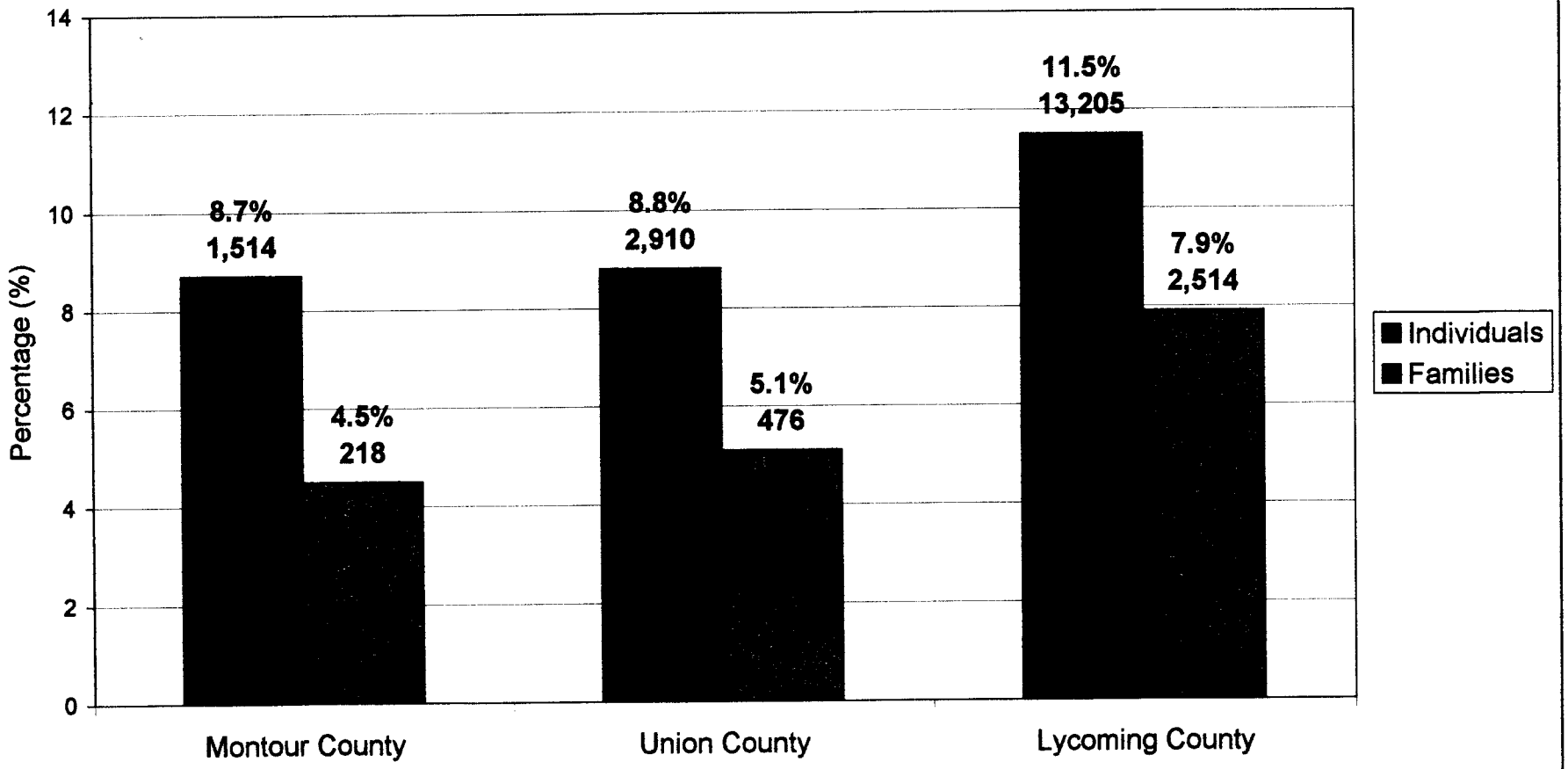
MEDIAN HOUSEHOLD INCOME



U.S. Census, 2000

Batiuk 2006

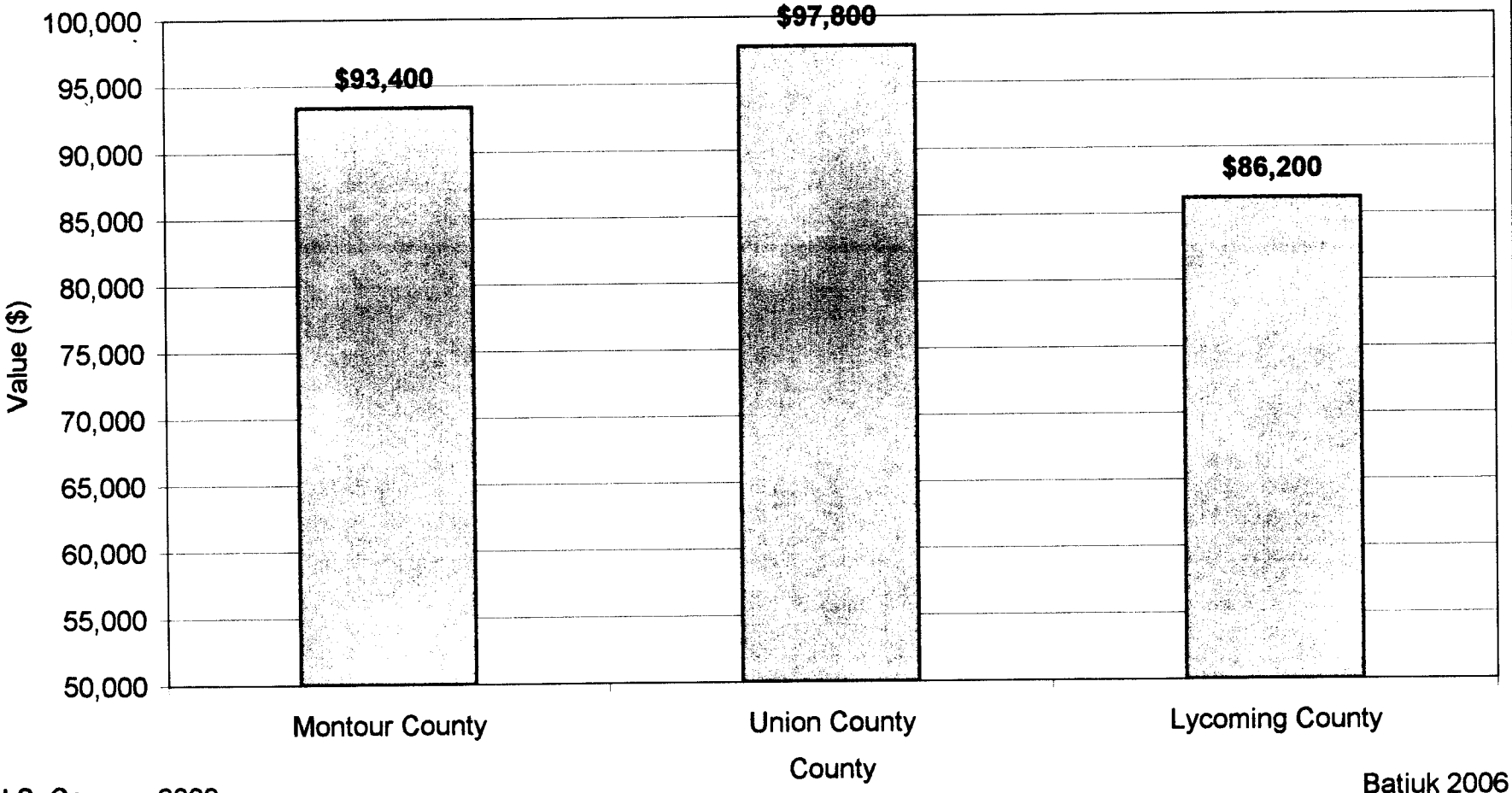
INDIVIDUALS AND FAMILIES BELOW POVERTY LEVEL



U.S. Census, 2000

Batiuk 2006

MEDIAN VALUE OF SINGLE FAMILY OWNER-OCCUPIED HOMES



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LYCOMING COUNTY PLANNING &

COMMUNTY DEVELOPMENT

Commissioners:
Rebecca A. Burke, *Chairperson*
Richard T. Nassberg, *Vice Chairperson*
Ernest P. Larson, *Secretary*

Location:
Executive Plaza
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Williamsport Pennsylvania 17701

Jerry S. Walls, AICP, *Director*

Voice: (570) 320 2130
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Mailing Address:
48 West Third Street
Williamsport Pennsylvania 17701

June 8, 2006

Mr. John Young, President
Young Industries
16 Painters Street
Muncy, PA 17756

Dear Mr. Young,

We appreciated learning of your concern about the Medicare reimbursement rates for Susquehanna Health System. We have researched the U.S. Census Bureau database known as American FactFinder. The attached charts are a graphical display of information available at that website. Here are some comments and observations regarding the attached material.

The attached charts will offer a comparison of three counties relative to demographic indices related to income and age. Montour County is the home of Geisinger, Union County is the home of Evangelical Hospital, and Lycoming County is the home of Susquehanna Health System and its three affiliated hospitals.

The charts suggest there is a great deal of similarity among the three counties. In fact, Lycoming County may have proportionally greater challenge in meeting the medical needs of its preschool and elderly populations.

The differential in Medicare reimbursement rates among the three counties places Susquehanna Health System at a competitive disadvantage.

Should you have any further questions please don't hesitate to contact me via Kurt Hausammann, Jr., AICP (320-4128).

Sincerely Yours,

Justin Batiuk
Planning Department Intern

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Arrhythmia Center of Connecticut, P.C.

MARK H. SCHOENFELD, M.D., F.A.C.C. MARK A. MARIEB, M.D., F.A.C.C.
MARK L. BLITZER, M.D., F.A.C.C.

June 7, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
7500 Security Blvd.
Baltimore, MD 21244

To Whom It May Concern:

I am writing you regarding the Medicare Program and proposed changes to the hospital inpatient perspective payment system in fiscal year 2007 rates as practicing electrophysiologist at the Hospital of St. Raphael in New Haven, Connecticut. I am very concerned that Medicare beneficiaries will have limited access to lifesaving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies, such as implantable cardiac defibrillators used to prevent sudden death may thereby have restricted access, particularly noteworthy since this technology has been particularly effective in reducing the nation's #1 cause of mortality. Cardiac ablations have been used to treat debilitating and life-threatening cardiac arrhythmias.

The full implantation of the proposed inpatient perspective payment system by CMS would have a devastating impact on my hospital's ability to serve patients in the community. These proposed reductions will clearly impact upon hospital staffing for these critical procedures, which will ultimately be translated into reduced patient access and care. Without adequate staffing and without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to quality improvement initiatives that have been recently mandated by CMS in Congress, such as the implementation of the ICD Registry recently undertaken through a joint effort of The American College of Cardiology and The Heart Rhythm Society in conjunction with the Centers for Medicare and Medicaid Services.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system; however, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice. Furthermore, it is troubling that significant errors in technical decisions have been made that may exacerbate the problem. It is my understanding that many hospitals were not included in the data set, including a large number of academic health centers, and this will clearly distort any analysis that CMS conducts.

