STATE OF LOUISIANA
DEPARTMENT OF HEALTH AND HOSPITALS

Kathleen Babineaux Blanco
GOVERNOR

Frederick P. Cerise, M.D., M.P.H.
SECRETARY

Hefter
Hartstein
Collins
Morey
Smith

June 21, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011,
Baltimore, MD 21244-1850.

Reference: CMS-1500-P

Dear Administrator McClellan:

The Louisiana Department of Health and Hospitals – Bureau of Primary Care and Rural Health appreciates the opportunity to comment on the proposed rule implementing changes to the hospital inpatient prospective payment systems and fiscal year 2006 rates, published in the May, 2005, **Federal Register**. Of particular concern, is the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding replacement or relocation of a Critical Assess Hospital (CAH) that has been designated as a necessary provider. In the Inpatient Prospective Payment System (IPPS) proposed rule, CMS only provides continued CAH status for necessary providers that are building replacement facilities at another location and can demonstrate their construction plans began before December 8, 2003 OR are building a replacement facility within 250 yards of the existing hospital campus. This arbitrary date restriction and 250 yard limitation for replacement facilities jeopardizes several CAH relocation projects currently planned or underway in Louisiana and leaves no flexibility for almost ALL of Louisiana's CAHs to relocate to new facilities in the future.

The Bureau of Primary Care and Rural Health (Bureau) is designated as the state's Office of Rural Health and is charged with the mission of developing and sustaining quality health care services for Louisiana's rural communities. The Bureau is also the state's grantee for the federal Office of Rural Health Policy - Rural Hospital Flexibility Grant Program (FLEX). As State Office of Rural Health and the FLEX grantee, the Bureau works to provide assistance to the state's CAHs and small rural hospitals in their efforts to convert to CAH status; develop and enhance small rural and CAH systems in order to optimize hospital performance; expand and leverage community networking opportunities to expand access to those in need and improve the overall quality of health care services provide to their patients. In this role, the Bureau has developed an understanding of the needs of Louisiana CAHs and their communities.

Louisiana currently has 22 CAHs, 20 of which were designated under the state's necessary provider provision. Of the 20 CAHs designated as necessary providers, two currently have relocation projects underway, five are considering relocation and two are considering renovations or expansion to their current facility (Attachment A). As is true with many small rural hospitals in the country, the majority of Louisiana's CAHs were built in the 1950s or the 1960s. As a result, many of these hospitals currently have antiquated floor plans, construction and utilities. The proposed rule will force these CAHs to allocate funds to renovate structures that no longer meet either the needs of their community or the demands of modern health care. The proposed rule prohibits newer facility designs, which enable improvements in patient safety and quality of care. Forcing hospitals to continue in outdated facilities is an inappropriate and avoidable risk for rural communities.

Franklin Foundation Hospital and St. James Parish Hospital currently have relocation construction projects underway. Both hospitals are confident that they can demonstrate that their construction plans began before December 8, 2003. If successful in their efforts to relocate to new facilities, both hospitals are also confident that they will meet the proposed 75% threshold CMS outlined in the rule that seeks to assure that a replacement or relocation CAH facility continues to meet the intent of its original necessary provider designation. **However, the proposed rule has seriously delayed financing from the United States Housing and Urban Development (HUD) for the St. James Parish Hospital project and is causing a serious financial strain on the hospital.**

As noted, many other CAHs in Louisiana also are planning or considering relocating to replacement facilities and will not be able to do so on their existing hospital campuses. The proposed rule would prohibit them from doing so, which will severely jeopardize their ability to compete in a hugely competitive health care market. In most rural communities, the local hospital is one of, if not the largest, employer in the community. Therefore, these CAHs have a significant impact on the local economy. The disincentive contained within CMS's proposed rules for CAHs to modernize their facilities places an unfair disadvantage on these hospitals' ability to compete within their markets, which will severely impact their local communities and economies.

In closing, the Bureau supports the 75% threshold outlined in CMS's proposed rule. We feel that this threshold sufficiently assures that a replacement or relocation CAH facility will continue to meet the intent of its original necessary provider designation. However, the Bureau respectfully requests that CMS to reconsider its proposed rule and remove the December 8, 2003 date restriction on construction plans for new replacement facilities for CAHs qualified as necessary providers. In addition, the Bureau strongly supports

replacing the new CAH facility 250-yard restriction with a more reasonable one-mile limitation. Your consideration of this request is appreciated. Please contact me at 225-342-3814 with any questions.

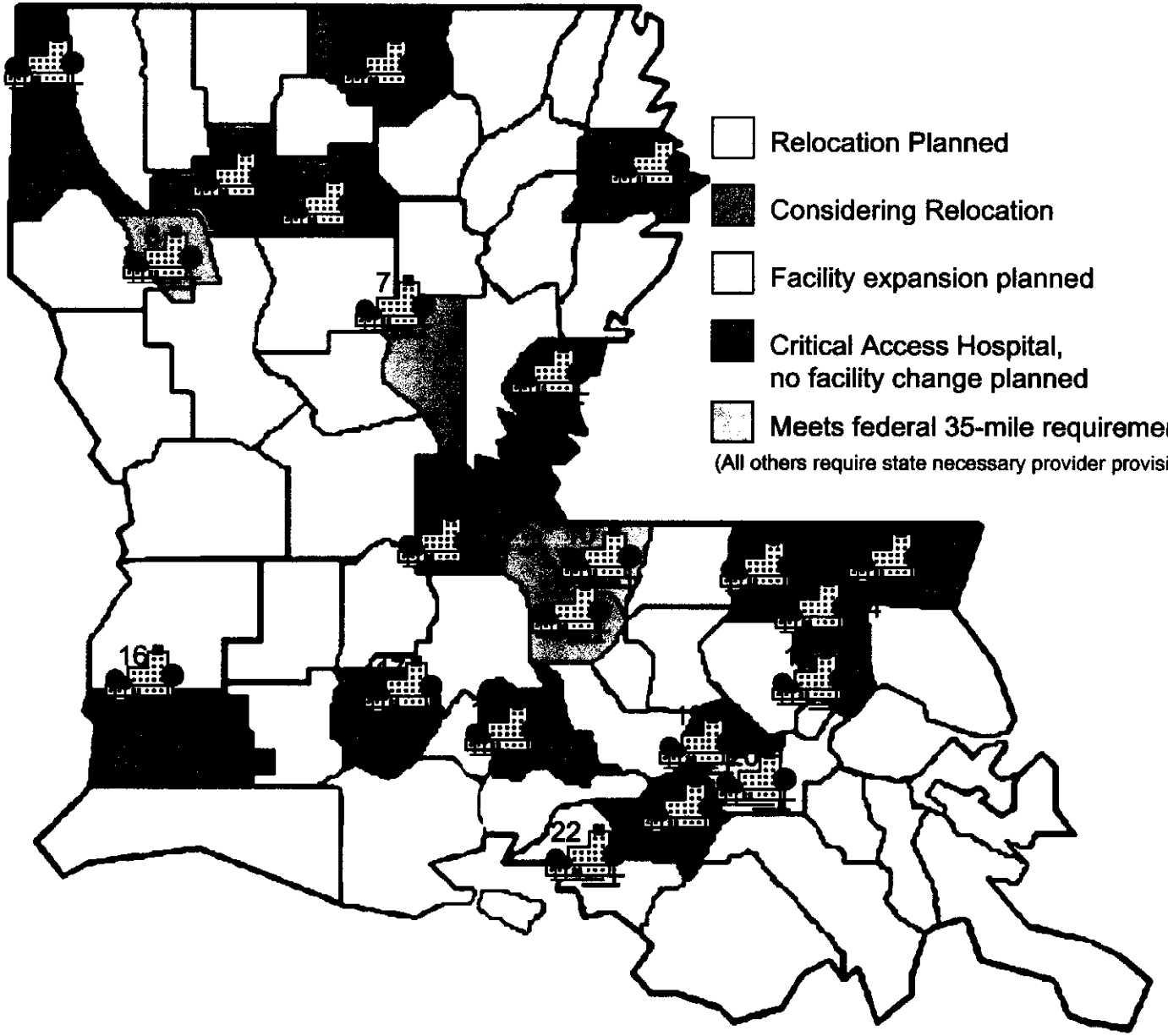
Sincerely,

Kristy H. Nichols
Director

enclosure

KN

Louisiana Critical Access Hospital Facility Plans



- Relocation Planned
- Considering Relocation
- Facility expansion planned
- Critical Access Hospital, no facility change planned
- Meets federal 35-mile requirement

(All others require state necessary provider provision)

1. North Caddo Medical Center
2. Union General Hospital
3. Bienville medical Center
4. Madison Parish Hospital
5. Jackson Parish Hospital
6. CHRISTUS Coushatta Healthcare Center
7. Hardtner Medical Center
8. Riverland Medical Center
9. Bunkie General Hospital
10. West Feliciana Parish Hospital
11. St. Helena Parish Hospital
12. Riverside Medical Center
13. Pointe Coupee General Hospital
14. Hood Memorial Hospital
15. LSU Lallie Kemp Regional Medical Center
16. DeQuincy Memorial Hospital
17. Acadia-St. Landry Hospital
18. St. Martin Parish Hospital
19. Prevost Memorial Hospital
20. St. James Parish Hospital
21. Assumption Community Hospital
22. Franklin Foundation Hospital

Mercy
MEDICAL CENTER
DES MOINES
A member of Mercy Health Network

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DSH
Transfers
& Data

1111 6th Ave.
Des Moines, IA 50314-2611
515-247-3222

ADMINISTRATION

Heffter
Hartstein
Smith
Walz
Hart
Bodden
Kushat

June 22, 2005

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS 1500-P
PO Box 8011
Baltimore, MD 21244-1850

RE: CMS 1500-P – Medicare Program; Changes to the Inpatient Prospective Payment System and Fiscal Year 2006 Rates; Proposed Rule

Dear Dr. McClellan:

Mercy Medical Center – Des Moines appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule establishing new policies and payment rates for hospital inpatient services for fiscal year 2006, and respectfully offer the following comments for your consideration.

DSH Adjustment Data:

We appreciate and concur with the CMS proposal to make MedPar LDS data available to all Providers prospectively and at no cost to Providers, regardless of the Providers' appeal status. We also agree with the proposal to provide the data for a period that encompasses the Provider's fiscal year when that differs from the federal fiscal year, which will allow Providers the opportunity to determine the most appropriate Medicare fraction to use in the DSH adjustment calculation.

However, we encourage CMS to take this data collection and reporting effort a step further to ensure that all Providers receive ***complete and consistent*** as well as current data to use in both the Medicare and the Medicaid fractions of the DSH calculation. In order to accomplish this, we propose the following:

1) We propose that CMS provide the raw data file, rather than just the MedPar LDS file, to all hospitals in order to allow them the ability to analyze and include all allowable days in the DSH calculation.

