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Consumers Union
Nonprofit Publisher of Consumer Reports

Stop Hospital Infections
A Project of Consumers Union

June 11, 2007

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

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

Dear CMS:

On behalf of the 179 people listed below, Consumers Union submits the following petition in support of the proposed sections entitled "DRGS: Hospital-Acquired Conditions" and "Reporting Hospital Quality Data for Annual Payment Update:"

We the undersigned, many of us personally affected by hospital-acquired infections, strongly support the proposal by the Centers for Medicare and Medicaid Services (CMS) to restrict payment for certain hospital-acquired infections and medical errors and to expand quality of care and patient safety measures to be reported to the public [CMS-1533-P]. Specifically we support:

- *Including urinary tract infections on the first list of conditions for which Medicare should withhold payment. Catheter-associated urinary tract infection is the most common hospital-acquired infection, accounting for more than 1 million cases in hospitals and nursing homes nationwide, nearly 1 million extra hospital days per year, at an estimated annual cost of between $424 and $451 million. [DRGs: Hospital-acquired conditions]*
- *Including Staph aureus bloodstream infections/septicemia, with a death rate of about 41% or 12,000 fatalities a year and an extra cost of $9.5 billion, on the first list for non-payment. [DRGs: Hospital-acquired conditions]*
- *Including additional items that are not slated for non-payment in the first year, especially hospital-acquired infections caused by methicillin-resistant Staphylococcus aureus MRSA (more than 95,000 Medicare cases each year), surgical site infections (300,000 cases each year), and vascular*

catheter-associated infections (250,000 cases each year). [DRGs: Hospital-acquired conditions]

- *Ensuring consumer protections to prevent hospitals and other health care providers from billing patients for the non-reimbursed costs of the hospital-acquired complications and to prevent hospitals from selectively avoiding patients perceived at risk of complications. [DRGs: Hospital-acquired conditions]*
- *Publicly reporting three additional measures relating to surgical site infections [Reporting Hospital Quality Data for Annual Payment Update].*

Sincerely,

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June 7, 2007

Centers for Medicare and Medicaid Services
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Re: Out-Migration Adjustment

We are writing to urge you to re-consider changes to the Centers for Medicare & Medicaid (CMS) proposed rules regarding the out-migration adjustment that uses the post-reclassification indices for determination of eligibility. As written, the proposed rule would hurt hospitals like UMass Memorial Medical Center, a not-for-profit hospital in Worcester, Massachusetts, as well as many other hospitals that have a high percentage of employees who reside in Worcester County but work in a different area such as Boston where the wage index is much higher.

This policy change contradicts the premise of providing for an increase in the wage index for hospitals where a high percentage of employees who commute to work in a difference area with a higher wage index. The proposed rule would have UMass Memorial Medical Center ineligible for the out-migration adjustment because it compares our core wage index to a diluted reclassed Boston-Quincy wage index.

We believe that the core wage index for both Boston-Quincy and the Worcester CBSA be considered the basis for determining the amount and eligibility for the out-migration adjustment.

Thank you for your attention to these concerns. We believe that the changes we have outlined will benefit patients, communities, and hospitals, and we strongly urge you to give them your full consideration.

Sincerely,

Todd Keating
VP/Chief Financial Officer

APIC
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June 11, 2007

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

Dear Ms. Norwalk:

The Association for Professionals in Infection Control and Epidemiology (APIC), an international professional association comprised of 11,000 infection prevention and control specialists, wishes to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide additional input to the CMS proposed IPPS changes.

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

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

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

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

Six conditions proposed for consideration for FY 2009

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

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

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

Recommendations for FY 2009

Support

Although our organization's focus is infection prevention, we do **support numbers 3, 4 and 5** that is, the three serious preventable events: object left in during surgery, air embolism and blood incompatibility, as appropriate conditions to include for FY 2009 These conditions have been identified and supported by the National Quality Forum (NQF) and are currently identifiable by discrete ICD-9 codes. For the most part, these conditions can also be coded by hospitals without dependence on POA codes. POA codes *will* be necessary for "object left during surgery" because recognition of this condition can occur months to years after the initial event and, according to a recent review, lead to readmission in 30% of cases.[1] These are events that can cause great harm to patients and for which there are known methods of prevention.. It will of course be essential to ensure that the definitions, surveillance methods, and coding of these

events are consistently applied and that certain specific medical circumstances are noted as exceptions. For example when patients deliberately have objects left in place, as opposed to accidental retained foreign objects, in emergencies when patients deliberately receive unmatched blood, or when air embolism is technically unavoidable because of a specific surgical procedure.

No support for FY 2009

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

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

We do not believe that each of these three conditions is always reasonably preventable. In our previous letter to CMS[3], we noted that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. After POA codes are functioning reliably, each of the following conditions will need additional exclusion codes to minimize the risk of including nonpreventable infections.

We offer the following specific comments on each of these conditions

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

CMS accepts the opinion of infectious disease experts that urinary tract infections may not be preventable after catheters have been in place for several days. The evidence based guideline referenced by CMS (http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html) was published in 1981 and is scheduled to be reviewed and updated by CDC's Healthcare Infection Control

Practices Advisory Committee (HICPAC). Although *preventive* interventions focus on timely removal of appropriately placed urinary catheters, there are patients who genuinely need long-term catheterization and who may suffer the complication of catheter-associated inflammation. Some host factors that appear to increase the risk of acquiring catheter-associated urinary tract infections including advanced age and debilitation may not be modifiable.

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

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

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

We believe this indicator could improve initial patient assessment for pressure ulcers, but there are a number of additional concerns that should be addressed by CMS beyond POA coding issues. This condition is not limited to hospitals; given the large number of transfers between hospitals and long-term care facilities a thorough examination and documentation of existing pressure ulcers on admission is of prime importance. According to Medicare coding rules, POA coding of pressure ulcers must rely solely on physicians' notes and diagnoses and cannot make use of notes from nurses and other practitioners. Although non-CDC guidelines exist and this condition is less complicated in terms of exclusion codes, all the concerns expressed previously about POA codes remain relevant.

The National Pressure Ulcer Advisory Panel recently released revised guidelines for staging pressure ulcers[4] and included a new definition for a suspected deep tissue injury. Although difficult to detect initially, this condition may rapidly evolve into an advanced pressure ulcer, and it is especially difficult to detect in individuals with darker skin tones. Even detection of stage I pressure ulcers on admission is difficult as the skin, although damaged, is not yet broken. Certain patients, including those at the end of life, may be exceptionally prone to

developing pressure ulcers, despite receiving appropriate care. If CMS decides to include pressure ulcers under the hospital-acquired conditions policy, the agency should exclude patients enrolled in the Medicare hospice benefit and patients with certain diagnoses that make them more highly prone to pressure ulcers such as hemiplegia, quadriplegia, wasting syndrome with advanced AIDS and/or protein malnutrition associated with a variety of serious end stage illnesses.

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

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

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

Seven conditions mentioned but not recommended for consideration for FY 2009

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

CMS has clearly identified the problems with each of these indicators based on lack of unique codes, complication codes or guidelines addressing reasonable preventability. Five of these seven conditions relate to infectious diseases, all of which are important causes of healthcare-

associated mortality and morbidity. Consequently, we recommend that CMS continue to address the coding challenges and determine if these conditions warrant inclusion in the hospital-acquired conditions policy in the future.[5] Identification of these conditions requires not only reliable use of POA codes but other unique definition and coding issues. Current efforts and measurable results show hospitals are reducing these complications, but they are not easily identified under current coding logic. Although judicious antibiotic use and appropriate infection control measures can reduce the burden of CDAD, a significant percentage of CDAD is unavoidable. Distinguishing community-acquired from hospital-associated CDAD is challenging, thus making this condition the least attractive of the group.

Potential FY 2009 recommendations

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

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

CMS states: "This code includes infections associated with all vascular devices, implants, and grafts. It does not uniquely identify vascular catheter associated infections. Therefore, there it is not a unique ICD-9-CM code for this infection. CDC and CMS staff requested that the ICD-9-CM Coordination and Maintenance Committee discuss the creation of a unique ICD-9-CM code for vascular catheter associated infections because the issue is important for public health. The proposal to create a new ICD-9-CM was discussed at the March 22-23, 2007 meeting of the ICD-9-CM Coordination and Maintenance Committee. A summary of this meeting can be found at: http://www.cdc.gov/nchs/icd9.htm. Coders would also assign an additional code for the infection such as septicemia. Therefore, a list of specific infection codes would have to be developed to go along with code 996.62. If the vascular catheter associated infection was hospital-acquired, the DRG logic would have to be modified so that neither the code for the vascular catheter associated infection along with the specific infection code would count as a CC."

Although we acknowledge the comments above and agree that as stated this condition would problematic, we would suggest another approach-- not dependent on POA or a special code for vascular catheters. We agree that at the moment there is no specific code for ***catheter-associated blood stream infection*** (CA-BSI) -- a reasonably preventable condition. However--***there are specific codes for insertion of catheters***. There may be an alternative approach to circumvent the absence of a unique ICD-9-CM code for CA-BSI, using specific codes for insertion of catheters, although this approach may be cumbersome to implement.

It is possible to:

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

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

CMS notes that "While there are prevention guidelines, it is not always possible to identify the specific types of surgical infections that are preventable. Therefore, we are not proposing to select surgical site infections as one of our proposed hospital-acquired conditions at this time."

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

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

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

Our coalition continues to work with the Centers for Disease Control and Prevention to prevent these conditions and disseminate successful infection prevention practices. We are committed to improving the safety of healthcare and look forward to working with CMS toward this goal. Should you require any follow up on our comments, please feel free to contact Denise Graham, Vice President of Public Policy at dgraham@apic.org or 202-454-2617.

Sincerely,

Denise M. Murphy

Denise Murphy, RN, BSN, MPH, CIC
2007 APIC President

References

[1] Lincourt AE, Harrell, A, Cristiano J et al. Retained Foreign Bodies After Surgery. J. Surgical Research 2007;138:170-4.

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

[3]APIC-IDSA-SHEA letter to Mark McClellan dated June 12, 2006

[4] National Pressure Ulcer Guidelines accessed at www.npuap.org/documents/PU_Definition_Stages.pdf

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

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JUN 12 200

June 11, 2007

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

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

Dear Ms. Norwalk:

We are writing to provide comments on the proposed Medicare Inpatient Hospital Prospective Payment System Rule for Fiscal Year 2008 ("Proposed Rule"). For more than 30 years, we have been actively involved with both hospitals and payers in developing and supporting DRG methodologies and DRG-based software. Our professional careers began with the original development of DRGs at Yale University and have continued through all of the federal and most state-specific variations on prospective payment from both a research and operational perspective. We were also actively involved in the development of a commercial adaptation of the severity-adjusted DRG methodology developed by CMS in the early 1990's.

As experts in this arcane discipline, we fully support the goal of refining the current CMS DRGs to ensure that inpatient hospital costs are more accurately reimbursed, as well as the steps that CMS is taking to achieve this goal. The proposed Medicare Severity DRGs (MS-DRGs) are a good step toward accomplishing this goal, while addressing many of the concerns voiced by ourselves and the industry last year.

The proposed MS-DRG system, unlike the methodology proposed last year, is transparent, builds upon the current CMS DRGs and is universally available to all constituents in the market. It shows meaningful improvements over the current CMS DRGs without being overly complicated, and preserves many of the industry-driven changes and enhancements made to the DRG methodology over the last 24 years. Relative to transparency, we would encourage CMS to ensure that the software actually distributed to the market through the National Technical Information Service (NTIS) is comparable to the software distributed today. Open source, good documentation and complete test data should be essential components of a transparent software distribution. As part of its commitment to transparency, we also encourage CMS to ensure that all changes to the DRG methodology, including enhancements to the complication and comorbidity (CC) list and major CC list, be accomplished in a manner

that is transparent to all affected individuals and entities and based on public comment and debate.

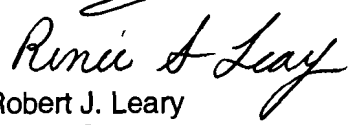
With regards to the proposed MS-DRGs, we caution that time be spent rigorously testing both the logic of the new system and the software which will be used to deploy this new logic. Thorough validation and testing of changes is crucial at a time when all aspects of the DRG methodology are changing. Using outside parties to assist in this process is more important than ever.

The proposed MS-DRGs create a classification framework that can be built upon and extended to increase the statistical performance and payment equity of the system. Annual refinements to the base MS-DRGs, as well as to CC and major CC lists, will allow for continued improvements over time. More importantly, the basic framework of the proposed system will allow for the introduction of logic to account for "additional" CCs or MCCs. Both the current CMS DRGs and the proposed MS-DRGs utilize a single CC or MCC for purposes of casemix classification. Research has shown, however, that appropriately accounting for additional, un-used CCs or MCCs can improve the statistical performance and payment equity of a DRG-based system. It is important, however, that any system or method which recognizes this additional clinical information be constructed in a way that is easy to comprehend and fully transparent to both health information coding professionals and end-users of the data.

We urge caution on the proposed withhold for anticipated coding improvements. Studies have shown that professional coders code to the CC list rather than to the structure of the DRG algorithm itself. Any withhold for coding improvement should be based upon a careful study of changes to the CC list and contents of the new major CC list.

We thank you for your consideration of these comments.

Sincerely,



Robert J. Leary
Renee S. Leary
320 Vineyard Point Road
Guilford, CT 06437

June 5, 2007

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-1533-P Medicare Program: Changes to the Inpatient Prospective Payment System and 2008 rates, April 13, 2007 Federal Register

Gentlemen:

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 2008, as published in the April 13, 2007 Federal Register.

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 healthcare services, including many specialized services. These intensive specialized services are those being impacted by this proposed rule and its changes to DRG weights. These cuts in funding for specialized services such as cardiac surgery, vascular interventional procedures and oncology services will dramatically affect the access to care for Medicare recipients. The adverse financial impacts of these proposed changes will leave us unable to cover our costs and thus unable to retain state of the art programs for the large geographic area we serve. We ask that CMS recognize and compensate Munson Medical Center and other Rural Referral centers for the unique services that they provide to their communities and the access to necessary and high quality care for Medicare beneficiaries.

Munson Medical Center is also concerned about the changes in the clinical criteria used for assignment of the new DRG weights. The elimination of many of the previously accepted conditions for comorbidities will alter the resultant payment rates unfairly. These conditions are significant medical issues that require appropriate care with the proper resources. Costs will not go away due to this revision, and obviously financial margins will be adversely affected. Further, we are concerned that reductions in payment for cases in which patients expire is punitive. Resource consumption for these cases will not diminish in the event of death.

The conditions present at admission (POA) are also problematic since many times these medical problems exist prior to the hospital stay. To assume that medical issues such as MSRA, clostridium difficile, or urinary tract infections were acquired during the hospital

stay if not documented otherwise places a significant burden upon the facility along with significant added expenses for this verification. We understand that when events occur within the Hospital's control we would be culpable, but for conditions that may have been present on admission, but not readily identifiable, is inappropriate to be penalized.

Our final concern involves the behavioral offset adjustment of 2.4%, reducing payment on all of our inpatient claims due to an assumption that somehow behavior will change when coding and classifying these discharges. We do not believe there are any opportunities to impact the coding for these cases as the criteria for the new DRG assignment is more restrictive and precise thus limiting these types of revisions. Until actual changes in patient severity are quantified, it's inappropriate to reduce payments on unfounded logic.

We trust that comments are adequately explained and complete, but if you have any questions on our concerns, please feel free to contact me at (231) 935-6910 or our Reimbursement Manager, Steven Leach at (231) 935-7797.

Sincerely,

Edwin Ness
President and CEO

EAN:kah
cc: Ed Carlson

131-O

Sampson Regional Medical Center
Phone (910) 590-8716 Fax (910) 590-2321
P.O. Box 260
Clinton, North Carolina 28329-0260

LARRY H. CHEWNING
Chief Executive Officer

June 6, 2007

Ms. Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS – 1533 – P
Post Office Box 8011
Baltimore, Maryland 21244-1850

Dear Ms. Norwalk:

On behalf of our rural community hospital and other community hospitals in our state and country, we appreciate the opportunity to comment on the Center for Medicare and Medicaid Services (CMS) proposal for Fiscal Year (FY) 2008 Hospital Inpatient Prospective Payment Program (PPS). While the American Hospital Association, North Carolina Hospital Association, and our hospital support many of the proposed rules and provisions, we specifically and strongly oppose the proposed Behavioral Offset cuts related to the move to severity–adjusted diagnosis–related groups (DRG s), and the cuts to capital payments. The impact of this proposal on our community hospital is estimated to be over $300,000. This is a devastating and underserved cut in payment for services rendered to Medicare inpatients. For a hospital that lies in the perfect storm of [redacted] worst in our state, we find these additional unwarranted cuts from Medicare intolerable.

The proposed rule would create 745 new Medicare–severity DRGs (MS-DRGs) to replace the current 538 DRGs, and would overhaul the complication or co-morbidity list. The proposed rule also includes a 2.4 percent cut to both operating and capital payments in both fiscal years 2008 and 2009. This additional cut has been proposed to eliminate what CMS claims to be the effect of classification changes that do not reflect real changes in case mix. The hospital supports meaningful changes to Medicare inpatient PPS. While we believe that MS-DRGs provide a reasonable framework to patient classification, it is our believe, in analyzing the proposed changes that once again, rural designated

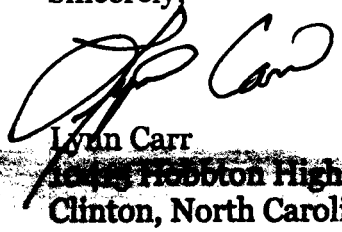
hospitals are adversely impacted as the proposed changes redistribute between 800 and 900 million dollars in hospital payments.

Long overdue is the need to end the senseless rule that base inpatient prospective payment reimbursement on a rural urban setting of a hospital. Since the inception of the Medicare Program, our hospital has been paid between eight and twelve percent (8% to 12%) less than the urban hospitals that surround us due to this senseless rule. We compete with these urban hospitals for nurses and other skilled healthcare professionals. However, we are paid a disproportionately low rate for providing the same care to the same patient based on the DRG classification system.

Again, the primary concern I have as a hospital board member is the financial survival and growth in patient care services delivered to a rural, at risk population. I strongly oppose the arbitrary and unnecessary cuts proposed in the behavioral offset rules. These "backdoor" budget cuts will further deplete scarce resources ultimately making our hospital's mission of caring for Medicare and Medicaid patients even more difficult.

Thank you for allowing me the opportunity to comment on this proposed rule and hope that you will take our concerns to heart as decisions are made about Medicare financing for fiscal year 2008.

Sincerely,



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LC/cb

nile's

help stop MRSA

Ty & Carole Moss

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June 7, 2007

The Honorable Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Attention: Marc Hartstein

Dear Acting Administrator Norwalk,

I write to urge the Centers for Medicare and Medicaid Services (CMS) to take action and address the most common form of HAIs- Methicillin-resistant Staphylococcus Aureus (MRSA).

From first hand experience I can tell you that MRSA and VRE is killing our children, our seniors and changing the lives too many helpless victims unnecessarily. Hospital Acquired Infections such as these are preventable and this is a proven fact. We have the knowledge to prevent these killer infections. We do not need a scientific breakthrough. Yet, hospitals have failed to act. They have never been held accountable for their actions and no one has forced them to clean up their act.

The key to resolving a large part of this problem is in your hands. It really does just boil down to dollars and cents.

When PCH4 findings prove that in one year $3 billion dollars were spent by the taxpayers of Pennsylvania to pay for victims of hospital acquired infection on Medicare and Medicaid, the reasons why this epidemic continues to grow has now become very clear. because they can....and because it is a very lucrative business. No one is held accountable.

Pennsylvania is a state with just over 12 million citizens $3billion Compared to California, a state with over 36 million citizens. Once California begins to tally the count the cost to care for Medicare and Medicaid patients by the taxpayers could very well exceed $9 Billion Dollars

When my neighbor sent her father to Mission Community Hospital aka CHOC at Mission Viejo California to have a small mole removed and her father was infected by MRSA in the hospital and died that Thanksgiving weekend. No attorneys would take the case. They knew the $250,000 maximum would barely cover what it would take to fight the case even if they were able to find a reputable doctor that would take the stand and clearly define where the hospital went wrong. No one at the hospital was held responsible for this criminal act that caused a family to loose their grandpa, their father, their son, their brother.

nile's

elp stop MRSA

When our 45 year old friend lost both hands and both feet , amputated due to the MRSA bacteria that he had been infected with while in the hospital for an unrelated illness. No one was held accountable for this criminal act that was preventable.

On Easter morning 2006 our son Nile Calvin Moss was admitted to the hospital with a high fever and difficulty breathing. The doctors could not find what was causing Nile's deteriorating health. As they moved Nile into pediatric ICU at Mission Hospital, Nile continued in true form to make the nurses laugh as he smiled and shared stories of his favorite adventures through his oxygen mask.

On Easter weekend, April 17th Nile Calvin Moss became one of the 90,000 people in 2006 that contracted and died of a Hospital Acquired Infection (HAI). Nile's young life ended abruptly from massive organ failure caused by MRSA (Methicillin-resistant Staphylococcus Aureus) an infection that seriously harms over 2 million people each year. Nile died less than 24 hours after he was admitted to the hospital. Three weeks prior to this tragedy, Nile had been in several medical facilities for testing, x-rays and an MRI. Exposure to MRSA in these medical facilities would be the cause of the infection that abruptly ended Nile's life.

No one was held accountable for this senseless tragedy. No attorney would take the case.

But everyone got paid.

Our lives are forever changed. we dearly miss the happy, loveable, sweet young man and the smile that appeared on his face every minute of every day Nile's family and friends are committed to ending this epidemic of deadly, preventable hospital-acquired infections.

We pray that you and your committee are as dedicated as we are.

Sincerely,
Carole Moss
Executive Director
951-657-4012
949-235-2925 cell

Carole L. Moss

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Ty & Carole Moss

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June 7, 2007

The Honorable Leslie Norwalk
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Centers for Medicare and Medicaid Services
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We pray that you and your committee are as dedicated as we are.

Sincerely,
Carole Moss
Executive Director
951-657-4012
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Carole L. Moss

nile's project Celebrate Life.

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June 8, 2007

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

Attention: CMS-1533-P

Dear Mr. Hartstein:

The College of American Pathologists (College) appreciates the opportunity to comment on the proposed rule CMS-1533-P entitled "*Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates.*" The College is a national medical specialty society representing more than 16,000 physicians who practice anatomic and/or clinical pathology. College members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

The College has a shared mission with the Centers for Medicare and Medicaid Services (CMS) to advocate for high-quality and cost-effective medical care. The College monitors changes in pathology practice and has become aware of an issue that threatens the quality of clinical pathology services. Pathologists spend a substantial portion of their practice time on the medical direction, supervision, management and oversight of hospital clinical laboratories; 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, pathologists continues to report that some hospitals are reducing or eliminating payment for oversight of the clinical laboratories. The failure of hospitals to compensate pathologists for their professional medical services threatens the availability and quality of clinical pathology services.

Professional clinical pathology services are required to be furnished for all hospital patients under the Medicare Conditions of Participation for Laboratory Services.[1] Hospitals are paid for these services as part of their prospective payment rates; however,

[1] *See* 42 C.F.R. §482.27

hospitals are failing to pass-through payment to the pathologists that furnish the services. To protect access by Medicare and other federal health care program beneficiaries to high quality clinical pathology services, the College asks the CMS to remind hospitals of their obligation to pass-through payment to pathologists for their professional clinical pathology services. The College also asks CMS to instruct hospitals on the proper methodology for reporting and reimbursement for these professional medical services that constitute the medical direction, supervision and management of hospital clinical laboratories. The College's comments address the section of the rule for Prospective Payment Rates for Hospital Operating Costs.

The College believes there is confusion by hospitals regarding Medicare reimbursement for the professional clinical pathology services that can be ameliorated with clarification from CMS in this rulemaking. The technical component of a clinical laboratory testing service is reimbursed through the Clinical Laboratory Fee Schedule. Many hospitals wrongly believe that pathologists can and should bill directly for the professional component of the testing service under Part B. Prior to 1983, many pathologists did receive direct reimbursement for these services under Part B, but in 1983 the Health Care Financing Administration issued regulations under the Tax Equity and Fiscal Responsibility Act of 1982 that required reporting and reimbursement under Part A. When the prospective payment system was introduced later the same year, the weighting of DRG payment included reimbursement for these services. Now Medicare considers the professional component to be a provider service that is reimbursed to the hospital on a reasonable cost basis.[2]

As noted above, hospitals are required as a condition of participation to maintain and offer laboratory services that meet certain quality standards, including all requirements of the Clinical Laboratory Improvement Amendments (CLIA).[3] Pathologists, in their capacity as medical directors of hospital clinical laboratories, furnish these valuable and necessary medical services for the benefit of all hospital patients. Specifically, under Subpart K of CLIA the medical director must maintain quality systems, which requires continuous improvement of a laboratory's performance and services through ongoing monitoring and evaluation. Under Subpart M, the director is responsible for the overall operation and management of the laboratory and ensuring satisfaction of the quality requirements. Other common duties of pathologists 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 bear professional liability.

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[2] *See* Section 2108 of the Medicare Provider Reimbursement Manual
[3] *See* 24 C.F.R. Part 493

Whether due to confusion or the lack of a specific allocation of the hospital's Part A reimbursement for provider services, without a clear mandate from CMS hospitals are disregarding their obligation to pass-through payments for clinical pathology 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. The College 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 CMS has the authority to instruct hospitals of their responsibility for reporting these services properly to their fiscal intermediaries and making pass-through payments to pathologists for these necessary medical services.

At this time we ask the CMS to reiterate the responsibility of hospitals to reimburse pathologists for their medical direction, supervision, management and oversight 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 College of American Pathologists is pleased to have the opportunity to comment on these regulations and appreciates your consideration of these comments. Any questions regarding the comments should be directed to Donna Meyer at 202-354-7112, or at dmeyer@cap.org.

Sincerely,

Thomas Sodeman MD FCAP

Thomas M. Sodeman, MD, FCAP
President

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ACR™
AMERICAN COLLEGE OF RADIOLOGY

www.acr.org

June 12, 2007

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

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

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

Dear Ms. Norwalk:

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

DRGs: Relative Weight Calculations

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

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

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Instead, as currently allowed, they spread these costs across the entire hospital on a per-square-foot basis (as fixtures). We believe that a closer examination of the hospital cost data used by RTI in making its recommendations relating to radiology services and other technologies in hospitals will confirm this, and thereby raise significant doubts about the appropriateness of making these recommended changes.

And while the focus of the immediate rulemaking exercise is the IPPS, we wish to note that any proposal to apply the RTI-recommended cost-to-charge ratio methodology to radiology services paid for under the OPPS would be especially problematic. As you know, under section 5102 of the Deficit Reduction Act of 2005, OPPS payment rates for imaging services also apply to the Medicare physician fee schedule. Any inaccuracies in the OPPS would affect payments to the hospitals and physician practices providing these imaging services, (i.e. all venues for imaging for Medicare beneficiaries). This could have an unintended negative impact on Medicare beneficiaries access for imaging services. Changes in access on a local level may not be initially evident in a roll-up of national data for imaging volumes.

In sum, we urge CMS to proceed with caution with respect to any change in the way in which the cost-to-charge ratio for radiology services is determined. In this regard, the ACR would be pleased to work with CMS to identify adjustments in hospital cost reporting instructions that would produce more consistent reporting by hospitals of the costs associated with radiology services.

Thank you for the opportunity to comment on this proposed rule. The ACR looks forward to a continuing dialogue with CMS officials about the cost-to-charge ratio for radiology services and other issues affecting radiology. If you have any questions about our comments, please contact Sneha Soni at (800) 227-5463, ext. 4576 or via e-mail at ssoni@acr.org.

Respectfully submitted,

Harvey L. Neiman, MD, FACR
Executive Director

cc: Marc Hartstein, CMS
Sheila Blackstock, CMS
John Patti, MD, FACR, Chair, ACR Commission on Economics
James Rawson, MD, Chair, ACR Committee on APC/HOPPS
Pamela J. Kassing, ACR
Angela J.Choe, ACR
Sneha Soni, ACR

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Charleston Area Medical Center

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JUN

June 11, 2007

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

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

The Charleston Area Medical Center ("CAMC") is a 913-bed teaching hospital located in Charleston, West Virginia. We provide highly specialized health care services to all of central and southern West Virginia. We have the only Level I trauma center in all of southern West Virginia and one of two Level III NICUs. In addition, we provide resident training to over 130 medical residents and interns. We are the true safety net hospital for southern West Virginia, providing over 22 percent of all charity care provided by acute care hospitals in the state. We are also the largest provider of health care to both Medicaid and Medicare beneficiaries in the state. We are proud of our tertiary care safety net mission, but it comes at a huge cost. Last year (FY 2006), we experienced a Medicaid loss of over $25 million and a Medicare loss of over $41 million.