Beyond this, CMS has failed to address issues related to "charge compression". The rule fails to fix the charge compression problem that has penalized technology intensive procedures for years. In fact, it exacerbates the situation. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost to charge ratios. Most devices and supplies are in a single cost center, and under this rule distinctions between procedures and even hospital departments are lost.

CMS proposes to implement a new system based on the severity of the patient's illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one.

However, technologies that represent increased complexity, but not greater severity of illness also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to the joint impact this year.

I thank you for your attention to the above comments on behalf of my patients and the Yale community that I serve as well as the many patients throughout Connecticut and adjacent states who are served by my practice. I do thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to correct any deficiencies noted above.

Sincerely,

Mark H. Schoenfeld, M.D., F.A.C.C., F.A.H.A., F.H.R.S.
Director, Cardiac Electrophysiology and Pacer Laboratory,
Hospital of St. Raphael
Clinical Professor of Medicine,
Yale University School of Medicine

MHS/dmp

UAB HEALTH SYSTEM

School of Medicine

June 3, 2006

Center for Medicare and Medicaid Services
Marc Hartstein
7500 Security Blvd.
Mail-Stop C4-08-06
Baltimore, MD 21244-1850

Dear Mr. Hartstein:

The Center for Medicare and Medicaid Services (CMS) recently posted the Proposed Hospital Inpatient Payment System (HIPPS) Rule which goes into effect in 2007. One aspect of the rule suggested a Consolidated Severity Adjusted (CSA) DRG system be implemented in 2008 or earlier. This letter will provide comment regarding this rule as well as background and information regarding the impact of the suggested CSA DRG system as it pertains to Ventricular Assist Devices used as bridge to heart transplantation and Destination Therapy (heart support until end of life).

In October of 2003, CMS created a National Coverage Determination for Ventricular Assist Devices used as Destination Therapy. In that decision, it was mandated centers be qualified by CMS to provide Destination Therapy. Qualification standards included reporting patient outcomes to a nationally audited Registry.

In collaboration with National Heart Blood and Lung Institute, (NHLBI) the Food and Drug Administration (FDA), and CMS, INTERMACS Mechanical Circulatory Support Database was created with mandated participation for centers providing Destination Therapy. The purpose of the Registry is to provide the pivot for continuing progress in the field of mechanical circulatory support in three ways: **the standard for current clinical device application**, for which the MCSD will provide information on selection and outcomes, foster identification of best practices, and facilitate regulatory oversight for post-marketing surveillance and reimbursement; **a platform for introduction of new technology**, supported by identification of target populations and benchmarks for performance, and validated by standardized components of baseline and outcome data with adverse event definitions; and **a laboratory for investigation into the physiology of mechanical circulatory support,** including patient-device interactions and the enhancement of myocardial regeneration and recovery.

It is imperative that the 69 center who are currently recognized by CMS as Destination Therapy LVAD Centers be reimbursed at an appropriate level. The new CSA DRG VAD cross walk as reported greatly reduces payment levels. It appears the CSA DRG payment would be a little more than half of what a VAD implant admission currently pays under DRGs 103 and 525. This oversight is due to the development of the APR-DRG system by 3M prior to changes implemented by CMS whereby cases including ICD-9-CM procedure code 37.66 were assigned to a pre-MDC and mapped to DRG 103. (Table 1)

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TABLE 1: DRG Assignment for ICD-9 37.66, FY2001-2005

Fiscal Year	N	Average LOS	Average Total Charges	Assigned DRG (MedPAR Source)	DRG base payment
2001	72	53 days	$434,000	DRG 525 (FY03)	$56,500
2002	83	45 days	$409,000	DRG 525 (FY04)	$73,400 [a]
2003	76	47 days	$561,000	DRG 103 (FY05)	$97,200
2004	158	42 days	$494,000	DRG 103 (FY06)	$95,600
2005	322	43 days	$565,000	DRG 103 (FY07 Pr.)	$104,000

Table 2: CMS Analysis of Number of Cases, Average LOS, and Average Charges Across Relevant Proposed CSA DRGs

CSA-DRG	Descriptor	N	Avg LOS	Avg Charges
4	HEART &/OR LUNG TRANSPLANT SOI 1 & 2	261	12.80	$200,583
5	HEART &/OR LUNG TRANSPLANT SOI 3	242	31.60	$328,397
6	HEART &/OR LUNG TRANSPLANT SOI 4	258	44.20	$524,070
*204**	*CARDIOTHORACIC PROCEDURES SOI 4*	*21,158*	*18.30*	*$182,309*
*207**	*CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 1*	*5,543*	*2.20*	*$86,365*
*208**	*CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 2*	*22,400*	*3.70*	*$97,810*
*209**	*CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 3*	*25,923*	*6.60*	*$118,694*

**Proposed CSA DRGs for VADs*

***Table 3 Proposed CSA DRGs for VADs CMS LVAD Median Base Payment**

DRG 204*		DRG 207*		DRG 208*		DRG 209*	
FY08P	n	FY08P	n	FY08P	n	FY08P	n
	69		69		69		69
	$70,794		$29,486		$33,603		$41,427

Table 4 Proposed CSA DRG for Heart Transplantation Median Base Payment

*DRG 103		DRG 4		DRG 5		DRG 6	
FY06	FY07P-1st	FY08P	n	FY08P	n	FY08P	n
	69		69		69		69
69	$148,753		$46,164		$95,220		$160,516

*Proposed payment for VADs in DRG 103 for 2007

If CMS plans to adopt the CSA DRG system ICD-9 37.66 cases should be assigned to DRGs 4, 5 and 6 instead of 204, 207, 208, and 209, which would be consistent with average charges and treatment of 37.66 cases since the FY04 Final Rule. These centers do not received additional reimbursement for reporting to the INTERMACs database. It is imperative that centers continue to

be reimbursed in the method and policy in which CMS has proposed for the last three years which is for implantation of LVAD be grouped with Heart Transplantation. Both require similar cost, resources and reporting which supports the continuation of CMS's earlier coverage and payment policies.

If you need additional information, please do not hesitate to contact me at 205-934-4202.

Sincerely,

James Kirklin, MD
Professor of Surgery
University of Alabama at Birmingham

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UNIVERSITY OF MINNESOTA

Leslie W. Miller, M.D.
Professor of Medicine
Director, Cardiovascular Division

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612-626-2178
Fax: 612-626-4571

June 5, 2006

Centers for Medicare and Medicaid Services
Mr. Marc Hartstein
7500 Security Blvd.
Mail-Stop C4-08-06
Baltimore, MD 21244-1850

Re: Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Proposed Payment System 2007 Rule

Dear Mr. Hartstein:

During the comment period for the Hospital Inpatient Proposed Payment System 2007 Rule (HIPPS), it is important to understand the specific impact of these recommendations on not only hospitals, but also on patient care. The following information will provide the perspective of patients facing end-stage heart failure and the centers who treat them.

Background

It is estimated that 250,000 patients in the United States are in the terminal phase of systolic heart failure suffering from severe symptoms, which are refractory to maximized medical therapy [1]. Historically, cardiac transplantation has been the only proven therapy to improve survival but available to a fraction of these patients.

In 2002, the U.S. Food and Drug Administration (FDA) approved the HeartMate (Thoratec Corporation, Pleasanton, California, USA) left ventricular assist device (LVAD) as long-term, Destination Therapy (DT) for patients with end-stage heart failure (ESHF) not eligible for heart transplantation. The Centers for Medicare and Medicaid Services (CMS) followed suit and approved reimbursement for the use of these devices as DT starting in October of 2003.

1. American Heart Association. Heart Disease and Stroke Statistics — 2005 Update. Dallas, Tex.: American Heart Association; 2005
2. Rose EA,et al; Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term mechanical left ventricular assistance for end-stage heart failure. N Engl J Med 2001; 345:1435–1443

Eligibility Criteria for Destination Therapy and Number of Medicare Patients

The CMS criteria for patient selection were based on the criteria used for patient entry into the REMATCH trial [2], including: (1) class IV New York Heart Association (NYHA) symptoms for at least 60 days despite maximized therapy with angiotensin-converting enzyme inhibitors, diuretics, digoxin or requirement of inotropic support as outlined by he AHA/ACC Guideline for heart failure treatment [5]; (2) left ventricular ejection fraction (LVEF) of 25% or less; and (3) peak oxygen consumption of <13 mL/kg/min or documented failure to wean intravenous inotropic therapy as evidenced by a fall in systolic blood pressure to <80 mmHg, decline in renal function, worsening symptoms, or objective physical examination signs of deterioration, and/or (4) contraindication to heart transplantation due to age greater than 65 years, insulin-dependent diabetes mellitus with end organ damage, chronic renal failure or other morbidities.

By January, 2006 three hundred eleven patients have undergone left-ventricular assist device (LVAD) implantation as Destination Therapy (DT) since the completion of the landmark REMATCH trial which first demonstrated the superiority of mechanical circulatory support over medical therapy for end-stage heart failure patients ineligible for transplantation [2]. Data was available in 258 of these DT recipients (due to lack of data release authorization from the hospitals), referred to as the post-REMATCH database or cohort. The patient demographics and hemodynamics were very similar to REMATCH patients, but survival after LVAD implantation continued to markedly exceed the survival benefit of medical therapy reported in the REMATCH trial. Importantly, there is encouraging data suggesting that the risk of adverse outcome can be reliably estimated prior to device implant to improve patient selection and timing of device implant, which together promise to continue to improve overall outcomes with device therapy*.

Though a relatively small number of patients fall under these criteria, these patients have no other reasonable alterative to the use of an LVAD as Destination Therapy. Table 1 provides the number of Medicare patients who have received Destination Therapy with a maximum number of more than 300 in 2005.

Table 1 DRG assignment for ICD-9 37.66 over time

MedPAR Fiscal Year	N	Average LOS	Average total charges	DRG assignment using MedPAR data	DRG base payment
2001	72	53 days	$434,348	DRG 525 (FY2003)	$56,500
2002	83	45 days	$409,785	DRG 525 (FY2004)	~ $70,000 **
2003	76	47 days	$561,751	DRG 103 (FY2005)	$97,200
2004	158	42 days	$494,064	DRG 103 (FY2006)	$95,600
2005	322	43 days	$565,431	DRG 103 (FY2007 pr.)	$104,000

The number of Medicare beneficiaries who bridge to heart transplantation with a VAD is even smaller.

Table 2 DRG assignment for ICD-9 37.65 over time

MedPAR Fiscal Year	N	Average LOS	Average total charges	DRG assignment using MedPAR data	DRG base payment
2001	117	15 days	$171,192	DRG 525 (FY2003)	$56,500
2002	142	13 days	$195,132	DRG 525 (FY2004)	~ $70,000 **
2003	127	18 days	$267,053	DRG 525 (FY2005)	$56,500 ***
2004	137	14 days	$312,503	DRG 525 (FY2006)	$58,900
2005	113	18 days	$352,541	DRG 525 (FY2007 pr.)	$64,000

- Source is MedPAR data, but data presented excludes heart transplant. Cases with both 37.65 and 37.66 were included in the 37.66 set and excluded from the 37.65 set (to avoid being
- ** All 37.65 cases were assigned to DRG 525 in FY2003-2004, but 37.62 was moved to DRGs 104/105 in FY2004, resulting in a significant payment difference for DRG 525 across the 2 years.