2) We urge CMS to address the treatment of dual eligible days, such as Medicare Part A Exhausted Benefit days and Medicare+Choice days, which are not included in the Medicare fraction (as Medicare did not "pay" for these patients). We do not believe it was Congress' intent to exclude these sickest of indigent patients from the

DSH coverage, and therefore if these patients are not included in the Medicare fraction, as has been proven repeatedly via the purchase of detailed MedPar files, then Providers should be allowed to include them in the Medicaid fraction.

To date, these dual eligible days have not been treated consistently by Intermediaries across the county; however, as Medicare is a national program, the Medicare DSH calculation and subsequent payments should be handled consistently on a national basis for all Providers. By ensuring that all dual eligible days are included in the appropriate fraction of the DSH calculation, Providers will receive consistent and accurate DSH payments across the country.

3) Determine and communicate the appropriate denominator to be used in the Medicare fraction of the DSH calculation; we propose that CMS instruct Providers and Intermediaries to use the PS&R data as the appropriate denominator in the Medicare fraction.

4) Finally, we recommend that CMS provide standard, explicit direction to the state Medicaid agencies to provide the eligibility information requested by hospitals in order to support the Medicaid fraction of the DSH calculation for Medicare. This direction will eliminate the varying processes and accountability depending on the state. Further, this instruction must also apply to the health plans that contract with the state Medicaid agencies so that hospitals can also have reasonable access to eligibility data on the population of Medicaid recipients enrolled in managed care.

Post Acute Transfer Payments:

The proposal to expand the post-acute care transfer provision – either to all DRGs or an additional 231 (increased from 223 after revisions to the proposed rule after it was released) —must be reversed. The inpatient PPS was developed with the intent of reducing the length of stay for patients by creating incentives for providing efficient care, while continuing to provide high quality medical services. To penalize hospitals for making good clinical decisions and discharging patients prior to the average length of stay when medically appropriate is in direct conflict with the design of the payment system. In addition, the annual recalibration of the system should already take into account the cases that are transferred prior to the average length of stay and thus, hospitals caring for patients falling into these categories whose stays are longer are already experiencing the financial burden of exceeding the average stay.

Further expansion of the policy also contradicts the mathematical premise of the inpatient PPS. In a system of averages, there will be cases when the patient's length of stay is below the average, as well as above. By reducing payment for cases below the average, CMS inhibits hospitals' ability to break even in the payment system. More importantly, any concerns policymakers may have had about early discharge of patients to gain additional payment by providing post-acute care have already been allayed. Significant cutbacks in Medicare payment and the shift to PPS for home health, skilled care and other post-acute care services have removed any previous incentive that may have been in place for early discharge. Further, each of these post-acute care payment systems have admission criteria that ensures patients are not discharged prematurely to a lower level of care. Finally, the policy reduces incentives to integrate care with other community providers, such as home health agencies, because it penalizes hospitals for

doing so at a time when consideration should be given to incorporating a continuum of care in the best interests of patients' needs and in order to achieve the best quality outcomes.

For the third year in a row, CMS is proposing extensive changes to the criteria a DRG must meet to be added to the post-acute care transfer policy. These continual changes in the DRGs subject to the policy create a situation that makes it nearly impossible for hospitals to plan financially from year-to-year as CMS attempts to arbitrarily change the criteria to ensure certain DRGs are included in the transfer policy.

Finally, CMS' proposed policy change on the post-acute transfers in this rule is inconsistent with the statements made by the agency in FY 2006 proposed rule for the skilled nursing facility (SNF) PPS. Specifically, in the May 19, 2005 proposed rule (page 29081), CMS states "Medicare should provide payments sufficient to ensure that beneficiaries receive high quality care in the most appropriate setting, so that admissions and any transfers between settings occur only when consistent with good care, rather than to generate additional revenue". A detailed evaluation of the outcomes associated with transferred patients is necessary before any further expansion of the policy occurs to identify not only length of stay changes but other items such as inpatient readmissions and level of care received in the post-acute setting as measured by the classification systems present in the SNF and home health payment systems.

Hospital Quality Data

Iowa hospitals are fully supportive of the reporting of quality data through the CMS initiative, as evidenced by the fact that 86 facilities are participating in the project, including 42 CAHs who are not affected by the payment reduction. However, we are concerned about CMS' proposal for additional requirements associated with chart validation in order to receive the full FY 2006 payment update. Although audits and data validation are necessary to ensure that the information being reported is reliable, **we oppose any attempt by CMS to link this validation process with the hospital update factor at this time.** CMS audits of 2004 data were often unreliable due to data problems and inconsistent definitions. These issues were not completely resolved by third quarter of 2004, which is the period that CMS is proposing as a basis for the update. Hospitals should not suffer a payment reduction due to technical problems with the data submission and validation process. Therefore, **we recommend that CMS withdraw its proposal for chart-audit validation until such time as all technical issues are resolved.**

Thank you for your consideration of these comments. If you have any questions or wish to discuss any issues further, please contact Merry Berns at 515-643-7251 or me at 515-643-4550.

Sincerely,

Steven F. Kukla, Senior Vice President/Chief Financial Officer
Mercy Medical Center – Des Moines

Heart Rhythm Society℠

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DRG-6 ---------- Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

June 23, 2005

Mr. Marc Hartstein
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850.

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 **(CMS-1500-P)**
Section II 4a. Automatic Implantable Cardioverter / Defibrillators.

Dear Mr. Hartstein:

The Heart Rhythm Society (HRS) appreciates the opportunity to comment on the CMS Proposed Rule on the Medicare Hospital Inpatient Prospective Payment System for FY 2006, published in the May 4, 2005 Federal Register (CMS-1500-P). The Heart Rhythm Society is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients and the primary information resource on heart rhythm disorders.

We believe that a prospective payment system has been an appropriate and successful means of controlling costs, encouraging efficiency, and simplifying payments for hospital services. An important requirement of any payment system, however, must be to pay appropriately for medical services so as not to limit access to care or diminish the quality of care. In addition, payments and the determination of such payments under the system must be reasonable and fair and based on accurate and complete data.

For FY 2006, we ask CMS not to remove 37.26 from the list of cardiac catheterization procedures that map to DRGs 535 and 536. We believe that 37.26 should be retained in DRGs 535 and 536 until definition and usage of 37.26 is clarified and adequate data is accumulated to determine whether a modification of the defibrillator DRGs is justified.

In previous DRG revisions CMS has stated that a full-scale electrophysiologic study (EPS) qualifies as a cardiac catheterization. However, the data do show that cardiac defibrillator cases with code 37.26 alone have lower average charges than those with other cardiac catheterization codes. This likely reflects coding problems in the use of

1400 K Street NW, Suite 500 | Washington, DC 20005 | USA | Phone: 202-464-3400 | Fax: 202-464-3401 | info@HRSonline.org | www.HRSonline.org

37.26, particularly in differentiating between device interrogations, noninvasive-programmed stimulation, intraoperative induction and testing, and full scale diagnostic EPS. We do not believe that removing 37.26 from the list of cardiac catheterization procedures that map defibrillator cases to DRGs 535 and 536 is warranted at this time. We believe that it is not appropriate to modify the DRGs based on charge data that includes such unequal procedures. The solution is to fix the coding, not to alter DRG assignment.

As noted in the proposed rule, the logic of DRG assignment for defibrillators rests partly on whether the patient received a cardiac catheterization during the stay. In the past, CMS has explained that cardiac catheterization is used to differentiate DRGs 535 and 536 from DRG 515 because "cardiac catheterization is generally performed to establish the nature of the patient's cardiac problem and determine if implantation of a cardiac defibrillator is appropriate" (Federal Register, August 1, 2004, p. 45356). CMS noted that cardiac catheterization is generally performed on an outpatient basis to establish the need for defibrillator implant prior to admission. Patients admitted with AMI, heart failure or shock who undergo cardiac catheterization during their stay are generally acute patients who require defibrillator implantation urgently. All of these statements are equally true for full scale diagnostic EPS.

Diagnostic cardiac catheterization involves threading catheters into the heart chambers to take pressure measurements. Among other things, diagnostic cardiac catheterization is used to determine the ejection fraction, a classic indicator associated with heart failure. In comparison, full scale EPS is also diagnostic. It also involves threading catheters into the heart chambers, this time to assess the electrical activity of the heart. The results of a full scale EPS, for example identifying inducible ventricular tachycardia, can be important in determining the need for a defibrillator as well as the appropriate device type and how it is programmed.

Full scale diagnostic EPS can be and often is performed on an outpatient basis to electively evaluate the need for a defibrillator. As with cardiac catheterization, EPS performed as an inpatient indicates an acute patient who requires urgent defibrillator implantation.

The problematic issue with the CMS data analysis is that code 37.26 is used for procedures other than full scale diagnostic EPS. This is an issue with the code, not with electrophysiologic studies or defibrillator implantation. During part of FY2004, the time frame for the MedPAR file used in the analysis, code 37.26 could be used to represent four different procedures:

- device interrogation without arrhythmia induction
- noninvasive programmed stimulation (NIPS)
- full scale diagnostic EPS
- intraoperative induction and device testing

While they share some features, these procedures differ considerably. Device interrogation can be performed bedside in the patient's room. Due to the risk to the

patient, NIPS must be performed in a fully equipped electrophysiologic laboratory but is non-invasive. EPS must also be performed in an EP lab but is invasive and requires special disposable catheters. It was also noted in the proposed rule that the inappropriate use of 37.26 for intraoperative testing exists within the coding community. Given the broad scope of the code and the wide variation in hospital resources across the procedures, it is not surprising that defibrillator cases with 37.26 showed lower average charges than procedures with cardiac catheterization.

Effective November 1, 2003, coders were instructed to stop using 37.26 for bedside interrogations (Coding Clinic, Third Quarter 2003, p.23). Although this was early in FY2004, new guidelines take time to disseminate among coding staff and to be reflected in coding systems. Moreover, it was not until the FY2005 ICD-9-CM updates that notes were placed on codes 37.26, 89.45, and the newly created 89.49 clearly differentiating bedside interrogation without arrhythmia induction from NIPS and EPS. Thus, it seems likely that the FY 2004 MedPAR data for 37.26 is skewed by the presence of bedside interrogations, a low resource procedure that is no longer coded to 37.26.

Throughout FY 2004, code 37.26 was used for both NIPS and full scale diagnostic EPS, which remains the practice today. These procedures are similar in that both must be performed in an EP lab and both involve inducing arrhythmias. However, EPS is invasive and is truly diagnostic. In contrast, NIPS is non-invasive and is performed to test a previously implanted device.