<u>Comment on DRG Reform and Proposed MS-DRGs</u>

The proposed rule would create 745 Medicare-Severity DRGs (MS-DRGs) to replace the current 538 DRGs and would overhaul the complication and co-morbidity list. We believe that MS-DRGs is an improvement to the current DRG system and should be fully implemented in 2008. We are, however, strongly opposed to the 2.4 percent "behavioral offset" to both operating and capital payments in both 2008 and 2009. This will result in a payment cut to CAMC of more than $7.0 million over the next two years. This will, without any question, negatively impact our ability to continue to

provide highly specialized tertiary care services to the poor and the elderly in southern West Virginia.

CAMC has operated under the current DRG system for 23 years. The proposed MS-DRG systems would simply be a refinement to what we are currently doing. You have no evidence that we will abuse the new system. The coding system that we have in place will remain with the same high quality staff. I can assure you that CAMC is already coding as carefully and accurately as possible, including complication and comorbidity ("CCs") at the correct level. (Since we are a tertiary care facility with a high case mix index, we have a large number of CCs.) In the proposed rule, CMS uses the experience of the Maryland hospitals moving to 3Ms All Patient Refined (APR)-DRGs as a basis for the behavioral offset. However, MS-DRGs and APR-DRGs are totally different systems. The current DRG system will only be marginally modified under MS-DRGs, whereas they are very different under APR-DRGs.

We are also strongly opposed to capital cuts. These cuts are unnecessary and will hinder our ability to improve or even maintain our facilities and technology. Our current average age of plant is already well above the national average for hospitals our size.

<u>In summary, CMS should not implement a behavioral offset at this time</u>.

I appreciate the opportunity to comment on the proposed changes.

Sincerely,

David L. Ramsey

David L. Ramsey
President and CEO

HEALTH MANAGEMENT ASSOCIATES, INC.
5811 Pelican Bay Boulevard, Suite 500
Naples, Florida 34108-2710
239/598-3131

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JUN 12 2007

June 11, 2007

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

Dear Ms. Norwalk:

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

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

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

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

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

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

Sincerely,

Robert Farnham
Senior Vice President
Chief Financial Officer

Kenneth M. Koopman
Senior Vice President of Reimbursement

RF/mk

137-0
(13)

Braxton, Shawn L. (CMS/OSORA)

From: OC AIMS Support [AIMSSupport@OC.FDA.GOV]
Sent: Tuesday, June 12, 2007 1:53 PM
To: Braxton, Shawn L. (CMS/OSORA)
Subject: FW: Public Submission

Attachments: C__Documents and Settings_jgallaspy_My Documents_Final IPPS Issues from PRT to Upload.doc; C__Documents and Settings_jgallaspy_My Documents_List of PRT Members for IPPS Comments.pdf


C__Documents and Settings_jgal...


C__Documents and Settings_jgal...

-----Original Message-----
From: no-reply@erulemaking.net [mailto:no-reply@erulemaking.net]
Sent: Tuesday, June 12, 2007 1:46 PM
To: OC AIMS Support
Subject: Public Submission

Please Do Not Reply This Email.

Public Comments on Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates:========

Title: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates FR Document Number: 07-01920 Legacy Document ID:
RIN:
Publish Date: 05/03/2007 00:00:00
Submitter Info:

First Name: Janet
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Country: United States
State or Province: MS
Postal Code: 39404
Organization Name: The Provider Roundtable

Comment Info: ==========

General Comment:This is a resubmission of information that was submitted under specific sections.
Due to technical problems and the character limitations, the document is being submitted to ensure the complete Provider Roundtable's comments are submitted for consideration.
Thank you.

PROVIDER ROUNDTABLE COMMENTS TO CMS ON PROPOSED 2008 IPPS RULE

The Provider Roundtable (PRT) is a group of 13 different hospitals and health systems representing over 48 hospitals from around the country (see the attached PDF file). Like many others, our hospitals, and the departments within our institutions, continue to struggle with the implementation of Medicare inpatient and outpatient regulations and the many associated coding and billing complexities. Providers are often too busy, or unaware of the overall process, to submit comments to CMS on their own. Therefore, the members of the PRT collaborate to provide substantive comments with an operational focus which we hope CMS' staff will find useful during its rule-making process. The PRT truly appreciates the opportunity to provide CMS with the following comment.

1. **DRG REFORM AND PROPOSED MS-DRGS: Changes to Case-Mix Index (CMI) From the Proposed MS–DRGs**

   The PRT does not support CMS' proposed payment reduction of 2.4% each year for 2008 and 2009 for an assumed improvement in hospital coding practices after the implementation of MS-DRGs. In recent years CMS has stated that it wants to base payment rates and policy decisions on the basis of provider data. If case-mix does indeed rise, CMS will be able to see this from the data and can then factor it into its annual recalibration process. However, this proposal goes against CMS' own statements about the importance of provider data and makes assumptions about increases in case-mix that may not pan out.

   Once CMS has collected two years worth of inpatient data under MS-DRGs, then it will be able to see whether case-mix has increased as a result of the new severity-adjusted DRG system. Until that time, it would be unfair to penalize hospitals in anticipation of coding changes by implementing an up front payment reduction. In fact, at this time CMS cannot know whether case-mix will increase or decrease and whether that movement will be due to coding changes or to hospitals treating more severe patients.

   Therefore, the PRT fundamentally believes CMS should continue recalibrating and rebasing the payment system based on actual provider clinical and cost data while leaving the issue of "case-mix creep" or "upcoding" to medical review and QIO monitoring.

2. **DRG Payment Fluctuations**

   The PRT is concerned regarding the large changes in reimbursement for service lines under the MS-DRGs. Cardiology services as a whole are greatly impacted. The PRT is concerned that such large payment rate fluctuations will compromises hospitals'

ability to plan, budget, and forecast from one year to the next. These large payment rate fluctuations may impact beneficiary access to care and certainly could impact their access to new devices. Given that CMS has changed its relative weight calculation methodology and is using both MedPAR and cost report data, we believe some of these fluctuations are an artifact of the variability in how providers complete their cost reports. The large disparity in the reporting of actual costs for certain devices may significantly impact the cost to charge ratios being utilized. This inconsistency across hospitals should be reviewed by CMS carefully as suggested in the RTI International report on charge compression. In the meantime, CMS should dampen large payment fluctuations. We believe that large shifts, either negative or positive should be examined and dampened, particularly for high volume service lines. Therefore, the PRT urges CMS to investigate mechanisms that can be used to dampen large payment rate fluctuations.

3. Capital IPPS

The PRT does not support CMS' proposal to eliminate the capital payment update or the capital payment add-on for urban hospitals. CMS states that hospital margins have been positive and therefore these cuts are justified. We strongly disagree with the notion that efficiency on the part of hospitals should result in CMS making such broad based cuts. The inpatient prospective payment system (PPS) is a system of averages that relies on historical provider data to set future payment rates. Under a system of averages, the principle that you (the hospital) "win some and you lose some", whether it applies an individual case or to annual aggregate revenue, is what allows for gains in some years to be reinvested and losses in other years that must be managed. Inherent in such a system is the incentive for hospitals to improve efficiency. If they succeed, they may see improved margins, yet this does not justify CMS making such an arbitrary decision to reduce payments. Ultimately this will impact beneficiary's access to newer technologies and equipment and the hospitals' ability to invest in improving their facilities. Moreover, this proposal is a gross departure from the principles inherent in a prospective payment system.

If CMS finalizes this proposal, it is essentially giving hospitals the signal that there is no reason to improve efficiency. In effect, hospitals are being penalized for being efficient. Capital payments are an important part of the funding mechanism and facilitate ongoing maintenance and improvement of our hospitals and enable us to continue advancing healthcare treatment through new and improved technologies. Therefore, the PRT strongly urges CMS not to implement these proposed capital payment cuts.

4. Replaced Devices

CMS has proposed to reduce the amount of the Medicare inpatient PPS payment when a full or partial credit towards a replacement device is made or the device is replaced without cost to the hospital or with full credit for the removed device.

DRG payments are fundamentally based on averages of historical costs and charges. To reduce the payment for cases involving replacement of a medical device assumes that either these types of cases have never occurred previously or are significantly on the rise thereby skewing the averages used to develop DRG weights. The PRT does not believe this is at the heart of CMS' proposal to reduce payments for replaced devices as CMS itself has acknowledged that device failures covered by manufacturers' warranties occur on a regular basis. If such device failures have occurred in the past, then hospital charge/cost data already reflect this and hence it is being factored into the relative weight calculation. This is part and parcel of a prospective payment system which is based on the concept of averages. Therefore, the PRT does not support CMS' proposal to reduce payment rates any further.

In addition, the PRT has significant concerns with CMS' proposal to require hospitals to submit invoices for claims that suspend due to the presence of condition codes 49 or 50. This proposal will result in significant operational burden and will essentially delay payment for otherwise "clean" claims. Asking hospitals to manually provide a fax or hard copy of the invoice is unduly burdensome. Therefore, we encourage CMS to obtain invoice cost information from hospitals by having them report this with a specific code similar to the use of HCPCS code C9399 in the outpatient setting for reporting new drugs without HCPCS codes. Hospitals are able to report this code and the NDC # for drugs in the remarks section of the claim form in form locator field 84. The PRT believes a similar approach can be used in the inpatient setting when Condition Code 49 or 50 is present on the claim. This would trigger the hospital to report the percentage of the device credit in the remarks field. This approach would provide CMS with the data it needs while eliminating the need for hard copy invoices. This mechanism will significantly reduce hospital reporting burden will allow CMS to have the data it needs.

5. Reporting Hospital-Acquired Conditions
Refer to "DRGs: Hospital-Acquired Conditions" Federal Register 24716-24726

The DRA requires CMS to identify, by October 1, 2007, at least two CC secondary diagnoses that are high cost, high volume, or both; result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis; and could reasonably have been prevented through the application of evidence-based guidelines.

The PRT appreciates CMS asking for comments on how many and which conditions should be selected for implementation on October 1, 2008, along with justifications for these selections. CMS has proposed 13 conditions, but recommends only 6 of the 13 conditions at this time. The PRT has comments on the top five conditions.

The PRT agrees that CMS should limit the number of conditions it begins with because of the significant challenges associated with identifying the cases on admission that meet the criteria outlined in the proposed rule. Some of the conditions may not be feasible to identify until further criteria for reporting these is developed and proper education provided both by CMS and by hospitals to physician and coding staff. The PRT strongly encourages CMS to delay the implementation of Catheter-

Associated Urinary Tract Infections and Pressure Ulcers. We explain our rationale for this below.

(a) Catheter-Associated Urinary Tract Infections

The PRT agrees with CMS that this item meets all of the criteria for selection as one of the initial hospital acquired conditions. However, catheter-associated urinary tract infections present a particular challenge and that is that in some cases they may be fully preventable but not in all, which makes it very difficult to say unequivocally that this should be preventable all the time.

Part of the consideration rationale, listed on page 24719 of May 3, 2007 Federal Register, states "once catheters are in place for 3 to 4 days, most clinicians and infectious disease/infection control experts do not believe urinary infections are preventable." The prevention guidelines listed on the website noted state that after 4 days, a urinary tract infection is unavoidable. Based on this information, it seems reasonable to infer that if a patient contracts a urinary tract infection within three days of the catheter being inserted, there was some process occurring prior to admission that had not yet manifested itself; and therefore could not be identified as present on admission.

From a clinical standpoint, there are many situations where a temporary indwelling urinary catheter is medically necessary, and depending on the individual patient's needs and situation, the time frames will vary significantly. For example, patients who undergo a hip or knee replacement procedure require a urinary catheter for several days after surgery in order to prevent movement that could be detrimental to the newly implanted joint. If a patient is incontinent after joint replacement surgery, there is increased danger of surgical wound infection, skin breakdown due to the acidic nature of urine, disruption of the newly implanted joint when the patient is moved to allow cleansing of the skin, and increased pain from movement. In this type of situation, not having the indwelling catheter could present more detrimental outcomes than a possible urinary tract infection.

Based on the CDC guidelines and the consideration statement, the PRT believes CMS should not include this condition effective for October 2008 discharges. If CMS does proceed, then we believe additional ICD-9-codes should be created to describe a catheter-associated urinary tract infection based on the time frame of"1-4 days" and "greater than 4 days".

(b) Pressure Ulcers

The PRT does not agree with the selection of this condition based on the discrepancy associated with the manifestation time frame of a pressure/decubitus ulcer. The PRT agrees with the stated concern that there will be some situations where there may be skin breakdown on admission that is not readily apparent because the skin is not broken yet.

From a clinical standpoint, the very early stages of a pressure ulcer may be deceiving and therefore not documented as a concern or finding upon the admission assessment. For example, if someone crosses their ankles, this event will create a reddened area on the patient's skin which could look like the beginning of a pressure ulcer. Under this new reporting it will be imperative that since current coding of pressure ulcers does not indicate stages, the "reddened" area of the skin would begin to be picked up on the assessment to indicate that the condition was present on admission. This could easily result in CMS seeing a lot of false positive data, as providers report even the slightest cases of reddened areas as a pressure ulcer being present on admission.

If CMS utilizes this condition as it is currently reportable with ICD-9-CM diagnosis codes, then it will most certainly appear that pressure ulcers are significantly increasing in the Medicare population when in reality this would simply be an artifact of having selected in inappropriate condition for present on admission reporting requirements. The current coding structure is based on pressure ulcers by body site, but does not take into consideration the stage of the ulcer. Early stages of true ulcers would be easy to miss, while reddened areas may be incorrectly reported as a pressure ulcer being present on admission. The PRT urges CMS to delay the inclusion of this condition until ICD-9-CM codes are created to distinguish between the different stages of an ulcer and a standardized method to stage the ulcers is adopted.

(c) Serious Preventable Events

The PRT agrees that the following three conditions should be selected as the initial hospital-acquired conditions. We believe these are very serious in nature, preventable, easily detectable, and easy to code.

- Serious preventable event – object left in surgery
- Serious preventable event – air embolism
- Serious preventable event – blood incompatibility

The PRT recognizes these conditions are typically rare and should essentially never occur. These serious preventable events are also very discreet conditions and easy to code, and we agree that hospitals should not receive a higher paying DRG when these conditions are present on admission.

Given that the POA reporting requirement is new for most hospitals, we believe it is important for CMS to begin implementation with conditions that are easy recognizable on admission, preventable, and codeable. This will almost certainly ensure CMS will receive more accurate data than if other conditions are selected.

Therefore, the PRT strongly recommends CMS select these three conditions for the first phase of hospitals reporting initial hospital-acquired conditions. As more experience is gained by hospitals and by CMS, additional conditions should be carefully considered and then added to the list.

6. CC List Comments:

As part of the effort to better recognize severity of illness, CMS conducted a comprehensive review of the CC list. A condition was included on the revised CC list if it could be demonstrated that the presence of the condition would lead to substantially increased hospital resource use (intensive monitoring, expensive and technically complex services, or extensive care requiring a greater number of caregivers). It is not clear what is considered "intensive monitoring" or "technically complex" for determining if a condition remains as a CC. Does intensive monitoring refer to additional nursing care on a daily basis, additional testing, intensive care unit care, extended length of stay, all of these factors, or some other factor? In some instances, we have noted that similar or comparable codes within the same group have remained a CC/MCC, while other clinically similar codes or codes requiring similar resources may have been omitted.

The PRT would like to comment on the following conditions that CMS is proposing to remove from the CC list and would make these recommendations:

CONGESTIVE HEART FAILURE, 428.0:
The revised CC list applied the criterion that chronic diagnoses having a broad range of manifestations are not assigned to the CC list as long as there are codes available that allow the acute manifestations of the disease to be coded separately. For some diseases, there are ICD–9–CM codes that explicitly include a specification of the acute exacerbation of the underlying disease. It is noted in the Federal Register that CHF, 428.0 would be deleted from the CC list. It is proposed to include only 428.21, 428.23, 428.31, 428.33, 428.41 and 428.43 (acute systolic, diastolic or acute on chronic systolic and diastolic heart failure). Your example states that those codes would be used for an acute exacerbation of congestive heart failure. However, according to the Official Coding Guidelines as stated in Fourth Quarter 2002 Coding Clinic for ICD-9-CM, these codes do not include "congestive" episodes of heart failure and would still require the use of the 428.0 code to show "congestive heart failure". The acute diastolic and systolic codes are for heart failure but do not specify them as "congestive heart failure". An additional code of 428.0 is still required. There is currently no code to state acute exacerbation of CHF. It would be necessary for a new code to be developed that simply stated CHF in acute exacerbation. This would capture those patients in a "congestive" episode of heart failure and this new code would be used as a secondary code to accompany the acute diastolic or systolic heart failure, if known.

DIABETIC MANIFESTATIONS, 250.xx:
We request that the codes for diabetes with manifestations should remain on the CC list. CMS has stated in the proposed rule that in general, a significant acute manifestation of the chronic disease must be present and coded for the patient to be assigned a CC. Exceptions were made for diagnosis codes that indicate a chronic disease in which the underlying illness has reached an advanced stage or is associated with systemic physiologic decompensation and debility. Patients with manifestations such as diabetic nephropathy, neuropathy, retinopathy etc have met these criteria and require more

resources and monitoring than a diabetic patient without manifestations. Additionally, patients may develop uncontrolled diabetes which requires changes in the management and monitoring of the patient. We request that these codes remain on the CC list.

ACUTE POSTHEMORRHAGIC ANEMIA, 285.1:
We request that this code remain on the CC list. This code is assigned when a physician documents acute post hemorrhagic anemia. It also includes acute postoperative anemia if the physician documents significant amount of blood loss resulting in anemia but does not label it as a postoperative complication. Treatment is dependent on the source of bleeding. If the source of bleeding is not identified, significant resources may be devoted to determining and controlling the source of bleeding. Even if the source of the bleeding is known and controlled, blood transfusions may be necessary. Blood transfusions represent additional resources in terms of the cost of blood storage and processing, blood administration and the significant monitoring required of these patients. Often patients that develop this condition will require closer monitoring of the condition with serial lab tests and may be given blood transfusions. Treatment may also consist of investigating the underlying source of the bleeding, thus increasing the resource utilization and costs.

HYPERTENSIVE HEART DISEASE: 402.xx
We request that codes in this range be assigned as CCs consistently. Some codes in this range such as 402.00, 402.01, 402.11 and 402.91 are considered CCs. This includes both hypertensive heart disease with and without heart failure. However, the individual codes of benign or unspecified hypertension (401.1 or 401.9) and congestive heart failure (428.0) are not CCs. We recommend that this be re-evaluated for consistency and that code 428.0 be reinstated as a cc.

CMS should address the inconsistencies within the CC list identified by physicians and hospitals. Where necessary, CMS should immediately obtain additional input from practicing physicians in the appropriate specialties to determine the standard of care and consequent increased hospital resource use. In situations where a new code is required, CMS should default to leaving the codes as CCs until new codes can be created"

Current List of Provider Roundtable Members and Sponsors

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Braxton, Shawn L. (CMS/OSORA)

From: OC AIMS Support [AIMSSupport@OC.FDA.GOV]
Sent: Tuesday, June 12, 2007 3:13 PM
To: Braxton, Shawn L. (CMS/OSORA)
Subject: FW: Public Submission

Attachments: C__Documents and Settings_jsims_My Documents_2008_PPS Acute_Comments on IPPS 2007 Final.doc

C__Documents and Settings_jsim...

-----Original Message-----
From: no-reply@erulemaking.net [mailto:no-reply@erulemaking.net]
Sent: Tuesday, June 12, 2007 2:59 PM
To: OC AIMS Support
Subject: Public Submission

Please Do Not Reply This Email.

Public Comments on Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates:========

Title: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates FR Document Number: 07-01920 Legacy Document ID:
RIN:
Publish Date: 05/03/2007 00:00:00
Submitter Info:

First Name: Scott
Last Name: Smith
Category: Hospital - HPA35
Mailing Address: P O Box 16389
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Country: United States
State or Province: MS
Postal Code: 39404-6389
Organization Name: Forrest General Hospital

Comment Info: ==========

General Comment:Forrest General Hospital is a two hospital system located in south Mississippi employing over 3,500 employees. We appreciate the opportunity to submit our comments in relation to the proposed rule, file code CMS-1533-P, published May 3, 2007. Please see the attached file for our comments.

Forrest General Hospital
Reaching out and touching lives

June 8, 2007

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

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

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the CMS proposed rule for the fiscal year 2008 hospital inpatient prospective payment system (PPS). Forrest General Hospital **supports** the comments and recommendations provided to you by the American Hospital Association, in their official comment letter dated June 4, 2007.

Listed below are items that we believe will have a substantial negative impact upon our facility, as well as many other hospitals throughout the United States.

- **DRG Reform and Proposed MS-DRGs** – We agree with the intent and purpose of the proposed MS DRG system. However, we concur with the AHA and urge CMS to allow a four-year transition period to adopt the MS-DRG methodology. This will allow hospitals and vendors the necessary time to incorporate the changes into their information systems, and ensure that the systems can adequately handle the complexities of the MS-DRG methodology. An unnecessary rush to implement a system as complex as the MS-DRGs may lend itself to issues as seen in previous changes, such as the change to Ambulatory Payor Classifications (APC).
- **Revised CC List** – We ask that CMS reconsider the proposal to remove the following diagnoses from the CC list:
  CONGESTIVE HEART FAILURE, 428.0
  DIABETIC MANIFESTATIONS, 250.xx:
  ACUTE POSTHEMORRHAGIC ANEMIA, 285.1:
  HYPERTENSIVE HEART DISEASE: 402.xx
- **DRG Reform and Proposed MS-DRGs: Behavioral Offset (Adjustment to Standardized Amount)** - We **totally oppose** the proposed "behavioral offset" adjustment, which includes a 2.4 percent cut in FY 2008 and FY 2009, to eliminate "supposed" changes in coding practices. We completely agree with the AHA comment on this proposed adjustment. Our facility has made significant improvements since the inception of DRGs, to ensure complete and accurate coding of visits, and will experience a serious negative financial impact if this rule change is implemented. We believe that CMS should look at actual data, from one complete year of facilities' coding under MS-DRG, and only then make a recommendation of offsets, **if warranted**.

- **Capital IPPS**: We oppose the zero update (0.8 percent cut) for all urban hospitals. We also oppose any consideration to eliminate the capital disproportionate share hospital (DSH) payment. These cuts will severely impair our ability to fund future capital projects, as well as maintain current obligations.
- **Hospital Quality Data** - We urge CMS to create and adopt a mechanism for hospitals and vendors to resubmit quality data when errors are discovered.
- **Labor-Related Share: Wage Index** - We oppose the consideration to use Bureau of Labor Statistics (BLS) data for purposes related to the wage index. The BLS data is not specific to the healthcare industry, and does not include items such as the cost of benefits, shift differential, and overtime.
- **Replaced Devices** - CMS proposes to reduce the amount of Medicare inpatient payment when a full or partial credit towards a replacement device is made, or the device is replaced by the vendor at no cost. **We are strongly opposed to this proposal**. The DRG payment system already takes the costs and charges of such devices into account, in the current weights based on historical data.
- **New Technology** - We agree with the AHA comment related to new funding for add-on payments for new medical services and technologies, and request that the marginal payment rate be increased to 80 percent rather than the current 50 percent.

As we noted earlier, we appreciate the opportunity to submit our comments and views concerning the proposed rule *(Vol. 72, No. 85), May 3, 2007.* While our list should not be considered all-inclusive, we feel it addresses the areas that will have the most significant negative impact on our facility as well as most other hospitals in the United States.

If you have any questions, please contact me at 601-288-1820.

Sincerely,

Scott Smith
Revenue Cycle Director
Forrest General Hospital

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COMMITTEES:
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AGRICULTURE, NUTRITION, AND FORESTRY

United States Senate

WASHINGTON, DC 20510-1401

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May 24, 2007

Mr. Herb Kuhn
Centers for Medicare and Medicaid Services
The Administrator
Post Office Box 8000
Baltimore, Maryland 21244

Dear Mr. Kuhn:

Because of the desire of this office to be responsive to all inquiries and communications, your consideration of the attached is requested.

Your findings and views, in duplicate form, along with the return of the enclosure, will be greatly appreciated. Please direct your reply to the attention of Darlee McCollum of my Washington office.

Thank you for your thoughtful attention.

Sincerely,

Richard G. Lugar
United States Senator

RGL/cgd
Enclosure

Lugar, Senator (Lugar)

From: Geraldine M. Hoyler CSC [ghoyler@cscsisters.org]
Sent: Wednesday, May 09, 2007 7:40 AM
To: Lugar, Senator (Lugar)
Subject: FY 08 IPPS Proposed Rule Senate Letter

07 MAY -9 P 10:23

Geraldine M. Hoyler CSC
General Treasurer
Sisters of the Holy Cross
309 Bertrand Hall - Saint Mary's
Notre Dame, IN 46556-5000

Dear Senator Lugar:

You should have received a "Dear Colleague" letter from Senators Ken Salazar (D-CO) and Pat Roberts (R-KS), asking you to join them in communicating to the Centers for Medicare and Medicaid Services (CMS) their strong opposition to portions of the Medicare inpatient payment proposed rule for Fiscal Year 2008.

I urge you to sign this letter to CMS to voice your objections to major cuts in hospital payments that could severely restrict Medicare beneficiary access to needed hospital services.

CMS has proposed cuts of $24 billion over five years to hospital payments by reducing inpatient prospective payments by 2.4 % under the dubious premise that implementation of a new severity adjusted Diagnosis Related Group (DRG) system will cause hospitals to "upcode" their diagnoses. The regulation provides a full market-basket update to payments of 3.3% as required by law, but then reduces payments 2.4% for a "behavioral offset," effectively reducing the update to less than 1% and far less than the increased costs of goods and services purchased by hospitals.

Congress has not passed any legislation to direct CMS to impose behavioral offsets in the inpatient prospective payment regulations. There is no justification for making a prospective cut of this magnitude without evidence of actual changes in hospital coding.

CMS also proposes to freeze capital payments for all hospitals in urban areas and to eliminate additional capital payments to large urban hospitals. This proposal cuts another $1 billion from hospital payments. Cuts in capital payments will slow adoption of much needed information technology and acquisition of advanced medical technology and equipment.

In the Fiscal Year 2008 Budget Resolutions recently passed by the House and Senate, Congress rejected the Administration's budget proposal to cut billions of dollars from hospital payments. CMS is circumventing Congress by cutting nearly $25 billion from hospital payments through the regulatory process.

We believe the -2.4% behavioral offset and the urban hospital capital cuts should be removed from the final Medicare inpatient rule. Please sign the letter to CMS requesting elimination of these two provisions.

Thank you for your consideration of this important issue.

Sincerely,

Geraldine Hoyler

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Boston Scientific

Parashar B. Patel
Vice President
Health Economics & Reimbursement

One Boston Scientific Place
Natick, MA 01760

June 12, 2007

HAND DELIVERED BY COURIER

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates (CMS-1533-P)

Dear Ms. Norwalk:

Boston Scientific Corporation appreciates the opportunity to provide comments in response to the Medicare Program's Proposed Changes to the Hospital Inpatient Prospective Payment System (IPPS) and Fiscal Year (FY) 2008 Rates (CMS-1533-P).

As the world's largest company focused on the development, manufacturing, and marketing of less-invasive medicine, Boston Scientific supplies medical devices and technologies used by the following medical specialty areas, all of which provide beneficiary care in the hospital inpatient setting:

- Cardiac Rhythm Management;
- Cardiovascular;
- Endosurgery; and
- Neuromodulation.

Executive Summary

Boston Scientific fully supports the goal of the Centers for Medicare and Medicaid Services (CMS) to improve payment accuracy in the inpatient prospective payment system and assure beneficiary access to services, including new technology. We recognize and appreciate CMS's significant efforts to address concerns expressed by Boston Scientific about consolidated, severity-adjusted DRGs in developing the proposed MS-DRGs for Fiscal Year 2008.

We also appreciate CMS's efforts to fully explore the dynamic of charge compression, exemplified by CMS's sponsorship of the Research Triangle Institute (RTI) report, which includes recommendations to address charge compression that would enhance payment accuracy. We urge CMS to adopt these recommendations in their final rule, most importantly the short-

term regression-based adjustments that would disaggregate the medical supply cost center and improve the accuracy of cost-based weights.

We also urge CMS to reconsider its use of Maryland's switch to APR-DRGs as the most appropriate comparison in estimating hospital coding behavior associated with moving to severity-based diagnosis related group (DRG) systems. Most hospitals already use all appropriate codes and have little opportunity for making behavioral changes. Rather than making a prospective adjustment in anticipation of potential behavioral changes, CMS should make a retrospective adjustment if hospital coding behavior changes in response to the introduction of MS-DRGs.

Below is a summary of our specific recommendations. Following this summary we provide additional context, discussion, and policy rationale to support our recommendations.