Patients access to Destination Therapy

The CMS LVAD DT National Determination also required hospitals to qualify as a CMS DT LVAD center. At this time, 69 Centers are recognized by CMS and have the ability to be reimbursed by Medicare.

CMS has proposed a new Consolidated Severity Adjusted (CSA) Diagnosis Related Group (DRG) system to reimburse for inpatient hospital cases which would drastically reduce payment for implanting a VAD.

Table 3 Proposed CSA Cross walk and Payment for implanted VADs

DRG	ICD-9-CM Procedure Code	FY06 Median Payment Across 69 DT Centers*	CSA DRG Proposed VAD cross walk	Proposed Payment Median FY 08 69 Centers
525	37.65 Implant of external VAD	$84,000	208	$33,603
103	37.66 Implant of internal VAD	$136,000	204	$70,794

If CMS plans to adopt the CSA DRG system ICD-9 37.66 cases should be assigned to DRGs 5, and 6 instead of 204, 207, 208, and 209, which would be consistent with the treatment of 37.66 cases since the CMS changes in the FY04 Final Rule. The following table reflects similar charges and payment between implantation of a VAD and CSA DRG Heart Transplantation.

Table 4 Recommended CSA Cross walk based upon charges and payment for implanted VADs and Heart Transplantation

DRG	ICD-9-CM Procedure Code	FY06 Median Payment Across 69 DT Centers*	Ave 2005 Charges for VAD	CSA DRG Rec.	CSA Payment Median FY 08 69 Centers
525	37.65 Implant of external VAD	$84,000	$352,541	5	$93,620
103	37.66 Implant of internal VAD	$136,000	$565,431	6	$157,819

With only 69 Centers recognized by CMS as Destination Therapy (DT) LVAD Centers, this type of reduction would place a significant burden on those centers providing this level of care for a very sick patient population. Patient access would be further compromised with the 69 Centers being unable to absorb such financial hardship.

Recommendations

CMS is encouraged to modify the suggested CSA DRG system to parallel the recommendations CMS made in the 2004 Inpatient Rule and is still in effect today which includes grouping implanted long-term VADs into the same DRG as Heart Transplantation or create new CSA DRGs for VADs which reflect the cost and resources required to provide the level of care.

Thank you for the opportunity to comment. If you have additional questions, please do not hesitate to contact me at 612-227-7498.

Sincerely,

Leslie W. Miller, M.D.
Professor of Medicine
Director, Cardiovascular Division

UPMC | University of Pittsburgh Medical Center

The Heart, Lung and Esophageal Surgery Institute

May 30, 2007

Cardiac Surgery Division

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Centers for Medicare and Medicaid Services
Marc Hartstein
7500 Security Blvd.
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Baltimore, MD 21244-1850

Re: Proposed Hospital Inpatient Prospective Payment System Rule – CMS-1488-P Comments on Left Ventricular Assist Device Procedures

Dear Mr. Hartstein:

I am writing to comment on the changes that the Center for Medicare and Medicaid Services has proposed in the 2007 Hospital Inpatient Prospective Payment System Rule.

As way of background, the University of Pittsburgh Medical Center (UPMC) is among the first centers to receive approval from CMS to implant left ventricular assist devices (LVADs). UPMC Artificial Heart Program is one of the most experienced in the United States. For more than 15 years our Artificial Heart Program has been a key player in the evolving use of mechanical support.

We are experience with VADs we are concerned of the consequences throughout the health care systems, with the potential adoption of Consolidated Severity Adjusted (CSA) DRGs as proposed by CMS for implementation by 2008. Many private plans base their payment on these DRGs and weights to establish payment. It is my understanding that the proposed CSA DRG utilizes a older crosswalk which was completed by 3M prior to CMS decision to group implanted LVADs ICD-9 37.66 to the Heart Transplant 103 DRG. CMS grouped these procedures together because the length of stay day, resources and cost were similar.

DRG Assignment for ICD-9 37.66, FY2003-2005

Fiscal Year	N	Average LOS	Average Total Charges	Assigned DRG (MedPAR Source)	DRG base payment
2003	76	47 days	$561,000	DRG 103 (FY05)	$97,200
2004	158	42 days	$494,000	DRG 103 (FY06)	$95,600

Source is MedPAR data, but data presented excludes heart transplant.

We would ask if the CSA DRG system is adopted, implanted LVADs would cross walk to Heart Transplant CSA 4, 5, 6 which is consistent with current CMS policy and payment.

CMS Analysis of Number of Cases, Average LOS, and Average Charges Across Relevant Proposed CSA DRGs

CSA-DRG	Descriptor	N	Avg LOS	Avg Charges
4	HEART &/OR LUNG TRANSPLANT SOI 1 & 2	261	12.80	$200,583
5	HEART &/OR LUNG TRANSPLANT SOI 3	242	31.60	$328,397
6	HEART &/OR LUNG TRANSPLANT SOI 4	258	44.20	$524,070

Thank you for allowing comment to this important rule. If you have any questions, do not hesitate to contact me.

Sincerely,

Robert L. Kormos, MD
Co-Director, Heart Transplantation
Director, Artificial Heart Program
Medical Director, McGowan Institute for Regenerative Medicine
University of Pittsburgh Medical Center

Congress of the United States

U.S. House of Representatives

COMMITTEE ON WAYS AND MEANS

1102 LONGWORTH HOUSE OFFICE BUILDING
(202) 225-3625

Washington, DC 20515-6348

http://waysandmeans.house.gov

282

May 30, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert Humphrey Building, Room 314-G
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Dr. McClellan:

I commend your agency for proposing to address the serious inaccuracies in the Medicare hospital inpatient payment system. As you know, the Medicare Payment Advisory Commission (MedPAC) in its March 2005 report to Congress found that the current system makes inaccurate payments in 65 percent of the cases by a factor greater than plus or minus 5 percent. Considering this problem, and in view of our mutual goal to improve the quality of hospital care, the Medicare payment system should be changed to more accurately pay based on the complexity of the patient and the relative cost of the service. Otherwise, the Medicare program will continue to provide financial incentives that distort the market and reward hospitals that provide the most profitable services to the least sick patients.

To correct the system, MedPAC recommended to Congress a different hospital inpatient payment structure that more accurately matches patient severity, costs and payments across different types of cases. The structure proposed by MedPAC contains the following features:

- differentiation between patients with none, one or multiple comorbidities within a diagnosis related group (DRG);

- neutralizes the effect of widely varying hospital markups across different departments and by certain types of hospitals that distorts the current system in favor of certain procedures, such as cardiac and orthopedic surgery (cost based and hospital specific relative value weights); and

- funds the outlier pool through the risk within each DRG rather than an across the board offset. This proposal requires a statutory change.

MedPAC found that this system will better align payments with costs across different types of services as well as for patients with different care requirements due to the severity of their illness. Because the statute grants discretion to HHS to determine the structure of hospital payments, it is within your authority to make these changes, and I encourage you to do so.

In fact, on April 12, your agency released a regulation that proposes to adopt a new method of calculating the weights or values of the DRGs that removes the effects of systematic variation in hospital mark-ups. CMS also proposes a new DRG system that differentiates the patients with multiple comorbidities from the other cases for implementation in FY 2008 (or earlier).

I ask that the CMS implement both of these proposals in FY 2007 for the following reasons:

- MedPAC analysis revealed significant inaccuracy in the current payment system and recommended implementation of both the new severity-refined DRGs and a revised method for the weights at the same time;

- It is inequitable to remove the subsidy provided by the overpayments for cardiac and orthopedic surgery prior to correcting the underpayments for the most severely ill patients;

- It is not reasonable to ask that some hospitals experience financial losses from implementing the new weights this year if implementing severity would have offset some or all of those losses. To stagger implementation will cause providers to experience unnecessary payment fluctuation between FY 2007 and FY 2008; and

- A delay is not beneficial to taxpayers as hospitals will have more time to up-code and increase their Medicare payments.

In making these changes to the payment system for FY 2007, the agency should continue to communicate with effected stakeholders. There may be technical problems with the calculation of the cost-based weights, specifically in the editing process and with the use of hospital weighting rather than discharge weighting of the cost to charge ratios. I ask that you look into this issue. These are fixable problems and need not delay the agency in moving forward with the changes this year.

Additionally, the Committee and the Administration worked together to create a solid foundation for pay for performance for hospitals in the Medicare program in the Deficit Reduction Act (DRA). Specifically, the DRA requires expanded reporting on quality, cost and efficiency for hospitals and the future development of a Medicare pay for performance plan. I ask that the Administration expand on their discussion in the proposed rule on cost data and require in the final regulation that:

- Hospitals report a range for all of their payments and an average self-pay amount for selected services;

- In FY 2007, CMS should work with the industry to develop the definitions for reporting the cost data; and

- The Office of Inspector General proposed rule from 2003 on maximum charges should be finalized immediately.

This price reporting structure may lead to decreases in health care costs. In contrast, a system that uses grossly inflated hospital charges as a benchmark or gives hospitals information to collude on prices will fuel inflation. Moreover, it can be implemented within the existing successful structure for hospital reporting to CMS.

I look forward to continue to work with you so that we can eliminate the perverse incentives created by inaccurate payments and hidden prices. I strongly encourage you to finalize the rule and adopt these payment changes concurrently in Fiscal Year 2007.

Best regards,

Bill Thomas

Bill Thomas
Chairman

WMT/dkw

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NANCY L. JOHNSON
5TH DISTRICT, CONNECTICUT

COMMITTEE ON
WAYS AND MEANS

SUBCOMMITTEES:
CHAIRMAN, HEALTH
HUMAN RESOURCES

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June 12, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Hubert Humphrey Building, Room 314-G
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan,

I appreciate the opportunity to comment on the hospital Inpatient Prospective Payment System proposed rule. The current hospital payment system is deeply flawed. The proposed rule begins to make reforms that are long overdue. Although the proposed rule is an improvement over the current system and moves in the right direction, there are concerns that need to be addressed.

First, on the issue of timing, I think it is imperative that implementation of cost-based payment weights and severity-adjusted diagnosis-related groups (DRG) occur concurrently. The two-step approach that has been proposed will create erratic swings in reimbursement year-over-year, particularly for those community hospitals whose overall margins have been plus or minus 1% for many years. It is therefore crucial that changes be implemented in such a way as to minimize swings in reimbursement. However, I appreciate that this fundamental change may require a transition period that mitigates the overall impact in any one year, and I encourage you to consider transition options for implementing both proposals simultaneously.

I commend efforts to move towards utilization of cost-based payment weights. I think this is an appropriate and much needed change and I support efforts to more closely match reimbursement to costs. However, as we move toward the use of cost-based payment weights, I strongly urge that CMS reverse the decision to edit a larger than usual proportion of hospital data from the formation of cost-based payment weights which has served to skew the base data.