The resource intensity of full scale diagnostic EPS on defibrillator DRGs cannot be properly assessed until these lesser procedures are no longer part of 37.26. Moving bedside interrogation out of 37.26 was a good step in the right direction. CMS should continue moving in this direction by separating NIPS and EPS within ICD-9-CM. This will result in a discrete code (37.26) to clearly identify full scale diagnostic EPS.

Instructing coders that 37.26 should not be used for intraoperative testing is equally important. In the short term, this can be accomplished through a clarification in the Federal Register, Final Rule that intraoperative testing is part of the procedure and is not reported separately as 37.26. The long-term solution is to provide coding clarification within the description of 37.94 which currently include "intraoperative procedures for evaluation of lead signals, and obtaining defibrillator threshold measurements."

Cardiac resynchronization therapy defibrillators improve the heart's pumping ability by delivering small electrical impulses that help synchronize contractions of the left ventricle. The left ventricle is the heart's main pumping chamber, and its ability to pump blood is enhanced when the muscular walls contract synchronously. In addition, cardiac resynchronization therapy defibrillators monitor the heart for potentially fatal rhythms. If such a rhythm is detected, a lifesaving shock is delivered, restoring normal heart rhythm and preventing sudden cardiac death.

Cardiac resynchronization therapy with defibrillation meets the criteria for a new technology. This technology is still inadequately reimbursed under the current system and provides substantial diagnostic and treatment improvement relative to technologies

previously available. We urge CMS to continue allowing for this higher payment in fiscal year 2006 for some Medicare-covered heart failure patients who receive a cardiac resynchronization therapy defibrillator device.

We hope that CMS will accept these recommendations from The Heart Rhythm Society and not remove code 37.26 from DRG 535 and 536. CMS should allow time for more accurate data to be collected with the removal of the unequal procedures out of code 37.26 and provide clear instruction regarding intraoperative testing. Thank for the opportunity to comment on the proposed inpatient rule. If you or CMS staff have questions please feel free to contact Brian Outland, Manager of Regulatory and Reimbursement Affairs at boutland@HRSonline.org or 202-464-3433

Sincerely,

Anne B. Curtis, MD
President, Heart Rhythm Society

Mark D. Carlson, MD
Chair – Health Policy Committee

EDWARD M. KENNEDY
MASSACHUSETTS

RECEIVED
JUN 2 4 2007
BY:..........

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United States Senate

WASHINGTON, DC 20510-2101

June 24, 2005

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Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Hubert H. Humphrey Building
Room 314G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mark,

I'm writing about changes in the Medicare payment level for external ventricular assist devices that I urge you to consider in the upcoming inpatient prospective payment system rule. As you know, patients with acute heart failure may require support from these devices, but the current payment rules strongly favor implantable devices over external devices.

The rules provide a financial incentive for using an implantable device, without first attempting to use an external device. Recovery of the patient's own heart is often the best possible clinical outcome. It is much less costly for the health system, and reduces the demand for heart transplants. While implantable devices are necessary in certain cases, they carry greater risk and are often much more costly. Yet payments for implanting a device are nearly twice the payments for an external device, and hospitals can receive multiple payments for performing multiple procedures.

Improvements in technology and in use of external devices have increased the period of support required for recovery from acute heart failure, but Medicare payments have not similarly increased. As a result, hospitals may actually lose money when deciding to use an external device.

Since my letter to you on this issue in March, new information from the Lewin Group and the Abiomed patient registry have been submitted to CMS that makes a compelling case for payment changes. The data demonstrate that the length of stay and average charges for heart recovery with an external device CMS is currently using is outdated. Current data shows improved recovery but longer lengths of stay and higher charges when compared with other treatments in the same diagnosis-related group, leading to underpayment for this procedure.

I urge you to address this issue when CMS issues its final regulation on the inpatient prospective payment system in August, in order to see that external device payments are appropriately reimbursed. Clearly, financial incentives should not unfairly influence physicians in deciding which type of device to use.

With respect and appreciation.

Sincerely,

Ted Kennedy

Edward M. Kennedy

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Congress of the United States
Washington, DC 20510

June 24, 2005

Mark McClellan
Administrator
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1500-P; Medicare Program, Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

Dear Mark:

We're writing to urge you to modify the proposed FY2006 Medicare inpatient prospective payment regulation so that the hospitals in Bristol County, Massachusetts can seek to be reclassified in the Boston wage index area.

The hospitals in Bristol County were included in the Boston wage index area for two decades before changes in 2005 that put these hospitals into the Providence Fall River wage area. The Bristol County labor market, however, is more like Boston than Providence. Nearly one-fourth -- 22 percent -- of working adults in Bristol County commute to Boston, while only 8.5 percent work in Providence. Bristol County hospitals must pay wages similar to Boston hospitals to recruit and retain health professionals in their community.

The Bristol County hospitals requested reclassification into the Boston wage index area, but the Medicare Geographic Classification Review Board concluded that the hospitals did not meet the county-wide proximity requirement and rejected the request. We believe that the review board adopted too narrow an interpretation of the proximity criteria established by CMS in its FY2005 final rule. The board's interpretation limits reclassification opportunities in Massachusetts and New England, even though similarly situated hospitals in any other region of the country would have had a reasonable opportunity to reclassify.

This disparate treatment between hospitals in New England and those in the rest of country arose because the 1990 wage index classification system for New England hospitals was based on New England County Metropolitan Areas, rather than the Consolidated Metropolitan Statistical Areas used in other regions. The review board interpreted the CMS rule very narrowly, so that the proximity criteria applied only to hospitals previously in CMSAs and not to hospitals in NECMAs.

We urge you to clarify that NECMA status can meet the 1990 proximity standard when hospitals apply to reclassify, and to use your authority to reclassify the Bristol County hospitals. We also urge you to remove the proposed provision in the draft regulation that would eliminate reclassification based on the 1990 proximity standard, which would prevent reclassification opportunities for New England hospitals.

Sincerely,

Edward M. Kennedy

John F. Kerry

James P. McGovern

Barney Frank

CMS-1500-P-821

Submitter : Edward Kennedy **Date:** 06/24/2005

Organization : U.S. Senate

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-821-Attach-1.DOC

3556

Submitter : Mr. Joseph Gatewood **Date:** 06/21/2005

Organization : AdvaMed

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-481-Attach-1.DOC

356

E Comment Attachment 481

NT
DRG/Gen
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Transfers
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Exhibit
MedPAC

June 21, 2005

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

File Code CMS-1500-P: Comments related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide our comment letter on the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2006 rates (CMS-1500-P), (hereinafter referred to as "Proposed Rule" or "NPRM"). AdvaMed is the largest medical technology trade association in the world, representing more than 1,300 medical device, diagnostic products, and health information systems manufacturers of all sizes. AdvaMed member firms provide nearly 90 percent of the $75 billion of health care technology products purchased annually in the U.S. and nearly 50 percent of the $175 billion purchased annually around the world. Nearly 70 percent of our members have fewer than $30 million in sales annually.

This letter reiterates and expands on some of AdvaMed's previously stated concerns about new technology add-on payments, including the definition of 'new' in the context of eligibility for new technology add-on payments. It also outlines our positions on a broad range of payment and policy issues contained in the Proposed Rule.

New Technology Issues

Before we begin to discuss our comments to the Proposed Rule, we would like to make a few general comments regarding new technology add-on payments. We believe that the new-technology add-on program is an extremely important payment mechanism designed to ensure patient access to new medical services and technologies and to recognize the often higher costs of new technologies more quickly than would otherwise be possible through the underlying DRG system. AdvaMed has been one of the major proponents of this program and we have worked extensively with both Congress and CMS to create and improve the program so that it most effectively meets the goal of earlier patient access to new medical technologies. AdvaMed and its member companies are committed to continuing to work with CMS to ensure that the program works as smoothly as possible.

CMS received eight applications for new-technology add-on payments in FY 2006. Of the eight applications, CMS proposed to deny payment for five products and deferred decisions on the remaining three until the final rule. While we are pleased that three applications remain under consideration, we also believe the Proposed Rule raises a number of product and policy issues that may inappropriately deny eligibility for a number of the remaining applications. In particular, we are concerned that the Proposed Rule raises issues regarding CMS's consistency on the definition of newness; the use of "substantial similarity" as a criterion in newness determinations; and implementation of certain provisions from the MMA. We provide detail on these and other concerns below, and request that you take these issues into consideration as you review all the applications for the final rule.

When new technologies are launched, manufacturers must rely on clear and definitive guidelines and processes to insure our reimbursement efforts and data collection meet the needs of CMS. If these guidelines are not clear, or are ever-changing, manufacturers lose valuable time in product adoption and patient access to life-changing technologies is greatly reduced. We respectfully request clarification on the issues noted below to ensure that the program requirements are as clear and predictable as possible.

CMS Should Attempt to Assign New Technology to an Appropriately Clinically Similar DRG, Where the Average Costs of Care Most Closely Approximate the Costs of Care Using the New Technology ("New Technology Applications")

For technologies satisfying the cost criteria and other qualifying requirements under the inpatient new technology provision, the MMA requires that CMS first seek an appropriate temporary DRG assignment before establishing a new technology add-on payment. In the Proposed Rule, CMS correctly notes that amended section 1886(d)(5)(K) of the Act requires that prior to establishing an add-on payment for a new medical service or technology, the Secretary (of HHS) shall "seek to identify one or more DRGs associated with the new technology, based upon **similar** clinical or anatomical circumstances and the cost of the technology and assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. Within such groups the Secretary shall assign an **eligible** new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care using the new technology..." (emphasis added).

However, CMS does not seem to acknowledge this statutory requirement in response to a specific request for DRG reassignment by one of this year's new technology applicants (CHARITE Artificial Disk). In the Proposed Rule CMS solicits comments on whether the agency should re-assign ICD-9-CM code 84.65 (Insertion of total spine disc prosthesis) to a new set of DRGs through the normal processes outside the context of the New Technology DRG program. For example, the agency separates the two issues by stating it is "interested in public comments on **both** the new technology application for CHARITE **and** the DRG assignment for spinal disc prostheses." (emphasis added). We

understand the applicant has requested DRG reassignment within the context of the New Technology DRG application.

We encourage CMS to follow its statutory mandate and attempt to first seek an appropriate, clinically similar DRG on a temporary basis into which the eligible applicant could fit, prior to considering the technology for an add-on payment. While we recognize that it may not be possible to assign all new eligible new technologies to existing DRGs, we do think CMS should more rigorously analyze, in accordance with its statutory mandate, whether an applicant meets the test for the temporary DRG assignment in the Proposed Rule.