General Policy Recommendations

- Begin moving forward in FY 2008 with the proposed MS-DRG system with a three year transition. We believe CMS should continue on this path and not introduce another severity DRG system in the next several years, so that hospitals do not have to make multiple changes to their clinical and administrative system in the course of only a few years.

- Under MS-DRGs, CMS should consider clinical complexity and resource intensity when determining appropriate DRG assignment for cases that would not group into higher-intensity DRGs based on diagnosis codes.

- Apply a retrospective adjustment to payment weights for any behavioral changes that may occur with the implementation to MS-DRGs.

- Implement charge compression adjustments as recommended in the RTI report, especially the regression-based estimates that improve the accuracy of cost-based weights.

- Modify the proposed device replacement/recall policy to minimize administrative burdens on hospitals and align financial incentives to ensure product is returned to manufacturers to promote quality.

- Restore the capital update for all urban hospitals (a 0.8 percent cut) and the large urban hospital add-on (an additional 3 percent cut).

Specific DRG Reclassification Recommendations

- Reclassify neurostimulator procedures as requested to better align payments with resource consumption.

- Reclassify certain resource-intensive coronary stenting cases to the MCC category to better align payment with the costs of such cases.

- Reclassify vascular procedure cases with certain diagnoses combinations to CC and MCC severity levels.

- Reclassify cochlear implants to a new MDC to better recognize resource consumption and clinical homogeneity of these procedures.

- Create separate DRGs for ICD pulse generator replacements and for ICD lead replacements.

- Finalize the proposed DRG reclassifications for intracranial angioplasty and stenting.

- Reconsider Boston Scientific's application for New Tech Add-on payment for the Wingspan intracranial stent, which is used to treat patients at high risk of stroke and death without treatment alternatives.

I. Proposed MS-DRGs

Boston Scientific applauds CMS's willingness to respond positively to public comments in crafting its approach to severity of illness (SOI) DRG implementation and creating the Medicare Severity DRG system (MS-DRGs). This approach is consistent with our request last year that CMS create a severity-based DRG system on the base of current CMS DRGs.

We also believe that a change of this nature should be transitioned over a three-year period to give hospitals time to learn the new system and ease impacts on different types of hospitals, especially smaller hospitals and those in rural areas.

A major advantage of the MS-DRGs is that they reflect the many improvements made to the Medicare DRG system over the past two decades. These changes include separate DRGs for drug-eluting stents created in 2003 and further refined for FY 2005 to adjust for severity and resource use (DRGs 557 & 558).

We believe that MS-DRGs are an excellent starting point and meet the concerns of stakeholders that called for CMS DRGs to be used as the basis for a new severity DRG system. We would note, however, that there are some practical considerations if CMS decides to go with one of the other severity DRG systems based on the findings of the RAND report. Therefore, in the absence of another severity DRG system offering a compelling advantage, we believe that CMS should continue with MS-DRGs. Otherwise the prospect of moving to another severity system in a few years would pose unnecessary disruptive challenges to hospitals.

Recognizing Resource Use Intensity in MS-DRGs

BSC is concerned that in the switch to MS-DRGs, there are certain instances where procedures on certain patients that are otherwise healthy outside their disease state may intensify resource consumption. Higher levels of resource use can occur because of the use of advanced technology or as a result of a particular mix of services and/or combinations of certain diagnoses.

Two examples of this issue and its impact on multi-vessel, multi-stent cases and vascular procedures are provided in Section V entitled "Specific DRG Reclassification Recommendations."

We urge CMS to build on its positive steps, such as its categorization of major devices to the higher severity level for cochlear implants and spinal disk devices, to recognize that complexity and resource intensity can also be a key factor in determining DRG case assignment.

In the April 2006 proposed inpatient rule, CMS addressed this dynamic in its discussion on a severity system and the need to recognize complexity. CMS stated it believed "that the consolidated severity-adjusted DRG system we are proposing would need to be further refined to assign cases based on complexity as well as severity to account for technologies like the full-system dual array neurostimulator pulse generator implants that increase costs."

Building upon CMS's recognition of complexity as a key variable in determining DRG assignment, we believe that CMS should consider clinical complexity and resource intensity when determining appropriate DRG assignment for cases that would not group into CC or MCC DRGs based on diagnosis codes.

Transition Options for Blending Current DRG Weights and MS-DRG Weights
We reviewed several approaches to transition from the current DRGs to the proposed MS-DRGs. Two approaches hold the most promise. We urge CMS to consider one of these approaches as an appropriate transition to the MS-DRGs. Regardless of the method used, we urge CMS to use a three-year phase-in to transition to MS-DRGs.

Under both methods, CMS would publish only the blended relative weights. Therefore hospitals and Medicare contractors would use only one grouping software, eliminating any burden associated with using two groupers simultaneously. In addition, a three-year transition would reduce the likelihood and magnitude of any potential changes in hospital coding behavior (see discussion below).

Blending Current DRG Weights with MS-DRG Weights
In this approach, to calculate a blended cost-based weight CMS could first calculate cost-based weights using the current DRGs. CMS could then calculate cost-based weights using the MS-DRGs. The blended weight for each MS-DRG would be based on the weighted average relative weights (based on the current DRGs from which cases group into the new MS-DRG) and the MS-DRG weight. Under this approach, CMS would continue to calculate cost-based weights for the current DRGs during the first two years of the transition period. This approach recognizes that a case has different relative weights in the new system versus the current DRG system. (See Appendix 1 for an example using proposed FY 2008 relative weights.)

Blending MS-DRG Base and Severity Level Weights
Under this approach, CMS would blend the actual MS-DRG weight with the weight of the base MS-DRG. The base MS-DRG weight is determined by using expected case mix volume among severity levels. For example, if a MS-DRG was broken into two subgroups of non-CC at 90% and CC at 10%, this ratio would be used as the basis for computing the base MS-DRG weight.

Under this approach, CMS would not have to calculate weights using two different DRG systems. On the other hand, this approach does not use the current system when calculating the blended rates. (See Appendix 2 for an example using proposed FY 2008 relative weights).

Recommendations and CMS Actions Requested

- While both options have merit, we urge CMS to consider the first option described, as it would better accounts for weights that would be calculated under DRG system.

CMS's Proposed 2.4% Behavioral Offset for 2008 and 2009

As part of its MS-DRG proposal, CMS would implement an across-the-board prospective adjustment of 2.4% in FY 2008 and 2.4% in 2009 to reflect the expected increase in hospital upcoding, or higher degree of coding that does not reflect case mix volume. CMS predicts this behavior will occur because hospitals would have incentives to more fully capture all diagnoses to increase the chances of claims being grouped to higher paying CC or MCC categories.

The behavioral offset is not necessary in our judgment. First, with any new DRG system, there are coding changes and new rules that are necessary just to "break even", that is, keep revenue at a neutral level. Perhaps more importantly, hospitals have operated under the current DRGs for 23 years. Therefore, incentives have already been in existence to fully document all diagnoses, allowing few opportunities for hospitals to more fully capture diagnoses as a means of moving cases to higher severity categories.

This 2.4% adjustment relies heavily on the experience of Maryland hospitals as they moved to APR-DRGs. This comparison is flawed for several reasons. Most notably, APR DRGs have four severity levels for each base DRG, while under MS-DRGs, only about half of the subgroups have three severity levels, with the other half having one or two severity levels. Under MS-DRGs, hospitals would be less capable of upcoding because there are more limited higher severity categories to which cases can potentially be assigned. Also, APR-DRGs consider interactions between primary and secondary diagnoses, which is not true for MS-DRGs. Therefore we believe that the 2.4% estimate overstates the behavioral changes that may occur with a transition to MS-DRGs.

Prospective Adjustment Unjustified

The amount of the prospective adjustment is unprecedented and unwarranted. If CMS predictions on upcoding do not materialize, CMS will effectively pay hospitals $2.4 billion less next year with no reported means or plan of adjusting hospital payment retrospectively. If a certain measure of upcoding does occur, say 1%, hospitals would effectively be shortchanged 1.4% of their payments in FY 2008, or about $1.4 billion in the aggregate. This amounts to about $400,000, on average, for each of the 3,500 hospitals paid under the inpatient hospital prospective payment system.

We believe that in the absence of data conclusively demonstrating such a surge in coding increases, CMS should refrain from any prospective adjustment and wait until the claims data comes in to identify the existence, if any, of upcoding. Retrospective adjustments could be made

commensurate with the extent of upcoding actually observed, without disadvantage to either the Medicare trust funds or the hospitals.

Recommendations and CMS Actions Requested

- Move forward with MS-DRGs in FY 2008 as the platform for introducing severity-related changes, using a three-year transition.

- Use resource-intensity as a key driver in determining DRGs for certain cases that have diagnoses and/or procedural combinations that drive resource use outside of the limited set of diagnoses slated for higher severity groupings.

- Apply a retrospective adjustment to ensure that hospitals are not unduly penalized by anticipated coding changes that do not materialize while leaving the Medicare hospital insurance trust fund whole.

II. Charge Compression

Boston Scientific appreciates CMS's continued study of charge compression, and believes the work of RTI in studying the effects of charge compression in calculating DRG relative weights provides compelling justification for instituting the recommended adjustments.

Charge compression, a result of hospitals' practice of applying a lower percentage markup to higher cost items and services and the method used to establish relative weights, results in inaccurate payment rates. The RTI study, commissioned by CMS, confirmed that charge compression introduces a systematic bias into payment rates and recommended changes to substantially reduce this bias. RTI recommended six short-term interventions, most importantly the use of regression-based estimates to split the cost-to-charge ratio (CCR) for the "Supplies" cost center into one CCR for "Devices and Implants" and a separate CCR for "Other Supplies."

MedPAC recommends fixing charge compression
In its June 2005 Report to the Congress, MedPAC discussed how charge compression leads to inaccurate cost estimates. In its comments on the FY 2007 inpatient proposed rule, the commission stated that the problem of charge compression should be addressed. They requested that CMS investigate interim solutions, one of which was using more detailed charge information on the SAF file to split the supplies revenue center into two or more subcategories. This suggestion is very comparable to RTI's recommendation noted above.

The MedPAC recommendation to address the persistent lack of uniformity of hospital charging practices follows six years of analysis showing the impact of charge compression on payment rates. With the RTI recommendation, CMS could take a significant step in addressing the charge compression issue consistent with MedPAC's concern on the need to improve the accuracy of payment rates.

While CMS indicated the need for delay before proceeding with the RTI recommendations, we urge that they be adopted immediately. We offer the following comments on CMS's stated reasons for the delay:

1. **The combined impact of RTI's recommendation and the proposed MS-DRGs has not been studied.**

   Comment: CMS states it is reasonable to believe that the impact of RTI's recommendation should not vary significantly under the proposed MS-DRG system as the base DRGs have not changed significantly under the new proposal. The fact that RTI's recommendation is relatively independent of the proposed MS-DRG changes was confirmed by an independent study commissioned by AdvaMed. RTI's recommendation should be implemented for FY 2008 as it represents a significant improvement in payment accuracy irrespective of whether the proposed MS-DRGs are implemented.

2. **The RAND analysis of the HSRVcc methodology and its interaction with MS-DRGs and RTI's recommendation have not been completed and may create payment swings if/when HSRVcc is implemented.**

   Comment: There is no reason to delay RTI's recommendation because RAND has yet to complete its HSRVcc analysis. The RTI recommendations would reduce a systematic bias and improve the accuracy of payment rates. Therefore, implementation of RTI's recommendations should proceed, independent of any future decision on the HSRVcc methodology. Potential redistributions that arise from a necessary policy change should not be cause to delay an important step in improving the accuracy of payment rates. Implementing RTI's short-term recommendations on the same schedule as the current cost-based transition will ease the impact of potential payment redistribution and provide payment rate stability.

3. **RTI's analysis only included inpatient claims.**

   Comment: While BSC agrees that the regression should include inpatient and outpatient claims, this adjustment has a relatively minor impact on RTI's recommendation for the FY 2008 inpatient rule. If CMS is unable to incorporate outpatient claims into the regression estimate at this time, this adjustment can simply be made next year with relatively minor impact. In fact, we urge CMS to use a regression that uses both inpatient and outpatient claims when making an adjustment for charge compression for the CY 2008 outpatient prospective payment system and use the same regression for subsequent years for both the inpatient and outpatient prospective payment systems.

CMS should implement RTI's recommendations for FY 2008

RTI's recommendation for disaggregating the CCR for devices and implants from the CCR for other supplies improves the accuracy of CMS data, reduces the systematic payment rate bias from charge compression, and can be executed in a simple and concise manner using CMS's own data files. The risks cited by CMS for not implementing changes seem rather insubstantial,

and should not justify a delay in improving in payment accuracy. For these reasons BSC recommends the following:

Recommendations and CMS Actions Requested

- Adopt the short-term recommendations of the RTI report to enhance the accuracy of DRG weights.

- If CMS deems that implementing all of RTI's short-term solutions are not feasible for FY 2008, CMS should implement RTI's recommendation to use regression-based estimates to disaggregate the cost center cost-to-charge ratio (CCR) for devices and implants from the CCR for other supplies.

- CMS should apply regression-based estimates to the hospital outpatient payment system.

III. CMS Policy on Recalled or Replaced Devices

BSC supports the goal of accurate payment for services provided and recognizes the need for a payment offset for devices that are replaced without cost or where a credit is furnished to the hospital for a replaced device.

We encourage CMS to be aware that the proposal will potentially increase hospitals' administrative burden. In addition, as proposed, the adjustment may have a negative impact on the ability to identify and track patterns of device failures, one of CMS's stated goals. We believe our recommendations will help CMS achieve accurate payments while minimizing the potential disruption to quality systems that are already in place. Because of the importance of this issue, BSC will also be asking to meet with CMS to discuss our comments on this section.

CMS's proposal introduces several administrative issues that could affect device returns:

1. At the time of device explant, the assignment of condition code 49 is based on the physician's and hospital's assumption that the device being replaced within the anticipated lifecycle may not be functioning properly. However, the removed device must be returned to, and analyzed by, the manufacturer to appropriately assess the device's functionality.

2. The 20% credit threshold for the payment offset may be considered too low when considering the administrative costs associated with determining the offset.

3. Determining if the credit percentage meets the threshold is administratively burdensome for the hospital and the fiscal intermediary (FI). Such a manual determination process will prolong claims processing, extend revenue cycle times for hospital, and increase the administrative burden for fiscal intermediaries.

Proposed Process is Administratively Burdensome for Hospitals
According to CMS transmittal 741, condition code 49 would be entered on the claim only if the hospital had reason to believe that the device was replaced "...earlier than the anticipated lifecycle due to an indication that the product is not functioning properly."

Condition code 49 is intended to identify claims subject to warranty credit. However, root cause analysis by the manufacturer is often required to determine if the product is malfunctioning and subject to warranty. Under the proposed process, CMS is requiring hospitals to prematurely state device functionality and warranty status without the information needed to make that a definitive conclusion. Therefore, many claims with condition code 49 will not receive a credit, while in other cases a credit may be paid on a device for which condition code 49 was not entered on the claim.

Under CMS's proposal, a submitted claim with condition code 49 will be suspended and manual payment not made until the fiscal intermediary receives documentation of the credit amount. Such a process may cause a six to eight week delay in payment for the hospital. In addition, root cause analysis most often shows that the device was functioning properly or that the warranty period has expired. This means that most condition code 49 claims will not have a warranty credit applied resulting in claims being suspended for no reason.

While manufacturers routinely provide credits to hospitals, there are additional administrative burdens for both hospitals (determine if device costs meet offset thresholds) and FIs (review manual claims to determine if the credit thresholds are met and manually adjudicate all condition code 49 claims). In fact, historically, CMS has viewed that requiring invoices with claims is an unreasonable burden for hospitals to shoulder, as in the case of brachytherapy seeds.

Potential Unintended Consequences
Administrative barriers as well as the lengthened revenue cycle potentially create an incentive for hospitals to bypass the warranty process. To avoid this administrative burden, a hospital could simply keep or dispose of the device and not be subject to a potential warranty credit. In this circumstance, payment in full could be received in a timely manner from CMS which may create an unintended disincentive to return explanted devices to manufacturers for root cause analysis.

BSC considers any possibility of discouraging device return from hospitals to be detrimental to industry efforts at identifying trends and improving the long term reliability of current and future products. Root cause analysis of returned devices makes it possible for device manufacturers to provide important reporting to clinicians to help them understand the reliability and failure causes through established Product Performance Reports (PPR).

The option of submitting claims up front, without condition code 49, achieves timely payment. The offset can then be handled through an adjusted claim when the hospital has received a credit from the manufacturer. In order to reduce hospitals' administrative burden and encourage device returns, we recommend the following changes:

Recommendations and CMS Actions Requested

- CMS should give hospitals the option to 1) submit device replacement claims without using condition code 49 or 2) hold the claims until the warranty credit is determined.

- CMS should work with hospitals to determine if the 20% threshold is appropriate given the administrative burden associated with tracking and offsetting credits provided by manufacturers.

- CMS should standardize the data needed for hospitals to accurately report the credit while not placing undo administrative burden on the hospitals or FI/MACs.

- CMS should minimize their data requirements and only require the amount of the credit when the credit exceeds the threshold. The credit amount can be submitted by the hospital through a standardized process without need for submission of an invoice.

IV. Capital Payment Update

We are concerned about CMS's proposal to eliminate the capital update for all urban hospitals (a 0.8 percent cut) and the large urban hospital add-on (an additional 3 percent cut). We are also concerned that CMS is considering discontinuing the IME and DSH adjustments to capital payments.

Capital cuts of this magnitude will increase financial challenges for hospitals already committed to long-term investments. In addition, these cuts will increase barriers to making new investments in technology to improve data and clinical outcomes.

Medicare margins are already at historic lows based on recent MedPAC estimates, and this proposal would cause more hardship for hospitals. Therefore, we urge CMS not to proceed with the proposed changes to capital payments.

Recommendations and CMS Actions Requested

- CMS should implement current law update of 0.8 percent for FY 2008 (and appropriate update for FY 2009) for all hospitals.

- CMS should continue 3.0 percent payments to hospitals in large urban areas.

- BSC opposes future possible reductions to the IME and DSH adjustments under the capital payment system.

V. Specific DRG Reclassification Recommendations

A. Neurostimulators

Boston Scientific and other manufacturers of neurostimulators met with CMS in February 2007 to express our concerns with Medicare's future payment rates for procedures that use these devices. One of our recommendations to facilitate more appropriate payment rates was to reassign inpatient cases with a principle diagnosis code of chronic pain (ICD-9 DX codes 338.0 - 338.4) from MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services) to the DRGs in MDC 01 (Diseases and Disorders of the Nervous System). We believe that many neurostimulator cases will have a principle diagnosis of chronic pain and, therefore, should be assigned to the Nervous System MDC and not a miscellaneous MDC. We are pleased that CMS has proposed to implement this change.

In our February meeting, we also outlined other possible options that CMS might consider to align payment rates with resource utilization for neurostimulators. Although CMS did not propose any of these suggestions, it requests that we examine the effects of CMS's proposed MS-DRGs on reimbursement for neurostimulators to determine if these changes will address our concerns. Consequently, we analyzed the effects of MS-DRGs on neurostimulator cases using FY 2006 MedPAR data and found the following results:

- The new MS-DRG system does not provide appropriate payment rates for neurostimulator cases relative to the resources used for such cases.
- 78% of the SCS cases would be classified into the 2 lowest severity MS-DRGs (MS-DRGs 030 and 491) under the new proposed system.
- Standardized charges of full system (FS) spinal cord stimulation (SCS) cases are $20,845 (57%) higher than non-SCS cases across the top 6 DRGs. (See Table A)
- Standardized charges of full system peripheral nerve stimulation (PNS) cases are $10,663 (30%) higher than non-PNS cases in the 5 most frequent DRGs. (See Table B)
- Limited data on rechargeable (RC) neurostimulators exist in 2006 MedPAR data.

We identified spinal and peripheral neurostimulator cases using ICD-9 procedure codes 03.93 and 04.92 respectively. Additionally, we pulled cases in which an implantable pulse generator (IPG) was implanted using ICD-9 procedure codes 86.94 - 86.99. Full system (FS) procedures were identified when both a lead insertion procedure code (03.93 or 04.92) and an IPG code (86.94-86.99) were recorded on the same claim. Rechargeable (RC) neurostimulator cases were identified by ICD-9 procedure code 86.98. We identified the top DRGs for SCS and peripheral nerve stimulation (PNS) by using 03.93 and 04.92 only. All hospital charges were standardized using the CMS method previously published.

Table A – SCS MedPAR 2006 Results

A	B	C	D	E	F
MS-DRG	# All Cases $ All Cases	# Non-SCS $ Non-SCS	# Any FS $ Any FS	# FS NRC $ FS NRC	# FS RC $ FS RC
028	1,638 ($87,301)	1,618 ($87,498)	14 ($71,161)	12 ($69,732)	2 ($79,730)
029	2,911 ($45,853)	2,774 ($45,563)	91 ($61,906)	84 ($60,161)	7 ($82,838)
030	3,807 ($26,798)	3,398 ($24,707)	280 ($52,950)	251 ($51,347)	29 ($66,825)
460	51,315 ($58,614)	51,288 ($58,605)	15 ($80,091)	15 ($80,091)	0
490	20,031 ($29,421)	19,852 ($29,188)	126 ($62,605)	110 ($62,942)	16 ($60,290)
491	59,480 ($17,317)	58,647 ($16,889)	610 ($55,448)	552 ($55,448)	58 ($54,382)
Top 6 MS-DRGs	139,182 ($35,965)	137,577 ($35,817)	1,136 ($56,662)	1,024 ($56,223)	112 ($60,679)

Table A above illustrates that the weighted average standardized charges for any full system SCS case (column D) for the top 6 SCS DRGs is $20,845 (57%) higher than non-SCS cases (column C) across the same 6 DRGs ($56,662 vs. $35,817 respectively). Additionally, full system SCS cases (n =1,136) comprise only 0.8% of the total cases (n =139,182) resulting in a negligible impact of SCS standardized charges within those DRGs. Also, column D shows that 78% (n = 890) of the SCS cases would be classified into the 2 lowest severity MS-DRGs (MS-DRGs 030 and 491) under the new proposed system, making payment disparities even greater.

Column F shows the limits of MedPAR data available in 2006 to evaluate the resource use for rechargeable neurostimulators (RC). Because the standardized charges for full system rechargeable (RC) SCS cases in DRG 491 were actually lower ($54,382) than non-rechargeable (NRC) cases ($55,448), we decided to perform some additional research examining only the data for hospitals that billed both a RC and an NRC case in FY 2006. Our analysis revealed that only 28 hospitals billed both RC and NRC in MS-DRG 491 and 13 hospitals billed both cases for RC and NRC in MS-DRG 030. DRGs 030 and 491 are the most frequent and lowest paying SCS MS-DRGs. When we recomputed the standardized charges for MS-DRG 491 using only hospitals that billed both types of IPGs, we found that RC devices had standardized charges that were $8,010 higher than NRC.

This analysis shows the instability of the charge data for RC devices due to the low volume in the MedPAR 2006 data. The ICD-9 procedure code that identifies RC cases (code 86.98) was not in effect until October 2005 (FY 2006). According to the Social Security Act [1886(d)(s)(k)(ii)(II)], a new technology add-on payment should be available until data can be collected for 2-3 years "beginning on the date on which an inpatient hospital code is issued with respect to the service or technology." Because the volume of data on RC cases in MedPAR 2006 is low, it may be worth extending the new technology add-on payment for a third year, as

allowed by law, in order to capture more robust information on these procedures. Moreover, although Boston Scientific's Precision rechargeable SCS was approved by the FDA in April 2004, the full market release of the product was not until one year later. We did not have enough systems in our inventory to fully launch the product upon FDA approval.

Table B – PNS MedPAR 2006 Results

A	B	C	D	E	F
MS-DRG	# All Cases	# Non-PNS	# Any FS	# FS NRC	# FS RC
040	4,813 ($65,060)	4,777 ($64,994)	28 ($72,844)	28 ($72,844)	
041	7,997 ($37,517)	7,906 ($37,388)	73 ($51,452)	73 ($51,452)	
042	5,502 ($30,140)	5,283 ($29,751)	153 ($42,837)	152 ($42,468)	1 ($98,880)
675	11,787 ($24,394)	11,726 ($24,390)	23 ($35,129)	23 ($35,129)	
876	1,848 ($38,739)	1,765 ($38,622)	76 ($41,387)	76 ($41,387)	
Top 5 MS-DRGs	31,947 ($35,625)	31,457 ($35,522)	353 ($46,185)	352 ($46,035)	

Table B above illustrates that the weighted average standardized charges for any full system PNS case (column D) for the top 5 PNS DRGs is $10,663 (30%) higher than non-PNS cases (column C) across the same 5 DRGs ($46,185 vs. $35,522 respectively). Additionally, these cases (n = 353) comprise only 1.1% of the total cases (n =31,947) resulting in a negligible impact of PNS standardized charges within those DRGs.

Based on our analysis of FY 2006 MedPAR data, we make the following recommendations for implementation in FY 2008.

Recommendations and CMS Actions Requested

- Reclassify full system SCS cases in MDC 01 into MS-DRG 029 – Spinal procedures w/CC and relabel the MS-DRG as Spinal procedures w/CC or non-rechargeable neurostimulator device.

- Reclassify full system PNS cases in MDC 01 into MS-DRG 041 – Peripheral & cranial nerve and other nervous system procedures w/CC and relabel the MS-DRG as Peripheral & cranial nerve and other nervous system procedures w/CC or non-rechargeable neurostimulator device.

- Rechargeable Neurostimulators:

- Option 1 – Reclassify full system RC neurostimulator cases (ICD-9 PX code 86.98) into MS-DRGs 028 and 040 and relabel MS-DRGs accordingly to specify implantation of RC neurostimulators.

- Option 2 – Because of limited data on RC neurostimulators, extend the new technology add-on payment for RC devices for one more year, as allowed by law. 2006 MedPAR data confirms the limited use of this technology in 2006.

B. Reclassification of Certain Multi-Vessel, Multi-Stent Coronary Stenting Cases

In our analysis of standardized charges contained in 2006 MedPAR data for the procedure combinations listed below (i.e. combinations of drug-eluting (36.07) and non-drug-eluting coronary stent insertion (36.06) ICD-9-CM procedure codes with multi-vessel (00.40-00.43) and multi-stent procedure codes (00.45-00.48)[1] we found they vary substantially from the mean standardized charges associated with the DRGs to which they are proposed to be assigned. Further, the data demonstrates that our recommendations for proposed DRG grouping of these combinations clearly meet the criteria (at least a 20-percent difference in average charges between subgroups and a $4,000 difference in average charge between subgroups articulated by CMS.

Specifically, as can be seen in Table C, the mean standardized charges for DRG 247 (where these cases are currently grouped) are $40,142. Yet, when the procedural combinations we cite below are analyzed it can be seen that the mean standardized charges for these cases range from 130 to 160% of mean standardized charges in DRG 247. The dollar difference is also significant – a range of $12,138 to $24,178. Clearly the variation in charges between the subgroups and the overall DRG average meet CMS's criteria for moving cases between DRGs.

Additionally, charges for the subgroups in question are more consistent with the mean standardized charges associated with DRG 246. While the degree of consistency obviously depends upon the particular procedural combinations, it should be noted that the range in charge differential is largely within CMS's "boundary."

1

00.40	PROCEDURE ON SINGLE VESSEL; Number of vessels, unspecified
00.41	PROCEDURE ON TWO VESSELS
00.42	PROCEDURE ON THREE VESSELS
00.43	PROCEDURE ON FOUR OR MORE VESSELS
00.47	INSERTION OF THREE VASCULAR STENTS
00.48	INSERTION OF FOUR OR MORE VASCULAR STENTS

Table C - 2006 MedPAR Analysis for Proposed MS-DRG 246-247 Structure

MS-DRG	Total Discharges	Mean LOS (Days)	Mean 2006 Standardized Charges	% of DRG 247 Charges	$ Var vs. DRG 247 Charges
DRG 246 w\MCC	**32738**	**6.32**	**$62,894**		
DRG 247 w\o MCC	**280981**	**2.23**	**$40,142**		
Cases with 00.40 & 00.48	1676	2.36	$57,424	143%	$17,282
Cases with 00.41 & 00.48	2593	2.22	$60,203	150%	$20,061
Cases with 00.42 & 00.47	2235	2.17	$52,280	130%	$12,138
Cases with 00.42 & 00.48	1278	2.28	$62,996	157%	$22,854
Cases with 00.43 & 00.47	206	2.12	$53,582	133%	$13,440
Cases with 00.43 & 00.48	504	2.41	$64,320	160%	$24,178
Subtotal	8,492	2.25	$58,074	146%	$17,932

The same is also true for procedural combinations cited below as they apply to DRGs 248 and 249, the MS-DRGs for non-drug eluting coronary stents. Specifically, as can be seen in Table D, the mean standardized charges for DRG 249 are $34,920. Yet, when the procedural combinations we cite above are analyzed it can be seen that the mean standardized charges for these cases range from 136 to 188% of mean standardized charges in DRG 249, where they are currently grouped. The dollar difference is also significant - a range of $12,729 to $30,618.