Additionally, I have concerns about the impact of charge compression in the ten cost centers used in CMS' methodology. While the proposed rule makes progress towards more closely aligning reimbursement with costs, charge compression could undermine advances in the new payment structure. The proposed 10 cost centers in addition to moving to cost-based weights may exacerbate charge compression, whereby high technology items with small markups could be penalized because they are put in the same cost centers as lower cost, high markup supplies. Consistent with MedPAC

recommendations, I encourage CMS to expand the costs centers to minimize charge compression within each center.

Regarding the proposed consolidated severity-adjusted DRGs, I support the policy goal, but I am deeply troubled about the lack of transparency in the development of the new groupers that are the basis of the new system. It is just plain wrong to have the basic logic and judgments made in developing this proposal unavailable to all interested parties. This information needs to be made available by CMS to all interested parties without delay. Anything less than immediate public disclosure of this information and complete transparency is unacceptable, and will have negative implications for hospitals, payers and other vendors. It also presents an opportunity for a single vendor to control a system that historically has maintained competition between highly skilled vendors offering various software options.

Lastly, we must overcome the reliance on outdated data. Now is the time, as we move to a system that is based on hospital cost reports to rectify that increasingly glaring and serious defect. I strongly believe that these reforms ought to be done in accordance with addressing weaknesses in hospital cost reports. MedPAC has identified a number of major shortcomings in the data currently available in the existing reporting process. MedPAC provided recommendations that would serve to help policymakers gain a better understanding of total financial performance, and improve the timeliness and accuracy of reporting. Timely, consistent, and accurate financial information will ultimately improve the accuracy of Medicare payments to providers. Given the pace of the evolution of medical practice we simply must have access to more timely information. Technological advances allow cost report data to be available for reimbursement and policy purposes in a timely fashion. CMS must make this a priority.

MedPAC is currently considering possible replacements for the wage-index system, which is fundamentally flawed and creates perverse incentives, especially for hospitals that manage to hold down labor costs. I understand that fundamental change to the wage-index system must be done legislatively but I urge you to work with Congress and MedPAC to find a solution to this ongoing problem. Should delay be necessary for any reason, all changes, these proposed and those in development on the wage-index adjustment should be evaluated for their impact on the system simultaneously and implemented together.

I am concerned that failing to address the above issues and work in accordance with stakeholders will undermine the potential of these significant and promising payment reforms. To that end, I strongly urge that CMS address these matters prior to a final rule taking effect.

Very truly yours,

Nancy L. Johnson
Member of Congress

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Congress of the United States
Washington, DC 20515

June 12, 2005

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Room 445–G, Hubert H. Humphrey
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code CMS–1488–P

Dear Dr. McClellan:

We applaud the Centers for Medicare and Medicaid Services (CMS) for its "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule." The suggestions in the proposed rule would make significant, but necessary, changes to the Medicare inpatient hospital payment system. We agree that payments should better reflect the cost of providing those services while accurately accounting for patient severity; however, we believe that several modifications may be warranted to best achieve the proposal's goals.

DRG Reclassifications

In its March 2005 report on Physician-Owned Specialty Hospitals, the Medicare Payment Advisory Commission (MedPAC) recommended many of the changes CMS addresses in the proposed rule. MedPAC is a leading authority on Medicare payment, and we urge CMS to adopt the methodological changes suggested by MedPAC in its comment letter on the proposed rule. These changes will help ensure the highest possible payment accuracy within the constraints of available data, while minimizing disruption.

The move to cost-based diagnosis related group (DRG) weights and severity-adjusted DRGs will help ensure that payments more closely reflect actual expenditures, and both should be implemented as soon as practicable. However, implementing these changes in different payment years could lead to a whip-saw effect where hospitals receive large payment increases or reductions in one year, only to see those effects mitigated the following year. For this reason, we urge CMS to implement the payment changes concurrently, as opposed to in consecutive years.

Many stakeholders have expressed concern with the methodology used to generate cost-based weights, and the effect of moving to consolidated severity-adjusted DRGs. Concerns about the short timeframe and unknown effects of implementing these changes are legitimate, but a wholesale delay is unnecessary. It seems that a transition period to the new payment system could ease these fears and allow for a thoughtful, timely implementation. Thus, we urge CMS to adopt the proposed changes as soon as practicable, but to address MedPAC's suggestions and include a sufficient transition period both to allow providers to adjust to the new rules, and to give CMS time to address any underlying methodological problems.

Sincerely,

Charles B. Rangel
Ranking Member
Committee on Ways & Means

Pete Stark
Ranking Member
Committee on Ways & Means
Subcommittee on Health

GINNY BROWN-WAITE
5TH DISTRICT, FLORIDA

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COMMITTEE ON FINANCIAL SERVICES

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Congress of the United States
House of Representatives
Washington, DC 20515

June 9, 2006

The Honorable Mark McClellan
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244
Re: CMS Proposed Rule for Hospital Inpatient Prospective Payment System

Dear Administrator McClellan:

I write with great concern over the CMS proposed rule for a hospital inpatient prospective payment system. A hospital in my Congressional district would be gravely affected if this proposed rule were implemented.

Leesburg Regional Medical Center (LRMC) is a 309-bed acute care not-for-profit hospital that serves a large retirement community in Central Florida. Approximately 75% of LRMC's patients are on Medicare, 5% are Medicaid, and 5% are uncompensated care, charity, or self-pay.

LRMC has evaluated the impact of the proposed changes. The estimated impact of the changes will result in a decrease of $6 million in annual payments to LRMC. The hospital estimates a real net decrease in reimbursement of over $2 million during FY 06 and FY 07, they correlate lost revenues to the decrease in cardiac DRG weights. LRMC does approximately one thousand cardiac surgeries and over 3,500 cardiac caths each year. These large volumes are a result of LRMC being the only facility in Lake and Sumter counties to provide comprehensive cardiac services.

I understand that the proposed changes reflect recommendations from the Medicare Payment Advisory Commission and respond to congressional concerns that the existing system may create incentives for hospitals to "cherry-pick" more profitable cases. The reforms will significantly affect payment to specialty hospitals that are typically owned, in whole or in significant part, by physicians who serve as referral sources. However, LRMC is not a specialty hospital and is not owned by physicians. Therefore, the hospital would be unfairly impacted by proposed changes because of unintended consequences of the proposed rules.

Roughly 1,100 people move to Florida each day, and my Congressional district is one of the fastest growing in the U.S. This growth is due in large part to retiring families in search of warm weather and tropical paradise in their golden years. My district is home to the largest number of Social Security and Medicare recipients in the nation; thus, the needs of my aging constituency are unique. It would be difficult to assume that LRMC would continue to meet adequately the needs of Medicare patients if these rules were put into place because of the financial loss it would suffer. I would have to assume, however, that these losses would be absorbed through reduced quality of care and services to the seniors in my area.

I urge you to reconsider the extreme reductions in the cardiac DRGs because these ill-advised cost-saving measures would compromise the quality of life my constituents deserve.

Sincerely,

Ginny

Ginny Brown-Waite
Member of Congress

GBW:aw

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June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1488-P
Room 445-G Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. McClellen:

The purpose of this letter is to provide a few brief comments on the proposed inpatient regulation for the Prospective Payment System based on Maryland's experience. While Maryland has a waiver from the PPS system as part of an all-payer system, many of the methodologies at issue in this proposal apply to the methodologies employed by the State's rate-setting agency, the Health Services Cost Review Commission (HSCRC). These comments are intended to highlight some of the methodological and transition issues faced by the State's hospitals as the HSCRC has moved to a severity-adjusted case mix system.

The HSCRC has had considerable experience with APR-DRGs, even though State Fiscal Year 2006 (the current fiscal year) is the first year for all the State's hospitals. In FY 2001, the Commission began to measure case mix for the State's two academic medical centers with APR-DRGs. A third hospital was added to this list in FY 2002. These institutions had presented credible evidence that the severity of their cases was not appropriately measured under CMS DRGs, particularly for neonatal and pediatric cases. In an all-payer system, this deficiency presented an important issue that the APR-DRG grouper was uniquely positioned to rectify.

While a number of items have emerged during the transition to APR-DRGs, two major issues have been the focus of attention. These items are discussed below.

Case Mix Growth and Coding

Correct ICD-9-CM coding that yields maximum reimbursement under the CMS-DRG system may understate a hospital's case mix under APR-DRGs. If hospitals have attempted to improve coding efficiency by coding only to get maximum reimbursement under Medicare, the facility may not have captured a complete picture of its patients' severity of illness under APR-DRGs. When APR-DRGs (or consolidated severity-adjusted DRGs based on APR-DRGs) are used for reimbursement, hospitals have the financial incentive to improve their clinical documentation and to code administrative records more completely. The HSCRC collects the principle diagnosis and up to 14 secondary diagnoses. Prior to moving to APR-DRGs, one Maryland hospital reported 15 codes for only 2.5 percent of its cases. Four years after moving to APR-DRGs, the hospital reported 15 codes for over 20 percent of its cases. The hospital experienced

substantial case mix growth over this period of time. An audit of the facility confirmed the accuracy of its coding.

In FY 2005, the HSCRC encouraged hospitals to improve their depth of coding prior to the transition to APR-DRGs. As this process began, case mix growth exceeded four percent for the State's hospitals on average, and in the current fiscal year, case mix growth is again near that mark. The HSCRC has implemented a policy for FY 2006 to limit the amount of case mix growth that is recognized for each hospital until depth of coding stabilizes. These limits have required the Commission to implement an appeals process for hospitals with new or expanding programs that generate rising case mix growth due to the complexity of the service in question.

Access to Resources

The HSCRC decided to move to APR-DRGs in June 2004. FY 2005 was established as a base year and hospitals were encouraged to begin their preparations for full implementation as of FY 2006 (beginning July 1, 2005). Despite the advance notice, a number of hospitals had not acquired the APR-DRG grouper until near the time for full implementation to begin. In addition to acquiring the grouper, hospitals had to deal with issues of integrating the grouper with other hospital systems, which was at times difficult with proprietary systems. (It has taken nearly two years for 3M and Quadramed to resolve issues about the appropriate interface between the APR-DRG grouper and Quadramed's end coder, which 11 of Maryland's 47 acute care hospitals use.) Finally, hospitals struggled to find coders as the demands on their existing staff increased with the demands for more complete coding. Maryland has 47 acute care hospitals. Moving the nation's entire hospital industry to a new system in a short period is likely to be much more difficult.

CMS has the opportunity to avoid some of the transition issues the HSCRC faced by placing the consolidated severity-adjusted DRG logic in the public domain or by requiring open licensing of the grouper at reasonable rates. While HSCRC required 3M to allow access to hospital vendors and consultants as part of the transition, the relationship has not always been smooth. As 3M has understandably tried to protect its proprietary interests, consultants and vendors to hospitals have struggled to obtain access to the grouper as they advised their clients. These consultant and vendor services are necessary for the hospitals to meet operational and regulatory requirements, however. We strongly recommend that this issue be address as part of any national transition to consolidated severity-adjusted DRGs.

I hope these brief comments are helpful. The HSCRC staff would be happy to answer any questions you might have about Maryland's experience with the use of APR-DRGs.