CMS Has Been Inconsistent in Determining the End-Point to Eligibility for New Technology Payments ("New Technology Applications")

CMS has been inconsistent in the manner in which it recognizes the reimbursement period for new technology, particularly when the payment eligibility period overlaps into a portion of another calendar year. In the Proposed Rule, CMS notes that a hip replacement product was available on the market in April 2003 and thus "charges reflecting the cost of the device may have been included in the data used to calculate the DRG weights in FY 2005 and the proposed DRG weights for FY 2006." CMS's preliminary conclusion is inconsistent with the agency's past rulings on other technologies, which were available on the market for nearly identical lengths of time as the hip replacement technology, and were approved by the agency for add-on payments.

Specifically, last year CMS approved add-on payments for cardiac resynchronization therapy with defibrillator (CRT-D). One such device received Food and Drug Administration (FDA) approval in May 2002, and another received FDA approval in June 2002. Both of these devices were deemed "new," since, according to CMS, the FY 2005 add-on payment year would represent the third year of the two-to-three year "new" window following the date of FDA approval. In addition, as CMS characterizes last year's decision on the CRT-D add-on payment in this year's Proposed Rule, "We also noted that we would extend new technology add-on payments for the entire FY 2005 even though the 2-3 year period of newness ended in May 2005 for CRT-D since predictability is an important aspect of the prospective payment methodology and, therefore, we believe it is appropriate to apply a consistent payment methodology for new technologies throughout the fiscal year."

CMS also approved add-on payments in FY 2005 for Bone Morphogenetic Proteins (BMP) for spinal fusions. This product received FDA approval in July 2002 and, according to CMS, "[It] was still within the 2-year to 3-year period during which a technology can be considered new under the regulations."

There appears to be no meaningful distinction between the timeframe at issue in the case

of the hip replacement technology in this year's Proposed Rule and the timeframes that existed in the cases of the CRT-D and BMP technologies. The hip product was available on the market in April 2003 and is being considered for an FY 2006 add-on payment. As with the two comparably approved add-ons, the hip product's two-to-three year period of newness would end in the middle of the third and final year of eligibility for an add-on payment. Under CMS's interpretation of its own regulations, not only is the hip product still within the two-to-three period during which a technology can be considered "new," it is eligible for an add-on payment for the full fiscal year. Moreover, it is puzzling that while CMS identifies predictability and consistency as "important aspect[s] of the prospective payment methodology," the agency does not apply these same principles to the way in which it counts the months after FDA approval for every new technology application it evaluates.

CMS Should Signal that Technologies don't Meet Eligibility Requirements in its Annual Hospital PPS Proposed Rule ("New Technology Applications")

To qualify for a new technology add-on payment, an applicant must meet the eligibility criteria contained at 42 C.F.R. § 412.87(b)(2) and (b)(3). The eligibility criteria define when a specific service or technology will be considered new, and under what circumstances the applicant will meet the cost thresholds. Assuming the eligibility criteria are met, CMS then focuses on whether the applicant technology is a substantial clinical improvement over existing technologies (42 C.F.R. 412.87(b)(1)). CMS states in the Proposed Rule that "we do not make determinations about substantial improvement unless a product has already been determined to be new and meet the cost criterion."

AdvaMed believes that the regulatory process would be improved if CMS would signal new technology applicants in the Proposed Rule whether they are unlikely to meet the eligibility requirements. This would permit applicants the opportunity to specifically address eligibility concerns during the comment period, after the proposed rule is issued. To the extent CMS waits until the final rule to reveal concerns about an applicant meeting the eligibility criteria, applicants are effectively left with no regulatory mechanism to provide feedback to CMS, and must wait an entire year to address CMS's concerns. The consequence is that the applicant essentially loses a year of eligibility to receive the new technology payment.

AdvaMed recognizes that it may not always be practicable, based upon lack of information, or other reasons, for CMS to take a preliminary position regarding a particular technology's eligibility in the proposed rule. However, AdvaMed believes that CMS often has at its disposal sufficient information to articulate at least a preliminary stance on eligibility when it issues the proposed rule. To the extent CMS has eligibility concerns, it should articulate them in the proposed rule and not wait until the final rule.

In such cases, AdvaMed requests that CMS more aggressively engage in dialogue with the industry and make its position known in the proposed rule.

CMS Should Raise the New Technology Add-On Payment Percentage From 50% to 80% ("New Technology Applications")

The MMA's report language urged CMS to consider raising the add-on payment level from 50 percent to 80 percent of the difference between the standard DRG payment and the cost of the procedure with the new technology. We were disappointed that CMS did not address this issue in the Proposed Rule, but hope that CMS will consider this as a future change, so that the add-on payment is conformed to the inpatient outlier payment level.

CMS Should Not Use Substantial Similarity as an Additional Criteria in the New Technology Add-On Process ("New Technology Applications")

A new technology applicant must meet three criteria ('eligibility criteria') to be eligible for the add-on payment. The criteria at 42 C.F.R. § 412.87(b)(2) and (b)(3) – related to newness and adequate reimbursement under existing DRG payments – have been described in the past by CMS as 'threshold criteria.' The newness and cost threshold criteria must be met before CMS will analyze whether the technology is a substantial clinical improvement over existing technologies, as required by 42 C.F.R. § 412.87(b)(1).

CMS has in the past expressly avoided making determinations on the key clinical issue, substantial improvement, in circumstances where the new technology applicant does not meet the newness and cost criteria. For example, in the FY 2005 Final Rule, in response to its decision not to discuss the substantial clinical improvement criteria with regard to one applicant, CMS stated "[w]e conduct sufficient analysis on each application in order to provide sufficient opportunity for comment. We do not believe that it is necessary to provide a full analysis of all the criteria in cases where, for example, we believe that sufficient criteria is available in order to propose denying the application on the basis of the newness criterion." 69 Fed. Reg. 49018-49019 (Aug. 11, 2004). And, in the Proposed Rule for FY 2006, CMS reiterated that, "we do not make determinations about substantial improvement unless a product has already been determined to be new and meet the cost criterion."

The threshold criteria neither include criteria for determining whether a technology is substantially similar to existing technology, nor do they even address that issue. Nonetheless, in the Proposed Rule, CMS opines that several new technology applicants are 'substantially similar' to existing technology in the absence of any clinical assessment. AdvaMed is concerned that CMS is using the determination of 'substantial similarity' as a basis to support a preliminary determination that these technologies are 'not new,' and therefore not eligible for the add-on payment, when no such requirement exists in the threshold criteria, and even when the products fall within the two- to three-year window to be considered new by CMS's criteria.

AdvaMed believes this type of analysis is a departure from CMS's past practices, and amounts to the application of a barrier that is not contained within the threshold criteria of 42 C.F.R. § 412.87(b)(2) and (3). AdvaMed is also concerned that CMS is imposing criteria that are either intended to be applied, or at least similar to, the clinical criteria that should be addressed at the final stage, not the threshold stage, of the new technology application process. CMS has always clearly delineated that it does not wish to engage in assessing clinical improvement until such time as the cost and newness issues are decided favorably. In the Proposed Rule, however, CMS appears to be engaging in at least some form of a clinical analysis when it opines that a bone growth factor product is 'similar' to another product.

AdvaMed's concerns are magnified by the fact that the regulations contain no stated criteria for determining whether a technology is 'substantially similar' to another, and, further by the fact that the regulations make no mention of a substantial similarity test within the threshold criteria. While CMS did solicit comments prior to the February 23, 2005 Town Hall meeting on the topic of when products should be considered 'substantially similar,' the agency has not implemented such criteria by regulation, and in the Proposed Rule rejected many possible criteria that were suggested at that meeting.

AdvaMed does not believe that the determination of whether a technology is substantially similar is a part of the threshold criteria. Instead, such determinations are more properly conducted within 42 C.F.R. § 412.87(b)(1) which states that "[a] new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." We do not believe it is appropriate for CMS to adopt or undertake an ad hoc clinical assessment during the eligibility phase of the new technology application process.

Eligibility of Add-on Payments for Subsequently Approved Products ("New Technology Applications")

We wish to call to CMS's attention an apparent inconsistency in the application of the "substantial similarity" provision regarding the eligibility of competing products for add-on payments. In numerous instances, CMS has stated that "an approval of a new technology for special payment should extend to all technologies that are substantially similar. Otherwise our payment policy would bestow an advantage to the first applicant to receive approval for a particular new technology" (May 4, 2005 Federal Register, page 23363). AdvaMed remains broadly supportive of this policy and believes it advances the goal of earlier patient access to new technology (despite our concerns with CMS' usage of "substantial similarity" as noted above).

AdvaMed is therefore surprised by CMS's statement that thoracic aortic stent grafts that are approved by the FDA subsequent to the FDA's approval of W.L. Gore & Associates' Endovascular Graft Repair of the Thoracic Aorta (GORE TAG) – which submitted the

new technology application – may only be considered as eligible for an add-on if the product receives FDA approval prior to publication of the FY 2006 rule (May 4, 2005 Federal Register, page 23363). It appears that imposing a requirement of FDA approval for subsequent products prior to an arbitrary date, such as the publication of the final rule, contradicts CMS's goal of not bestowing an advantage to the first product to reach the market. In addition, since all endovascular stent grafts for thoracic aneurysm will be identified by the same new ICD-9-CM procedure code, CMS will be operationally incapable of determining which products are eligible for add-on payments and which ones are not. We therefore urge CMS to revise its stated position on eligibility for add-on payments and clarify that the subsequent date of FDA approval for "substantially similar" thoracic endografts will have no bearing on whether such products are eligible for add-on payment if the initial applicant is approved.

DRG Reclassifications Issues

Stroke Reimbursement ("DRG Reclassifications")

AdvaMed applauds CMS for meeting with industry representatives from several hospital stroke centers and seeking comment on their recommended modification of the existing stroke DRGs 14 and 15 by using the administration of reperfusion agents as a proxy to identify patients who have severe stroke. Cases that involve reperfusion agents such as thrombolytic therapy are highly resource intensive, as shown in CMS's analysis. To ensure that Medicare resources are allocated efficiently to the most severe stroke discharges, we recommend that CMS create a separate DRG for patients receiving a reperfusion agent outside of the existing DRGs 14 and 15. AdvaMed notes that Medicare hospital reimbursement for stroke-related procedures has historically been relatively poor. Accordingly, AdvaMed supports the proposed modifications to DRGs 14 and 15 that would improve reimbursement and patient access to the most efficacious therapies for stroke patients who are disproportionately covered by Medicare. CMS's timely attention towards DRG restructuring will dramatically improve the barriers faced by hospitals today in providing these treatments, thereby improving patient outcomes for this urgent disease state.

Automatic Implantable Cardioverter/Defibrillator ("DRG Reclassifications")

We ask CMS to withdraw its proposal to remove hospital procedure code 37.26 (cardiac electrophysiological and recording studies [EPS]) from the list of cardiac catheterization procedures that map to DRGs 535 and 536. We believe that code 37.26 should be retained in DRGs 535 and 536 until CMS clarifies coding issues surrounding code 37.26 and accumulates adequate data to determine whether a modification of the defibrillator DRGs is justified.