As was the case with the mean standardized charges of our selected procedural combinations being closer to the mean standard charges in the higher-paying DRG in the 246/247 pair, the charges from the combinations cited below are closer to those in DRG 248 than 249. The range of variance from the mean standardized charges in DRG 248 is 15% less to 2% more of the mean standardized charges in 249.

Table D - 2006 MedPAR Analysis for Proposed MS-DRG 248-249 Structure

MS-DRG	Total Discharges	Mean LOS (Days)	Mean 2006 Standardized Charges	% of DRG 249 Charges	$ Var vs. DRG 249 Charges
DRG 248 w\MCC	**5023**	**6.52**	**$55,918**		
DRG 249 w\o MCC	**29720**	**2.54**	**$34,920**		
Cases with 00.40 & 00.48	159	3.08	$47,649	136%	$12,729
Cases with 00.41 & 00.48	129	2.60	$50,689	145%	$15,769
Cases with 00.42 & 00.48	42	2.90	$55,736	160%	$20,816
Cases with 00.43 & 00.47	<11	7.00	$65,538	188%	$30,618
Cases with 00.43 & 00.48	17	2.12	$48,958	140%	$14,038
Subtotal	349	2.85	$49,912	143%	$14,992

Given CMS's interest in improving payment accuracy and its interest as stated "to create homogeneous subgroups that are significantly different from one another in terms of resource use, that have enough volume to be meaningful, and that improve our ability to explain variance in resource use," we believe that when procedure code 36.07 is used in combination the procedural pairs in Table C and those cases are then assigned to DRG 246, and when procedure

code 36.06 is used in combination with the procedural pairs in Table D and those cases are assigned to DRG 248 the Agency will take another important step to achieving its goals.

Recommendation and CMS Action Requested

- Assign ICD-9-CM procedure code 00.66\36.07 (procedure on vessels, insertion of stent) when combined with any of the following: 00.40 & 00.48, 00.41& 00.48, 00.42 & 00.47, 00.42 & 00.48, 00.43 & 00.47 and 00.43 & 00.48 into proposed coronary drug-eluting stent MS-DRG 246 with MCC.

- Assign ICD-9-CM procedure code 00.66\36.06 (procedure on vessels, insertion of stent) when combined with any of the following 00.40 & 00.48, 00.41 & 00.48, 00.42 & 00.48, 00.43 & 00.47 and 00.43 & 00.48 into proposed coronary non-drug-eluting stent MS-DRG 248 with MCC.

C. Reassignment of Vascular Procedure Claims among Vascular Procedure MS-DRGs

We evaluated the diagnoses associated with MS-DRGs 252-254 (Vascular Procedures) to assess whether diagnoses not on the CC or MCC lists were driving higher resource utilization.

Using FY 2006 MedPAR claims, Boston Scientific reviewed costs and charges and related diagnoses for all procedures mapping into MS-DRGs 253-254 (MS-DRG 252 not analyzed as claims in this MS-DRG are already grouped into the highest paying MS-DRG for vascular procedures). We identified the following diagnosis codes that were routinely associated with substantially higher mean standardized charges (>20%) than the mean standardized charges for the MS-DRG as a whole, regardless of the procedures performed:

Table E: ICD-9-CM Diagnosis Codes Resulting in Higher Mean Standardized Charges when Reported in Combination

25070 DMII CIRC NT ST UNCNTRLD
2639 PROTEIN-CAL MALNUTR NOS
2761 HYPOSMOLALITY
2762 ACIDOSIS
27651 DEHYDRATION
2767 HYPERPOTASSEMIA
2768 HYPOPOTASSEMIA
2800 CHR BLOOD LOSS ANEMIA
2851 AC POSTHEMORRHAG ANEMIA
2875 THROMBOCYTOPENIA NOS
41071 SUBENDO INFARCT, INITIAL
4271 PAROX VENTRIC TACHYCARD
42731 ATRIAL FIBRILLATION
4401 RENAL ARTERY ATHEROSCLER

44024 ATH EXT NTV ART GNGRENE
44422 LOWER EXTREMITY EMBOLISM
4589 HYPOTENSION NOS
49121 OBS CHR BRONC W(AC) EXAC
496 CHR AIRWAY OBSTRUCT NEC
5119 PLEURAL EFFUSION NOS
5180 PULMONARY COLLAPSE
5990 URIN TRACT INFECTION NOS
6826 CELLULITIS OF LEG
6827 CELLULITIS OF FOOT
70715 ULCER OTHER PART OF FOOT
7854 GANGRENE
7907 BACTEREMIA
99662 REACT-OTH VASC DEV/GRAFT
9971 SURG COMPL-HEART
99811 HEMORRHAGE COMPLIC PROC

We then reviewed MS-DRGs 253-254 claims to determine what percentage of total claims were impacted. Our findings are summarized in the Table F below.

Table F. Analysis of FY 2006 MedPAR Data: MS-DRGs 252-254

Proposed MS DRG		Claim Volume	Standardized Charge (mean)	% Mean Std. Charges for Entire MS-DRG	% of Mean Std. Charges for Next Higher Paying MS-DRG
252 Other vascular procedures w MCC	All Cases (regardless of Diagnoses)	43,720	$51,878	n/a	n/a
253 Other vascular procedures w CC	All Cases (regardless of Diagnoses)	45,972	$40,856	n/a	n/a
	claims containing >=2 of diagnosis codes	14,797	**$51,381**	126%	**99.9%**
254 Other vascular procedures w/o CC/MCC	All Cases (regardless of Diagnoses)	58,207	$28,134	n/a	n/a
	claims containing >=2 of diagnosis codes	891	**$38,219**	136%	**93.5%**

Source: 2006 MedPAR 2006 Data

As illustrated above, claims in MS-DRG 253 having two or more of the diagnosis codes listed above have mean standardized charges that are inconsistent with those of MS-DRG 253 as a whole and are more closely aligned to claims for MS-DRG 252. The same is true for claims in MS-DRG 254 having two or more of the diagnosis codes listed above (mean standardized charges are better aligned with MS-DRG 253's mean standardized charges).

Because the diagnoses at issue are not currently on the proposed CC or MCC lists, claims containing them are likely to be assigned to MS-DRGs with payment rates that are lower than appropriate. The underpayment of these claims will no doubt continue in future years unless additional diagnoses are properly assigned to either the CC or MCC list. Moreover, these findings were not a phenomenon unique to the vascular procedure MS-DRGs. Boston Scientific also evaluated all other MS-DRGs to determine the impact of the indicated diagnoses. After narrowing the list of MS-DRGs to the top 50 based on the number of times two or more of the diagnosis codes appear, we found that situations where two or more of the diagnoses of interest were reported, mean standardized charges were more than 20% higher than the mean standardized charges for the MS-DRG as a whole for an average of 29 out of 50 MS-DRGs (58%).

To prevent underpayment of vascular procedure claims where two or more of the identified diagnosis codes are reported together, we ask that CMS assign these claims to the next higher paying MS-DRG. Such a reassignment would result in both stronger resource and clinical homogeneity across vascular procedure MS-DRGs. For these claims, the proposed change would result in greater clinical homogeneity, as patients with the listed diagnoses are obviously more severely ill than patients without them.

Recommendation and CMS Action Requested

- Reassign vascular procedure cases containing two or more of the identified diagnosis codes from MS-DRG 253 to MS-DRG 252.

- Reassign vascular procedure cases containing two or more of the identified diagnosis codes from MS-DRG 254 to MS-DRG 253.

D. Cochlear Implants

We appreciate CMS's recognition of cochlear implants (CIs) under the MS-DRG system by classifying them to MS-DRG 129, Major Head and Neck Procedures w/CC/MCC or Major Device. We understand that MS-DRG 129 has the highest weight within MDC 03, Diseases and Disorders of the Ear, Nose, Mouth, and Throat. The principal diagnoses associated with CIs are in the 389.1X series of ICD-9 diagnosis codes (sensorineural hearing loss) and these diagnosis codes are classified into MDC 03 in the MS-DRG grouper logic. Therefore, this MS-DRG classification makes sense for CIs in this situation. However, as Table G below demonstrates, even when these procedures are classified into the highest weighted MS-DRG within MDC 03,

the standardized charges are nearly $20,000 (60%) higher than all other cases within MS-DRG 129.

We believe that one possible solution to create more accurate payment rates for CIs would be to reclassify these cases into MS-DRG 024, Craniotomy with Major Device Implant or Acute Complex CNS Diagnosis w/o MCC, as was recently done for the Kinetra dual-array deep brain neurostimulator. As Table G shows, the standardized charges for MS-DRG 024 are much more similar to CI cases than to other cases with MS-DRG 129 (+$7,262 vs.-$19,995).

Table G – 2006 MedPAR Cochlear Implant Analysis Results

MDC	MS-DRG	# All Cases	# CI	# Other
03	129	1,461 ($34,919)	106 ($53,426)	1,355 ($33,471)
MDC	MS-DRG	# All Cases	# Kinetra	# Other
01	023	3,126 ($90,580)		
	024	2,594 ($60,688)	196 ($67,799)	2,398 ($60,107)
	025	204 ($38,833)		
	026	1,126 ($40,534)		
	027	14,639 ($36,188)		

In addition to resource coherence with MS-DRG 024, we also believe that CIs are clinically similar to other cases within MS-DRG 024 such as implantation of Kinetra. As described below, clinical input we have received from surgeons indicates that cochlear implantation and craniotomy procedures are clinically similar in numerous respects. Therefore we request that CMS reconsider its current position on this issue.

Both are complex surgical procedures performed in an OR under general anesthesia with common procedural components and specialized tools (e.g., operative microscopes), operative risks, requirements for specialized clinical staffing support, nursing care, monitoring and rehabilitation services, etc. In fact, while Kinetra and cochlear implants are both multi-channel neurostimulators, cochlear implants are substantially more complex devices and have 12 to 22 electrodes compared to 8 electrodes for dual-array neurostimulators used for deep brain stimulation. Also, cochlear implants remain the only device capable of replacing a human sense.

From a procedural perspective, a craniotomy requires drilling and sawing the skull to access the dura, open the dura, perform a repair or removal procedure and replace the bone flap. Cochlear implantation requires drilling of the skull to the dura to fit the neuroreceiver package, and significant and precise additional drilling in the mastoid cavity of the skull and the cochlea to gain access to the auditory branch of the 8th cranial nerve. The neuroreceiver package is secured into the bone bed in the skull, the electrode array is inserted into the scala tympani of the cochlea

and the cochleostomy is packed with fascia. Facial nerve monitoring is also typically used throughout the cochlear implantation procedure because of the need to precisely drill within millimeters of the facial nerve. Table H provides a brief comparison of the two procedures.

Table H - Comparison of Craniotomy and Cochlear Implantation Procedures

Craniotomy and Cochlear Implant Procedures	
Shave hair on the scalp	
Administer general anesthesia	
Place head on round or horseshoe-shaped headrest	
Set up and perform neural activity monitoring, e.g. facial nerve monitoring for cochlear implantation, ENG, EEG, EMG, etc.	
Make scalp incision to expose skull	
Craniotomy Procedure	**Cochlear Implant Procedure**
Drill burr holes into exposed skull	Drill bone bed in skull for implant receiver body (expose dura)
Saw between burr holes and remove bone flap (expose dura)	Drill mastoidectomy in skull to access cochlea
Open the dura to expose area for repair/removal	Drill cochleostomy
Perform repair/removal, e.g., ruptured blood vessel, blood clot, tumor	Secure implant receiver body to skull within bone bed
Replace excised bone flap	Insert electrode array through cochleostomy and pack cochleostomy
Craniotomy and Cochlear Implant Procedures	
Close muscle and skin flap	

Otologists and neurotologists typically perform skull-based surgery such as cochlear implantations and undergo specialized training similar to that received by neurosurgeons.

Cochlear implantation and craniotomies also share many of the same operative risks including surgical infections, cerebrospinal fluid leakage, flap necrosis, and risks associated with general anesthesia. In addition, there are significant, specific operative risks associated with cochlear implantation procedures including possible facial nerve damage, obliteration of the cochlea and meningitis among others.

We understand that there is a technical issue with the MS-DRG grouper software that could prevent CI inpatient cases from being reclassified into MS-DRG 024. That is, the principle diagnosis codes for hearing loss are currently classified to MDC 03 as opposed to MDC 01. We believe we have a solution to this issue. CMS can reclassify the ICD-9 diagnosis codes for sensorineural hearing loss (codes 389.1X) into MDC 01. According to the ICD-9 diagnosis coding book, these codes are already classified into the chapter on Nervous System and Sense Organ diagnosis codes. In fact, the ICD-9 book refers to these codes as "nerve conduction causing hearing loss," and it is well documented in the peer-reviewed literature and medical community that sensorineural hearing loss is a nervous system disorder. CMS recently proposed a MDC reclassification for new chronic pain diagnosis codes 338.0 - 338.4 from MDC 23 to

MDC 01 for similar reasons. When the diagnosis codes are reclassified into MDC 01, the new MS-DRG system could easily accommodate our request of reclassifying CI procedure codes (ICD-9 procedure codes 20.96 - 20.98) into MS-DRG 024.

In summary, we encourage CMS to implement the following changes with regard to cochlear implants:

Recommendations and CMS Actions Requested

- Reclassify the ICD-9 diagnosis codes for sensorineural hearing loss (codes 389.1X) into MDC 01.

- Reclassify CI procedure codes (ICD-9 procedure codes 20.96 - 20.98) into MS-DRG 024.

E. Pulse Generator Replacements

We appreciate that CMS has split out the ICD pulse generator replacements and leads (DRG 245) from the DRGs for pacemaker system implants as this breakout more closely aligns the resource use associated with these separate and distinct procedures.

To this end, we would also recommend that CMS further delineate proposed DRG 245 by creating separate DRGs for ICD lead procedures (37.95, 37.97, and 00.52) and for ICD pulse generator procedures (37.96, 37.98, and 00.54). As shown in the table below the standardized mean charges for ICD pulse generator procedures, at $62,438, are nearly 50% higher than the standardized mean charges for ICD lead procedures, at $42,045.

DRG 245 Procedure Breakdown	Claim Volume	Standardized Charges (mean)	Difference in Std. Charges (%)
Pulse Generator (37.96, 37.98, and 00.54)	3,969	$62,438	49%
Lead (37.95, 37.97, and 00.52)	2,307	$42,045	-

Separate DRGs for these vastly different procedures will better reflect charges, improve the accuracy of reimbursement, and would be more consistent with the pacemaker DRG structure which already separates pacemaker pulse generator replacements from pacemaker lead procedures. We recommend that CMS should follow through with their proposal to create separate DRGs for both ICD pulse generator replacements and for ICD lead procedures eve if MS-DRGs are not implemented for FY 2008.

Recommendation and CMS Action Requested

- Finalize proposal to create separate DRGs for ICD pulse generator replacements and for ICD lead replacements.

F. Intracranial Stents

We commend CMS for proposing to reassign intracranial angioplasty with and without stenting cases (as defined by ICD-9 code, 00.62) to the Craniotomy DRGs 1, 2, and 543, including the crosswalk to the corresponding MS-DRGs (023, 024, 025, 026, and 027) in the proposed FY 2008 inpatient payment system. We believe this reassignment places these cases in DRGs of more appropriate clinical and resource homogeneity.

Recommendation and CMS Action Requested

- Finalize the proposal to reclassify intracranial angioplasty and stenting cases (ICD-9-CM code 00.62) to DRGs 1, 2 and 543 (MS-DRGs 023, 024, 025, 026, and 027)

G. New Technology Add-On for Wingspan® Stent System with Gateway ™ PTA Balloon Catheter

CMS requested additional information in its review of the New Technology Add-on Payment application for the Wingspan® Stent System. We have sent comments to CMS on this issue separately, and urge CMS to consider the additional information that demonstrates how Wingspan meets the substantial clinical improvement and cost criteria.

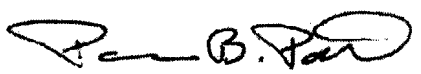
Recommendation and CMS Action Requested

- We urge CMS to approve the Wingspan® Stent System for New Technology Add-on Payment status.

* * * *

Boston Scientific supports CMS's goal of improving payment accuracy, and looks forward to working with CMS to ensure that DRG changes and technical refinements advance this objective. We appreciate the opportunity to comment on CMS's proposed hospital inpatient rule. If you or your staff has questions, please do not hesitate to contact me (508-650-8681; patelp@bsci.com).

Sincerely,



Parashar B. Patel
Vice President, Health Economics & Reimbursement

cc: Herb Kuhn, Acting Deputy Administrator
Elizabeth Richter, Acting Director, Center for Medicare Management
Marc Hartstein, Deputy Director, Division of Acute Care Service
Scott Reid, Director, Health Policy & Payment, Boston Scientific

APPENDIX 1

Example of MS-DRG Transition Using Blend of Current DRG Weight and MS-DRG Weight

						Blended Weight for 2008			Example of 3-Year Transition		
Old DRG		FY 2007 DRG Weight	Cases	Case-Wghtd. Avg. Weights				MS-DRG Weight	FY 2008	FY 2009	FY 2010
557	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W MAJOR CV DX	2.631	26,955	2.5141		246	Percutaneous cardiovascular proc w drug-eluting stent w MCC	3.3982	2.8058	3.1451	3.3982
558	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W/O MAJ CV DX	1.961	5,708	2.5141							
557	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W MAJOR CV DX	2.631	101,768	2.2045		247	Percutaneous cardiovascular proc w drug-eluting stent w/o MCC	2.0956	2.1686	2.1315	2.0956
558	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W/O MAJ CV DX	1.961	178,278	2.2045							

APPENDIX 2

Example of MS-DRG Transition Using Blend of Base MS-DRG Weight and Severity Level Weight

Blended Weight for 2008					**Example of 3-Year Transition of Base MS-DRG Weight**					
		Cases	MS-DRG Weight	Base MS-DRG Weight		FY 2008	FY 2009	FY 2010		
246	Percutaneous cardiovascular proc w drug-eluting stent w MCC	32,663	3.3982	2.2317		2.6166	3.0132	3.3982		
247	Percutaneous cardiovascular proc w drug-eluting stent w/o MCC	280,046	2.0956	2.2317		2.1868	2.1405	2.0956		
The transition MS-DRG weight is determined by blending the weights for the MS-DRG severity levels with the relative weight calculated for the base MS-DRG.										

Boston Scientific

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June 12, 2007

HAND DELIVERED BY COURIER

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates (CMS-1533-P)

Dear Ms. Norwalk:

Boston Scientific Corporation appreciates the opportunity to provide comments in response to the Medicare Program's Proposed Changes to the Hospital Inpatient Prospective Payment System (IPPS) and Fiscal Year (FY) 2008 Rates (CMS-1533-P).

As the world's largest company focused on the development, manufacturing, and marketing of less-invasive medicine, Boston Scientific supplies medical devices and technologies used by the following medical specialty areas, all of which provide beneficiary care in the hospital inpatient setting:

- Cardiac Rhythm Management;
- Cardiovascular;
- Endosurgery; and
- Neuromodulation.

Executive Summary

Boston Scientific fully supports the goal of the Centers for Medicare and Medicaid Services (CMS) to improve payment accuracy in the inpatient prospective payment system and assure beneficiary access to services, including new technology. We recognize and appreciate CMS's significant efforts to address concerns expressed by Boston Scientific about consolidated, severity-adjusted DRGs in developing the proposed MS-DRGs for Fiscal Year 2008.

We also appreciate CMS's efforts to fully explore the dynamic of charge compression, exemplified by CMS's sponsorship of the Research Triangle Institute (RTI) report, which includes recommendations to address charge compression that would enhance payment accuracy. We urge CMS to adopt these recommendations in their final rule, most importantly the short-

term regression-based adjustments that would disaggregate the medical supply cost center and improve the accuracy of cost-based weights.

We also urge CMS to reconsider its use of Maryland's switch to APR-DRGs as the most appropriate comparison in estimating hospital coding behavior associated with moving to severity-based diagnosis related group (DRG) systems. Most hospitals already use all appropriate codes and have little opportunity for making behavioral changes. Rather than making a prospective adjustment in anticipation of potential behavioral changes, CMS should make a retrospective adjustment if hospital coding behavior changes in response to the introduction of MS-DRGs.

Below is a summary of our specific recommendations. Following this summary we provide additional context, discussion, and policy rationale to support our recommendations.

General Policy Recommendations

- Begin moving forward in FY 2008 with the proposed MS-DRG system with a three year transition. We believe CMS should continue on this path and not introduce another severity DRG system in the next several years, so that hospitals do not have to make multiple changes to their clinical and administrative system in the course of only a few years.

- Under MS-DRGs, CMS should consider clinical complexity and resource intensity when determining appropriate DRG assignment for cases that would not group into higher-intensity DRGs based on diagnosis codes.

- Apply a retrospective adjustment to payment weights for any behavioral changes that may occur with the implementation to MS-DRGs.

- Implement charge compression adjustments as recommended in the RTI report, especially the regression-based estimates that improve the accuracy of cost-based weights.

- Modify the proposed device replacement/recall policy to minimize administrative burdens on hospitals and align financial incentives to ensure product is returned to manufacturers to promote quality.

- Restore the capital update for all urban hospitals (a 0.8 percent cut) and the large urban hospital add-on (an additional 3 percent cut).

Specific DRG Reclassification Recommendations

- Reclassify neurostimulator procedures as requested to better align payments with resource consumption.

- Reclassify certain resource-intensive coronary stenting cases to the MCC category to better align payment with the costs of such cases.

- Reclassify vascular procedure cases with certain diagnoses combinations to CC and MCC severity levels.

- Reclassify cochlear implants to a new MDC to better recognize resource consumption and clinical homogeneity of these procedures.

- Create separate DRGs for ICD pulse generator replacements and for ICD lead replacements.

- Finalize the proposed DRG reclassifications for intracranial angioplasty and stenting.

- Reconsider Boston Scientific's application for New Tech Add-on payment for the Wingspan intracranial stent, which is used to treat patients at high risk of stroke and death without treatment alternatives.

I. Proposed MS-DRGs

Boston Scientific applauds CMS's willingness to respond positively to public comments in crafting its approach to severity of illness (SOI) DRG implementation and creating the Medicare Severity DRG system (MS-DRGs). This approach is consistent with our request last year that CMS create a severity-based DRG system on the base of current CMS DRGs.

We also believe that a change of this nature should be transitioned over a three-year period to give hospitals time to learn the new system and ease impacts on different types of hospitals, especially smaller hospitals and those in rural areas.

A major advantage of the MS-DRGs is that they reflect the many improvements made to the Medicare DRG system over the past two decades. These changes include separate DRGs for drug-eluting stents created in 2003 and further refined for FY 2005 to adjust for severity and resource use (DRGs 557 & 558).

We believe that MS-DRGs are an excellent starting point and meet the concerns of stakeholders that called for CMS DRGs to be used as the basis for a new severity DRG system. We would note, however, that there are some practical considerations if CMS decides to go with one of the other severity DRG systems based on the findings of the RAND report. Therefore, in the absence of another severity DRG system offering a compelling advantage, we believe that CMS should continue with MS-DRGs. Otherwise the prospect of moving to another severity system in a few years would pose unnecessary disruptive challenges to hospitals.

Recognizing Resource Use Intensity in MS-DRGs

BSC is concerned that in the switch to MS-DRGs, there are certain instances where procedures on certain patients that are otherwise healthy outside their disease state may intensify resource consumption. Higher levels of resource use can occur because of the use of advanced technology or as a result of a particular mix of services and/or combinations of certain diagnoses.

Two examples of this issue and its impact on multi-vessel, multi-stent cases and vascular procedures are provided in Section V entitled "Specific DRG Reclassification Recommendations."

We urge CMS to build on its positive steps, such as its categorization of major devices to the higher severity level for cochlear implants and spinal disk devices, to recognize that complexity and resource intensity can also be a key factor in determining DRG case assignment.

In the April 2006 proposed inpatient rule, CMS addressed this dynamic in its discussion on a severity system and the need to recognize complexity. CMS stated it believed "that the consolidated severity-adjusted DRG system we are proposing would need to be further refined to assign cases based on complexity as well as severity to account for technologies like the full-system dual array neurostimulator pulse generator implants that increase costs."

Building upon CMS's recognition of complexity as a key variable in determining DRG assignment, we believe that CMS should consider clinical complexity and resource intensity when determining appropriate DRG assignment for cases that would not group into CC or MCC DRGs based on diagnosis codes.

Transition Options for Blending Current DRG Weights and MS-DRG Weights
We reviewed several approaches to transition from the current DRGs to the proposed MS-DRGs. Two approaches hold the most promise. We urge CMS to consider one of these approaches as an appropriate transition to the MS-DRGs. Regardless of the method used, we urge CMS to use a three-year phase-in to transition to MS-DRGs.

Under both methods, CMS would publish only the blended relative weights. Therefore hospitals and Medicare contractors would use only one grouping software, eliminating any burden associated with using two groupers simultaneously. In addition, a three-year transition would reduce the likelihood and magnitude of any potential changes in hospital coding behavior (see discussion below).

Blending Current DRG Weights with MS-DRG Weights
In this approach, to calculate a blended cost-based weight CMS could first calculate cost-based weights using the current DRGs. CMS could then calculate cost-based weights using the MS-DRGs. The blended weight for each MS-DRG would be based on the weighted average relative weights (based on the current DRGs from which cases group into the new MS-DRG) and the MS-DRG weight. Under this approach, CMS would continue to calculate cost-based weights for the current DRGs during the first two years of the transition period. This approach recognizes that a case has different relative weights in the new system versus the current DRG system. (See Appendix 1 for an example using proposed FY 2008 relative weights.)

Blending MS-DRG Base and Severity Level Weights
Under this approach, CMS would blend the actual MS-DRG weight with the weight of the base MS-DRG. The base MS-DRG weight is determined by using expected case mix volume among severity levels. For example, if a MS-DRG was broken into two subgroups of non-CC at 90% and CC at 10%, this ratio would be used as the basis for computing the base MS-DRG weight.

Under this approach, CMS would not have to calculate weights using two different DRG systems. On the other hand, this approach does not use the current system when calculating the blended rates. (See Appendix 2 for an example using proposed FY 2008 relative weights).

Recommendations and CMS Actions Requested

- While both options have merit, we urge CMS to consider the first option described, as it would better accounts for weights that would be calculated under DRG system.

CMS's Proposed 2.4% Behavioral Offset for 2008 and 2009

As part of its MS-DRG proposal, CMS would implement an across-the-board prospective adjustment of 2.4% in FY 2008 and 2.4% in 2009 to reflect the expected increase in hospital upcoding, or higher degree of coding that does not reflect case mix volume. CMS predicts this behavior will occur because hospitals would have incentives to more fully capture all diagnoses to increase the chances of claims being grouped to higher paying CC or MCC categories.

The behavioral offset is not necessary in our judgment. First, with any new DRG system, there are coding changes and new rules that are necessary just to "break even", that is, keep revenue at a neutral level. Perhaps more importantly, hospitals have operated under the current DRGs for 23 years. Therefore, incentives have already been in existence to fully document all diagnoses, allowing few opportunities for hospitals to more fully capture diagnoses as a means of moving cases to higher severity categories.

This 2.4% adjustment relies heavily on the experience of Maryland hospitals as they moved to APR-DRGs. This comparison is flawed for several reasons. Most notably, APR DRGs have four severity levels for each base DRG, while under MS-DRGs, only about half of the subgroups have three severity levels, with the other half having one or two severity levels. Under MS-DRGs, hospitals would be less capable of upcoding because there are more limited higher severity categories to which cases can potentially be assigned. Also, APR-DRGs consider interactions between primary and secondary diagnoses, which is not true for MS-DRGs. Therefore we believe that the 2.4% estimate overstates the behavioral changes that may occur with a transition to MS-DRGs.

Prospective Adjustment Unjustified

The amount of the prospective adjustment is unprecedented and unwarranted. If CMS predictions on upcoding do not materialize, CMS will effectively pay hospitals $2.4 billion less next year with no reported means or plan of adjusting hospital payment retrospectively. If a certain measure of upcoding does occur, say 1%, hospitals would effectively be shortchanged 1.4% of their payments in FY 2008, or about $1.4 billion in the aggregate. This amounts to about $400,000, on average, for each of the 3,500 hospitals paid under the inpatient hospital prospective payment system.

We believe that in the absence of data conclusively demonstrating such a surge in coding increases, CMS should refrain from any prospective adjustment and wait until the claims data comes in to identify the existence, if any, of upcoding. Retrospective adjustments could be made

commensurate with the extent of upcoding actually observed, without disadvantage to either the Medicare trust funds or the hospitals.