Sincerely,

D. Patrick Redmon, Ph.D.
Deputy Director, Research and Methodology
Health Services Cost Review Commission
4160 Patterson Avenue
Baltimore, MD 21215
(410) 764-2605

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~~CMS-1317-P-3~~

Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services

Submitter : Dr. Richard Aud **Date & Time:** 06/09/2006

Organization : University of Louisville

Category : Physician

Issue Areas/Comments
CBSAs-Revised OMB
Metropolitan Area Definitions

CBSAs-Revised OMB Metropolitan Area Definitions

I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS or the Agency) proposed rule entitled Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. 71 Fed. Reg. 23996 (April 25, 2006). I strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in patient care activities. The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. BackgroundThe proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician s office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not related to patient care . This position reverses the Agency s position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty. [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I support the Agency s 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs. Residency Program Activities and Patient CareI firmly believe that with the possible exception of extended time for bench research, there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician s educational development into an autonomous practitioner. In addition, I cannot conceive of how I would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS s newly defined patient care time from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Where am I to find the funding to pay for the staff person that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden. To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

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Sun Health

Taking your health personally

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FiscalYear 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of the community board of directors of Sun Health Corporation, Sun Health Boswell Hospital and Sun Health Del E. Webb Hospital, the following comments are offered regarding the proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates for Medicare Providers.

The Sun Health Boswell and Del E. Webb Hospitals serve the northwest portion of the Phoenix, Arizona metropolitan region in predominately retirement communities. The combined hospital Medicare beneficiary discharges represent approximately 70% of all discharges.

Accordingly, we would voice strong support for the American Hospital Association position on the payment restructuring and request a one-year delay in the implementation to October 2007. From a service, quality and financial perspective for the thousands of Medicare beneficiaries we serve, a one-year delay will allow Sun Health to appropriately plan for the proposed changes in the payment system and to make adjustments in its 2007 and 2008 budgets to reflect the financial and operating impact. Enacting the changes as early as October 2006 will adversely impact the 2006 operating and capital budgets for Sun Health as preliminary analysis indicates the proposed changes will result in a significantly adverse financial impact to Sun Health's operating statements. During a period when Sun Health is planning access to the capital markets to meet community hospital needs, it will be critical to be able to plan for the payment restructuring in a reasonable, time-effective manner.

The Centers for Medicare & Medicaid Services is respectfully requested to establish an effective date for the adoption of the payment restructuring of October 1, 2007.

13180 N. 103rd Dr. Sun City, AZ 85351 • P.O. Box 1278 Sun City, AZ 85372 • 623/876-5301

On behalf of the Sun Health community boards of directors and the community we serve, we appreciate the opportunity to submit our comments for consideration.

Sincerely,

Leland W. Peterson, FACHE
President/CEO

LWP/dk

cc: Senator Jon Kyl
Senator John McCain

Representative Trent Frank
Representative J. D. Hayworth

John Rivers, CEO
Arizona Hospital and Healthcare Association

L. Birt Kellam, Chairman
Sun Health Board of Directors

Sandra Foell, Chairman
Sun Health Boswell Hospital Board of Directors

Andrea Somerville, Chairman
Sun Health Del E. Webb Hospital Board of Directors

INSTITUTE FOR LOW BACK
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June 5, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: X Stop – St. Francis Medical
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I see about 10 to 15 patients each month with spinal stenosis, most of whom are elderly. Many of these patients try a course of epidural injections, physical therapy, and pain medications that are quite costly to the Medicare program. In my judgment, perhaps 70 percent of patients with spinal stenosis might benefit from X Stop. In post-operative MRI imaging, I clearly see minimal changes in the sagittal alignment. The implant allows an increase in the canal area and the foramen without affecting any of the adjacent levels.

Many of my patients with spinal stenosis suffer from conditions like heart disease and COPD, which disqualifies them for invasive spinal decompression surgeries. The X Stop procedure can be completed in under one hour, involves a short (1-2 day) hospital stay, and about half the patients can undergo local anesthesia with minimal monitoring. For patients who have exhausted conservative treatments like epidural injections, physical therapy and pain drugs, I typically would recommend laminectomy. Having X Stop allows me to offer an intermediate intervention, one that is minimally invasive, safer, and also effective.

I believe that X Stop is a useful procedure for patients who want to try a safe and less invasive intervention. The device does not eliminate future surgical options as it preserves the original spinal processes and does not interfere with the spinal canal.

Sincerely,

Richard M. Salib, M.D.
Administrative Director

RMS/SDM

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MHSI *Michigan Head & Spine Institute, PC*

29275 Northwestern Highway, Suite 100, Southfield, Michigan, 48034

Fernando G. Diaz, MD, PhD
Cerebrovascular Surgery
Spine Reconstructive Surgery

Richard D. Fessler, MD
Endovascular Neurosurgery

Mark L. Goldberger. DO, MS
General Neurosurgery & Minimally Invasive Spine Surgery

Sophia Grias-Radwanski, MD
Physical Medicine & Rehabilitation

Robert R. Johnson II, MD
Epilepsy & Adult Neurosurgery

Paul K. King, MD
Reconstructive Spine Surgery

Eun Kucway, MD
Physical Medicine & Rehabilitation

Cheryl Lerchin, MD
Physical Medicine & Rehabilitation

Miguel Lis-Planells, MD
Adult Neurosurgery & Pain Management

Lisa Metler, PhD
Neuropsychology

Daniel B. Michael, MD, PhD
Adult & Trauma Neurosurgery

Todd Y. Nida, MD
Complex Spinal Surgery

Mick J. Perez-Cruet, MD
Minimally Invasive Spine Surgery

Daniel R. Pieper, MD
Cerebrovascular Surgery and Skull Base

Harold D. Portnoy, MD
Adult & Pediatric Neurosurgery and Cerebrovascular Surgery

Henry C. Tong, MD, MS
Physical Medicine & Rehabilitation

Abutaher Yahia, MD
Endovascular Neurosurgery, Neurocritical Care and Stroke

May 31, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: X STOP Interspinous Decompression System
P.O. Box 8011
Baltimore, Maryland 21244-1850

To Whom It May Concern:

I feel that the X STOP IPD is an excellent option for patients with spinal stenosis. It provides good outcomes and is a relatively straightforward surgical procedure that provides substantial relief in patients who are quite debilitated.

In my neurosurgery practice at the Michigan Head and Spine Institute, I see about 40 patients each month with LSS, the majority of whom are elderly. I would typically recommend conservative treatment (steroid injections, physical therapy, and anti-inflammatory or pain medications) for about 25 percent of these patients. Perhaps 50 percent receive laminectomy (including with fusion). I estimate that perhaps one-quarter of my LSS cases could benefit from X STOP IPD.

Typically, I do x-ray images after X STOP implant, and I have seen no significant changes in intervertebral angles, lateral bending, or axial rotation. From a functional standpoint, my patients report increased mobility, better performance of activities of daily living, and longer walking distances. Patients tell me they can return to normal life activities, and their mental outlook has improved.

So far, my experience with X-stop has been good to excellent. I believe it offers and inexpensive, well-tolerated alternative to lumbar fusion in the elderly population.

Sincerely,

Mark Goldberger, DO, MS
Michigan Head and Spinal Institute

SAINT JOSEPH'S
Hospital

June 9, 2006

Mark B. McClellan, MD, PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-1850
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment System and 2007 Rates

Dear Dr. McClellan:

Saint Joseph's Hospital of Atlanta (Saint Joseph's) appreciates the opportunity to submit comments on the proposed 2007 Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Prospective Payment System (IPPS) and 2007 DRG rates released on April 12, 2006. The proposed changes have been identified by hospital administrative and reimbursement professionals as the most significant changes to the hospital inpatient payment system in the last 20 years and will have an impact on the operation and financial health of every hospital in the country in some way.

While Saint Joseph's supports the intent of CMS and Medicare/DRG reform, due to significant policy, technical, and data concerns related to the proposed IPPS methodology and 2007 DRG rates, Saint Joseph's respectively asks that CMS postpone the implementation of any changes to the IPPS system for at least one year until further research and analysis is conducted.

This request is consistent with the concerns expressed by our parent organization Catholic Health East, the American Hospital Association, and numerous other providers who have raised similar methodological, analytical, and public policy questions with the proposed IPPS changes and 2007 rates.

Saint Joseph's Hospital of Atlanta

Saint Joseph's is a 410-bed acute care community hospital located in Atlanta, Georgia, that provides a full array of adult acute care services with the exception of obstetrical and maternity care. As a result, Saint Joseph's has historically experienced a higher percentage of Medicare patients than the typical community hospital and is therefore

keenly aware of the impact that even the slightest changes in Medicare policy and payment rates can have on a hospital's financial health. Saint Joseph's is perhaps best known for its nationally regarded heart and vascular services, and was a participant in HCFA's cost-saving cardiac demonstration programs in the 1990's. The Hospital prides itself on the quality of care it provides to patients and currently holds the distinction of being one of only three hospitals in the country to have been named to all three of Solucient's 2005 Top 100 Hospital lists for National Benchmarks, Performance Improvement, and Cardiovascular Care. Based on this experience, we believe Saint Joseph's is uniquely qualified to comment on the proposed Rule.

MedPAC Recommendations on Specialty Hospitals

Although not directly stated, clearly the proposed IPPS changes and reimbursement methodologies are a response to the Medicare Payment Advisory Commission's (MedPAC) 2005 Report to Congress on Physician-Owned Specialty Hospitals. In that report, MedPAC concluded that the physician-owned specialty hospitals were intentionally treating less severe patients and selectively concentrating on particular DRGs (especially cardiac and orthopaedic) which are more profitable than what is experienced at community hospitals that treat the full range of DRGs as they fulfill their community mission. The report states:

> *"Many of the differences in profitability across and within DRGs that create financial incentives for patient selection can be reduced by improving Medicare's inpatient prospective payment system for acute care hospitals".*

As CMS addresses the issues and recommendations presented in the MedPAC report on physician–owned specialty hospitals by attempting to "improve" the IPPS, it is important to keep in mind that the vast majority of Medicare patients treated are in community hospitals that are not owned by physicians, and that any changes to the IPPS system with the intention of correcting patient selection and DRG profitability will impact all hospital providers. This is especially true of the cardiac DRGs sighted in the MedPAC report that were associated with unfair competitive advantages and patient selection by physician–owned specialty heart hospitals.

To Saint Joseph's it seems that the goal of CMS with the proposed IPPS changes was to be consistent with the following MedPAC recommendations as follows:

- Improve payment accuracy in the hospital prospective payment system by capturing differences in severity of illness, base weights on cost of care rather than charges, and base weights on the national average of hospitals relative values in each DRG.

- Adjust DRG relative weights to account for differences in the prevalence of high-cost outlier cases.

- Implement case-mix measurement and outlier policies over a transitional period.

However, as has been repeatedly identified by numerous analysts, there are significant flaws and concerns with the proposed CMS methodologies, background data, and implementation timeline.

The Proposed IPPS IS Not Based On Accurate Costs

CMS proposed shift to a cost-based versus a charge-based methodology is an acceptable approach and consistent with how private insurers treat costs associated with advancing technologies. However, a significant concern with CMS's proposed methodology is the accuracy and timing of cost data used in the calculations. Private insurers are utilizing data in real-time and are paying actual invoice costs for technology used in the care of patients. Conversely, in the CMS proposed rule, the cost for a particular category of DRGs is not the actual price the hospital pays for the items and services required to treat patients, rather it is a rough approximation of costs.