Currently code 37.26 covers a diagnostic electrophysiology study and a non-invasive

programmed stimulation (NIPS). CMS is concerned that intraoperative device interrogation (currently included in code 37.94, ICD system implant) may also be commonly coded as 37.26. When one code embodies several disparate procedures with varying purposes, sites of service, and intensity, we believe the resultant data is not representative of any one of the procedures. Until the coding issue is addressed, the charge data for cases in DRG 535 and 536 involving 37.26 is invalid and should not be used as the basis for this proposed modification. The coding changes needed to eliminate the confusion surrounding code 37.26 were submitted to CMS on February 11, 2005, and will be on the agenda for the September 29, 2005, meeting of the ICD-9-CM Coordination and Maintenance Committee meeting.

CMS should withdraw its proposal to remove code 37.26 from the list of cardiac catheterization procedures that affects the DRG assignment for defibrillator cases. Separate codes should be assigned to the separate procedures currently described by code 37.26. Charge data should be gathered for these distinct procedures to determine if the data justifies a modification of the defibrillator DRGs. Once coherent charge data has been collected, we would welcome the opportunity to evaluate future refinement of the current defibrillator DRGs based on appropriate resource utilization.

Coronary Artery Stents ("DRG Reclassifications")

AdvaMed supports CMS as it continues to maintain a separate reimbursement structure for discharges involving the insertion of drug-eluting coronary artery stents (DES). This temporary structure has allowed hospitals to obtain some incremental reimbursement for the more costly DES cases as compared to patients receiving bare metal stent (BMS) devices. While hospital utilization of BMS devices has declined, CMS should not eliminate the temporary DES DRGs until such time that BMS represent an insignificant proportion of the total coronary stent discharges.

CMS has proposed to modify this structure in FY 2006 by splitting out the two existing coronary stent DRGs for AMI patients (516 and 526) based on the presence or absence of a secondary diagnosis on the existing CC list. Specifically, CMS is proposing to delete DRGs 516 and 526 and replace them with four DRGs: DRG 547 (Percutaneous Cardiovascular Procedure with AMI with CC), DRG 548 (Percutaneous Cardiovascular Procedure with AMI w/out CC), DRG 549 (Percutaneous Cardiovascular Procedure with DES with AMI with CC and DRG 550 (Percutaneous Cardiovascular Procedure with DES with AMI w/out CC).

As exhibited in the FY 2004 MedPAR file, there is a clear differential in the average hospital charges for AMI patients with and without CCs. AdvaMed supports the creation of the four new DRGs for FY 2006 that would differentiate reimbursement for these sets of AMI patients which represent approximately 27 percent of all coronary stent discharges. At the same time, AdvaMed, agrees with the agency that this structure should "not preclude proposals in subsequent years to restructure the coronary stent

DRGs based either or both on the multiple vessel treatment or insertion of multiple stents."

AdvaMed congratulates CMS for acting quickly to create four new ICD-9-CM codes identifying multiple stent insertion (codes 00.45, 00.46, 00.47 and 00.48) and four new codes identifying multiple vessel stent (MVS) treatment (codes 00.40, 00.41, 00.42 and 00.43). We believe these codes will provide CMS with important data as it continues to analyze and refine both coronary and peripheral stent DRGs. AdvaMed looks forward to working with the agency as the data from these new multi-vessel/multi-stent codes become available.

The creation of four new DRGs and eight new ICD-9-CM procedure codes related to coronary and peripheral vascular stenting in FY 2006 may present challenges for hospitals initially when billing and coding for DES procedures. We encourage CMS to support collaborative education efforts with the American Hospital Association Coding Clinic to ensure that hospitals are aware of the new codes and DRGs. AdvaMed members also plan similar education efforts to ensure that the data derived from the new codes is accurate.

Carotid Artery Stents ("DRG Reclassifications")

As the agency notes in the Proposed Rule, CMS established codes for carotid artery stenting procedures (CAS) on October 1, 2004. AdvaMed commends CMS and the ICD-9-CM Coordination and Maintenance Committee for working with industry to create these new procedure codes to properly identify and track this breakthrough therapy.

For the Proposed Rule, CMS completed an analysis using FY2004 MedPAR data to determine charges and length of stay associated with carotid artery stenting in DRGs 533 and 534 by using procedure codes 39.50 and 39.90 in combination with diagnosis code 433.10. This code combination is an excellent proxy to identify carotid stenting cases given that the new ICD-9 codes were not effective for the FY2004 MedPAR data. The analysis of FY2004 MedPAR indicates that carotid artery stenting cases have average charges of $29,737 and $22,002 for DRG 533 and 534, respectively, compared to average charges of $24,464 and $15,873 for all cases within DRG 533 and 534, respectively, resulting in charge differentials of $5,273 (22%) and $6,129 (39%).

In analyzing the FY2004MedPAR data, we noted an even greater difference in average charges between carotid stent cases and the average charge for the entire DRG as evidenced in the table below:

DRG	With or without 39.50 and 39.90	Discharges	Average Length of Stay	Average Charge	Average Standardized Charge
533	All Cases	35,730	3.1	$ 23,910	$ 21,286
533	DRG without codes 39.50 and 39.90	33,992	3.1	$ 23,294	$ 20,845
533	DRG with codes 39.50 and 39.90	1,738	3.1	$ 35,961	$ 29,903
534	All Cases	37,457	1.7	$ 17,012	$ 15,166
534	DRG without codes 39.50 and 39.90	35,911	1.7	$ 16,580	$ 14,870
534	DRG with codes 39.50 and 39.90	1,546	1.5	$ 27,042	$ 22,065

Based on analysis of the MedPAR data, the increase in charges between carotid stent cases and DRGs 533 and 534 is $8,617 (40%) and $6,899 (45%), respectively, indicating the potential for significant under payment for carotid stenting cases in these DRGs. This potential underpayment for carotid stenting procedures is likely understated as the 2004 MedPAR data came at a time prior to FDA approval of any carotid devices and thus only included discharges for patients participating in clinical trials. As a result, it is likely that few, if any, hospitals included the full cost, or any significant cost, of the carotid stenting devices in their FY 2004 charges. The differential between carotid and non-carotid cases will likely grow more pronounced in the FY 2005 MedPAR data as hospitals begin to include the charges for the FDA-approved carotid stent cases in their claims to CMS.

Although, we appreciate CMS' attention to establishing the appropriate payment for this technology, given the significant difference in charges, we recommend that CMS create new DRGs for carotid stenting cases, split on the presence or absence of complications or co-morbidities. In the analysis, the volume of carotid artery stent cases appears small, but, given the recent availability of FDA approved devices new and ongoing clinical trials, multiple post market registries, and expanded Medicare coverage the volume of carotid stent cases is and will continue to increase. The increase in patient volume and the inadequate payment for carotid artery stent cases will create a financial hardship on facilities providing this technology, potentially resulting in decreased beneficiary access to a beneficial therapy. Therefore, we encourage the agency to consider a new DRG pair for carotid artery stenting in FY 2006.

Hip and Knee Replacements -- DRG Split of Revision Procedures ("DRG Reclassifications")

AdvaMed commends CMS for its efforts to provide appropriate payment for revision hip and knee arthroplasty by proposing to split DRG 209 into DRG 544 (primary hip and knee arthroplasty) and DRG 545 (revision hip and knee arthroplasty), and to expand the scope of the relevant ICD-9-CM procedure codes. The new codes, in particular, are an important component in aligning hospital reimbursement with hospital costs and patient

benefits of total joint arthroplasty. We look forward to working with CMS to ensure that total joint arthroplasty procedures are tracked properly and paid for appropriately in the future.

We would encourage CMS to engage in dialogue with industry and providers regarding further DRG changes related to primary joint arthroplasty procedures, which represent approximately 90% of total hip and knee arthroplasty procedures. We are concerned about the unintended consequence of curtailing both medical technology innovation and limiting Medicare patient access to continued advances in treatment related to joint arthroplasty.

Industry is committed to continuously improve medical technologies used in joint arthroplasty. These improvements offer better outcomes to Medicare patients, and extend implant survivorship, which help reduce the need for future revision procedures. We look forward to providing guidance and support to CMS with regard to any further changes to DRGs related to total hip and knee arthroplasty procedures.

Comprehensive Review/Refinement of Complications/Comorbidities List ("DRG Reclassifications")

We agree with CMS that changes in resource utilization and in inpatient hospital care, particularly the focus on decreasing length of stay, may be resulting in the complications/comorbidities (CC) distinction not being able to differentiate resource utilization and patient severity as well as it has in the past. We also agree that it may be valuable to conduct a substantive and comprehensive review of the CC list for the future. However, we caution the agency to conduct this review with as much transparency and stakeholder involvement as possible and not to rush its analysis simply to meet the deadline for the FY 2007 rule. In fact, the agency may find it apparent when it begins to undertake its review and revision of the CC list that attempting to revise the CC list for the FY 2007 rule may be an unrealistic goal and additional time may be required, particularly to ensure stakeholder involvement in the review and revision.

In the Proposed Rule, CMS provides several examples of how the standards for determining the list of CCs might be revised. We recommend that CMS analyze several methodologies and publicly disseminate both the methods tested and the results of the analysis for comment. The final methodology, standards and final CC list should also be subject to public comment with sufficient time to allow for significant changes if needed before implementation in the final rule, thus, they should be released well ahead of the proposed inpatient rule for FY 2007. We encourage CMS to evaluate both the potential impact a secondary diagnosis may have on length of stay and on hospital charges as well as a comparison of the CC lists used with other DRG systems. The revision of the CC list will potentially have an extensive impact on hospital revenue streams, so any review and revision should be completed and implemented cautiously, systematically and thoroughly, using external expertise and maintaining transparency and stakeholder involvement throughout the process.

Post Acute Transfer Policy Issue

Post Acute Transfer Policy ("Post Acute Care Transfers")

We commend CMS for continuing to refine the DRG payment methodology to more appropriately align patient severity and facility resources with reimbursement. While the Post Acute Transfer policy may achieve efficiencies for some types of care, AdvaMed is concerned about the potential that it could undermine hospital incentives to shorten patient lengths of stay. As a result, more patients could be retained, for longer periods of time, in expensive acute short stay hospitals. We suggest, however, that it is premature to significantly increase the number of DRGs subject to the Post Acute Transfer Payment Policy since the reimbursement methodologies and treatment have changed significantly since 1998 when the policy was first implemented. AdvaMed is concerned that the criteria for Option 1 and Option 2 are based only on statistical analysis of postacute discharges or relationship to another DRG rather than a review of clinical treatment provided in the first and second days of an admission. As a result, the selection of DRGs is inconsistent and contradictory to the goal of aligning patient severity with payment.