Recommendations and CMS Actions Requested

- Move forward with MS-DRGs in FY 2008 as the platform for introducing severity-related changes, using a three-year transition.

- Use resource-intensity as a key driver in determining DRGs for certain cases that have diagnoses and/or procedural combinations that drive resource use outside of the limited set of diagnoses slated for higher severity groupings.

- Apply a retrospective adjustment to ensure that hospitals are not unduly penalized by anticipated coding changes that do not materialize while leaving the Medicare hospital insurance trust fund whole.

II. Charge Compression

Boston Scientific appreciates CMS's continued study of charge compression, and believes the work of RTI in studying the effects of charge compression in calculating DRG relative weights provides compelling justification for instituting the recommended adjustments.

Charge compression, a result of hospitals' practice of applying a lower percentage markup to higher cost items and services and the method used to establish relative weights, results in inaccurate payment rates. The RTI study, commissioned by CMS, confirmed that charge compression introduces a systematic bias into payment rates and recommended changes to substantially reduce this bias. RTI recommended six short-term interventions, most importantly the use of regression-based estimates to split the cost-to-charge ratio (CCR) for the "Supplies" cost center into one CCR for "Devices and Implants" and a separate CCR for "Other Supplies."

MedPAC recommends fixing charge compression
In its June 2005 Report to the Congress, MedPAC discussed how charge compression leads to inaccurate cost estimates. In its comments on the FY 2007 inpatient proposed rule, the commission stated that the problem of charge compression should be addressed. They requested that CMS investigate interim solutions, one of which was using more detailed charge information on the SAF file to split the supplies revenue center into two or more subcategories. This suggestion is very comparable to RTI's recommendation noted above.

The MedPAC recommendation to address the persistent lack of uniformity of hospital charging practices follows six years of analysis showing the impact of charge compression on payment rates. With the RTI recommendation, CMS could take a significant step in addressing the charge compression issue consistent with MedPAC's concern on the need to improve the accuracy of payment rates.

While CMS indicated the need for delay before proceeding with the RTI recommendations, we urge that they be adopted immediately. We offer the following comments on CMS's stated reasons for the delay:

1. **The combined impact of RTI's recommendation and the proposed MS-DRGs has not been studied.**

   Comment: CMS states it is reasonable to believe that the impact of RTI's recommendation should not vary significantly under the proposed MS-DRG system as the base DRGs have not changed significantly under the new proposal. The fact that RTI's recommendation is relatively independent of the proposed MS-DRG changes was confirmed by an independent study commissioned by AdvaMed. RTI's recommendation should be implemented for FY 2008 as it represents a significant improvement in payment accuracy irrespective of whether the proposed MS-DRGs are implemented.

2. **The RAND analysis of the HSRVcc methodology and its interaction with MS-DRGs and RTI's recommendation have not been completed and may create payment swings if/when HSRVcc is implemented.**

   Comment: There is no reason to delay RTI's recommendation because RAND has yet to complete its HSRVcc analysis. The RTI recommendations would reduce a systematic bias and improve the accuracy of payment rates. Therefore, implementation of RTI's recommendations should proceed, independent of any future decision on the HSRVcc methodology. Potential redistributions that arise from a necessary policy change should not be cause to delay an important step in improving the accuracy of payment rates. Implementing RTI's short-term recommendations on the same schedule as the current cost-based transition will ease the impact of potential payment redistribution and provide payment rate stability.

3. **RTI's analysis only included inpatient claims.**

   Comment: While BSC agrees that the regression should include inpatient and outpatient claims, this adjustment has a relatively minor impact on RTI's recommendation for the FY 2008 inpatient rule. If CMS is unable to incorporate outpatient claims into the regression estimate at this time, this adjustment can simply be made next year with relatively minor impact. In fact, we urge CMS to use a regression that uses both inpatient and outpatient claims when making an adjustment for charge compression for the CY 2008 outpatient prospective payment system and use the same regression for subsequent years for both the inpatient and outpatient prospective payment systems.

CMS should implement RTI's recommendations for FY 2008

RTI's recommendation for disaggregating the CCR for devices and implants from the CCR for other supplies improves the accuracy of CMS data, reduces the systematic payment rate bias from charge compression, and can be executed in a simple and concise manner using CMS's own data files. The risks cited by CMS for not implementing changes seem rather insubstantial,

and should not justify a delay in improving in payment accuracy. For these reasons BSC recommends the following:

Recommendations and CMS Actions Requested

- Adopt the short-term recommendations of the RTI report to enhance the accuracy of DRG weights.

- If CMS deems that implementing all of RTI's short-term solutions are not feasible for FY 2008, CMS should implement RTI's recommendation to use regression-based estimates to disaggregate the cost center cost-to-charge ratio (CCR) for devices and implants from the CCR for other supplies.

- CMS should apply regression-based estimates to the hospital outpatient payment system.

III. CMS Policy on Recalled or Replaced Devices

BSC supports the goal of accurate payment for services provided and recognizes the need for a payment offset for devices that are replaced without cost or where a credit is furnished to the hospital for a replaced device.

We encourage CMS to be aware that the proposal will potentially increase hospitals' administrative burden. In addition, as proposed, the adjustment may have a negative impact on the ability to identify and track patterns of device failures, one of CMS's stated goals. We believe our recommendations will help CMS achieve accurate payments while minimizing the potential disruption to quality systems that are already in place. Because of the importance of this issue, BSC will also be asking to meet with CMS to discuss our comments on this section.

CMS's proposal introduces several administrative issues that could affect device returns:

1. At the time of device explant, the assignment of condition code 49 is based on the physician's and hospital's assumption that the device being replaced within the anticipated lifecycle may not be functioning properly. However, the removed device must be returned to, and analyzed by, the manufacturer to appropriately assess the device's functionality.

2. The 20% credit threshold for the payment offset may be considered too low when considering the administrative costs associated with determining the offset.

3. Determining if the credit percentage meets the threshold is administratively burdensome for the hospital and the fiscal intermediary (FI). Such a manual determination process will prolong claims processing, extend revenue cycle times for hospital, and increase the administrative burden for fiscal intermediaries.

Proposed Process is Administratively Burdensome for Hospitals
According to CMS transmittal 741, condition code 49 would be entered on the claim only if the hospital had reason to believe that the device was replaced "...earlier than the anticipated lifecycle due to an indication that the product is not functioning properly."

Condition code 49 is intended to identify claims subject to warranty credit. However, root cause analysis by the manufacturer is often required to determine if the product is malfunctioning and subject to warranty. Under the proposed process, CMS is requiring hospitals to prematurely state device functionality and warranty status without the information needed to make that a definitive conclusion. Therefore, many claims with condition code 49 will not receive a credit, while in other cases a credit may be paid on a device for which condition code 49 was not entered on the claim.

Under CMS's proposal, a submitted claim with condition code 49 will be suspended and manual payment not made until the fiscal intermediary receives documentation of the credit amount. Such a process may cause a six to eight week delay in payment for the hospital. In addition, root cause analysis most often shows that the device was functioning properly or that the warranty period has expired. This means that most condition code 49 claims will not have a warranty credit applied resulting in claims being suspended for no reason.

While manufacturers routinely provide credits to hospitals, there are additional administrative burdens for both hospitals (determine if device costs meet offset thresholds) and FIs (review manual claims to determine if the credit thresholds are met and manually adjudicate all condition code 49 claims). In fact, historically, CMS has viewed that requiring invoices with claims is an unreasonable burden for hospitals to shoulder, as in the case of brachytherapy seeds.

Potential Unintended Consequences
Administrative barriers as well as the lengthened revenue cycle potentially create an incentive for hospitals to bypass the warranty process. To avoid this administrative burden, a hospital could simply keep or dispose of the device and not be subject to a potential warranty credit. In this circumstance, payment in full could be received in a timely manner from CMS which may create an unintended disincentive to return explanted devices to manufacturers for root cause analysis.

BSC considers any possibility of discouraging device return from hospitals to be detrimental to industry efforts at identifying trends and improving the long term reliability of current and future products. Root cause analysis of returned devices makes it possible for device manufacturers to provide important reporting to clinicians to help them understand the reliability and failure causes through established Product Performance Reports (PPR).

The option of submitting claims up front, without condition code 49, achieves timely payment. The offset can then be handled through an adjusted claim when the hospital has received a credit from the manufacturer. In order to reduce hospitals' administrative burden and encourage device returns, we recommend the following changes:

Recommendations and CMS Actions Requested

- CMS should give hospitals the option to 1) submit device replacement claims without using condition code 49 or 2) hold the claims until the warranty credit is determined.

- CMS should work with hospitals to determine if the 20% threshold is appropriate given the administrative burden associated with tracking and offsetting credits provided by manufacturers.

- CMS should standardize the data needed for hospitals to accurately report the credit while not placing undo administrative burden on the hospitals or FI/MACs.

- CMS should minimize their data requirements and only require the amount of the credit when the credit exceeds the threshold. The credit amount can be submitted by the hospital through a standardized process without need for submission of an invoice.

IV. Capital Payment Update

We are concerned about CMS's proposal to eliminate the capital update for all urban hospitals (a 0.8 percent cut) and the large urban hospital add-on (an additional 3 percent cut). We are also concerned that CMS is considering discontinuing the IME and DSH adjustments to capital payments.

Capital cuts of this magnitude will increase financial challenges for hospitals already committed to long-term investments. In addition, these cuts will increase barriers to making new investments in technology to improve data and clinical outcomes.

Medicare margins are already at historic lows based on recent MedPAC estimates, and this proposal would cause more hardship for hospitals. Therefore, we urge CMS not to proceed with the proposed changes to capital payments.

Recommendations and CMS Actions Requested

- CMS should implement current law update of 0.8 percent for FY 2008 (and appropriate update for FY 2009) for all hospitals.

- CMS should continue 3.0 percent payments to hospitals in large urban areas.

- BSC opposes future possible reductions to the IME and DSH adjustments under the capital payment system.

V. Specific DRG Reclassification Recommendations

A. Neurostimulators

Boston Scientific and other manufacturers of neurostimulators met with CMS in February 2007 to express our concerns with Medicare's future payment rates for procedures that use these devices. One of our recommendations to facilitate more appropriate payment rates was to reassign inpatient cases with a principle diagnosis code of chronic pain (ICD-9 DX codes 338.0 – 338.4) from MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services) to the DRGs in MDC 01 (Diseases and Disorders of the Nervous System). We believe that many neurostimulator cases will have a principle diagnosis of chronic pain and, therefore, should be assigned to the Nervous System MDC and not a miscellaneous MDC. We are pleased that CMS has proposed to implement this change.

In our February meeting, we also outlined other possible options that CMS might consider to align payment rates with resource utilization for neurostimulators. Although CMS did not propose any of these suggestions, it requests that we examine the effects of CMS's proposed MS-DRGs on reimbursement for neurostimulators to determine if these changes will address our concerns. Consequently, we analyzed the effects of MS-DRGs on neurostimulator cases using FY 2006 MedPAR data and found the following results:

- The new MS-DRG system does not provide appropriate payment rates for neurostimulator cases relative to the resources used for such cases.
- 78% of the SCS cases would be classified into the 2 lowest severity MS-DRGs (MS-DRGs 030 and 491) under the new proposed system.
- Standardized charges of full system (FS) spinal cord stimulation (SCS) cases are $20,845 (57%) higher than non-SCS cases across the top 6 DRGs. (See Table A)
- Standardized charges of full system peripheral nerve stimulation (PNS) cases are $10,663 (30%) higher than non-PNS cases in the 5 most frequent DRGs. (See Table B)
- Limited data on rechargeable (RC) neurostimulators exist in 2006 MedPAR data.

We identified spinal and peripheral neurostimulator cases using ICD-9 procedure codes 03.93 and 04.92 respectively. Additionally, we pulled cases in which an implantable pulse generator (IPG) was implanted using ICD-9 procedure codes 86.94 – 86.99. Full system (FS) procedures were identified when both a lead insertion procedure code (03.93 or 04.92) and an IPG code (86.94-86.99) were recorded on the same claim. Rechargeable (RC) neurostimulator cases were identified by ICD-9 procedure code 86.98. We identified the top DRGs for SCS and peripheral nerve stimulation (PNS) by using 03.93 and 04.92 only. All hospital charges were standardized using the CMS method previously published.

Table A – SCS MedPAR 2006 Results

A	B	C	D	E	F
MS-DRG	# All Cases $ All Cases	# Non-SCS $ Non-SCS	# Any FS $ Any FS	# FS NRC $ FS NRC	# FS RC $ FS RC
028	1,638 ($87,301)	1,618 ($87,498)	14 ($71,161)	12 ($69,732)	2 ($79,730)
029	2,911 ($45,853)	2,774 ($45,563)	91 ($61,906)	84 ($60,161)	7 ($82,838)
030	3,807 ($26,798)	3,398 ($24,707)	280 ($52,950)	251 ($51,347)	29 ($66,825)
460	51,315 ($58,614)	51,288 ($58,605)	15 ($80,091)	15 ($80,091)	0
490	20,031 ($29,421)	19,852 ($29,188)	126 ($62,605)	110 ($62,942)	16 ($60,290)
491	59,480 ($17,317)	58,647 ($16,889)	610 ($55,448)	552 ($55,448)	58 ($54,382)
Top 6 MS-DRGs	139,182 ($35,965)	137,577 ($35,817)	1,136 ($56,662)	1,024 ($56,223)	112 ($60,879)

Table A above illustrates that the weighted average standardized charges for any full system SCS case (column D) for the top 6 SCS DRGs is $20,845 (57%) higher than non-SCS cases (column C) across the same 6 DRGs ($56,662 vs. $35,817 respectively). Additionally, full system SCS cases (n =1,136) comprise only 0.8% of the total cases (n =139,182) resulting in a negligible impact of SCS standardized charges within those DRGs. Also, column D shows that 78% (n = 890) of the SCS cases would be classified into the 2 lowest severity MS-DRGs (MS-DRGs 030 and 491) under the new proposed system, making payment disparities even greater.

Column F shows the limits of MedPAR data available in 2006 to evaluate the resource use for rechargeable neurostimulators (RC). Because the standardized charges for full system rechargeable (RC) SCS cases in DRG 491 were actually lower ($54,382) than non-rechargeable (NRC) cases ($55,448), we decided to perform some additional research examining only the data for hospitals that billed both a RC and an NRC case in FY 2006. Our analysis revealed that only 28 hospitals billed both RC and NRC in MS-DRG 491 and 13 hospitals billed both cases for RC and NRC in MS-DRG 030. DRGs 030 and 491 are the most frequent and lowest paying SCS MS-DRGs. When we recomputed the standardized charges for MS-DRG 491 using only hospitals that billed both types of IPGs, we found that RC devices had standardized charges that were $8,010 higher than NRC.

This analysis shows the instability of the charge data for RC devices due to the low volume in the MedPAR 2006 data. The ICD-9 procedure code that identifies RC cases (code 86.98) was not in effect until October 2005 (FY 2006). According to the Social Security Act [1886(d)(s)(k)(ii)(II)], a new technology add-on payment should be available until data can be collected for 2-3 years "beginning on the date on which an inpatient hospital code is issued with respect to the service or technology." Because the volume of data on RC cases in MedPAR 2006 is low, it may be worth extending the new technology add-on payment for a third year, as

allowed by law, in order to capture more robust information on these procedures. Moreover, although Boston Scientific's Precision rechargeable SCS was approved by the FDA in April 2004, the full market release of the product was not until one year later. We did not have enough systems in our inventory to fully launch the product upon FDA approval.

Table B – PNS MedPAR 2006 Results

A	B	C	D	E	F
MS-DRG	# All Cases	# Non-PNS	# Any FS	# FS NRC	# FS RC
040	4,813 ($65,060)	4,777 ($64,994)	28 ($72,844)	28 ($72,844)	
041	7,997 ($37,517)	7,906 ($37,388)	73 ($51,452)	73 ($51,452)	
042	5,502 ($30,140)	5,283 ($29,751)	153 ($42,837)	152 ($42,468)	1 ($98,880)
675	11,787 ($24,394)	11,726 ($24,390)	23 ($35,129)	23 ($35,129)	
876	1,848 ($38,739)	1,765 ($38,622)	76 ($41,387)	76 ($41,387)	
Top 5 MS-DRGs	31,947 ($35,625)	31,457 ($35,522)	353 ($46,185)	352 ($46,035)	

Table B above illustrates that the weighted average standardized charges for any full system PNS case (column D) for the top 5 PNS DRGs is $10,663 (30%) higher than non-PNS cases (column C) across the same 5 DRGs ($46,185 vs. $35,522 respectively). Additionally, these cases (n = 353) comprise only 1.1% of the total cases (n =31,947) resulting in a negligible impact of PNS standardized charges within those DRGs.

Based on our analysis of FY 2006 MedPAR data, we make the following recommendations for implementation in FY 2008.

Recommendations and CMS Actions Requested

- Reclassify full system SCS cases in MDC 01 into MS-DRG 029 – Spinal procedures w/CC and relabel the MS-DRG as Spinal procedures w/CC or non-rechargeable neurostimulator device.

- Reclassify full system PNS cases in MDC 01 into MS-DRG 041 – Peripheral & cranial nerve and other nervous system procedures w/CC and relabel the MS-DRG as Peripheral & cranial nerve and other nervous system procedures w/CC or non-rechargeable neurostimulator device.

- Rechargeable Neurostimulators:

- Option 1 - Reclassify full system RC neurostimulator cases (ICD-9 PX code 86.98) into MS-DRGs 028 and 040 and relabel MS-DRGs accordingly to specify implantation of RC neurostimulators.

- Option 2 - Because of limited data on RC neurostimulators, extend the new technology add-on payment for RC devices for one more year, as allowed by law. 2006 MedPAR data confirms the limited use of this technology in 2006.

B. Reclassification of Certain Multi-Vessel, Multi-Stent Coronary Stenting Cases

In our analysis of standardized charges contained in 2006 MedPAR data for the procedure combinations listed below (i.e. combinations of drug-eluting (36.07) and non-drug-eluting coronary stent insertion (36.06) ICD-9-CM procedure codes with multi-vessel (00.40-00.43) and multi-stent procedure codes (00.45-00.48)[1] we found they vary substantially from the mean standardized charges associated with the DRGs to which they are proposed to be assigned. Further, the data demonstrates that our recommendations for proposed DRG grouping of these combinations clearly meet the criteria (at least a 20-percent difference in average charges between subgroups and a $4,000 difference in average charge between subgroups articulated by CMS.

Specifically, as can be seen in Table C, the mean standardized charges for DRG 247 (where these cases are currently grouped) are $40,142. Yet, when the procedural combinations we cite below are analyzed it can be seen that the mean standardized charges for these cases range from 130 to 160% of mean standardized charges in DRG 247. The dollar difference is also significant - a range of $12,138 to $24,178. Clearly the variation in charges between the subgroups and the overall DRG average meet CMS's criteria for moving cases between DRGs.

Additionally, charges for the subgroups in question are more consistent with the mean standardized charges associated with DRG 246. While the degree of consistency obviously depends upon the particular procedural combinations, it should be noted that the range in charge differential is largely within CMS's "boundary."

1

00.40	PROCEDURE ON SINGLE VESSEL; Number of vessels, unspecified
00.41	PROCEDURE ON TWO VESSELS
00.42	PROCEDURE ON THREE VESSELS
00.43	PROCEDURE ON FOUR OR MORE VESSELS
00.47	INSERTION OF THREE VASCULAR STENTS
00.48	INSERTION OF FOUR OR MORE VASCULAR STENTS

Table C - 2006 MedPAR Analysis for Proposed MS-DRG 246-247 Structure

MS-DRG	Total Discharges	Mean LOS (Days)	Mean 2006 Standardized Charges	% of DRG 247 Charges	$ Var vs. DRG 247 Charges
DRG 246 w\MCC	**32738**	**6.32**	**$62,894**		
DRG 247 w\o MCC	**280981**	**2.23**	**$40,142**		
Cases with 00.40 & 00.48	1676	2.36	$57,424	143%	$17,282
Cases with 00.41 & 00.48	2593	2.22	$60,203	150%	$20,061
Cases with 00.42 & 00.47	2235	2.17	$52,280	130%	$12,138
Cases with 00.42 & 00.48	1278	2.28	$62,996	157%	$22,854
Cases with 00.43 & 00.47	206	2.12	$53,582	133%	$13,440
Cases with 00.43 & 00.48	504	2.41	$64,320	160%	$24,178
Subtotal	8,492	2.25	$58,074	146%	$17,932

The same is also true for procedural combinations cited below as they apply to DRGs 248 and 249, the MS-DRGs for non-drug eluting coronary stents. Specifically, as can be seen in Table D, the mean standardized charges for DRG 249 are $34,920. Yet, when the procedural combinations we cite above are analyzed it can be seen that the mean standardized charges for these cases range from 136 to 188% of mean standardized charges in DRG 249, where they are currently grouped. The dollar difference is also significant – a range of $12,729 to $30,618.

As was the case with the mean standardized charges of our selected procedural combinations being closer to the mean standard charges in the higher-paying DRG in the 246/247 pair, the charges from the combinations cited below are closer to those in DRG 248 than 249. The range of variance from the mean standardized charges in DRG 248 is 15% less to 2% more of the mean standardized charges in 249.

Table D - 2006 MedPAR Analysis for Proposed MS-DRG 248-249 Structure

MS-DRG	Total Discharges	Mean LOS (Days)	Mean 2006 Standardized Charges	% of DRG 249 Charges	$ Var vs. DRG 249 Charges
DRG 248 w\MCC	**5023**	**6.52**	**$55,918**		
DRG 249 w\o MCC	**29720**	**2.54**	**$34,920**		
Cases with 00.40 & 00.48	159	3.08	$47,649	136%	$12,729
Cases with 00.41 & 00.48	129	2.60	$50,689	145%	$15,769
Cases with 00.42 & 00.48	42	2.90	$55,736	160%	$20,816
Cases with 00.43 & 00.47	<11	7.00	$65,538	188%	$30,618
Cases with 00.43 & 00.48	17	2.12	$48,958	140%	$14,038
Subtotal	349	2.85	$49,912	143%	$14,992

Given CMS's interest in improving payment accuracy and its interest as stated "to create homogeneous subgroups that are significantly different from one another in terms of resource use, that have enough volume to be meaningful, and that improve our ability to explain variance in resource use," we believe that when procedure code 36.07 is used in combination the procedural pairs in Table C and those cases are then assigned to DRG 246, and when procedure

code 36.06 is used in combination with the procedural pairs in Table D and those cases are assigned to DRG 248 the Agency will take another important step to achieving its goals.

Recommendation and CMS Action Requested

- Assign ICD-9-CM procedure code 00.66\36.07 (procedure on vessels, insertion of stent) when combined with any of the following: 00.40 & 00.48, 00.41& 00.48, 00.42 & 00.47, 00.42 & 00.48, 00.43 & 00.47 and 00.43 & 00.48 into proposed coronary drug-eluting stent MS-DRG 246 with MCC.

- Assign ICD-9-CM procedure code 00.66\36.06 (procedure on vessels, insertion of stent) when combined with any of the following 00.40 & 00.48, 00.41 & 00.48, 00.42 & 00.48, 00.43 & 00.47 and 00.43 & 00.48 into proposed coronary non-drug-eluting stent MS-DRG 248 with MCC.

C. Reassignment of Vascular Procedure Claims among Vascular Procedure MS-DRGs

We evaluated the diagnoses associated with MS-DRGs 252-254 (Vascular Procedures) to assess whether diagnoses not on the CC or MCC lists were driving higher resource utilization.

Using FY 2006 MedPAR claims, Boston Scientific reviewed costs and charges and related diagnoses for all procedures mapping into MS-DRGs 253-254 (MS-DRG 252 not analyzed as claims in this MS-DRG are already grouped into the highest paying MS-DRG for vascular procedures). We identified the following diagnosis codes that were routinely associated with substantially higher mean standardized charges (≥20%) than the mean standardized charges for the MS-DRG as a whole, regardless of the procedures performed:

Table E: ICD-9-CM Diagnosis Codes Resulting in Higher Mean Standardized Charges when Reported in Combination

25070 DMII CIRC NT ST UNCNTRLD
2639 PROTEIN-CAL MALNUTR NOS
2761 HYPOSMOLALITY
2762 ACIDOSIS
27651 DEHYDRATION
2767 HYPERPOTASSEMIA
2768 HYPOPOTASSEMIA
2800 CHR BLOOD LOSS ANEMIA
2851 AC POSTHEMORRHAG ANEMIA
2875 THROMBOCYTOPENIA NOS
41071 SUBENDO INFARCT, INITIAL
4271 PAROX VENTRIC TACHYCARD
42731 ATRIAL FIBRILLATION
4401 RENAL ARTERY ATHEROSCLER

44024 ATH EXT NTV ART GNGRENE
44422 LOWER EXTREMITY EMBOLISM
4589 HYPOTENSION NOS
49121 OBS CHR BRONC W(AC) EXAC
496 CHR AIRWAY OBSTRUCT NEC
5119 PLEURAL EFFUSION NOS
5180 PULMONARY COLLAPSE
5990 URIN TRACT INFECTION NOS
6826 CELLULITIS OF LEG
6827 CELLULITIS OF FOOT
70715 ULCER OTHER PART OF FOOT
7854 GANGRENE
7907 BACTEREMIA
99662 REACT-OTH VASC DEV/GRAFT
9971 SURG COMPL-HEART
99811 HEMORRHAGE COMPLIC PROC

We then reviewed MS-DRGs 253-254 claims to determine what percentage of total claims were impacted. Our findings are summarized in the Table F below.

Table F. Analysis of FY 2006 MedPAR Data: MS-DRGs 252-254

Proposed MS DRG		**Claim Volume**	**Standardized Charge (mean)**	**% Mean Std. Charges for Entire MS-DRG**	**% of Mean Std. Charges for Next Higher Paying MS-DRG**
252 Other vascular procedures w MCC	All Cases (regardless of Diagnoses)	43,720	$51,878	n/a	n/a
253 Other vascular procedures w CC	All Cases (regardless of Diagnoses)	45,972	$40,856	n/a	n/a
	claims containing >=2 of diagnosis codes	14,797	**$51,381**	126%	**99.9%**
254 Other vascular procedures w/o CC/MCC	All Cases (regardless of Diagnoses)	58,207	$28,134	n/a	n/a
	claims containing >=2 of diagnosis codes	891	**$38,219**	136%	**93.5%**

Source: 2006 MedPAR 2006 Data

As illustrated above, claims in MS-DRG 253 having two or more of the diagnosis codes listed above have mean standardized charges that are inconsistent with those of MS-DRG 253 as a whole and are more closely aligned to claims for MS-DRG 252. The same is true for claims in MS-DRG 254 having two or more of the diagnosis codes listed above (mean standardized charges are better aligned with MS-DRG 253's mean standardized charges).

Because the diagnoses at issue are not currently on the proposed CC or MCC lists, claims containing them are likely to be assigned to MS-DRGs with payment rates that are lower than appropriate. The underpayment of these claims will no doubt continue in future years unless additional diagnoses are properly assigned to either the CC or MCC list. Moreover, these findings were not a phenomenon unique to the vascular procedure MS-DRGs. Boston Scientific also evaluated all other MS-DRGs to determine the impact of the indicated diagnoses. After narrowing the list of MS-DRGs to the top 50 based on the number of times two or more of the diagnosis codes appear, we found that situations where two or more of the diagnoses of interest were reported, mean standardized charges were more than 20% higher than the mean standardized charges for the MS-DRG as a whole for an average of 29 out of 50 MS-DRGs (58%).

To prevent underpayment of vascular procedure claims where two or more of the identified diagnosis codes are reported together, we ask that CMS assign these claims to the next higher paying MS-DRG. Such a reassignment would result in both stronger resource and clinical homogeneity across vascular procedure MS-DRGs. For these claims, the proposed change would result in greater clinical homogeneity, as patients with the listed diagnoses are obviously more severely ill than patients without them.

Recommendation and CMS Action Requested

- Reassign vascular procedure cases containing two or more of the identified diagnosis codes from MS-DRG 253 to MS-DRG 252.

- Reassign vascular procedure cases containing two or more of the identified diagnosis codes from MS-DRG 254 to MS-DRG 253.

D. Cochlear Implants

We appreciate CMS's recognition of cochlear implants (CIs) under the MS-DRG system by classifying them to MS-DRG 129, Major Head and Neck Procedures w/CC/MCC or Major Device. We understand that MS-DRG 129 has the highest weight within MDC 03, Diseases and Disorders of the Ear, Nose, Mouth, and Throat. The principal diagnoses associated with CIs are in the 389.1X series of ICD-9 diagnosis codes (sensorineural hearing loss) and these diagnosis codes are classified into MDC 03 in the MS-DRG grouper logic. Therefore, this MS-DRG classification makes sense for CIs in this situation. However, as Table G below demonstrates, even when these procedures are classified into the highest weighted MS-DRG within MDC 03,

the standardized charges are nearly $20,000 (60%) higher than all other cases within MS-DRG 129.