Specific concerns with the proposed Rule include:

- There is currently a highly-prevalent problem of devices and other implantables being stepped down to routine cost centers rather than the ancillary cost center which is where their matching charges are reported. This understates cost in the supply category and under-weights the corresponding DRGs.

- There is a significant data validity problem as CMS used 2003 cost reports to derive the FY 2007 weights. 2003 was the year in which drug-eluting stents and other cardiac devises including bi-ventricular pacemakers/defibrillators were first introduced and their costs are not adequately reflected in the 2003 cost reports.

- Rather than using earlier year cost reports, CMS should use the most recent (2004) cost reports, but only after the hospitals have revised them to properly match costs and charges.

- There are reported discrepancies between hospitals posting charges in MedPAR with where they report charges in the cost reports. Therefore, RCCs developed from the cost reports applied to MedPAR charges will result in distorted DRG weights.

- Overall, before implementing a cost-based methodology CMS should require all hospitals to revise their cost reports so that costs and charges are reported in the same way they're reported on the claims, which feed into MedPAR.

The HSRVcc Weighting Methodology is Not What MedPAC Recommended

The purpose of changing the DRG weighting and grouping methodologies is to improve the consistency of the cost margins among the DRGs. MedPAC recommended several changes (including cost-based weights, the HSRV methodology, refined DRGs, and DRG-specific outlier financing) to improve payment accuracy. However, the DRGs and weights that CMS is proposing are not what MedPAC recommended.

- CMS, in what is identified as the HSRVcc methodology, would group MedPAR charges into 10 cost centers, compute charge-based weights for each cost center, and blend the weights into a single national weight for each DRG. Weighting using national cost center data rather than hospital specific claim data will remove the differences of cost-to-charge ratios across departments. The use of a national average will not take into account variations based on location, size, teaching, and other factors.

- Various data and methodology concerns have been identified including the exclusion of organ acquisition costs, inconsistent inclusion or exclusion of hospitals in various stepwise calculations, and the consistency of data use between the cost report data and MedPAR data.

- In 1992, the RAND Corporation compared weighting methodologies and observed that HSRVs compress the DRG weights but that this problem could be offset with outlier payments. If so, then the HSRV methodology worked about as well as the current methodology - but not better. Given the difficulties in accurately estimating outlier thresholds, further analysis needs to be done before implementing the HSRVs.

- HSRVs date back to the early 1980's prior to low-cost, high-speed data collection and processing. Current data processing technology supports regression analysis and other modeling of cost per case that should be considered as an alternative.

In addition, the Medicare DRGs and their weights are used extensively outside of the IPPS and implications of the proposed changes will most likely result in negative consequences throughout the health care system. This includes private insurers and the fact that any change in plan rates to reflect the new DRGs and weights may negatively impact hospitals locked-in with multi-year contracts.

Concerns With The Proposed CS-DRG Severity of Illness Methodology

The proposed rule attempts to change the method of identifying the variation in patients' severity of illness that would be implemented in 2008. Again, while this approach has validity, there are significant concerns with the proposed CS-DRG methodology.

- The CS-DRGs are problematic because they were not designed to accommodate non-Medicare populations. In addition, many hospitals use DRGs for quality and other outcomes measurement and the proposed CS-DRGs may not be clinically appropriate for these purposes.

- CS-DRG severity levels are largely based on clinical and demographic patient characteristics, which may not correlate well with resource consumption, requiring CMS compute cost margins for the CS-DRGs and verify that the CS-DRGs are valid and appropriate.

Proposed 2007 Cardiac DRG rates

Saint Joseph's is one of the leading providers of cardiac and vascular services in the Southeast. Based on our clinical, administrative and financial understanding of cardiac care there are significant concerns about the implications of the proposed 2007 cardiac DRG rates.

The impact of the proposed 2007 cardiac DRG rate reductions will reduce reimbursement to every hospital providing cardiac services by approximately 10%. The provision of cardiac services are, to a greater of lesser extent, a key financial component to the successful operation of every hospital in the country, and the DRG rate changes proposed will place these hospital at a severe financial risk going forward.

- These proposed reductions to cardiac services are not based on any type of realistic mechanism for assessing the true costs to provide treatment.

- Recent advances in life-saving patient care and technologies, encouraged by CMS and other national policy makers, will be severely impacted with proposed DRGs payments for stents reduced 24 to 34%, ICD implants reduced 22 to 24% and pacemakers reduced 12 to 14%.

- Implementation of the proposed rates will lead to limitations on patient access to leading edge technology because hospitals will not be able to adequately recover their acquisition costs.

- While the intent of CMS was to address the concerns of favorable patient selection and financial abuse in physician–owned specialty hospitals, the proposed DRG rate changes cannot be implemented in its current form without a total disruption to all hospitals providing cardiac service across the country.

Clearly, the negative consequences to patients and community hospitals with the implementation of the proposed 2007 DRG rates is not what CMS intended when attempting to correct abuses in physician-owned specialty hospitals. Delaying implementation of any changes to cardiac services reimbursement until more accurate realistic cost information can be analyzed is the only correct public policy alternative.

The Proposed IPPS Implementation Schedule is Totally Inadequate

The proposed IPPS Rule and rate changes, as discussed above, are individually significant and in previous years would individually be considered a major modification to the payment system with a specified implementation and phase-in timeline. Proposing all of these changes in a single regulation, with implementation in 2007, is not only unprecedented but would cause a major disruption of patient care in every hospital across the country. A more appropriate timeline for the implementation of the proposed changes is from three to five years on a phased schedule.

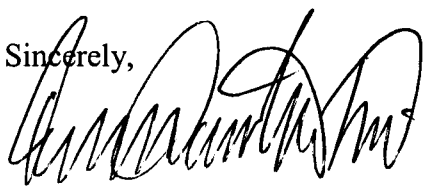
Summary

Saint Joseph's sincerely appreciates the opportunity to provide commentary on the 2007 CMS IPPS proposal. We recognize the extremely complex issues involved in establishing appropriate reimbursement for procedures performed in the inpatient setting and supports CMS's efforts to ensure that Medicare beneficiaries have continued access to high quality, efficient, and effective services.

However, as stated above, given then numerous concerns with the proposed IPPS and 2007 rate changes, Saint Joseph's asks that you postpone implementation of the Rule until further study and a through impact analysis of each of the changes is conducted.

If you have any questions please don't hesitate to contact us.

Sincerely,



Eugene D. Davidson, MD
CEO and President

292

University of Wisconsin
Department of Orthopedics & Rehabilitation

Clifford B. Tribus, M.D.

K4/751, 600 Highland Avenue
Madison, WI 53792-7375
Phone: 608-263-9456 Fax: 608-265-6375

June 13, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Re: X Stop interspinous process decompression
PO Box 8011
Baltimore, MD 21244-1850

Dear Sir/Madame,

Interspinous process decompression has a substantial benefit for older patients with neurogenic intermittent claudication secondary to lumbar spinal stenosis. Spinal stenosis comes in many forms and can be broken into two basic categories; those patients with spinal stenosis with a straight spine and those patients with spinal stenosis with a curved spine. In my orthopedic surgery practice I estimate that about half of the spinal stenosis patients that I see monthly are Medicare patients. More than half of these patients have spinal stenosis in the setting of a curved spine. Typically I start my treatment of these patients with physical therapy, epidural steroids and medical therapy prior to suggesting any surgical interventions. The Interspinous device made by St. Frances Medical Technologies can shift the load on the spine, reducing degeneration over time. In its placement between two spinous prostheses the distraction affects an increase in spinal canal diameter thus alleviating the symptoms of spinal stenosis.

There are two patient groups that fail conservative therapy; one group would be a reasonable candidate for traditional decompressive surgery or decompression and fusion surgery. The other group is two sick or frail to undergo traditional surgical intervention. Both of these groups can potentially benefit from the use of the St. Francis Medical Technologies device. In the latter group, which is not a candidate for traditional surgery the lesser surgical insult sustained by the patient in placement of the X-Stop device allows these critically ill patients a very viable surgical option and a reasonable pathway to alleviate them from their spinal stenosis symptoms. In the other group which might be a candidate for traditional approaches, the X-Stop device provides a surgical approach of a substantially less destructive nature. This is enormously true if the traditional approach would be a decompression and fusion.

University of Wisconsin
Department of Orthopedics & Rehabilitation

My x-rays post operatively suggest there is minimal change in the lumbar lordosis at the inserted level and overall lumbar lordosis is well maintained. On average my patients are quite pleased with the outcome and I've currently performed this operation on more than 20 people and they have consistently reported significantly less pain and better ability to walk and higher levels of activity. I do have one patient that reports that the symptoms have continued relatively unabated and while this is somewhat concerning to me I realize that even in more traditional approaches such as decompression fusion which would have been this patients surgical alternative, she would very likely have had ongoing complaints as she had several concordant diagnosis that complicated her pain picture.

In my view the St. Francis X-Stop is an enormous benefit to patients. It lessens the surgical insult substantially and is particularly important as a surgical alternative to decompression and spinal fusion surgery.

Sincerely,

Clifford B. Tribus, M.D.
Associate Professor

CBT/tld

University Orthopedics
K4/7 Clinical Science Center MC7375
600 Highland Avenue
Madison, WI 53792-7375

Rehabilitation Medicine
6630 University Avenue MC9430
Middleton, WI 53562-9430

South Park Orthopedics
1 South Park Street
Madison, WI 53715

293-D
(4)

LAIRD MEMORIAL HOSPITAL

1612 South Henderson Boulevard
Kilgore, Texas 75662
(903) 984-3505

2006 JUN 21 PM 3:39

June 12, 2006

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of Laird Memorial Hospital, Kilgore, Texas, representing our 220 employees and physicians, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) and occupational mix adjustment proposed rules. The rule proposes the most significant changes in the calculation of diagnosis-related group (DRG) relative weights since 1983 by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc).

It also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008. In addition, the rule would update the payment rates, outlier threshold, hospital wage index, quality reporting requirements, and payments for rural hospitals and medical education, among other policies.

While we support many of the proposed rule's provisions, we have serious concerns about the proposed changes to the DRG weights and classifications. More time is needed to understand the significant proposed policy changes, which redistribute from $1.4 to $1.7 billion within the inpatient system. Analysis shows the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payment. And the validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is uncertain.

Laird Memorial Hospital supports the following:

• **One-year Delay:** LMH supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. 0000
• **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.
• **A New Classification System Only if the Need Can Be Demonstrated:** LMH does not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.
• **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.
• **Three-year Transition:** Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.
• **Collaborative Approach to Moving Forward**: LMH commits to working with CMS to develop and evaluate alternatives for new weights and classifications.

Further, we support the comments submitted by the American Hospital Association that further explain our concerns and recommendations on the proposed DRG weight and classification system changes, as well as our position on many other issues in the proposed rule.

Laird Memorial Hospital appreciates the opportunity to submit these comments. If you have any questions about our remarks, please feel free to me at 903-983-4352 or bellzey@lairdmemorialhospital.com.