To illustrate, of the 231 Post Acute Transfer DRGs, 58, or 25%, have a Geometric Mean Length of Stay (GMLOS) of less than 3.0 days which contradicts the criteria listed by CMS for Option 2. The policy to include a DRG "paired" with one that meets the criteria was based on a concern that is no longer valid, as most hospital coding systems interface to the billing system, and if the DRGs are paired with CCs, hospitals are not likely to delete the CC code. Secondly, the Transfer Policy allows for two types of payment to compensate for the higher intensity of first day care. However, there was no evaluation by CMS to determine if these payments are sufficient to cover that care. Although the Special Payment policy does provide that 50% of the DRG reimbursement be paid on the first day, it is not apparent from reading the Proposed Rule what criteria were utilized to select the DRGs subject to this policy. The result is inconsistent application. For example, DRG 109 (Coronary Bypass w/o PTCA or Cardiac Cath) is assigned the Special Pay policy while DRGs 107 (Coronary Bypass w PTCA) and 108 (Coronary Bypass w Cardiac Cath) will not be paid under the Special Policy. DRGs 107 and 108 are surgical types of DRGs in which the significant majority of resources are expended on the surgical procedures grouped to these DRGs, and therefore should be subject to the Special Payment policy.

AdvaMed notes that the basis for the post acute transfer policy was established on July 31, 1998 at 42 CFR § 412.4. The law that enacted this regulation was accompanied by "The Conference Agreement" in which the Conferees wanted "...strong incentives to treat patients in the most effective and efficient manner,....". At that time the policy went into effect, Medicare reimbursement for Post Acute Transfer services was based on costs. The current status has changed, and most of these services have transitioned to prospective payment systems (SNF PPS 10/1/1998; HHA PPS 10/01/2000; IRFS 01/01/2002; LTCH 10/01/2002; and IPF 01/01/2005). Medical technologies, innovative

treatment modalities, reimbursement policies and physician practice patterns have also significantly changed treatment delivery in a variety of settings since the initial regulations were implemented.

Since CMS has indicated in the Proposed Rule that it will be conducting an analysis of patient severity payment methodologies in response to the MedPAC recommendations, it would make sense to conduct the evaluation of the Post Acute Transfer Policy on DRG payments within that analytic framework. In the proposed rule of May 8, 1998, Appendix E provided cost analysis for each DRG subject to the Post Acute Transfer Policy. A review of a similar analysis and various severity adjustment methodologies may provide more appropriate alignment of payment with patient care and facility resource costs rather than adding additional payment rules that appear to have no clinical basis. We respectfully request postponing any change in the post acute transfer policy until a thorough analysis and review of severity methodology options is completed. We request that CMS undertake such changes only with ample notice and opportunity for meaningful comment from industry.

Blood Reimbursement Issue

Blood Reimbursement ("Hospital Market Basket" and "Excluded Hospital Market Basket")

As noted in the preamble to the Proposed Rule, CMS included in the FY 1997 based market basket a separate cost category for blood and blood products. This action was consistent with a 2001 MEDPAC Report to Congress entitled, "Blood Safety in Hospitals and Medicare Inpatient Payment." MedPAC made the following recommendation:

> When CMS revises the hospital market basket, it should explicitly account for the cost of blood and blood products by reintroducing a separate component for their prices.

MedPAC noted in that report that blood and blood products were included as a separate cost category in the Market Basket prior to fiscal year 1997. The category was combined with the chemicals component beginning in fiscal year 1997 but was listed as a separate category again beginning in fiscal year 2003. MedPAC further noted that CMS's decision to add blood and blood products to the chemicals component was motivated by "a lack of appropriate data for calculating a weight for blood services."

AdvaMed notes that the basis for CMS's motivation to add blood and blood products to the chemicals component, i.e. a lack of appropriate data, no longer exists. CMS was not only able to calculate a weight for the 2003 market basket (0.875), but was also able to list the weight (1.082) in the Proposed Rule. We urge CMS to act in accordance with the MedPAC recommendation and retain blood and blood and blood products as a separate cost category in the Market Basket.

Additionally, we appreciate CMS's review of three alternative price proxies for blood and blood products. As noted in the Proposed Rule, CMS previously used the Bureau of Labor Statistics (BLS) PPI (commodity code #063711) for blood and derivatives as a price proxy. While we agree that price movements in the major component of the PPI for blood and derivatives recently were not consistent with trends in blood costs for all the products used by hospitals for inpatient care, we are not aware of data that would provide a basis for the assertion that the PPI for finished goods, less food and energy, has "moved most like the recent blood cost and price trends," as CMS states. CMS goes on to say that it believes that this index will "best be able to proxy price changes (not quantities or required tests) associated with blood purchased by hospitals," but fails to support its rationale in the Proposed Rule.

We request that CMS provide the public, in particular the blood banking community, with the data upon which CMS is making this judgment that blood costs most closely track finished goods costs. Absent disclosure and public discourse of convincing data, we believe that blood should not be moved temporarily to yet another unrelated category to which an unrelated PPI is being applied. Instead, AdvaMed supports the expeditious establishment of a new blood-related PPI that accurately tracks changes in blood costs that hospitals purchased for inpatient care. The BLS has begun work in creating this new PPI and we look forward to continued dialog and involvement with BLS and CMS on this initiative. We understand that these comments are consistent with those of AABB and other organizations representing blood stakeholders. AdvaMed fully supports such comments that are consistent with the language above.

Additional Miscellaneous Issues

MedPAR Data Should be Released Earlier to Make it More Useful

CMS uses the most current Medicare Provider Analysis and Review (MedPAR) data file in its process of drafting both the Proposed and Final Inpatient Rules, and releases current MedPAR data on a semi-annual basis. We remain concerned regarding the lack of availability to the public of current MedPAR data at the time that CMS requests public comment on both the Proposed and Final Inpatient Rules. In the past, and including the release of this most recent FY 2006 NPRM, CMS has only made the MedPAR data available to the public approximately two to three weeks prior to the close of the comment period. This year, the Proposed Rule was released on April 25, but MedPAR data was not released by CMS until more than a month later, on June 3, 2005. AdvaMed believes that CMS is able to and should make the MedPAR data available to the public for the **entire** comment period. Releasing the MedPAR data to coincide with the release of the requests for comments for both the Proposed and Final Rules will enable more complete responses to issues raised, and will ensure more meaningful dialogue between CMS and the public. We also believe that CMS should consider release of the MedPAR data on a more frequent, quarterly basis.

CMS Should be Willing to Accept and Use External Data Submitted by the Public

AdvaMed believes that CMS should be open to consider the use of external data to determine eligibility for new technology payment and also for determining the most appropriate initial DRG assignment for a new technology not eligible for add-on payment or for which an add-on payment application has not been filed. In the case of technologies that are not subject to add-on payment, CMS should consider using external data to assign a new technology to an appropriately paying DRG as soon as possible after FDA approval.

AdvaMed's February 15, 2005 Position Statement on External Data responded to CMS's request for greater clarification on the needs of industry in this area, and provided examples of specific situations in which external data could be utilized by CMS. The major points of the position paper were as follows:

1) CMS should acknowledge that different types of data are appropriate for different uses.
2) CMS should distinguish between proprietary data and publicly available data when requiring that external data be made available for public inspection.
3) When hospitals cannot be identified due to confidentiality agreements, CMS should be willing to accept external data that are denitrified by geographic location and pseudo-identifier.
4) CMS should allow the use of external data from recent timeframes without corresponding MedPAR data, particularly for those procedures involving new technologies and codes.
5) When a company submits external cost data to CMS, CMS should accept the disclosure of discount and rebate data at the estimated aggregate level.
6) CMS should request that medical technology companies offer the typical device-related HCPCS and ICD-9 codes that seem most clinically appropriate to a particular procedure.

ICD-10 Implementation Should Proceed as Expeditiously as Possible

The MMA's report language urged CMS to move forward with the implementation of ICD-10 as quickly as possible. While we understand that there are many complexities involved with the transition from ICD-9 to ICD-10, it is also our understanding that the number of available codes under ICD-9 is rapidly dwindling and that the availability of new codes has been raised in public meetings as a potential basis for CMS to deny applications for new codes. AdvaMed notes that in 2003, after several years of hearings, the National Committee on Vital and Health Statistics (NCVHS) raised concerns about the viability of the ICD-9-CM as it was 'increasingly unable to address the needs for

accurate data for health care billing, quality assurance, public health reporting, and health services research.' NCVHS also noted in 2003 that these concerns have been 'well documented' in the testimony and letters provided to the NCVHS over the past several years. NCVHS recommended in 2003 that HHS act expeditiously to initiate the regulatory process for adoption of ICD-10CM and ICD-10 PCS.

While the NCVHS acknowledged that the migration to ICD-10 was potentially complex, it also indicated it was 'in the best interests of the country' to replace ICD-9 with ICD-10, and recommended in 2003 that HHS move forward expeditiously with initiation of the regulatory process for full implementation. As of 2005, we are still awaiting a process from HHS to begin this important transition. In the meantime, ICD-9 is quickly becoming outdated because of the lack of codes left to identify new procedures and new technologies. We note that at the March 30, 2005 meeting of the ICD-9-CM Coordination and Maintenance Committee, a number of comments were made objecting to the issuance of certain new procedure codes for new services and technologies. The concerns raised at the meeting mentioned the lack of availability of new codes within the ICD-9-CM. Several commenters appeared to be advocating a higher threshold for the award of new codes based on the ever decreasing number of available codes under ICD-9-CM. AdvaMed is very concerned that reluctance to issue new codes will hinder appropriate tracking, identification, and analysis of new medical services and technologies. ICD-10 is the next generation of coding system, and would modernize and expand CMS's capacity to keep pace with changes in medical practice and technology. Its unique structure would incorporate all new procedures as unique codes that would explicitly identify the technology used to perform the procedure. AdvaMed accordingly requests that CMS move forward with implementation of ICD-10 as quickly as possible.

CMS's Response to MedPAC Recommendations ("MedPAC recommendations")

MedPAC has recently made a number of recommendations to the hospital inpatient PPS reimbursement system. Although broad in scope, the MedPAC recommendations are designed to address reimbursement issues that arise in the context of reimbursement for specialty hospitals. According to GAO, as of February 2003, the year CMS first imposed the moratorium, specialty hospitals numbered only 92 nationwide, and as of FY 2000, accounted for less than 1 percent of Medicare spending for inpatient services. AdvaMed is concerned about the potential for disruption and unintended consequences that may result from making fundamental changes to the entire Medicare hospital inpatient PPS system based on irregularities that are purportedly occurring in such a small percentage of hospitals nationwide. Perhaps further study could result in a mechanism that would more specifically target the aspects of concern.