We believe that one possible solution to create more accurate payment rates for CIs would be to reclassify these cases into MS-DRG 024, Craniotomy with Major Device Implant or Acute Complex CNS Diagnosis w/o MCC, as was recently done for the Kinetra dual-array deep brain neurostimulator. As Table G shows, the standardized charges for MS-DRG 024 are much more similar to CI cases than to other cases with MS-DRG 129 (+$7,262 vs.-$19,995).

Table G – 2006 MedPAR Cochlear Implant Analysis Results

MDC	MS-DRG	# All Cases	# CI	# Other
03	129	1,461 ($34,919)	106 ($53,426)	1,355 ($33,471)
MDC	MS-DRG	# All Cases	# Kinetra	# Other
01	023	3,126 ($90,580)		
	024	2,594 ($60,688)	196 ($67,799)	2,398 ($60,107)
	025	204 ($38,833)		
	026	1,126 ($40,534)		
	027	14,639 ($36,188)		

In addition to resource coherence with MS-DRG 024, we also believe that CIs are clinically similar to other cases within MS-DRG 024 such as implantation of Kinetra. As described below, clinical input we have received from surgeons indicates that cochlear implantation and craniotomy procedures are clinically similar in numerous respects. Therefore we request that CMS reconsider its current position on this issue.

Both are complex surgical procedures performed in an OR under general anesthesia with common procedural components and specialized tools (e.g., operative microscopes), operative risks, requirements for specialized clinical staffing support, nursing care, monitoring and rehabilitation services, etc. In fact, while Kinetra and cochlear implants are both multi-channel neurostimulators, cochlear implants are substantially more complex devices and have 12 to 22 electrodes compared to 8 electrodes for dual-array neurostimulators used for deep brain stimulation. Also, cochlear implants remain the only device capable of replacing a human sense.

From a procedural perspective, a craniotomy requires drilling and sawing the skull to access the dura, open the dura, perform a repair or removal procedure and replace the bone flap. Cochlear implantation requires drilling of the skull to the dura to fit the neuroreceiver package, and significant and precise additional drilling in the mastoid cavity of the skull and the cochlea to gain access to the auditory branch of the 8th cranial nerve. The neuroreceiver package is secured into the bone bed in the skull, the electrode array is inserted into the scala tympani of the cochlea

and the cochleostomy is packed with fascia. Facial nerve monitoring is also typically used throughout the cochlear implantation procedure because of the need to precisely drill within millimeters of the facial nerve. Table H provides a brief comparison of the two procedures.

Table H - Comparison of Craniotomy and Cochlear Implantation Procedures

Craniotomy and Cochlear Implant Procedures	
Shave hair on the scalp	
Administer general anesthesia	
Place head on round or horseshoe-shaped headrest	
Set up and perform neural activity monitoring, e.g. facial nerve monitoring for cochlear implantation, ENG, EEG, EMG, etc.	
Make scalp incision to expose skull	
Craniotomy Procedure	**Cochlear Implant Procedure**
Drill burr holes into exposed skull	Drill bone bed in skull for implant receiver body (expose dura)
Saw between burr holes and remove bone flap (expose dura)	Drill mastoidectomy in skull to access cochlea
Open the dura to expose area for repair/removal	Drill cochleostomy
Perform repair/removal, e.g., ruptured blood vessel, blood clot, tumor	Secure implant receiver body to skull within bone bed
Replace excised bone flap	Insert electrode array through cochleostomy and pack cochleostomy
Craniotomy and Cochlear Implant Procedures	
Close muscle and skin flap	

Otologists and neurotologists typically perform skull-based surgery such as cochlear implantations and undergo specialized training similar to that received by neurosurgeons.

Cochlear implantation and craniotomies also share many of the same operative risks including surgical infections, cerebrospinal fluid leakage, flap necrosis, and risks associated with general anesthesia. In addition, there are significant, specific operative risks associated with cochlear implantation procedures including possible facial nerve damage, obliteration of the cochlea and meningitis among others.

We understand that there is a technical issue with the MS-DRG grouper software that could prevent CI inpatient cases from being reclassified into MS-DRG 024. That is, the principle diagnosis codes for hearing loss are currently classified to MDC 03 as opposed to MDC 01. We believe we have a solution to this issue. CMS can reclassify the ICD-9 diagnosis codes for sensorineural hearing loss (codes 389.1X) into MDC 01. According to the ICD-9 diagnosis coding book, these codes are already classified into the chapter on Nervous System and Sense Organ diagnosis codes. In fact, the ICD-9 book refers to these codes as "nerve conduction causing hearing loss," and it is well documented in the peer-reviewed literature and medical community that sensorineural hearing loss is a nervous system disorder. CMS recently proposed a MDC reclassification for new chronic pain diagnosis codes 338.0 - 338.4 from MDC 23 to

MDC 01 for similar reasons. When the diagnosis codes are reclassified into MDC 01, the new MS-DRG system could easily accommodate our request of reclassifying CI procedure codes (ICD-9 procedure codes 20.96 - 20.98) into MS-DRG 024.

In summary, we encourage CMS to implement the following changes with regard to cochlear implants:

Recommendations and CMS Actions Requested

- Reclassify the ICD-9 diagnosis codes for sensorineural hearing loss (codes 389.1X) into MDC 01.
- Reclassify CI procedure codes (ICD-9 procedure codes 20.96 - 20.98) into MS-DRG 024.

E. Pulse Generator Replacements

We appreciate that CMS has split out the ICD pulse generator replacements and leads (DRG 245) from the DRGs for pacemaker system implants as this breakout more closely aligns the resource use associated with these separate and distinct procedures.

To this end, we would also recommend that CMS further delineate proposed DRG 245 by creating separate DRGs for ICD lead procedures (37.95, 37.97, and 00.52) and for ICD pulse generator procedures (37.96, 37.98, and 00.54). As shown in the table below the standardized mean charges for ICD pulse generator procedures, at $62,438, are nearly 50% higher than the standardized mean charges for ICD lead procedures, at $42,045.

DRG 245 Procedure Breakdown	Claim Volume	Standardized Charges (mean)	Difference in Std. Charges (%)
Pulse Generator (37.96, 37.98, and 00.54)	3,969	$62,438	49%
Lead (37.95, 37.97, and 00.52)	2,307	$42,045	-

Separate DRGs for these vastly different procedures will better reflect charges, improve the accuracy of reimbursement, and would be more consistent with the pacemaker DRG structure which already separates pacemaker pulse generator replacements from pacemaker lead procedures. We recommend that CMS should follow through with their proposal to create separate DRGs for both ICD pulse generator replacements and for ICD lead procedures eve if MS-DRGs are not implemented for FY 2008.

Recommendation and CMS Action Requested

- Finalize proposal to create separate DRGs for ICD pulse generator replacements and for ICD lead replacements.

F. Intracranial Stents

We commend CMS for proposing to reassign intracranial angioplasty with and without stenting cases (as defined by ICD-9 code, 00.62) to the Craniotomy DRGs 1, 2, and 543, including the crosswalk to the corresponding MS-DRGs (023, 024, 025, 026, and 027) in the proposed FY 2008 inpatient payment system. We believe this reassignment places these cases in DRGs of more appropriate clinical and resource homogeneity.

Recommendation and CMS Action Requested

- Finalize the proposal to reclassify intracranial angioplasty and stenting cases (ICD-9-CM code 00.62) to DRGs 1, 2 and 543 (MS-DRGs 023, 024, 025, 026, and 027)

G. New Technology Add-On for Wingspan® Stent System with Gateway ™ PTA Balloon Catheter

CMS requested additional information in its review of the New Technology Add-on Payment application for the Wingspan® Stent System. We have sent comments to CMS on this issue separately, and urge CMS to consider the additional information that demonstrates how Wingspan meets the substantial clinical improvement and cost criteria.

Recommendation and CMS Action Requested

- We urge CMS to approve the Wingspan® Stent System for New Technology Add-on Payment status.

* * * *

Boston Scientific supports CMS's goal of improving payment accuracy, and looks forward to working with CMS to ensure that DRG changes and technical refinements advance this objective. We appreciate the opportunity to comment on CMS's proposed hospital inpatient rule. If you or your staff has questions, please do not hesitate to contact me (508-650-8681; patelp@bsci.com).

Sincerely,

Parashar B. Patel
Vice President, Health Economics & Reimbursement

cc: Herb Kuhn, Acting Deputy Administrator
Elizabeth Richter, Acting Director, Center for Medicare Management
Marc Hartstein, Deputy Director, Division of Acute Care Service
Scott Reid, Director, Health Policy & Payment, Boston Scientific

APPENDIX 1

Example of MS-DRG Transition Using Blend of Current DRG Weight and MS-DRG Weight

					Blended Weight for 2008			Example of 3-Year Transition		
Old DRG		FY 2007 DRG Weight	Cases	Case-Wghtd. Avg. Weights			MS-DRG Weight	FY 2008	FY 2009	FY 2010
557	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W MAJOR CV DX	2.631	26,955	2.5141	246	Percutaneous cardiovascular proc w drug-eluting stent w MCC	3.3982	2.8058	3.1451	3.3982
558	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W/O MAJ CV DX	1.961	5,708	2.5141						
557	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W MAJOR CV DX	2.631	101,768	2.2045	247	Percutaneous cardiovascular proc w drug-eluting stent w/o MCC	2.0956	2.1686	2.1315	2.0956
558	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W/O MAJ CV DX	1.961	178,278	2.2045						

APPENDIX 2

Example of MS-DRG Transition Using Blend of Base MS-DRG Weight and Severity Level Weight

Blended Weight for 2008					**Example of 3-Year Transition of Base MS-DRG Weight**				
		Cases	MS-DRG Weight	Base MS-DRG Weight		FY 2008	FY 2009	FY 2010	
246	Percutaneous cardiovascular proc w drug-eluting stent w MCC	32,663	3.3982	2.2317		2.6166	3.0132	3.3982	
247	Percutaneous cardiovascular proc w drug-eluting stent w/o MCC	280,046	2.0956	2.2317		2.1868	2.1405	2.0956	
The transition MS-DRG weight is determined by blending the weights for the MS-DRG severity levels with the relative weight calculated for the base MS-DRG.									

Rec'd 6/12/07

CATHOLIC HEALTH INITIATIVES

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(2)

Memorial Health Care System

June 11, 2007

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

REF: CMS-1533-P

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

Dear Ms. Norwalk:

Memorial Health Care System appreciates the opportunity to comment on the proposed rule CMS-1533 -P. Memorial Health Care System is part of Catholic Health Initiatives, a faith-based, mission-driven health system that includes 72 hospitals, 42 long-term care, assisted-living and residential units, and two community health service organizations in 19 states.

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

DRG REFORM AND PROPOSED MS-DRGS:

Severity of Illness

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

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

Memorial Health Care System supports the adoption of a new or revised DRG classification system to better account for differences in patient severity and resource consumption. The

proposed MS-DRG system may be a substantial improvement over the current system. However, the proposed changes have not been reviewed by the RAND Corporation, the company retained by CMS to evaluate alternative classification systems. We believe an independent review and evaluation of the MS-DRGs should be undertaken before the new system is implemented to make sure this is the best approach.

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

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

Behavioral Offset

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

This behavioral offset would cause significant and unjustified financial harm to Memorial Health Care System. The behavioral offset appears to be a back-door attempt to budget cut rather than a valid regulatory proposal.

Inpatient hospitals have operated under the current DRG system for 23 years. The proposed MS-DRGs would be a refinement of the existing system; the underlying classification of patients and "rules of thumb" for coding would be the same.

There is no evidence that an adjustment of 4.8 percent over two years is warranted when studies by RAND, looking at claims between 1986 and 1987 at the beginning of the inpatient prospective payment system (PPS), showed only a 0.8% growth in case mix due to coding. Even moving from the original cost-based system to a new patient classification-based PPS did not generate the type of coding changes CMS contends will occur under the MS-DRGs.

Once MS-DRGs are fully implemented, CMS can investigate whether payments have increased due to coding rather than the severity of patients and determine if an adjustment is necessary. CMS is not required to make an adjustment beforehand and should not do so without an understanding of whether there will even be coding changes in the first few

years of a refined system. CMS can always correct for additional payments made as a result of coding change in a later year if there is sufficient evidence to warrant an adjustment.

Memorial Health Care System urges CMS to remove the 2.4 percent behavioral offset for FY 2008 and FY 2009.

CAPITAL IPPS:

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

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

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

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

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

Memorial Health Care System urges CMS to provide a full update in FY 2008 for urban and rural capital payments; maintain the large urban hospital capital add-on; eliminate the -2.4 percent behavioral offset for capital payments; and continue indirect medical education and disproportionate share hospital adjustments to capital payments.

HOSPITAL ACQUIRED CONDITIONS:

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

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

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

The remaining three of the six proposed conditions – catheter-associated urinary tract infections, pressure ulcers and staphylococcus aureus septicemia – are serious concerns but these conditions are not ready for inclusion in FY 2009. The correct identification of all three of these conditions will rely on the correct identification and coding of conditions that are present on admission. CMS implementation of present-on-admission coding has been pushed back to January 1, 2008 due to technical difficulties. Implementing a present-on-admission coding indicator will be a major challenge for hospitals and it will take time and intense educational efforts to achieve reliable data.

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

HOSPITAL QUALITY DATA:

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

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

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

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

RURAL FLOOR:

CMS proposes applying the budget-neutrality adjustment associated with the rural floor to the wage index rather than the standardized amount in FY 2008.

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

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

Memorial Health Care System urges CMS to remove the compounding effect of applying the budget-neutrality adjustment for the rural floor to the standardized amount annually since 1998.

Thank you for the opportunity to review and comment on the proposed IPPS rule for Fiscal Year 2008.

Sincerely,

Ruth W. Brinkley

Ruth W. Brinkley
President & Chief Executive Officer
Memorial Health Care System

141-1

CATHOLIC HEALTH INITIATIVES

Memorial
Health Care System

June 11, 2007

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

REF: CMS-1533-P

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

Dear Ms. Norwalk:

Memorial Health Care System appreciates the opportunity to comment on the proposed rule CMS-1533 -P. Memorial Health Care System is part of Catholic Health Initiatives, a faith-based, mission-driven health system that includes 72 hospitals, 42 long-term care, assisted-living and residential units, and two community health service organizations in 19 states.

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

DRG REFORM AND PROPOSED MS-DRGS:

Severity of Illness

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

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

Memorial Health Care System supports the adoption of a new or revised DRG classification system to better account for differences in patient severity and resource consumption. The proposed MS-DRG system may be a substantial improvement over the current system.

However, the proposed changes have not been reviewed by the RAND Corporation, the company retained by CMS to evaluate alternative classification systems. We believe an independent review and evaluation of the MS-DRGs should be undertaken before the new system is implemented to make sure this is the best approach.

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

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

Behavioral Offset

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

This behavioral offset would cause significant and unjustified financial harm to Memorial Health Care System. The behavioral offset appears to be a back-door attempt to budget cut rather than a valid regulatory proposal.

Inpatient hospitals have operated under the current DRG system for 23 years. The proposed MS-DRGs would be a refinement of the existing system; the underlying classification of patients and "rules of thumb" for coding would be the same.

There is no evidence that an adjustment of 4.8 percent over two years is warranted when studies by RAND, looking at claims between 1986 and 1987 at the beginning of the inpatient prospective payment system (PPS), showed only a 0.8% growth in case mix due to coding. Even moving from the original cost-based system to a new patient classification-based PPS did not generate the type of coding changes CMS contends will occur under the MS-DRGs.

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

result of coding change in a later year if there is sufficient evidence to warrant an adjustment.

Memorial Health Care System urges CMS to remove the 2.4 percent behavioral offset for FY 2008 and FY 2009.

CAPITAL IPPS:

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

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

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

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

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

Memorial Health Care System urges CMS to provide a full update in FY 2008 for urban and rural capital payments; maintain the large urban hospital capital add-on; eliminate the -2.4 percent behavioral offset for capital payments; and continue indirect medical education and disproportionate share hospital adjustments to capital payments.

HOSPITAL ACQUIRED CONDITIONS:

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

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

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

The remaining three of the six proposed conditions – catheter-associated urinary tract infections, pressure ulcers and staphylococcus aureus septicemia – are serious concerns but these conditions are not ready for inclusion in FY 2009. The correct identification of all three of these conditions will rely on the correct identification and coding of conditions that are present on admission. CMS implementation of present-on-admission coding has been pushed back to January 1, 2008 due to technical difficulties. Implementing a present-on-admission coding indicator will be a major challenge for hospitals and it will take time and intense educational efforts to achieve reliable data.

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

HOSPITAL QUALITY DATA:

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

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

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

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

RURAL FLOOR:

CMS proposes applying the budget-neutrality adjustment associated with the rural floor to the wage index rather than the standardized amount in FY 2008.

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

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

Memorial Health Care System urges CMS to remove the compounding effect of applying the budget-neutrality adjustment for the rural floor to the standardized amount annually since 1998.

Thank you for the opportunity to review and comment on the proposed IPPS rule for Fiscal Year 2008.

Sincerely,

Carol Newton

Carol Newton
Senior Vice President & Chief Financial Officer
Memorial Health Care System

IPPS Hard Copy 142

~~CMS-1551-P-3~~ **Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2008**

Submitter : Kimber Langton NOT **Date & Time:** 06/08/2007

Organization : Kimber Langton IRF

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

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

You propose the following titles for these MS-DRGs:

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

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

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

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

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

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

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

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

Thank you for your time!

Hard Copy Inpt Orig

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~~CMS-2258-EC-1~~ **Cost LImit for Providers Operated by Units of Government and Provisions to Ensure the Integrity of Federal-State Financial Partnership**

Submitter : **Mr. Martin Richman** **Date & Time:** **06/08/2007**

Organization : **Jamestown Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

We are opposed to Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates; Proposed Rule (Vol. 72,, No. 85), May 3, 2007.
Martin I Richman
CEO
Jamestown Hospital
Jamestown, N.D.

1421

May 3, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20510

Dear Ms. Norwalk:

We, the undersigned hospital organizations, write to urge you to eliminate two provisions in the proposed rule for the FY 2008 hospital inpatient prospective payment system (PPS). At a time when increasing numbers of people rely on the Medicare program for their health care, it is necessary to strengthen the ability of hospitals to care for patients. Yet, inexplicably, the Centers for Medicare & Medicaid Services (CMS) has chosen a different course, one that would weaken hospitals' ability to provide needed services. In its proposed rule, CMS offers two proposals that cut, by $25 billion over the next five years, Medicare payments for hospital services provided to America's seniors and disabled. The first proposal would cut all operating and capital inpatient payments by 2.4 percent in each of FY 2008 and FY 2009 for coding changes that CMS believes "might" happen with the implementation of its proposed changes to the diagnosis-related groups (DRG) classification system. The second proposal would reduce capital payments to hospitals located in urban areas. We strongly urge you to eliminate both provisions from the final regulation.

2.4 Percent Cut for Coding Changes = $24 billion over the next 5 years
CMS bases its proposal to cut hospital operating and capital payments on its misinformed concerns that hospitals would change their coding practices in response to a CMS proposal to modify the existing DRGs to account better for patients' severity of illness. CMS' proposal would reconfigure the existing 538 DRGs into 745 refined Medicare Severity DRGs (MS-DRGs). The underlying system of classifying patients and "rules of thumb" for coding under the proposed MS-DRGs is generally the same as current practice. Therefore, hospitals will have little ability to change their classification and coding practices.

There are no relevant data or experiences to support a prospective 2.4 percent cut for anticipated behavioral changes in each of the next two years. Not even in the initial years of the inpatient PPS was coding change found to be of the magnitude of CMS' proposed cuts for FY 2008 and FY 2009. This type of behavioral offset is unprecedented and unnecessary. CMS' rationale for the 2.4 percent cut stems from the recent transition of Maryland hospitals, which are excluded from Medicare's inpatient PPS, to a completely new type of classification and coding system called All Patient Refined DRGs (APR-DRGs). MS-DRGs and APR-DRGs are two completely different systems for classifying patients, and generalizing from one to the other is completely inappropriate.

Inpatient PPS hospitals have been coding under the DRG system since 1983. That's more than 20 years of experience with coding under today's system. The vast majority of hospitals already are coding as carefully and accurately as possible because of other incentives in the system to do so, such as risk adjustment in various quality reporting systems. Analysis of Medicare claims from 2001 to 2005 suggests that hospitals have been coding complications and co-morbidities (CCs) at high rates for many years. More than 70 percent of claims already include CCs. Most Medicare claims not only include CCs but also include more than 9 CCs, the maximum number accepted by Medicare's computer program for grouping cases into appropriate DRGs. CMS' proposal incorrectly assumes that hospitals have the ability to use even more CCs, but this ability is, in fact, very low and an offset is unnecessary.

Capital-related Payment Cuts = $1 billion over the next 5 years
Medicare is required to pay for the capital-related costs of inpatient hospital services to help fund Medicare's share of expenses for new facilities, renovations, expensive clinical information systems and high-tech equipment (such as MRIs and CAT scanners). Since the PPS for inpatient capital costs uses DRGs in its payment formula, the 2.4 percent cut already reduces payments for urban and rural hospitals. In addition, CMS' proposed rule would eliminate the annual update for capital payments for all hospitals in urban areas, and would eliminate additional capital payments made to large hospitals in urban areas.

These proposed cuts to capital payments would make it more difficult to purchase the advanced technology, equipment and clinical information systems that consumers have come to expect, and could have the effect of slowing clinical innovation. Capital cuts of this magnitude will disrupt the ability of urban hospitals to meet their existing long-term

financing obligations. Hospitals have committed to these improvements under the expectation that Medicare's PPS for capital-related costs would remain a stable source of income. Reducing capital payments creates significant financial difficulties for our nation's most innovative and cutting edge hospitals.

CMS has chosen a path that is in direct opposition to policy makers on Capitol Hill. In fact, 223 representatives and 43 senators recently signed letters clearly stating their opposition to any effort to cut Medicare and Medicaid funding. Hospitals cannot sustain additional cuts in an already under-funded system. In fact, according to the Medicare Payment Advisory Commission, the independent commission that advises Congress on Medicare payment policy, overall Medicare margins will reach a ten-year low in 2007 at negative 5.4 percent.

In short, there is no rationale behind imposing such dramatic cuts to hospital payments for the services that millions of our Medicare patients rely on. They are not mandated; they are not supported by Congress and they are unnecessary. At a time when Medicare should be strengthened to meet rising demand, CMS must eliminate this arbitrary and unwise provision from the final regulation. Today's—and tomorrow's—patients deserve better.

Sincerely,

Rich Umbdenstock
President
American Hospital Association

Darrell Kirsh
President
Association of American Medical Colleges

Charles N. Kahn
President
Federation of American Hospitals

Larry Gage
President
National Association of Public Hospitals and Health Systems

Margaret Reagan
Corporate Vice President
Premier, Inc.

Curt Nomomaque
President and CEO
VHA Inc.

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AMERICAN HEADACHE SOCIETY
www.AmericanHeadacheSociety.org

June 12, 2007 143

By E-Mail Delivery

The Honorable Leslie V. Norwalk
Administrator (Acting)
Centers for Medicare & Medicaid Services
Room 445-G, Hubert H. Humphrey Bldg
200 Independence Avenue SW
Washington, DC 20201

Attn: CMS-1533-P

Re: Proposed Hospital IPPS Rule for FY 2008;
DRG Classification of Inpatient Headache Cases

Dear Ms. Norwalk:

The American Headache Society ("AHS") is pleased to submit these comments in connection with CMS' proposed Medicare Severity DRG ("MS-DRG") system of classifying inpatient hospital cases. AHS represents headache specialists throughout the country involved in clinical care, research and education. The Society's members treat Medicare patients in both inpatient and outpatient settings for migraine and related disorders. They practice in varied settings, from community based care to highly specialized tertiary referral centers.

DRG Reform and Proposed MS-DRGs

AHS supports Medicare payment policies that recognize clinically appropriate distinctions and reflect demonstrated differences in severity of headache illness, and resulting differences in the intensity and cost of care. This is particularly true in inpatient hospital care where the differences between short stay acute interventions in community hospitals, and much longer and more intensive multi-disciplinary care in specialized programs, is quite substantial.

Historically, the DRG classification system has not adequately captured the differences in severity of illness experienced by Medicare patients suffering from severe, chronic headache. This was the case with respect to both the single DRG 564 now in use for FY 2007, and the previous DRGs 024 and 025 used prior to this year. Unfortunately, it appears that the proposed new MS-DRGs 102 and 103 also fail to capture the most relevant clinical

considerations, as expressed in secondary diagnoses, which drive the cost of care for the most complex inpatient headache cases. We believe this to result from the classification of secondary diagnoses into "complicating conditions" ("CCs") and "major complicating conditions" ("MCCs") for use with respect to all primary diagnoses, rather than the establishment of CCs and MCCs specific to headache.

Specifically, the Agency's proposed list of MCCs excludes certain medication overuse and dependency diagnoses that, when combined with underlying headache illness, makes the patient's care much more complex, resulting in much longer lengths of stay and higher hospital inpatient costs. To truly account for differences in severity of illness for inpatient headache cases, any new MS-DRG classification system needs to recognize the impact medication overuse, particularly opioid dependence, has on the progression of the illness, and the difficulty of achieving successful patient outcomes without aggressive and longer stay inpatient intervention.

AHS has reviewed the comments submitted to the Agency in this rulemaking by the Michigan Head Pain and Neurological Institute ("MHNI") which set forth the issues summarized here in much more detail, with supporting data from individual hospital experience, and the collective research and clinical judgment of headache specialists as reflected in the medical literature. AHS endorses those comments and urges CMS to carefully consider MHNI's recommendations as it develops a final rule.

AHS has supported the efforts of Dr. Joel Saper of MHNI, a former AHS President, to bring these matters to the attention of your staff. The Society very much appreciates the willingness of CMS to work with Dr. Saper and other leaders in the field to find solutions that appropriately value the contribution of inpatient programs dealing with the most severely ill headache patients. Without those solutions, access to these programs will be impaired, and Medicare patients will suffer.

I personally appreciate your consideration of these issues of great import to our Society, its members, and the patients they serve. If the Society and I can be of any assistance to you or your staff at any time, please call on us.

Respectfully submitted,

Paul Winner, DO, FAAN
President

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astellas
Leading Light for Life

144
submitted electronically earlier today

BY HAND DELIVERY AND ELECTRONIC SUBMISSION
(http://www.cms.hhs.gov/eRulemaking)

June 12, 2007

Leslie V. Norwalk, Esq.
Acting 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-1533-P; Comments Regarding the Proposed Changes to the Hospital Inpatient Prospective Payment Systems Fiscal Year 2008

Dear Ms. Norwalk:

Astellas Pharma US, Inc. (Astellas) appreciates the opportunity to comment on the proposed Medicare Inpatient Prospective Payment Systems Proposed Rule for Fiscal Year 2008 (IPPS Proposed Rule) published by the Centers for Medicare and Medicaid Services (CMS).[1] Astellas is among the top 20 global research-based pharmaceutical companies, with global sales of approximately $8 billion, and the number two Japan-based pharmaceutical company. Our fundamental goal is to use our expertise in a number of therapeutic areas to improve the health of Americans by developing and marketing cures for unmet medical needs. Our North American product lines, which focus on the therapeutic areas of infectious disease, immunology, cardiology, dermatology, and urology, are used in a variety of settings, including hospitals.

This letter addresses CMS' application of § 5001(c) of the Deficit Reduction Act of 2005 (DRA), which concerns the Medicare payment to hospitals for treating inpatients with certain hospital-acquired conditions. This statutory provision requires CMS to select, by October 1, 2007, at least two conditions that: (a) are 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. Beginning in fiscal year 2009, hospitals will not receive the additional payment

[1] Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 24680 (May 3, 2007).

otherwise due for treating the secondary conditions selected by CMS (unless the condition was present when the patient was admitted to the hospital).

In selecting diagnoses to which DRA § 5001(c) should apply, it is imperative that CMS preserve hospitals' ability to furnish appropriate care to hospital inpatients, who are some of the sickest Medicare beneficiaries. Financial penalties for failing to prevent certain diagnoses may be an appropriate strategy for improving quality of care in certain cases, such as where the preventability of the condition in question is well-established and clearly attainable through adherence to clinical guidelines. Applied inappropriately, however -- e.g., to conditions for which etiologies can be hard to prevent or even ascertain -- policies of this type could make it difficult for hospitals to afford providing optimum patient care. Hospitals' efforts to avoid such financial penalties could result in over-utilization of diagnostic tests and other procedures. The resulting threats to sound patient care and unnecessary costs to Medicare and the overall healthcare system must be avoided.