Sincerely,

Bob S. Ellzey, FACHE
President/CEO

294

[redacted]

medical solutions

2006 JUN 19 PM 5:59

June 10, 2006

Mark B. McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1488-P (Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates)

Dear Administrator McClellan:

Amphion Medical Solutions is grateful for the opportunity to submit comments on the proposed rule regarding Medicare's inpatient hospital payment system. Amphion is a coding consulting company that provides ongoing prebilling coding review and outsourced coding services to more than 75 hospitals, clinics, physicians, and ambulatory surgery centers.

While we are not paid by Medicare under the inpatient hospital prospective payment system (IPPS), we assist customers that are paid under this system. In this capacity, we have identified a number of concerns with the proposed rule, particularly related to the proposed changes to the Diagnosis Related Group (DRG) classification system. Foremost among these concerns is the need for transparency with regard to any changes to the DRG classification system because the lack of such transparency has the potential to cripple our ability to continue to assist our customers. We also think that CMS should not rush into this change in the upcoming fiscal year and that it should consider the complexity of any revision and the impacts on hospital coding and billing. These concerns are discussed below.

A. Transparency

Currently, we are able to access the complete DRG classification methodology, which CMS makes available equally to all members of the public. Complete and timely access to this methodology is crucial to our business because we are often the source for providing education regarding the complexities of the DRG grouper to HIM and coding staff. It is important that as CMS changes the DRG system, vendors such as us retain access to the underlying methodology at a level equivalent to what we experience today. There seems to be no guarantee that this would remain the case under the proposed move to All Patient Refined Diagnosis Related Group (APR-DRG) classification system.

As you know, the APR-DRG system is a proprietary system and nothing in the proposed rule provides us with any comfort that if the agency were to move to the APR-DRG system the same level of detail that is currently available would continue to be available.

Indeed, the proposed rule offers a website for more detail on APR-DRGs, but that site contains a very limited amount of disclosure about the methodology, a level that is insufficient for our business purposes. Our concern is that the vendor whose proprietary system CMS ultimately might use would have a significant advantage over other vendors in our line of business unless CMS were to insure that all interested parties were able to get access to source code, comprehensive system and user documentation, test data and quality support from the owner of the methodology at costs similar to what the industry now pays relative to the DRG system and well enough in advance of implementation (10-12 months) to be able to support our clients effectively.

We are also perplexed regarding the CMS selection of the APR DRG grouper in lieu of either utilizing the refined DRG grouper already developed by CMS through a federal contract (thus providing open access to its methodology), or evaluating other refined DRG groupers currently on the market that are considerably more compatible with the current Medicare DRG grouper than APR DRGs and whose developers would be willing to provide open access to their methodology should their product be selected by CMS.

Given the above issues, we strongly urge CMS, irrespective of the revision of the DRG system adopted by the agency, to ensure that as much detail about the new system is made available as CMS currently makes available under the existing DRG system. We also ask that details regarding the new system become available as soon as possible so that the impact of this system on hospital data processing, billing and management systems can be fully evaluated. We also ask that Medicare continue to make the DRG update process totally transparent. We need the same level of dialogue with CMS regarding DRG changes as has existed since the advent of the inpatient PPS.

B. Need for Time to Adapt to DRG Change

According to the proposed rule, CMS might move to the APR-DRGs as soon as October 1, 2006. Based on our experience in working with hospitals, we believe this would be an unrealistic time frame for such a dramatic change to the inpatient hospital payment system. Hospitals would not have time to effectively plan for and implement this system. Moreover, consultants such as Amphion need to develop educational materials to assist our clients in making this transition to a considerably more complex grouping scheme than the current Medicare DRGs. Adequate time needs to be provided for education to ensure that DRG groupings continue to achieve the current level of accuracy. Errors in DRG groupings offer the potential to disrupt Medicare's budget-neutral commitment for inpatient prospective payment. They can also be quite costly to

hospitals who are already undergoing major changes in the methodology for setting DRG relative weights.

Quite simply, it is highly unlikely that all necessary actions could be accomplished by October 1 of this year and we therefore recommend that CMS not change the classification system in fiscal year 2007.

C. Considering Other Methodologies

While the proposed rule discusses only APR-DRGs, there are other classification systems that could be used but do not seem to have been considered by CMS as was mentioned earlier in these comments. For example, Amphion highly encourages CMS to evaluate and compare alternative systems, especially the All-Payer Severity-Adjusted DRGs, as well as Refined DRGs and S-DRGs. These systems are built on top of the current CMS DRG system and achieve similar or better statistical performance while introducing less disruption to the coding and billing processes. We ask that CMS address other alternatives to the APR-DRGs and allow the public the opportunity to comment on a DRG classification system change before any such change is adopted.

D. Minimizing Complexity and Burden

Obviously, a change to the DRG system will be a complex endeavor that will be burdensome for hospitals. However, there seem to be strategies for making this change less complex and less burdensome to hospitals. For example, we suggest that CMS look toward a system that uses a similar coding framework as is currently being used. Otherwise, greater complexity will decrease coder productivity and lengthen revenue cycles. Coders are already facing the implementation of ICD-10 CM and ICD-10-PCS, both coding classifications which will require complete retraining of all coders in the United States. Implementing a complex DRG grouping system such as APR DRGs will be yet another complex system the coders must learn. Current coder shortage in the United States, and hospitals' need to rely on third party billers to maintain their A/R goals will only be exacerbated by the acknowledged impact on coder productivity when this new grouping system is implemented. Therefore, it would be prudent to select the severity adjustment system that best explains variances among clinically coherent patient groups and is the most compatible to the current DRG system.

As an industry we are already facing changes required by UB-04, ICD-10 and the quality provisions of the Deficit Reduction Act. There is only so much change that any industry can withstand. If we could streamline and coordinate these changes there would be a positive overall impact on healthcare management and the associated expense of this process.

We also foresee the overlay of the proposed DRG system change and the possible movement to the International Classification of Diseases, 10th Revision (ICD-10). The latter would present a second major shift affecting the DRG system and

hospitals and we suggest that CMS carefully consider the timing of these two major changes, as it may make more sense to implement these changes concurrently rather than one coming on the heels of the other. CMS should announce its intentions regarding these changes and allow the public to comment on this topic

Again, Amphion Medical Solutions appreciates the opportunity to comment on the proposed rule. We hope that the agency will carefully consider these comments as it moves forward regarding the DRG system. Thank you for your consideration.

Sincerely,

Pam Wirth, RHIA

Pam Wirth, RHIA
President, Coding Division
Amphion Medical Solutions

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May 25, 2006

Centers for Medicare and Medicaid Service
Department of Health and Human Services
Attn: CMS-1488-P
P.O. Box 80011
Baltimore, MD 21244-1850

Dear Sirs:

I am aware of plans to change the method of payment for medical devices, advanced medical technology and medical services. Since 1984, Medicare patients to hospitals for acute care services have been paid under a national Prospective Payment System (PPS). Rather than setting a payment for each individual service, Medicare currently groups patients into Diagnosis Related Groups (DRGs) based on the complexity of the patient including the number and type of diagnostic, therapeutic, and services required. Each DRG is assigned a national weight. The higher the weight, the higher the payment.

Today, Medicare uses the charges on the latest available medical hospital claims to establish the payment weights. One criticism of current charge based weights is that hospitals have full discretion in setting their charges and therefore, charge based weights may not reflex the true variation in resources or cost across the grouping in hospitals. Your proposal would make the most significant change to the payment system for acute care hospitals since the system was established more than 20 years ago.

First, you are purposing to move to an estimated "cost base" system rather than a charge base system for determining the payment weights for each patient category in 2007.

Second, you are purposing to change the method for identifying the variation in patient severity of illness that would be implemented in 2008.

Each change is significant and in previous years would be considered a major modification to the payment system. Purposing both of these changes in a single regulation, with implementation in 2007, is unprecedented.

Wisconsin Heart and Vascular Clinics, S.C.

Comprehensive Cardiac & Peripheral Vascular Medicine

Center of Excellence
At The Wisconsin Heart Hospital
601 N. 99th Street
Suite 201
Wauwatosa, Wisconsin 53226
414 266 9700
FAX 414 266 9701

www.whve.org

Jack C. Manley, M.D., F.A.C.C., F.S.C.A.I.
L. Samuel Wann, M.D., M.A.C.C.
Timothy Vellinga, M.D., F.A.C.C., F.S.C.A.I.
David K. Ashpole, M.D., F.A.C.C., F.S.C.A.I.
Krishna Kumar, M.D., F.A.C.C.
Lisa L. Armaganian, M.D., F.A.C.C.
Srinivas R. Pamidi, M.D., F.A.C.C.
Brian D. Nelson, M.D., F.A.C.C.

Retired
Gerald T. McInerney, M.D., F.A.C.C.
James F. King, M.D., F.A.C.C., F.S.C.A.I.
Henry H. Gale, M.D., F.R.C.P. (C)

Brookfield
2205 North Calhoun Rd.
Brookfield, WI 53005
262 785 1500
FAX 262 785 3828

Franklin
7400 West Rawson Ave.
Suite 243
Franklin, WI 53132
414 425 8150
FAX 414 425 8553

Milwaukee – St. Luke's
2801 W. Kinnickinnic River Pkwy.
Suite 425
Milwaukee, WI 53215
414 266 9700
FAX 414 266 9701

West Allis
2424 S. 90th St.
Suite 408
West Allis, WI 53227
414 266 9700
FAX 414 266 9701

Wauwatosa
601 N. 99th St.
Suites 200 & 201
Wauwatosa, WI 53226
414 266 9700
FAX 414 266 9701

Further, you purpose to base payments on "costs". However, the cost of a particular category of patient is not an approximation of the actual price the hospital pays for the item and services required to treat the patients, but rather a "rough approximation of cost". Since hospitals have varying mark-ups, the cost estimation generally underestimates the value of high priced items and overestimates the value of low cost items.

This current proposal to modify the DRGs is flawed and should be rejected until the data and methodology are corrected. I believe that the most appropriate course of action would be for you to return to the current charge-based methodology for the coming fiscal year and work to improve hospital cost reporting processes before any transition to cost-based weights.

Thank you for allowing me to express my opinion.

Sincerely,

Jack Manley

Jack C. Manley, MD, FACC

JCM/gmb

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ST. MARY'S SPINE CENTER
ONE SHRADER STREET
SAN FRANCISCO, CA 94117
(415) 750-5846

Jerel Glassman, MPH, DO
Physical Medicine and Rehabilitation
Osteopathic Manipulative Medicine
Electrodiagnosis

June 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
P.O. Box 48011
Baltimore, MD 21244-1850

RE: X-Stop interspinous process decompression

To Whom It May Concern:

I wish to report my personal experience with the X-Stop surgical device. This instrument was developed here at St. Mary's Spine Center, which is a multidisciplinary clinic where surgeons and non-surgeons work on restoration of function in challenging spinal disorders. I am a physiatrist and have had the opportunity to work from a rehabilitation standpoint with patients undergoing the X-Stop procedure, both prior to surgery and following surgery.