Included in MedPAC's recommendations addressing specialty hospitals are the replacement of DRG charge-based weights with cost-based weights, the use of hospital-specific relative weights, the replacement of DRGs with severity-based APR-DRGs, and DRG-specific outlier reductions. These proposed changes have the potential to cause enormous and unpredictable effects to hospital inpatient PPS reimbursement. AdvaMed

notes that the MedPAC recommendations focus on changes to the entire PPS systems based on a perceived problem with a relatively small subset of claims related to specialty hospitals. Moreover, in advocating that its proposed changes be implemented incrementally, over a lengthy time, MedPAC is tacitly acknowledging the potential for unpredictable and potentially undesirable effects of these comprehensive changes.

In the Proposed Rule, CMS mentions several potential issues that would arise and/or make it difficult to currently implement the MedPAC recommendations, including difficulties in obtaining current cost to charge data, and charge compression if hospital-specific weights are adopted. AdvaMed echoes CMS's concern regarding the difficulties in obtaining current cost to charge data. Assuming the MedPAC recommendations become slated to be implemented, it is essential that this concern be addressed prior to the implementation. In the outpatient setting, the calculation of the Ambulatory Payment Classification (APC) rates for outpatient PPS system has, from its inception, been hampered by significant omissions in the claims data, especially for device-related services. While CMS has attempted to modify its rate calculation methodology, there have been longstanding problems in the outpatient PPS system related to shortcomings in data. AdvaMed therefore is in full agreement with CMS's reservations regarding the feasibility of implementing MedPAC's recommendations given the difficulties of obtaining current cost to charge data. AdvaMed also agrees that any approach to significantly modify the inpatient PPS system should come only after CMS takes a measured, studied, and fully transparent approach to address these issues.

As we discussed in a prior section in this letter, CMS has indicated that it intends to undertake a comprehensive and systematic review of the complication/comorbidity list for the 2007 IPPS rule. CMS has also stated that it may undertake a selective review of specific DRGs that are cited by MedPAC as problematic. AdvaMed believes that CMS should complete these projects before considering whether to implement the MedPAC proposals. AdvaMed also agrees with CMS that further detailed examination and analysis of the MedPAC proposals, the potentially disruptive effects of the proposals, and careful examination and study of alternatives, are warranted at this time.

Please contact us directly if you have any questions on the letter. We thank you for the opportunity to provide comments, and look forward to continuing to work with you on these important issues.

Sincerely,

/s/

David H. Nexon
Senior Executive Vice President

Cc: Thomas A. Gustafson
Liz Richter
Marc Hartstein
Herb Kuhn

Submitter : **Mr. Oliver J. Booker** **Date: 06/21/2005**

Organization : **Monroe County Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Attention: I have submitted comments also under the Critical Access Hospitals issue area.

I am the CEO of the Monroe County Hospital in Forsyth, Georgia. At least in our case, the proposed CMS rule concerning CAH neccessary provider status relocations is not appropriate as proposed for a number of reasons.

Background: Our Board and community are just now beginning a strategic initiative to build a new hospital. In other words, we are beginning the planning process for a new building. Until we learned of this proposed rule, we were excited and optimistic that we could achieve this goal. Both local banks have expressed interest. We have some indication that County would be able to contribute some sales tax dollars. We also have a very active hospital foundation that would be able to make a dent in construction cost.

Our hospital was built in 1976. The roof, plumbing, electrical, and other infrastructure is in poor condition and needs either replacement or overhaul. Just to fix active problems would run about half a million dollars. The hospital is built on the side of a hill with the main OP departments and ER in the back, at the base of the hill, ?hidden? from sight and with poor parking. The IP is front-door, on-grade. This arrangement is opposite of the way modern healthcare works.

We have run out of space in lab and x-ray. There is no room to add any new service, and privacy is nonexistent. The ER was built in the old style of construction with a nurses? station hidden from the actual rooms ? this is not conducive to efficient and best quality patient care.

The 250-yard requirement is arbitrary and unworkable. In our case, this hospital was built in the middle of a residential neighborhood. The hospital is landlocked. We have no other property. It is not visible from any major highway or thoroughfare, and is hard to find.

I have heard that CMS wishes to talk about a ?city limits? requirement. Those who know about rural towns know that almost all of these towns of 3,000-5,000 were created in the late 1800?s or turn of the century, and their city limits are pretty much drawn in the shape of a circle, which is 3-5 miles in diameter. All the land is occupied, for the most part. You cannot stipulate that the hospital must be rebuilt inside the city limits. If there is a distance limit, I think a 5-mile limit is reasonable.

In addition, the "under development" date of December 8, 2003 quashes most small hospital new building programs. The date requirement should be eliminated entirely.

In closing, I urge you to strongly consider the recommendations made by the American Hospital Association. They have taken many small hospital administrator comments like these and represent our ideas very well.

Thanks for the opportunity to address these issues.

Sincerely,
Oliver J. Booker

CMS-1500-P-472-Attach-1.DOC

E Comment
Attachment 472

CAH/Reloc

357

Monroe County Hospital Building Issues

Hefler
Hartstein
Collins
Morey
Smith

First hospital – 1957 – still standing in front of 1976 hospital

- Decaying, needs to be demolished, but four doctors occupy it
- No place to build new office building close to campus

Current hospital – 1976

- Located in residential neighborhood
- Landlocked, no land to build
- Not worth renovating as a medical facility - $2M to renovate

Built wrong for current day services

- Built on the side of a hill. First floor admissions/OP down hill in back. Inconvenient, poor parking
- Second floor IP – wrong emphasis
- NO handicapped facilities at all

Out of room, poor function

- Radiology in 2500 SF – need another 2000 SF, no where to build
- Admissions shares ER check in. Need another 500-700 SF. No where to expand. Privacy and safety issues.
- Lab in 1000 SF – need 1500 SF
- ER – shotgun arrangement. Need central nurses station and better visibility, better communication, provide for staff safety
- All OP functions are accessed by walking through the heart of the ER

Location and utilities

- Utilities all above ground, downtime frequent
- Facility hard to find – have to weave through downtown to get to hospital
- Needs to be convenient and next to interstate – competition factor

Old hospital would be reused

- County would take the building when hospital moved
- Turn hospital into county offices and run a rural health clinic out of the old ER
- Makes sense for this community and would meet the county's needs – they are out of space and would probably trade SPLOST for a better building

Need to attract better paying patients and get off the gov't dole

- Forsyth is growing – need to build and plan for the future
- Over 300 homes building now (see attachment)
- State will place 500 jobs in Forsyth next year

Submitter : Mr. Calvin Green **Date: 06/21/2005**

Organization : Franklin Foundation Hospital, Franklin, LA

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

Our hospital is offering public comments on the topic of relocation or replacement of a Critical Access Hospital. Please see attachment:

CMS-1500-P-474-Attach-1.DOC

CAH/Reloc 358

E-Comment
Attachment 474

Hefter
Hartstein
Collins
Mercy
Smith

June 20, 2005

Comments on Critical Access Hospital issues relating to replacement, relocation, and "necessary provider" status:

Franklin Foundation Hospital is a 25 bed Critical Access Hospital located in St. Mary Parish, a rural coastal LA parish with a population of 53,500. The hospital was approved for CAH status effective April 1, 2003 under a state waiver and is in the process of beginning to build a new replacement facility. The decision to build a replacement facility was made because our current physical plant is in excess of 50 years old and it was constructed primarily to address the inpatient needs of practice patterns of past decades. The current structure is also costly to maintain, and creates staffing inefficiencies which are a drain on financial resources.

The demographics of the patient population that we serve contain several factors that point to our critical need including the following: 1) roughly 25% of our residents live below the poverty level; 2) we have an unemployment rate of almost 10%; and 3) 30% of our citizens are uninsured. With the above statistics in mind, access to healthcare is a primary concern of our patients. There is no public transportation system available that is capable of delivering our patients to facilities in surrounding parishes which are two PPS reimbursed facilities that are 25 and 28 miles away. The closest Critical Access Hospital is in Breaux Bridge, LA approximated 50 miles from Franklin.

With the above need in mind our Board of Commissioners began planning for a replacement facility some 3 to 4 years ago. Currently our plan design and architectural plans have been completed and the project is out for bids. Additionally, our financing which includes a $5,000,000 grant from the State of LA, as well as, USDA funding for $12,600,000 has been obtained and is in place. However, at this point we will not be able to finalize our financing for this project because of the uncertainty caused by some of the provisions in the proposed regulations.

Specifically we have two concerns with the proposed regulations related to the Determination of the Relocation Status of a CAH. Our first concern has to do with the distance requirement associated with relocation status. Our plans are to build a replacement facility approximately 2.2 miles from our current location. We will be serving the same population with the same staff and offering the same services and we will not be moving any closer to another provider. However, our interpretation of the proposed rules indicates that there is a chance that this could be considered to be a cessation of business which would invalidate our CAH status. While we believe we can make a case for "Relocation Status" the uncertainty caused by the proposed rules will require us to delay our plans and could cause us to loose our funding. Our second concern has to do with the proposal that necessary providers that embarked on a replacement facility project before the sunset provision was enacted on December 8, 2003 but find that they cannot be operational in the replacement facility by January 1, 2006 can retain their necessary provider status. Again, while we believe that in our specific situation we can make a persuasive case that we had embarked on the replacement facility project

prior to December 8, 2003 the possibility that we may not qualify because of ambiguity or differences in interpretation is a significant concern.

We believe that a significant number of existing Critical Access Hospitals will face problems similar to ours and in fact most facilities that are not as far along in the planning process as we are will be in jeopardy if they cannot make sound business decisions that allow them to serve there patients in a cost efficient manor. We believe that new regulations can be crafted that will address the needs of CAH to relocate and maintain there necessary provider status. We support proposals similar to ones that were discussed with the American Hospital Association that would allow Critical Access Hospitals to maintain their essential provider status if they meet 3 of the following 5 criteria when they relocate:

1) Serve 75% of the same population
2) Employ 75% of the same staff
3) Provide 75% of the same services
4) Move within 3 miles of their current location
5) Base relocation on a needs assessment

359

Submitter : Dr. Joseph McNerney **Date:** 06/21/2005

Organization : St.John Health System

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1500-P-466-Attach-1.DOC

359

E Comment
Attachment 466

GME/Affil
IME

Heffer
Hartstein
Truong
Lefkowitz
Ruiz

June 21, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1500-P
Room C5-14-03
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: [CMS-1500-P] Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Payment Rates (42 *Federal Register 405, 412, 413, 415, 419, 422, and 485*), May 4, 2005

To whom it may concern:

As a member of the resident teaching faculty of St. John Health (SJH), a Southeast Michigan health system with eight hospitals and over 400 interns and residents in allopathic, osteopathic, dental, and podiatry training programs, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the 2005 Inpatient Prospective Payment System (PPS), published May 4, 2005 in the *Federal Register*. The adequacy of Medicare payments to cover the cost of training our future generation of physicians is essential to maintain financially viable teaching hospitals in Michigan and across the United States to ensure the adequacy of future Medicare beneficiary access.