We recognize the difficulties associated with implementing DRA 5001(c), and we commend CMS on its thoughtful discussion in the IPPS Proposed Rule of the issues presented by application of the statute. We also commend CMS on its proposal to apply the statute to several appropriate candidates, including objects left in surgery, air embolisms, and blood incompatibility. We emphasize, however, that applying the statute to serious infections raises special concerns that must be taken into account. **Policies that inhibit hospitals' ability to use appropriate pharmaceuticals to combat bacterial infections not only could jeopardize the health of individual patients -- they also have the potential to contribute to the growing problem of microbial resistance**, as discussed further below.

In our comments, we explain concerns with applying DRA § 5001(c) to serious infections generally, and then focus on certain specific bacterial infections discussed in the IPPS Proposed Rule[2] -- specifically, Staphylococcus Aureus septicemia, ventilator-associated pneumonia, vascular catheter-associated infections, methicillin-resistant Staphylococcus Aureus, and surgical site infections -- and whether these conditions satisfy the statutory requirement that the condition could reasonably have been prevented through the application of evidence-based guidelines. We also discuss Clostridium difficile-associated disease (CDAD), and support CMS' efforts to increase early diagnosis of this condition and to reduce CDAD morbidity.

* * *

[2] CMS developed a list of 13 conditions that could potentially meet the criteria in DRA § 5001(c). From that list of 13 conditions, CMS proposed to select six conditions for application of the DRA § 5001(c) payment regime. The six conditions proposed for selection are: (1) catheter-associated urinary tract infection; (2) pressure ulcers; (3) serious preventable event-object left in surgery; (4) serious preventable event-air embolism; (5) serious preventable event-blood incompatibility; and (6) staphylococcus aureous septicemia. The seven conditions CMS considered, but has not proposed for selection are: (1) ventilator-associated pneumonia/pneumonia; (2) vascular catheter associated infections; (3) clostridium difficile associated disease; (4) methicillin resistant staphylococcus aureous (MRSA); (5) surgical site infections; (6) serious preventable event-wrong surgery; and (7) hospital falls.

I. General Concerns with Applying DRA § 5001(c) to Serious Infectious Diseases

Under DRA § 5001(c), hospitals will not receive additional payment (on or after October 1, 2008) for cases in which one of the conditions selected by CMS is a secondary diagnosis (unless the condition in question was present on admission). If patients develop these conditions, the hospital will not receive additional payments to treat the condition even if necessary interventions have significant additional costs beyond the otherwise payable DRG.[3]

Hospitals should not have any concerns that compete with the prompt and most effective treatment of serious and life-threatening infectious diseases. As CMS undoubtedly appreciates, infectious diseases affecting hospital inpatients are frequently very complicated and difficult to prevent, diagnose, and treat. In many cases it is critical that the team treating these patients have access to the complete armamentarium of anti-infective drugs to minimize otherwise significant morbidity and mortality. The denial of additional payment through application of DRA § 5001(c) could make it difficult for hospitals to consider all available anti-infective drugs to treat a given infectious disease; this could result in less expensive but potentially less effective anti-infectives being used for these conditions to lower costs. This could adversely affect the quality of patient care for a population in which death from serious infection is not uncommon. The mere possibility of DRA § 5001(c) having such an effect is reason enough for CMS carefully to consider the prudence of selecting an infectious disease as a DRA § 5001(c) condition.

In addition to the potential for compromised patient care, applying DRA § 5001(c) to serious infections could fuel the growing threat of microbial resistance. Judicious and appropriate use of antibiotics is the cornerstone of minimizing the development of resistance.[4] Denying hospitals the payment otherwise due to treat serious infections could encourage overuse of older and less expensive antibiotics, thus increasing resistance to those products and, ultimately, depleting the arsenal of effective antibiotics and causing more hospitals to harbor drug-resistant bacteria. This greater resistance could endanger the lives of individual patients and undercut important public health goals by setting back infection control efforts. This is a dangerous sequence of events that CMS must avoid.

CMS also should be careful not to apply DRA § 5001(c) in a way that could encourage hospital resource misallocation and cost growth. Inappropriate application of this provision to serious infections could cause hospitals to "over-screen" incoming patients for potential infections so that the hospital could protect itself against financial penalties. For example, any effort to determine with certainty whether incoming patients have methicillin resistant staphylococcus aureous (MRSA) or other infections would require hospitals to screen patients by

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[3] As an example, ICD-9-CM 995.91, 995.92 (sepsis and severe sepsis) that are coded in Staphylococcus Aureus (SA) Bloodstream Infection/Septicemia, are Major Complications or Comorbidities (MCCs). Under DRA § 5001(c), additional payment would not be available if this condition was selected.

[4] See Management of Multidrug -Resistant Organisms in Healthcare Settings, 2006, CDC, page 16, available at http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf

using myriad screening or diagnostic tests to detect every potential nidus of infection or colonization in the patient. Such practices could divert hospital resources from higher-priority activities simply to reduce financial risks, and could increase overall healthcare expenditures with no clear benefit. Accordingly, it will be important for CMS to apply DRA § 5001(c) in a way that anticipates and avoids adverse unintended consequences.

Astellas believes strongly in encouraging hospitals to follow evidence-based guidelines that can reduce the number of preventable conditions. In cases that involve serious infections, however, payment cuts are a high-risk strategy for furthering these goals. CMS should thus proceed carefully, ensuring that DRA § 5001(c) is not implemented in a manner that could deprive patients of critical anti-infective therapies or that could actually frustrate infection control efforts. For serious infectious disease, a more prudent approach to attaining prevention goals might be positive efforts such as pay-for-performance for adherence to evidence-based guidelines, or public reporting of adherence to such guidelines. A "carrot" approach to prevention is likely to create fewer risks in the long-term than the "stick" approach of underpaying for necessary treatment when certain infections occur despite best practices.

II. Staphylococcus Aureus (SA) Bloodstream Infection/Septicemia[5]

We urge CMS to reconsider its proposal to include SA Bloodstream Infection/Septicemia (SA Septicemia) as one of the hospital-acquired conditions to which DRA § 5001(c) would apply.

We agree with CMS that SA septicemia is a very serious infection,[6] and that all reasonable measures should be taken to prevent the condition, as well as to detect and appropriately treat it. Prevention of a condition like septicemia of course requires that physicians be able to identify and prevent all of the underlying causes of the disease. In many cases, this can be difficult or impossible with SA septicemia, because the condition can be caused by, and overlap with, a number of other infections. In the IPPS Proposed Rule, CMS correctly identified pneumonia due to *S. aureus* as an infection that may be present on admission and could later lead to septicemia during the hospital stay. There are numerous other infections that can cause or overlap with septicemia, including: (1) endocarditis; (2) urinary tract infections; (3) complicated skin infections; (4) meningitis; and (5) osteomyelitis. Moreover, Jensen has shown that in a

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[5] Septicemia is defined as a "systemic disease associated with the presence and persistence of pathogenic microorganisms or their toxins in the blood." Dorland's Medical Dictionary, 1989. Therefore, a "bloodstream infection" is the same as septicemia. Literature indicates that SA septicemia accounts for approximately 20 percent of all nosocomial septicemia cases, meaning that the remaining 80 percent of nosocomial septicemia infections in the U.S. are not caused by *S. aureus*. Wisplinghoff H, et al. Nosocomial bloodstream infections in US hospitals: Analysis of 24,179 U.S. nosocomial septicemia cases during 1995-2002 from a prospective nationwide surveillance study. Clinical Infectious Diseases. 2004; 39:309-17.

[6] The severity of SA septicemia was discussed by Ogston as early as 1882. See Ogston A. Micrococcus poisoning. Journal of Anatomy. 1882;17:24-58.

significant percentage of cases, no focus of septicemia is identified.[7] Prevention of SA septicemia is also problematic because of the many underlying risk factors for the condition that are difficult to modify. Some of these risk factors include: (1) catheters (both vascular and urinary); (2) surgery; (3) dialysis; (4) diabetes mellitus; (5) immunosuppression; and (6) chronic dermatitis. Though much attention has focused on "catheter-associated" septicemia, this is in many cases a diagnosis of exclusion, meaning that because no actual cause is found the septicemia is attributed to the catheter.[8,9]

It is also often difficult to determine whether SA septicemia cases are in fact the result of a failure of hospitals to provide appropriate care. Patients themselves are frequently the source of the bacteria that causes SA septicemia through nasal colonization, which is very difficult to control or eradicate.[10] In other cases, it is difficult to determine whether the septicemia was community- or hospital-acquired. In Morin's study, almost half of all *S. aureus* infections with bacteremia were community acquired; this high number of community-acquired cases, coupled with the difficulty of detecting SA septicemia at admission, suggests that some SA septicemia cases diagnosed as "hospital-acquired" may in fact be community-acquired.[11]

In light of all of these considerations, it is difficult to determine whether septicemia cases are hospital-acquired, or to develop evidence-based guidelines that reasonably could prevent those septicemia cases that can be identified as hospital-acquired. For these reasons, we urge CMS to reconsider its proposal to include SA Bloodstream Infection/Septicemia as one of its initial hospital-acquired conditions.

III. Ventilator-associated pneumonia (VAP)

We agree with CMS' proposal not to select VAP as one of its initial hospital-acquired conditions. In addition to significant coding issues, CMS made the following observation in the IPPS Proposed Rule concerning the preventability of VAP:

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[7] Jensen AG. Importance of focus identification in the treatment of *Staphylococcus aureus* bacteremia. Journal of Hospital Infection. 2002; 52:29-36.

[8] See Fowler VG Jr et al. Clinical identifiers of complicated *Staphylococcus aureus* bacteremia. Archives of Internal Medicine. 2003; 163:2066-72.

[9] For further discussion of the difficulty of diagnosing SA septicemia and its overlap with other infections, see Slide Presentation of Sumnathi Nambiar, MD. MPH, Medical Team Leader, Division of Anti-Infective Drug Products, US Food and Drug Administration, October 14, 2004, Anti-infective Drugs Advisory Committee Meeting available at http://www.fda.gov/ohrms/dockets/ac/04/slides/2004-4077s1.htm.

[10] See Von Eiff C, et al. Nasal carriage as a source of *Staphylococcus Aureus* bacteremia. New England Journal of Medicine. 2001; 344:11-16. See also Archer GL, Climo MW. *Staphylococcus aureus* bacteremia -- consider the source. New England Journal of Medicine. 2001; 344:55-56.

[11] Morin CA, Hadler JL. Population-based incidence and characteristics of community-onset *Staphylococcus aureus* infections with bacteremia in 4 metropolitan Connecticut Areas, 1998. The Journal of Infectious Diseases. 2001; 184:1029-34.

> Prevention guidelines are located at the following website: http://www.cdc.gov/ncidod/dhqp/ gl_hcpneumonia.html. However, it is not clear how effective these guidelines are in preventing pneumonia. Ventilator-associated pneumonia may be particularly difficult to prevent."[12]

The peer-reviewed published infectious disease literature clearly supports CMS' conclusions about the difficulty of preventing VAP.

Intubation (the insertion of an endotracheal tube (ETT)) is a necessary step in mechanical ventilation (unless the patient has a tracheostomy). The pathogenesis of VAP is closely related to the presence of the ETT.[13] Ramirez has recently reviewed the literature on prevention measures for VAP.[14] In her paper, which draws from 86 other published articles, she notes that:

> The accumulation of secretions from the oropharnyx or the gastrointestinal tract in the subglottic space may be demonstrated by radiography or the quantification of the material obtained by local aspiration. Endogeneous or exogeneous colonization of these secretions is practically unavoidable and the causal relationship with VAP has been well established.[15]

One of the preventive measures reviewed by Ramirez is impeding leakage between the ETT and the tracheal wall through the maintenance of the correct ETT cuff pressure.[16] A theory is that insufficient cuff pressure may allow the entry of subglottic secretions between the ETT and the trachea. But too much ETT cuff pressure "may compromise the microcirculation of the tracheal mucosa and cause ischemic lesions."[17] Therefore, properly titrating the cuff pressure for each patient is challenging. After an extensive review of the literature, Ramirez concludes the following regarding the ETT cuff pressure (P_{cuff}):

> [A]lthough it is obvious that adequate healthcare intubation and mechanical ventilation must be accompanied by correct P_{cuff} and that the leakage of secretions to the bronchial tree depends on the P_{cuff} and its characteristics, there is scarce scientific evidence

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[12] 72 Fed. Reg. at 24722 (emphasis added).

[13] Safdar N, Crnich CJ, Maki DG. The pathogenesis of ventilator-associated pneumonia: Its relevance to developing effective strategies for prevention. Respiratory Care 2005; 50:725-741.

[14] Ramirez P, Ferrer, Torres A. Prevention measures for ventilator-associated pneumonia: a new focus on the endotracheal tube. Current Opinion in Infectious Diseases 2007; 20:190-197.

[15] Id. at 190 (emphasis added).

[16] ETTs are surrounded by an inflatable cuff which allows for proper positioning in the patient's trachea.

[17] Ramirez et al., supra, at 191.

> justifying a close relationship between these elements and the appearance of VAP.[18]

Another technique examined by Ramirez in her review is subglottic secretions drainage. Only two of four randomized prospective studies reviewed by Ramirez showed statistically significant reduction in VAP with intermittent or continuous aspiration of subglottic secretions, and according to Ramirez three of these four studies support the conclusion that "[a]spiration of subglottic secretions does not seem to have any effect on mortality, the duration of the mechanical ventilation or intensive care unit (ICU) or hospital stay."[19]

Ramirez's review is current and comprehensive, and she also examines less established prevention techniques such as decontamination of subglottic secretions and prevention, elimination, and decontamination of biofilm (related only to certain types of VAP),[20] and early tracheostomy. She concluded that the evidence from studies on biofilm is insufficient to recommend any of the techniques in the prevention of VAP. As for tracheostomy, she noted that "[a] recent meta-analysis concluded that early tracheostomy achieves a reduction in the duration of mechanical ventilation and ICU stay but does not modify either the mortality or the risk of VAP."[21]

Given the state of the evidence on the effectiveness of prevention techniques for VAP, we agree with CMS' assessment that "[v]entilator-associated pneumonia may be particularly difficult to prevent."[22] CMS may only select a condition for the application of DRA § 5001(c) if the condition could reasonably have been prevented by following evidence-based guidelines. It is apparent from the published literature that a set of evidence-based prevention measures that reasonably can prevent VAP have not yet been identified. In the future, the prevention of this infection and associated prevention techniques may be better understood.

IV. Vascular Catheter-Associated Infections

We agree with CMS' proposal not to select vascular catheter-associated infections as one of the initial hospital-acquired conditions subject to DRA § 5001(c). CMS has identified two important reasons DRA § 5001(c) cannot be applied to vascular catheter-associated infections: the facts that "circumstances might prevent such practice [changing the catheters at certain time intervals]," and that "a patient may acquire an infection from another source which can colonize the catheter."[23] Both of these issues indicate that this condition is difficult to prevent, and thus does not meet the DRA § 5001(c) criteria.

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18 Id. (emphasis added).

19 Id.

20 For further explanation on the significance of biofilm in VAP, See id. at 193.

21 Id. at 195. (emphasis added).

22 72 Fed. Reg. at 24722.

23 Id. at 24723.

As mentioned above, vascular catheters as a cause of septicemia is frequently a diagnosis of exclusion. Also, in inpatients who are frequently hemodynamically unstable with limited IV access, discontinuing the IV catheter is not an option. While we wholeheartedly support good catheter care, we agree with CMS that it is difficult to determine if catheters are an infection source or a destination for bacteria from another source. We also recognize very significant challenges in preventing these infections, and for these reasons support CMS' proposal not to select this condition.

V. Methicillin-Resistant Staphylococcus Aureus (MRSA)

We support CMS' proposal not to select MRSA as one of the initial hospital-acquired conditions subject to DRA § 5001(c). Aside from the coding issues CMS discussed in the IPPS Proposed Rule, **MRSA would be a highly inappropriate -- and dangerous -- choice for DRA § 5001(c) application.**

Hospitals need the complete armamentarium of antibiotics to treat MRSA successfully. *S. aureus* resistance to vancomycin and even newer agents has been documented, and the limited number of antibiotics currently effective against MRSA helps to make this type of infection particularly difficult to treat, presenting a significant public health problem and, for some patients, life-threatening situations. Applying DRA § 5001(c) payment reductions to MRSA infections could exacerbate the public health problems associated with MRSA in two fundamental ways: (1) DRA payment reductions could compromise hospitals' ability to combat the infection in individual patients with the most appropriate therapies available; and (2) payment-induced shifts in antibiotic use away from the optimum protocols for dealing with MRSA could lead to increased MRSA resistance. Both of these outcomes would undermine, rather than further, the goal of improving quality of care for Medicare patients by harming the healthcare providers' immediate and longer-term ability to treat these serious infections.

Moreover, as CMS correctly notes, MRSA preventability "may be hard to ascertain since [MRSA] has become so common both inside and outside of the hospital."[24] As discussed above in section I, hospitals would have to employ a battery of tests to approach some degree of certainty as to whether a patient might be harboring a community-acquired MRSA infection somewhere in their body at the time of admission. This calls into question whether it would even be feasible for hospitals to determine whether MRSA is present at admission, and presents concerns in terms of the costs that would be incurred by hospitals in attempting to do so in the interest of avoiding the financial penalties of application of DRA § 5001(c).

Accordingly, given the severity of this condition, the limited number of antibiotics that can successfully treat MRSA infections, the uncertainty about prevention, and the administrative and coding challenges, CMS should finalize its proposal not to include MRSA among the hospital acquired conditions subject to DRA § 5001(c).

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[24] Id. at 24724.

VI. Surgical Site Infections

We agree with CMS' proposal not to select Surgical Site Infections as one of the hospital-acquired conditions subject to DRA § 5001(c). CMS has observed that current ICD-9-CM diagnosis codes are insufficient to describe and code this condition for the purposes of applying DRA § 5001(c). Aside from the significant coding issues, CMS has also identified another key problem with applying § 5001(c) to surgical site infections: "While there are prevention guidelines, it is not always possible to identify the specific types of surgical infections that are preventable."[25]

Surgical site infections are a broad class of infections that can have many potential causes and involve various tissue types. Important factors (among many others) include the underlying disease and the type of surgery. CMS should work with expert stakeholders to sub-classify infections that are included in the broad class of Surgical Site Infections. This additional precision might ultimately allow CMS to determine the causes of some of these infections and thus to identify potential prevention measures.

VII. Clostridium Difficile-Associated Disease (CDAD)

As CMS mentions in the IPPS Proposed Rule, there are no available prevention guidelines for CDAD. Furthermore, the life cycle of *C. Difficile* includes spores that can persist in the hospital for many months and are resistant to many commonly used disinfectants. This characteristic makes prevention particularly difficult.

We cannot overstate the importance of CMS' recognition in the IPPS Proposed Rule of the natural history of CDAD and the significance of early treatment: "[i]f found early CDAD cases can easily be treated."[26] Through education, vigilance, early diagnosis and early treatment, patients can avoid the CDAD complications of severe pseudomembranous colitis and possibly colonic perforation and death. Diagnostic tests for CDAD are highly sensitive and can lead to early treatment through recognition of the signs and symptoms (which are generally nonspecific) of CDAD. We look forward to collaborating with CMS in the future to reduce the morbidity associated with CDAD.

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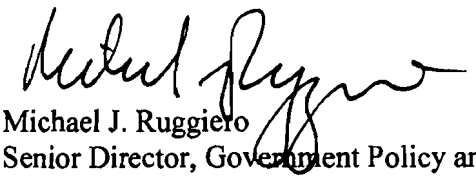
[25] Id.

[26] Id. at 24723.

We appreciate the opportunity to provide these comments. If you have any questions or would like additional information, please contact me at 202-812-6162 or via email michael.ruggiero@us.astellas.com.

Sincerely,



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June 12, 2007

By Hand Delivery

The Honorable Leslie Norwalk
Administrator
Centers for Medicare & Medicaid Services
Room 445-G, Hubert H. Humphrey Bldg
200 Independence Avenue SW
Washington, DC 20201

Attn: CMS-1533-P

Re: Proposed Hospital IPPS Rule for FY 2008;
DRG Classification of Inpatient Headache Cases

Dear Ms. Norwalk:

I am pleased to submit these comments on behalf of my center and several other medical directors of similar programs in connection with CMS' proposed Medicare Severity DRG ("MS-DRG") system of classifying inpatient hospital cases. These comments address the application of the proposed new system to inpatient hospital stays for severe headache cases of the type treated by our centers. These programs treat the most complex cases on referral from less specialized community care systems. Appropriate classification and payment for these complex patients is critical to the survival of these programs, and thus to ensuring continued access for Medicare patients who suffer this disabling condition.

The policy recommendations set forth in these comments are not simply those of a single institution. Rather, they are amply supported in the medical literature which has evolved over the last twenty years, and which is summarized in detail under the heading "Clinical Justification for Recommended Changes" below. We urge CMS to take full account of this documented research as it develops and refines the new MS-DRG payment system.

DRG Reform and Proposed MS-DRGs

We strongly support a DRG classification system that adjusts payment for the severity of illness and corresponding appropriate intensity of service, and believes that properly designed at the outset, and refined over time, such a system

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can properly account for the very different resource costs needed to treat different types of headpain cases requiring hospitalization. We also support use of secondary diagnoses as one building block in a system to better adjust case payments for severity of illness within a DRG category defined by a primary diagnosis of headache.

It is less clear, at least as proposed, whether sorting those secondary diagnoses that make a patient's care more complex, and therefore more costly, into "complicating conditions" ("CCs") and "major complicating conditions" ("MCCs") is useful and appropriate in a new system. As a general matter, the use of these distinctions would appear appropriate where they lead to at least three different payment rates for a primary diagnosis. Otherwise, when CCs are grouped with non-CCs into a single rate, the effect is to lower payment for those cases that are of moderate complexity while raising the rate for the least complicated patients. Similarly, where CCs and MCCs are grouped together in a single rate category, payment for the most complex cases will be averaged with those of moderate complexity to the detriment of the former and the benefit of the latter.

The more serious problem with the structure of the proposed MS-DRG classification system—indeed, its fatal flaw—is the "all or none" character of the CC and MCC distinctions. As proposed, a secondary diagnosis is categorized as a CC, an MCC or a non-CC for all primary diagnoses, and not separately analyzed for its contribution, or the cumulative, synergistic contribution, to the severity of illness and required intensity of service with respect to each specific primary diagnoses. This is much too blunt an instrument if the ultimate goal is to properly differentiate costs and payments within each of the primary DRG classifications. We believe this feature of the proposal accounts for its failure to capture the true complexity of inpatient headache cases, and we suspect the same would be true for many other illnesses.

DRGs: Headaches and Seizures

The Current Situation

We much appreciate the Agency's efforts over the past year to better understand the nature of complex inpatient headache patients, and strongly supports the Agency's proposal to abandon its single adult headache classification DRG 564 implemented for FY 2007. That classification did not classify headache cases based on the presence or absence of complicating conditions, and instead lumped all headache cases together in a single payment rate, and assumed a relatively short length of stay. The result was an IPPS payment that was grossly inadequate to cover the costs of treating the severely complex chronic headache sufferers that are referred to specialized treatment centers like ours.

Whereas DRG 564 assumed an average length of stay ("ALOS") of only 3.4 days, my program at Chelsea Community Hospital had an ALOS for Medicare patients in the prior year over 10 days. Medicare's case payment to Chelsea for DRG 564 in the current year is approximately $3850. Its direct costs per case were almost double that amount (approximately $7300), and when overhead is added, almost triple (over $11,000). Obviously, no hospital can afford to subsidize Medicare patients to that degree for an extended period of time

My center and others like mine attract many of the "toughest of the tough" cases from around the country. The impact of DRG 564 on my program may be more extreme than at some

other programs; however, we are hardly alone in serving Medicare patients with complex chronic headache conditions. One Midwestern program, for example, reports an ALOS of over 8 days for its current Medicare headache patients. A third program in the Northeast reports an ALOS of 6.4. Several others have ALOS well above the 3.4 days assumed in DRG 564, and the 5.1 and 3,2 days assumed in proposed DRGs 102 and 103 respectively. Thus, a DRG classification system that accounts for differences in severity of illness within the primary diagnosis of headache is critically important if referral programs are going to continue treating Medicare patients with the most complex needs.

The Proposed MS-DRGs for 2008

Unfortunately, the proposed new MS-DRGs 102 (Headache with MCC) and 103 (Headache without MCC) risk making a bad situation worse. While the restoration of two or more headache DRGs based on complications is fully appropriate, the secondary diagnoses that drive cost and LOS for headache patients are not captured on the proposed MCC list in Table 6J. We presume this result is attributable to the "all or none" feature of the new classification system discussed under our first comment above. Indeed, headache may be a perfect example of why that structural feature of the proposal prevents the new MS-DRG system from properly capturing severity in the case of some illnesses.

In the case of headache, certain secondary diagnoses related to medication overuse and dependency are now the principal drivers of cost and LOS for inpatient hospitalization. Yet these diagnoses are not considered MCCs for headache, presumably because the data does not support their listing as MCCs for enough other (unrelated to headache) primary diagnoses. MHNI does not have the data to judge the impact of these medication-related secondary diagnoses on non-headache DRGs, but for headache, both the data and the clinical experience is clear.

In the case of my program at Chelsea Hospital and similar tertiary care programs, recent data shows medication overuse of any kind to be a statistically reliable indicator of increased LOS relative to other headache patients without a history of such overuse. The effect is most dramatic for patients overusing opioid drugs. The clinical reasons for this correlation, and the supporting research base, are set forth in detail under "Clinical Justification" below. As noted there, medication overuse actually worsens the underlying condition in headache, making these cases much more difficult to treat. This phenomenon apparently has not been documented in other illnesses, including even other pain conditions.

The common secondary diagnosis codes used for patients with medication overuse and dependency are ICD-9 codes 30400 through 30491. Most appear on the proposed CC list but none are on the proposed MCC list. As a result, the vast majority of our inpatients would not qualify for MS-DRG 102 and would instead be paid at the lower rate of proposed MS-DRG 103 with an assumed LOS of only 3.2 days, even lower than the current DRG 564.

Recommended Changes

We believe there are several ways the proposed MS-DRG classifications could more accurately capture case complexity in the particular field of inpatient headache care.

One approach would be to include on the list of MCCs ICD-9 codes 30400 through 30491. These are true indicators of case complexity, and patients with these complications should certainly be paid at the higher of the two rates if there are to be only two adult headache DRGs.

If moving these codes to the MCC list has unintended consequences for too many other, non-headache, DRGs, then a second approach would be to add a modifier to the CC list recognizing these codes as MCCs for headache purposes only.

A third approach would be to add a third headache MS-DRG specifically for the opioid and other medication overuse codes. Based on our data and judgment, this would be the most clinically appropriate manner in which to differentiate between the least severe headache cases, those with moderate severity, and those of the highest severity.

Any of these approaches would be preferable to the current single adult headache DRG, or the two proposed MS-DRGs, but the third option would be most consistent with efforts already underway to capture medication overuse as part of a primary headache diagnosis. Unfortunately, these efforts are focused on ICD-10, and thus are not available for FY 2008.

Clinical Justification for Recommended Changes

Unlike other chronic pain conditions, the progression and intensity of chronic headache is physiologically influenced by the excessive use of analgesics and related "abortive" agents (those taken to reverse or "abort" an acute incident). Excessive use of pain killers promotes the progression as well as the intractability and refractoriness of chronic headache disorders. Since 1983 it has been known that the overuse (more than two days per week) of analgesics or abortive medication would promote the progression of migraine (Saper 1983). By the late 1990s, this phenomenon was demonstrated with the triptans (Diener, at al. etc.). Over the years many authorities and studies have confirmed these observations. In 2006 the International Headache Society formally defined *medication overuse* (formerly *medication rebound*) as a condition in which headache progresses under the direct influence of acute medications when used regularly beyond 2-3 days per week (International Classification of Headache Disorders, *Cephalalgia* 2004;24(suppl):94-5, Mathew et al. 1990, Diener et al. 2001, Srikiatkhachorn 2001, Silberstein et al. 2002, Saper et al., 2006 Headache Currents).

This phenomenon of medication overuse aggravating the underlying disease is now the leading indicator of severity of illness in headache patients requiring hospitalization. That this phenomenon has apparently not yet been observed with respect to other illnesses, including other chronic pain disorders, is no reason to exclude its significance for predicting severity of illness for headache.

The Implications for Hospitalization

The clinical implications of this phenomenon have direct impact on the care of patients with this condition. Patients trapped in this overuse cycle experience progressive and intractable headaches made worse each day by the continuing use of medications. 99% of these patients have daily persistent pain, many of them 24 hours a day, day after day and week after week. Despite the progression, attempts to reduce the medication bring dramatic escalation and

intensification of headache along with associated symptoms of nausea and vomiting and related "withdrawal phenomena." As a result of the intensification when discontinuation is undertaken, only those individuals with simple and modest medication overusage are sufficiently tolerant of the pain to withstand withdrawal on an outpatient basis. Most advanced cases, particularly those using opioids, will require hospitalization.