In my clinical experience, the immediate potential for improvement and mobility is dramatic. Patients who would otherwise have to undergo extensive surgery involving general anesthesia are able to improve their functional capacity within days and have no adverse effects. In the older population, the opportunity to avoid general anesthesia and major surgical intrusion to achieve a functional outcome is very exciting.

At our center, we have treated over 150 spinal stenosis patients with the X-Stop spinous process device. In addition, I have reviewed other cases over the years, and the high potential for functional improvement with the low morbidity is particularly appealing. The cost ultimately from reduced morbidity and from the simplicity of the procedure will also be significant savings to Medicare.

I urge very careful and immediate evaluation to increase Medicare's role in approving the hospital payment add-on for the X-Stop. The potential to reduce morbidity and improve function and save Medicare significant costs is too great not to give it a high priority in your evaluation process.

Sincerely,

Jerel Glassman, D.O.
JG/tcg

297

JOHN E. SWEENEY
20TH DISTRICT, NEW YORK

COMMITTEE ON APPROPRIATIONS

RURAL HEALTH CARE COALITION

CONGRESSIONAL HORSE CAUCUS
CO-CHAIR

NORTHERN BORDER CAUCUS
CO-CHAIR

HUDSON RIVER CAUCUS
CO-CHAIR

NANOTECHNOLOGY CAUCUS

AD HOC COMMITTEE ON IRISH AFFAIRS

Congress of the United States
House of Representatives
Washington, DC 20515–3220

June 14, 2006

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

Subject: CMS-1488-P
Table 9B: Hospital Reclassifications and Redesignations by Individual Hospital Under Section 508 of Pub. L. 108-173 – FY 2007

To Whom it May Concern:

I am writing to request that the Secretary use his discretion to revise the proposed FY 2007 Medicare wage index classification of Northern Dutchess Hospital, which is located in my congressional district, and to redesignate that hospital as part of the New York City Medicare wage index for all of FY 2007 instead of for FY 2007 only through March 31, 2007. This would be done by changing the designation for Northern Dutchess Hospital in the final version of the FY 2007 inpatient prospective payment system rule.

The circumstances surrounding Northern Dutchess Hospital's projected mid-year change in wage index classification are extremely unusual and are therefore, I believe, deserving of an unusual response – in this case, the exercise of the Secretary's discretion.

Northern Dutchess Hospital was reclassified, under section 508 of the Medicare Modernization Act of 2003, into the New York-Wayne-White Plains NY-NJ labor market area for three years: from April 1, 2004 through March 31, 2007. This left the hospital in the unusual position of needing to seek renewal of this reclassification, or reclassification elsewhere, in the middle of a federal fiscal year.

I share with hospital officials their belief that the hospital qualifies for such reclassification on several grounds. First, it met the section 508 criteria, as noted above. In addition, a *Federal Register* notice of August 11, 2004 established a special exception to the wage index classification policy, stating that any hospitals that meet all three criteria specified in the notice "will be assigned the wage index of the area identified in their FY 2004 or FY 2005 urban country group application" – in this case, the New York City wage index area. Those criteria, as stated in the *Federal Register*, are:

- The hospital was part of an urban county group reclassification application for FY 2004 or FY 2005 that failed solely on the basis of the standardized amount criterion.

416 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
202-225-5614

939 ROUTE 146
SUITE 430
CLIFTON PARK, NY 12065
518-371-8839

SENATOR CHARLES D. COOK OFFICE BUILDING
111 MAIN STREET
DELHI, NY 13753
607-746-9700

21 BAY STREET
GLENS FALLS, NY 12801
518-792-3031

7578 NORTH BROADWAY
RED HOOK, NY 12571
845-758-1222

- At least one-third of the hospitals that had been parties to the urban county group reclassification application have subsequently been reclassified for FY 2005 either through the regular MGCRB reclassification process or the special one-time wage index appeal process under section 508 of MMA.
- The hospitals can demonstrate that the hospitals that have since reclassified to another area have a wage index at least 10 percent higher than the wage index of the NMSA where the hospital is located.

Northern Dutchess Hospital is located in Dutchess County, New York, and it and the two other hospitals located in that county – the Vassar Brothers Medical Center and St. Francis Hospital – met all three of these criteria. On the basis of meeting these criteria, the latter two hospitals were recognized as meeting the special exceptions criteria and, through an exercise of the Secretary's discretion, reclassified into the New York City wage index area for the period of October 1, 2004 until September 31, 2007.

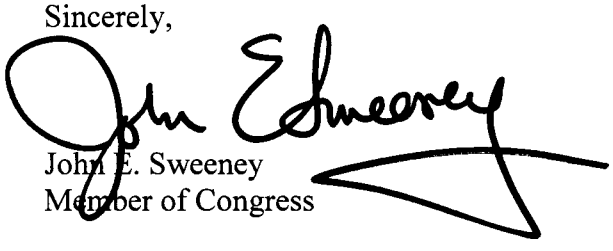
Although it was clear that Northern Dutchess Hospital qualified for reclassification on both grounds – on its own and under the August 11, 2004 special exceptions criteria – what remained unclear was what process might be employed to pursue reclassification when the hospital's mid-FY 2007 reclassification expired. After numerous attempts by hospital officials to ascertain from CMS what that process might be were rebuffed by CMS, I intervened on my constituents' behalf, communicating with Herb Kuhn, Director of the Center for Medicare Management. Mr. Kuhn's reply was that there is no such process and that the hospital had no recourse for reclassification for the second half of FY 2007. A subsequent inquiry that I made received no reply.

While I acknowledge that provisions of the regulations for FY 2005 include no specific process for this reclassification, I believe this a regulatory shortcoming that most likely reflects only the highly unusual nature of this situation. The same regulation clearly indicates that Northern Dutchess Hospital should be entitled to reclassification into the New York City wage index area – like Vassar Brothers Medical Center and St. Francis Hospital – because it meets all three of the special exceptions criteria for reclassification delineated in the regulation. I recognize that this mid-year reclassification would be good for only six months and that Northern Dutchess will need to apply for reclassification for FY 2008 by September 1, 2006.

Because Northern Dutchess Hospital clearly qualifies for reclassification and because reclassifying the hospital would be the right thing to do, I request that Table 9B in the final version of the FY 2007 inpatient prospective payment system rule be revised to change the Medicare wage index classification for Northern Dutchess Hospital to the New York-Wayne-White Plains NY-NJ for all of FY 2007.

I appreciate your timely response to this request. If you have any questions or need further information, please feel free to contact Victoria Sanville of my staff at (202) 225-5614.

Sincerely,



John E. Sweeney
Member of Congress

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~~CMS-1540-P2-1~~ **Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2007**

Submitter : **Mr. Derek Berz** **Date & Time:** **06/09/2006**

Organization : **Providence Holy Cross Medical Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

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Dear Administrator McClellan:

I wanted to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rules for IPPS Changes which are the biggest changes to the calculation of diagnosis-related group (DRG) relative weights since the creation of the prospective payment system (PPS). These changes would significantly redistribute payments among the DRGs and among hospitals. Specifically, CMS proposes the use of hospital-specific relative values (HSRVs) and a modified version of cost-based weights rather than charge-based weights in fiscal year (FY) 2007. CMS also proposes an alternative patient classification system called consolidated severity adjusted DRGs (CS-DRGs), with implementation likely in FY 2008.

While I believe it is approrirate to Weight the DRG payments with a more accurate adjustment like the severity levels, I am not confident the current proposal will effectively do that. I believe more time is necessary to look at the methodology of payment based on costs. These two methods could be phased in -- start with severity adjustment and then costs if after a 3 year period of study of the impact. This is because with such a large change could destroy hospital's reimbursement and ability to remain sustainable. It would be better to have the severity adjustment and then to work on an IPPS for Physician Reimbursemnt in order to align Physician and Hospital Incentives for Quality and Efficiency rather than go to the cost methodology which is flawed especailly since suppliers of hospitals are not regulated in the same manner.

Please consider these comments as well as the recommendations from CHA.

Thank you

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June 13, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
PO Box 8011
Baltimore, MD 21244-1850

RE: Revised Inpatient PPS DRG Weights

To Whom It May Concern

In response to your recent proposed changes to the Hospital Inpatient Prospective Payment System relating to the revisions to the Inpatient DRG Weights, please be advised that Huntington Hospital supports this policy change. We believe that this proposal is a market-based response to complaints from the not-for-profit community providers that niche providers were drawing the most profitable cases from general community hospitals. By adjusting the weights and expanding and revising the DRGs, you have successfully improved the accuracy of payments by attempting to equalize surgical and medical DRGS thereby removing the incentive to specialize in a particular service.

For a number of years, community hospitals have incurred substantial losses at the expense of specialty hospitals who received a disproportionate share of reimbursement for their services. Community hospitals treat a large number of medical cases admitted through Emergency Rooms and it is critical that the reimbursement formula recognizes the high costs of treating these patients. We believe this change should be made as soon as possible and that no "phase in" is necessary.

On behalf of Huntington Hospital, we would like to express our thanks for addressing this issue.

Sincerely,

Kevin F. Lowlier
President & C.E.O.

KFL/cal
Copy: Nassau-Suffolk Hospital Council, HANDS

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May 26, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: X STOP Interspinous Decompression System
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir/Madam:

I recommend that CMS approve a FY 2007 DRG new technology add-on for the X Stop Interspinous Decompression System. The X Stop offers an undeniable and significant advance in spinal surgery, which significantly improves patient outcomes over time. I urge CMS to make this technology available to Medicare patients, many of whom are not candidates for surgery and fail conservative treatments for lumbar spinal stenosis. I also have specific comments regarding the issues raised in the proposed rule:

Patient Selection: I treat about 250 patients with lumbar spinal stenosis each month, and approximately 50 percent are Medicare beneficiaries. About 35 percent of the patients are candidates for laminectomies and fusions. However, the vast majority (65 percent) of these patients are not candidates for surgery, and I typically prescribe medical management, including epidural steroid injections (3, typically over 3-6 weeks), physical therapy (3 times a week for 6 weeks), as well as medications like NSAIDS and hydrocodone. When the patients fail conservative treatments, however, I may suggest the X Stop Interpinous Decompression System. In my practice, about 15 percent of all patients might be candidates for the X Stop.

Patient Outcomes: My patients have achieved significant clinical improvement after receiving the X Stop procedure. One Medicare patient who relied upon a walker prior to surgery now walks without assistance. Another patient who could not exercise without pain has been able to resume regular physical activity. These patients were in severe pain prior to surgery and reported barely discernable pain afterwards.

Site of Care: Two-thirds of my X Stop cases are treated in inpatient settings. The vast majority of these cases would be classified as ASA grade 2, i.e., requiring basic monitoring by the anesthesiologist. However, about 33 percent of my cases could be classified as ASA grade 3, which requires basic and special monitoring by the anesthesiologist, including vascular invasion for hemodynamic and fluid administration control, and possibly multiple anesthesia drugs.

In conclusion, I recommend that CMS approve the X Stop application for a new technology DRG add-on, because the procedure is making a significant impact on patient's health. Many patients who are in severe pain but want to avoid a spine operation and fusion now can live a better lifestyle and make a more productive contribution to society.

Sincerely,

Thomas Sweeney, M.D.

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