In the last decade, with the dramatic change in prescribing patterns involving opioids (narcotics), which are now used increasingly to treat non-malignant conditions, such as migraine and other headaches, specialists have witnessed a dramatic increase in the number of patients requiring admission and longer lengths of stay based entirely on the amount of narcotics and case complexity issues. It is now known that opioids have a profound adverse influence on brain mechanisms related to pain pathogenesis (Mao 2002, Lim 2005, Porreca 2005, Saper et al. 2006, Diener 2000, Katsarava 2005). As a result, the treatment of headache has become more complex and requires more intensity of care and longer hospitalizations.

Why Not just Treat the Substance Abuse?

Unlike a primary substance abuse problem, the headache patient is not a patient with principally addictive disease but instead a desperate individual who takes more and more medication to control pain, which has not been otherwise adequately controlled. As the headache patient attempts to reduce the drugs on the doctor's recommendation, he/she experiences an increase in both painful and other disabling symptoms, some of which include frank withdrawal phenomena (sweating, shaking, crawling skin, sleeplessness, changes to blood pressure and pulse). Nausea and vomiting are common and must often be addressed. For a successful outcome, the patient must be effectively withdrawn from the offending medication, **while simultaneously addressing the escalating pain,** and controlling it with intravenous medication and other support, including intravenous fluid replacement, sedation, etc. This care requires hospitalization with 24hour medical and nursing treatment, in some for as long as 1 to 2 weeks.If the hospital stay is excessively shortened and the pain not effectively controlled , the patient will not comply with outpatient restrictions to avoid these offending medications, resulting in noncompliance, recidivism, and recurrence of the original problem. And because the adverse brain receptor changes that occur as a result of drug misuse are prolonged in their effect, hospitalization is often longer than desirable, since pain control is generally not possible until the physiological effects dissipate.

Thus, it is necessary to treat the overuse problem and the behavioral antecedents that lead to it, as well as the pain and its accompaniments. Some patients are treated as outpatients, but the more complex patients require hospitalizations.

Severity of Cases Seen in Referral Centers

In 1978 Saper and colleagues established the first comprehensive inpatient program for intractable headache, principally to treat this problem. At that time overuse was generally confined to over-the-counter medications, ergotamine tartrate, and Fiorinal and related products, some with codeine. By the late 1990s and currently, a large percentage of patients requiring hospitalization are dependent on opioids as well as several other offending medications, which collectively have a cumulative and adverse effect on headache pathophysiology and treatability.

Several centers exist within the United States that treat these patients. Some treat more complex patients than others. Most of the patients referred have failed outpatient and aggressive treatment in local and regional treatment facilities. The patients are referred to the national programs primarily because of case complexity and intractability and the need for greater intensity of care and expert intervention. Those admitted are much more difficult to treat than patients generally seen in local communities and local community hospital settings. The length of stay required to effectively treat this population of patients ranges from 5 to 16 days (and sometimes longer), depending on several variables, which include the number and types of drugs used, the medical vulnerabilities of the patient, the age of the patient, and the patient's durability, behavioral issues, and the duration of the offending therapy prior to admission.

Outcome studies support the view that successful treatment of these patients is possible with proper care (Lake and Saper 2006; Lake and Saper, 1999; Lake and Saper, 1993; and others), but Medicare reimbursement, which does not cover many days of this treatment, threatens the survival of these programs, which have effectively treated complex and disabled Medicare patients and help to confront the prescription drug abuse problem in the United States.

Conclusion

I want to reiterate my personal appreciation for the efforts of CMS staff to understand the unique factors that drive costs and length of stay for that subset of Medicare patients who suffer from severe, chronic headache to the point that lengthy hospitalization is necessary. I particularly appreciate the opportunity and time your staff spent allowing us to distinguish the difference between the average short stay admissions to break an acute headache from the longer stay admissions required by the circumstances described above. That appreciation is shared by others in the headache community with programs similar to that at MHNI and Chelsea Hospital. I look forward to continuing our productive working relationship in the hope that we can soon achieve a refined MS-DRG classification system that fairly compensates hospitals and assures access for these desperate and needy patients.

Respectfully submitted,

Joel R. Saper, MD, FACP, FAAN
Founder and Director

c: Ms. Liz Richter
Mr. Marc Hartstein

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June 12, 2007

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

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

Dear Ms. Norwalk:

The American Association of Orthopaedic Surgeons (AAOS) and the American Association of Hip and Knee Surgeons (AAHKS) would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the proposed inpatient prospective payment system (IPPS) rule.

I. Introduction

The AAOS and AAHKS are organizations with strong and primary commitments to access to quality care for our patients. The IPPS proposed rule has several provisions that directly affect patient access to quality musculoskeletal care. The AAOS and AAHKS appreciate the steps that CMS has taken to improve the system. The following comments highlight the areas where the AAOS and AAHKS believe that CMS has adequately addressed some of the concerns that we have brought to its attention in the past. There are, however, other areas that we believe are in greater need of improvement and refinement. Those areas are set forth in our comments as well.

The AAOS and AAHKS have made it a priority to continue our work with CMS as all stakeholders propose changes to enhance the efficiency of our health care system. The AAOS and AAHKS recognize that in order to achieve that goal, physicians and hospitals must find new mechanisms to collaborate on systems that will enhance the quality of care for our patients and ensure appropriate resource utilization given the financial realities of our health care system. To this end, the AAOS and AAHKS have sought input from CMS regarding our efforts to establish a national total joint registry. The registry project seeks to improve the quality of total joint replacement surgery and decrease the cost of providing that care through feedback to surgeons and their institutions. The AAOS and AAHKS hope that by including CMS in the planning of this important effort, areas of synergy may be identified and the project may yield outcomes beneficial to all stakeholders.

II. "DRG Reform and Proposed Lower Extremity Arthroplasty MS-DRGs"[1]

The AAHKS, along with the AAOS, is appreciative of the opportunity to provide input on the proposed DRG reforms. As you know, this is an area of great interest to our organizations and our patients, and we have commented previously on the impact of refinements to the TJA DRG's on quality and access to care for Medicare beneficiaries. Based on our prior analysis, we made a request in 2005 for CMS to split DRG 209 into two separate DRG's, one for primary TJA and one for the more complex and resource intensive revision TJA procedures. We were pleased that CMS agreed with our recommendation, and in fiscal year (FY) 2006 DRG 209 was split into DRGs 544 (primary) and 545 (revision). In January 2007, we suggested additional refinements to the TJA DRGs, with the goal of more accurately and appropriately aligning reimbursement with resource utilization for these procedures. Our comments were based on analysis of clinical characteristics, patient outcomes, and resource utilization from over 6,000 patients who underwent primary or revision TJA procedures at one of 4 high volume TJA centers (University of California, San Francisco; Mayo Clinic, Rochester, Minnesota; Massachusetts General Hospital, Boston, Massachusetts; and Hospital for Special Surgery, New York, New York) between October 2005 and June 2006. Our goal in performing this analysis was to identify clinical and demographic predictors of resource utilization associated with TJA procedures.

In response to our request, CMS outlined refinements to the TJA DRGs in its IPPS Proposed Rule for FY 2008. In the proposed rule CMS implemented some, but not all of our suggested refinements. Instead, CMS proposed new adjustments to these DRGs for Severity of Illness of the patients served and a major redefinition of conditions representing major and/or co-morbid/complicating conditions (MCCs and CCs).

Our refinement concerns raised in 2005 addressed equitable payment for hospitals that perform a disproportionate share of complex revision surgeries and avoidance of perverse incentives for access by Medicare beneficiaries due to admission selection. Issues included assuring that appropriate payment recognition is given to both severity of illness and surgical complexity. These are independent predictors of resource utilization in TJA that may coexist at the individual patient level. Our analysis and comments will address both of these issues separately.

A. Surgical Complexity

Accurately classifying surgical complexity is necessary to assure equitable reimbursement for hospitals that perform a disproportionate share of complex TJA cases. From a quality perspective, referral of complex patients to regional centers assures sufficient volume for these hospitals and physicians to safely and effectively meet the complex clinical needs of this challenging beneficiary population. Since surgical complexity is known prior to admission, inequitable payment can also create perverse incentives that can cause inappropriate selective admissions (e.g., 'cherry-picking'). Matching payment levels to resource needs will assure that clinical rather than financial considerations drive patient care. The basic structure of the Version 25 Medicare Severity Diagnosis Related Groups (MS-DRGs) recognizes the primary complexity dimensions for Bilateral, Revision, and Primary/Routine TJA. However, we believe that using

[1] *Federal Register*, Vol. 72, No. 85, 24691 (May 3, 2007).

primary and *revision* as the sole differentiator does not sufficiently or appropriately distinguish *simple* from *complex* TJA procedures. Although prior to FY 2006, limitations in the ICD-9 coding system restricted CMS' ability to distinguish among different types of revision TJA procedures, the addition of new, more descriptive ICD-9-CM diagnosis (996.4x and 731.3) and procedure (00.7x and 00.8x) codes related to TJA procedures in FY 2006 have given us (and CMS) the opportunity to further analyze differences in clinical characteristics and resource intensity among TJA patients and procedures. As we noted in our previous comments, certain revision procedures are far less resource intensive (particularly those that only replace worn modular components without removal of the implants attached to bone). Because there is an interaction effect between surgical procedure complexity and the severity measure used, we are recommending modifying the definition of complex vs. routine for MS-DRGs:

DRG		Complexity
0070	REVISION OF HIP REPLACEMENT, BOTH ACETABULAR AND FEMORAL COMPONENTS	Complex
0071	REVISION OF HIP REPLACEMENT, ACETABULAR COMPONENT	Complex
0072	REVISION OF HIP REPLACEMENT, FEMORAL COMPONENT	Complex
0080	REVISION OF KNEE REPLACEMENT, TOTAL (ALL COMPONENTS)	Complex
0081	REVISION OF KNEE REPLACEMENT, TIBIAL COMPONENT	Complex
0082	REVISION OF KNEE REPLACEMENT, FEMORAL COMPONENT	Complex
8153	REVISE HIP REPLACEMENT*	Complex*
8155	REVISE KNEE REPLACEMENT*	Complex*
	*Note: for "Unspecified" Revisions, consider Complex for FFY08 analysis and setting initial weights only and Routine for payment and thereafter to encourage accurate coding	
0073	REVISION OF HIP REPLACEMENT, ACETABULAR LINER AND/OR FEMORAL HEAD ONLY	Routine
0083	REVISION OF KNEE REPLACEMENT, PATELLAR COMPONENT	Routine
0084	REVISION OF KNEE REPLACEMENT, TIBIAL INSERT (LINER)	Routine
0085	RESURFACING HIP, TOTAL, ACETABULUM AND FEMORAL HEAD	Routine
0086	RESURFACING HIP, PARTIAL, FEMORAL HEAD	Routine
0087	RESURFACING HIP, PARTIAL, ACETABULUM	Routine
8151	TOTAL HIP REPLACEMENT	Routine
8152	PARTIAL HIP REPLACEMENT	Routine
8154	TOTAL KNEE REPLACEMENT	Routine
8156	TOTAL ANKLE REPLACEMENT	Routine
8157	REPL JOINT OF FOOT, TOE	Routine
8159	REV JT REPL LOW EXT NEC	Routine

The resources for the complex procedures are significantly higher than for the routine procedures. They typically require significantly more operative time, hospital days, and patient recovery time. The relative resources for the "routine" revisions are much closer to those of other routine primary arthroplasty procedures and should be grouped with them as recommended in our previous comments.

B. Severity of Illness

The proposed MS-DRGs are more reflective of procedural complexity than the CSA-DRGs proposed last year, which represents an improvement over CSA-DRGs in predicting resource use. In addition, the process is fairly straight forward, making it easier to understand, with public domain grouping logic promised. Given the scope of the modifications and the short time frame available, we were unable to fully analyze the updated list of MCCs and CCs. It does appear to address a number of the anomalies we noted in analysis of last year's severity proposal such as removal from the CC list of common diagnosis codes that no longer represent higher resource use (e.g. post-operative anemia for TJA cases.) We will continue to analyze these changes and provide further recommendations to CMS.

One concern we note is that the proposal incorporates combining adjacent MCC/CC/w/o CC subgroups when differences are "not material." To create separate subgroups in a base DRG, currently ALL FIVE of the following criteria must be met:

1. A reduction in variance of charges of at least 3%
2. At least 5% of the patients in the MS-DRG fall within the MCC or CC subgroup
3. At least 500 cases are in the MCC or CC subgroup
4. There is a 20% difference in average charges between subgroups
5. There is a $4,000 difference in average charge between subgroups

The criteria are designed to assure that resulting DRGs have a sufficient number of cases and are different enough to be material. However, the requirement that ALL FIVE conditions must be met in all cases is overly restrictive, lacks face validity, and creates perverse admission selection incentives for hospitals by significantly overpaying for cases w/o a CC and underpaying for cases with a CC. For example, we compared cases with a principal diagnosis of unexplained cardiac arrest which includes separate DRGs for patients with and w/o a CC (MS-DRGs 297 and 298) which DID meet the specified criteria with routine TJA cases that did NOT meet the criteria to split patients with a CC from those w/o CC (both collapsed into MS-DRG 470):

Criteria and/or Comparison		MEETS Criteria: Cardiac Arrest MS-DRGs 297-298	NOT Meet Criteria: Primary TJA MS-DRG 470	Difference: (TJA vs. MS-DRGs 297-298)
3	Discharges, US	1,501	410,707	273 times higher
2	with CC # (%)	945 (63%)	91,177 (22%)	% is 2.8 times lower
5	Charge Difference	$ 5,021	$ 5,563	1.1 times higher
4	% Charge Difference	56%	16%	3.5 times lower
	Avg. CC Cost	945@ $ 4,686	91,177 @ $ 13,304	
	Avg. w/o Cost	556 @ $ 3,012	319,530 @ $ 11,449	
	Avg. Cost (CC & w/o)	$ 4,066	$ 11,861	2.9 times higher
6	Diff. (Avg. – CC cost)	($ 620)	($ 1,443)	2.8 times higher
7	Total CC underpayment*	($ 586,000)	($ 592,000,000)	1,011 times higher
	Admission	Unplanned	Planned	Encourages perverse patient selection

**Note: The cases w/o CC will be overpaid in total by $586,000 MS-DRGs 297-298 and $592,000,000 for MS-DRG 470*

We recommend these five criteria be refined to acknowledge cases such as MS-DRG 270, where the total dollars under consideration ($592,000,000) is high, due to the large numbers of procedures performed (410,707), but the % difference in average charges falls just short of the 20% threshold. The example above only represents one combined pair, with a half-billion dollar perverse admission selection incentive for this one pair alone. Due to time constraints, we have not been able to analyze most other combined pairs for materiality, but note that similar patterns apply to Bilateral TJA, with a smaller underpayment of $5 million (still 10 times higher than DRGs 297-298.) We also recommend using Cost rather than Charges to minimize perverse incentives for charge manipulation (cost is much closer to current payments.) Costs vary by hospital, but are approximately 1/3 of Charges (.3378 on average.)

The existing five criteria are appropriate for low volume subgroups to assure materiality. On average, the MS-DRG splits that currently differentiate cases with a CC from those without avoid underpaying the CC cases by an average of approximately $100,000 for each MS-DRG.

For higher volume MS-DRG subgroups, we recommend that two other criteria be considered, particularly for non-emergency, elective admissions:

- Is the per-case underpayment amount significant enough to affect admission vs. referral decisions on a case-by-case basis? And
- Is the total level of underpayments sufficient to encourage systematic admission vs. referral policies, procedures, and marketing strategies?

As we have noted in our previous comments, CMS payment policy can have a significant impact on Medicare beneficiary access to care, quality, and referral patterns, particularly when perverse financial incentives are created by inadequately matching reimbursement to resource utilization based on patient severity of illness and surgical complexity.

To address continuity with existing criteria while addressing the above concerns, we recommend refining the five existing criteria for MCC/CC/w/o subgroups as follows:

- Create subgroups if they meet the five existing criteria, with Cost difference between subgroups ($1,350) substituted for Charge difference between subgroups ($4,000);
- If a proposed subgroup meets criteria # 2 and # 3 (at least 5% and at least 500 cases) but fails one of the others, then create the subgroup if either of the following criteria are met:
    - 6 - At least $ 1,000 cost difference per case between subgroups; **OR**
    - 7 - At least $ 1,000,000 overall cost should be shifted to cases with a CC (or MCC) within the base DRG for payment weight calculations.

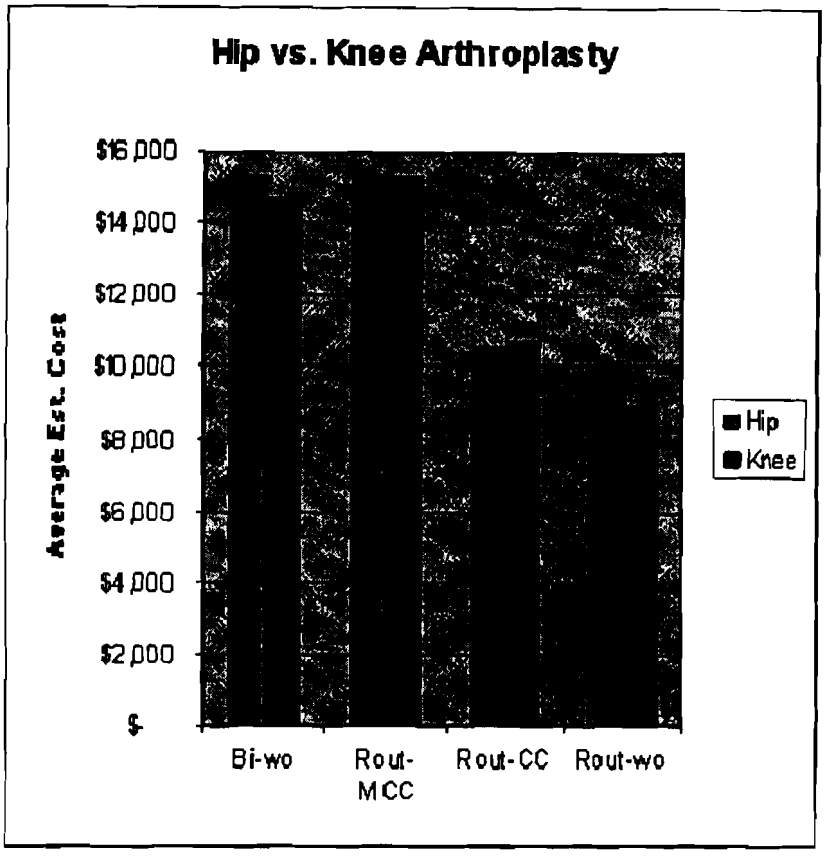
This will balance material accuracy/simplicity and help align payment with resource utilization to avoid perverse incentives. **We specifically recommend that the 7 TJA MS-DRGs currently proposed be expanded to 9 to reverse the collapsing w/ CC and w/o/ CC cases for MS-DRGs 470 and 462 and therefore provide equitable payment levels for these procedures.**

C. Bilateral or Multiple TJA

We noted previously that under Version 23 of the Medicare Grouper that in some cases, a patient with multiple components but only one knee being revised would group into the Bilateral DRG 471. The Version 24 modification correctly removed these cases; however, the logic also removed some legitimate Bilateral TJA cases from DRG 471. These latter cases represent patients receiving both a revision to one leg and a primary TJA to the other (approx. 70%), identical component revisions in both legs (approx. 20%), a total revision on one leg with a component revision on the other or a combined hip and knee Arthroplasty (approx. 5% each.) One of our research partners will be commenting and providing our proposed Grouper logic separately to address this issue. Resource use for these cases more closely matches the bilateral cases they should be grouped with rather than the single revision cases where they are now grouped.

D. Procedure Site: Hip vs. Knee

After implementing the refinements recommended above (reclassify routine revisions in with primary TJA procedures), separate ALL MCC/CC/w/o levels for each complexity group – 9 MS-DRGs vs. 7), most of the significant differences in resource utilization between total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures disappears (for 92% of cases.) This is primarily due to THA patients tending to be older with more MCC and CC conditions, so using all three severity levels adjusts for most of the differences in resource utilization in THA and TKA procedures. Therefore, if our recommendations are implemented, we do not believe it is necessary to create separate DRGs for hips and knees.



We are continuing to explore the other subgroups (complex revisions, bilateral with MCC/CC) to see how much of the remaining differences in resource utilization are due to severity factors such as infection and major osseous defects that can be addressed in the MCC and CC tables without having to define further DRGs. We look forward to continuing to work with CMS to identify clinically relevant predictors of resource utilization for TJA procedures for inclusion in future DRG, CC, and MCC refinements.

E. "Changes to the Case Mix Index (CMI) From the Proposed MS-DRGs"[2]

CMS has proposed an across-the-board reduction of standardized amounts by 2.4 percent in fiscal years 2008 and 2009.[3] The AAOS and AAHKS recommend that CMS reconsider the application of this policy. Both the AAOS and AAHKS have been very supportive of working with CMS to create more accurate classifications and definitions for particular procedures, particularly in the case of total joint arthoplasties and revisions. We believe that this work has resulted in a classification system that leaves little to no discretion in how these procedures are coded, and therefore, any coding changes under the proposed MS-DRG system for these and other musculoskeletal procedures would reflect real changes in case-mix. CMS' proposed policy

[2] *Federal Register*, Vol. 72, No. 85, 24708 (May 3, 2007).
[3] *Federal Register*, Vol. 72, No. 85, 24710-11 (May 3, 2007).

would inflict a negative disproportionate impact on those providers who have dedicated time and resources to creating a more accurate coding system, and we hope that CMS will acknowledge this by reconsidering the application of this across-the-board adjustment.

III. "DRGs: Hospital-Acquired Conditions"[4]

A. Public Comment Process

The AAOS and AAHKS appreciate CMS' efforts to solicit public comment on not only the "hospital-acquired conditions" to be chosen under this provision, but also the process by which those conditions will be selected. As with all aspects of CMS' decision-making processes, transparency and open deliberation are necessary characteristics for the integrity of the programs which CMS administers. We encourage CMS to continue to provide the opportunity for input through the rulemaking process in this and all other areas.

B. Temporal Concerns Regarding Acquisition of Condition or Infection

The AAOS and AAHKS share CMS' sentiments that payments made through the IPPS should encourage quality care for our patients. However, given clinical limitations in determining the precise time at which a condition or infection was acquired, CMS must proceed cautiously before financially penalizing providers when treating these conditions and infections. CMS recognized this concern in the proposed rule by stating that "a condition acquired during a hospital stay may arise from another condition that the patient had prior to admission, making it difficult to determine whether the condition was reasonably preventable."[5] We encourage CMS to incorporate this into the payment policy decisions that it makes with respect to this provision. However, the statement should be changed to read "whether the condition was reasonably preventable *by that provider during the current episode of care.*"

Regarding the "(l) Serious Preventable Event – Surgery on Wrong Body Part, Patient, or Wrong Surgery" listed "condition," the AAOS has been a leader in developing protocols and campaigns to ensure that these events never occur. With respect to this provision, however, the AAOS agrees with CMS that it is not an appropriate candidate given that Medicare already does not provide payment because the "service" is not "reasonable and necessary." We encourage CMS to continue to view the AAOS and AAHKS as partners in preventing these events from ever occurring.

C. Concerns on Preventability and Avoidability of Condition or Infection

As required by law, one of the criteria for selecting a condition for this provision is that the condition "could reasonably have been prevented through the application of evidence-based guidelines."[6]

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[4] *Federal Register*, Vol. 72, No. 85, 24716 (May 3, 2007)
[5] *Federal Register*, Vol. 72, No. 85, 24718 (May 3, 2007).
[6] 42 U.S.C. §1395ww(d)(4)(D)(iv)(III).

Regarding section "(m) Falls," the AAOS and AAHKS agree that the coding complications and inability to distinguish between preventable and non-preventable falls make this a poor candidate for inclusion in this payment policy.

Regarding section "(k) Surgical Site Infections," the AAOS and AAHKS agree that coding limitations should eliminate this from consideration for this proposal. However, even if coding improvements were made to better identify possible infections, the AAOS and AAHKS would still have strong reservations about the application of "surgical site infections" as the basis for denial of payment precisely because of the "preventability" criterion. The concept of not paying for known complications that are a biological inevitability at a certain predictable rate, regardless of safe practice, is discriminatory to patients at greater risk. Patients who are older or have medical co-morbidities are at greater risk of infection (as well as other complications). Medicare beneficiaries with co-morbidities are already finding it more difficult to obtain care. If applied ineffectively, this policy would negatively impact the quality of life and access to care of vulnerable groups and will not improve quality given that in many situations infections are simply biological certainties. The AAOS and AAHKS appreciate CMS' acknowledgement that "it is not always possible to identify the specific types of surgical infections that are preventable."[7]

Regarding section "(b) Pressure Ulcers," there is a risk that patients presenting for total joint replacement, particularly those from nursing homes, already have pressure issues that will likely progress to decubitis ulcers. Again, at that stage there is little that can be done to prevent this condition and all surgeons can really do is thoroughly assess the patients and document pre-existing conditions upon admission. Therefore, the AAOS and AAHKS have significant clinical concerns about the inclusion of this on the list of "conditions" because of its inability to meet the "preventability" criterion.

Regarding sections "(a) Catheter-Associated Urinary Tract Infections" and"(f) Staphylococcus Aureus Bloodstream Infection/Septicemia," the AAOS and AAHKS have significant concerns. Even when all guidelines are followed these infections may still occur during treatment of diseases that have a much greater cost, morbidity and mortality. Existing prevention guidelines, while providing recommendations for preventing or treating these infections, are not all evidence-based and may not have been developed with the involvement of stakeholder groups to which they may be applied. Additionally, the existence of and compliance with the guideline does not always guarantee the prevention of an infection.

In both cases, patients may be admitted with underlying infections which are not detectable through standard pre-operative screening. Another subset of patients may be predisposed to these types of infections due to comorbidities (e.g., diabetes, peripheral vascular disease) or physiology that cannot be compensated for with existing prophylactic regimens. In spite of adherence to accepted preoperative screening and post-surgical care protocols, these infections are not always preventable.

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[7] *Federal Register*, Vol. 72, No. 85, 24724 (May 3, 2007).

Exacerbating the situation, current Medicare reimbursement does not cover the increased cost of antibiotic coated catheters which have been shown to decrease the incidence of catheter infections, even when guidelines are followed. The best way to decrease cost and morbidity from this treatment-related morbidity is to change Medicare payment policy to encourage the application of proven existing technology that can prevent the larger cost of treatment.

This proposal appears to be a mechanism for shifting the cost of treating these infections to hospitals and physicians. *Staphylococcus aureus* septicemia and catheter-associated urinary tract infections will exist as long as we have to hospitalize patients and treat disease. Shifting the cost burden of treatment to hospitals and physicians only further deteriorates the current medical system and quality of care for patients.

IV. "IME Adjustment"[8]

The AAOS and AAHKS vigorously oppose the CMS' proposal to decrease indirect medical education (IME) payments for residents' sick leave and vacation time. Academic centers depend upon graduate medical education funding not only to cover costs of residents' education, salaries, research, but also the increased burden of indigent care and care for medically complex patients. Many of the costs that the IME adjustment includes are fixed costs such as employee benefits, overhead expenses for programs, and educational conferences that continue even when a resident is on sick or vacation leave. Hospitals' other missions will be adversely affected due to the loss of IME payments.

CMS' proposal would further burden residents many of whom are already over-worked. Hospitals would have an incentive only to offer the minimum vacation time and strictly limit maternity/paternity leave. Resident participation in academic activities such as the presentation of research at conferences or taking electives in third world medicine will be adversely impacted as well.

As proposed, vacation and sick time would be removed from the total time considered to constitute a full time equivalency (FTE) resident. Therefore, this time would be removed from both the numerator and denominator of the FTE calculation. CMS acknowledges that the proposal will result in lower FTE counts for some hospitals and higher counts for other hospitals, based on this regulatory change. The AAOS and the AAHKS object to altering the number of residency slots at teaching hospitals due to this proposed FTE calculation. Much more dialogue and stakeholder input needs to occur prior to implementing CMS' proposed decision to amend residency FTEs.

In the proposed rule, orientation time would continue to be included as part of the FTE determinations. The AAOS and AAHKS recommend that CMS count sick and vacation time in the same manner as orientation time and continue to include that time in the full-time equivalency calculations.

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[8] *Federal Register*, Vol. 72, No. 85, 24812 (May 3, 2007).

V. Conclusion

We look forward to working with you on these issues. Should you have any questions, please contact Kevin Bozic via at bozick@orthosurg.ucsf.edu or phone at 415-476-3900 or Bob Jasak via e-mail at jasak@.aaos.org or phone at 202-546-4430.

Sincerely,

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