My comment is regarding New Teaching Hospitals in Medicare GME Affiliated Groups (§413.79 (e) (1)) of the proposed rules beginning on page 23440 of the May 4, 2005 Federal Register.

CMS proposes to allow new urban hospitals that qualify for an adjustment under §413.79 (e) (1) may enter into a Medicare GME affiliation agreement only if the resulting adjustment is an increase in the new teaching hospital's DGME and IME caps as a result of the affiliation agreement.

I fully concur with this proposed policy update. New urban teaching hospitals should be provided with the flexibility to start new teaching programs without jeopardizing their ability to count additional FTE residents training at the hospital under an affiliation agreement. This flexibility will occur if new urban teaching hospitals are allowed to enter into affiliation agreements with other teaching hospitals to increase their DGME and IME FTE caps.

By definition, a new urban teaching hospital would initially have a resident FTE cap of zero, (0). When residents from existing teaching hospitals rotate to the new urban teaching hospital, it is appropriate for the new urban teaching hospital to receive a positive, increased, adjustment to their FTE cap allowing the new urban teaching hospital to receive Medicare IME and DGME payments. These additional Medicare payments are necessary for the new teaching hospital to cover the direct and indirect costs the new urban teaching hospital will be incurring to train the "in rotating" residents from other hospital teaching programs.

Thank you for considering my comment regarding your proposed improvement to the Medicare program's existing payment rules for graduate medical education.

Sincerely,

Joseph P McNerney,DO,FACOFP,dist.
Director of Medical Education Osteopathic Division
St. John Health

360

Submitter : Mr. Kenneth Salazar

Date: 06/21/2005

Organization : United States Senate

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Letter includes US Senator Wayne Allard and US Representative Marilyn Musgrave.

CMS-1500-P-470-Attach-1.PDF

KEN SALAZAR
COLORADO

COMMITTEES:
AGRICULTURE, NUTRITION, AND FORESTRY
ENERGY AND NATURAL RESOURCES
VETERANS' AFFAIRS

E Comment
Attachment 470

360

United States Senate

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CAH/RelOC

June 20, 2005

Heffer
Hartstein
Collins
Nick
Smith

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATT: CMS – 1500 – P
Post Office Box 8011
Baltimore, MD 21244-1850

Re: CRITICAL ACCESS HOSPITALS-Comment Regarding Proposed Rule RN 0938AN57

Dear Sir/Madam:

We write to provide comments to the Inpatient Prospective Payment System (IPPS) proposed rule regarding critical access hospitals, published in the Federal Register in Vol.70/No.85/Wednesday May 4, 2005/Proposed Rules under the listing of RN 0938 AN57.

As you know, the Critical Access Hospital (CAH) Program was created by Congress to provide cost-based reimbursement to limited service hospitals in rural areas to support the fragile health care delivery systems that exists in many rural communities. In order to qualify for CAH eligibility, a hospital must not be located within 35 miles of another hospital or must be designated by the state as a "necessary provider" of health care to its community, among other requirements.

The Medicare Modernization Act (MMA) prohibits a state from designating a hospital as a "necessary provider" after January 1, 2006. Congress's intent was to limit the states' ability to designate necessary providers because of the proliferation of CAHs that might not fulfill the goals of the program—to support rural hospitals serving a distinct population. The MMA did not intend to impact the existing CAHs that are necessary providers.

The proposed rule addresses whether presently designated CAHs that renovate and/or relocate facilities may retain the "necessary provider" designation. Two provisions of this rule are problematic, and actually work to undermine access to health care in rural communities.

The first provision provides that CAHs that renovate facilities may only be considered a "replacement facility" and retain their necessary provider designation if they renovate their current building or construct a new building within 250 yards of the current building. This proposed rule is unduly restrictive and fails to serve the goals Congress envisioned in designing the Critical Access Hospital program. CAHs exist to provide residents in rural areas access to quality, affordable health care. This rule undermines that goal because it prevents CAHs, many of which are older facilities, from expanding and updating their facilities to provide quality care to their residents. Many of these facilities exist on land that restricts their ability to renovate or expand. In these cases, it

KEN SALAZAR
COLORADO

COMMITTEES:
AGRICULTURE, NUTRITION, AND FORESTRY
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simply is not feasible for CAHs to renovate or expand their facilities on their physical locations. This rule assumes that existing hospitals have geographic land to expand on site. In some instances, the hospitals may have been given donated land on which to expand. Under this rule, hospitals that wish to renovate and relocate to donated land and serve the same community would lose their necessary provider status.

The second provision provides that for a Critical Access Hospital to maintain its "necessary provider" status and to be considered to be "relocating" according to PL 106-173, the facility must demonstrate construction plans were "under development" by December 8, 2003 (RN0938 AN57 – 5(B)(3)(a)). This date limits the plans of CAHs that commenced renovation plans after this date but before this proposed rule was published, and thus were unaware that their necessary provider designation would be in jeopardy when they initiated plans to rebuild their hospitals. In Colorado, two CAHs with necessary provider designations began plans to rebuild and invested substantial resources in the planning stages. This rule will endanger their designation if they proceed with their moves. Conversely, if they chose to remain at their current locations, they will be unable to renovate and modernize their facilities to provide quality care to the rural communities they serve.

Ultimately, this policy could mean less medical care for rural areas. We suggest a more flexible rule that grandfathers all CAHs with "necessary provider" designations provided they continue to meet the same needs of the population they were previously serving with substantially the same staff. We leave CMS to outline these guidelines, with the objective to promote the original intent of the CAH "necessary provider" designation—to promote the health care delivery systems in rural areas to provide quality, affordable health care to their residents. Necessary providers should not be forever foreclosed from modernizing their facility. Health care delivery is dynamic, incorporating technological advances that promise to improve quality and reduce the costs of health care. Necessary providers in Colorado and nationwide should be given flexibility to promote technological advances. Our state's rural areas count on these facilities and we must assist them in meeting the health care challenges of tomorrow.

Thank you for your careful consideration of these comments.

Ken Salazar
Ken Salazar
United States Senator

Wayne Allard
Wayne Allard
United States Senator

Marilyn Musgrave
Marilyn Musgrave
United States Representative

321

Submitter : Mr. Kenneth Salazar **Date:** 06/21/2005

Organization : United States Senate

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Included on Letter:
Wayne Allard, US Senator
Marilyn Musgrave, US Representative

CMS-1500-P-464-Attach-1.PDF

KEN SALAZAR
COLORADO

COMMITTEES:
AGRICULTURE, NUTRITION, AND FORESTRY
ENERGY AND NATURAL RESOURCES
VETERANS' AFFAIRS

E - Comment
Attachment 464

361

United States Senate

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June 20, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATT: CMS – 1500 – P
Post Office Box 8011
Baltimore, MD 21244-1850

Re: CRITICAL ACCESS HOSPITALS-Comment Regarding Proposed Rule RN 0938AN57

Dear Sir/Madam:

We write to provide comments to the Inpatient Prospective Payment System (IPPS) proposed rule regarding critical access hospitals, published in the Federal Register in Vol.70/No.85/Wednesday May 4, 2005/Proposed Rules under the listing of RN 0938 AN57.

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The Medicare Modernization Act (MMA) prohibits a state from designating a hospital as a "necessary provider" after January 1, 2006. Congress's intent was to limit the states' ability to designate necessary providers because of the proliferation of CAHs that might not fulfill the goals of the program—to support rural hospitals serving a distinct population. The MMA did not intend to impact the existing CAHs that are necessary providers.

The proposed rule addresses whether presently designated CAHs that renovate and/or relocate facilities may retain the "necessary provider" designation. Two provisions of this rule are problematic, and actually work to undermine access to health care in rural communities.

The first provision provides that CAHs that renovate facilities may only be considered a "replacement facility" and retain their necessary provider designation if they renovate their current building or construct a new building within 250 yards of the current building. This proposed rule is unduly restrictive and fails to serve the goals Congress envisioned in designing the Critical Access Hospital program. CAHs exist to provide residents in rural areas access to quality, affordable health care. This rule undermines that goal because it prevents CAHs, many of which are older facilities, from expanding and updating their facilities to provide quality care to their residents. Many of these facilities exist on land that restricts their ability to renovate or expand. In these cases, it

KEN SALAZAR
COLORADO

COMMITTEES:
AGRICULTURE, NUTRITION, AND FORESTRY
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simply is not feasible for CAHs to renovate or expand their facilities on their physical locations. This rule assumes that existing hospitals have geographic land to expand on site. In some instances, the hospitals may have been given donated land on which to expand. Under this rule, hospitals that wish to renovate and relocate to donated land and serve the same community would lose their necessary provider status.

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Ultimately, this policy could mean less medical care for rural areas. We suggest a more flexible rule that grandfathers all CAHs with "necessary provider" designations provided they continue to meet the same needs of the population they were previously serving with substantially the same staff. We leave CMS to outline these guidelines, with the objective to promote the original intent of the CAH "necessary provider" designation—to promote the health care delivery systems in rural areas to provide quality, affordable health care to their residents. Necessary providers should not be forever foreclosed from modernizing their facility. Health care delivery is dynamic, incorporating technological advances that promise to improve quality and reduce the costs of health care. Necessary providers in Colorado and nationwide should be given flexibility to promote technological advances. Our state's rural areas count on these facilities and we must assist them in meeting the health care challenges of tomorrow.

Thank you for your careful consideration of these comments.

Ken Salazar
United States Senator

Wayne Allard
United States Senator

Marilyn Musgrave
United States Representative

DRG/GEN TRANSFERS

362 BROOKS FAGAN GRUBER KELLY HUE WALZ HART HEFTER HARTSTEIN

E Comment Attachment 369

Centers for Medicare and Medicaid Services
Department of Health and Human Services,
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear CMS Staff:

Currently, transferring hospitals receive twice the per diem rate for the first day of treatment and the per diem rate for each following day of stay before the transfer, up to the full DRG payment for cases discharged to another PPS Acute Care hospital. No matter the patient's DRG. However, there is a sub-set of DRGs for which hospitals receive 50 percent of the full DRG payment plus a single per diem for the first day of the stay, and 50 percent of the per diem for the remaining days of the stay, up to the full DRG payment for patients transferred to post-acute care. **Why don't hospitals get this same payment for the cases in these DRGs that are transferred to acute care hospitals?** Their consumption of resources and LOS are similar to the patients discharged to the post-acute setting. If the costs and LOS are similar, this payment policy should apply to all transfers whether they be acute and post-acute in the DRGs where it has been identified that a very high percentage of the cost occur very early in the hospital stay.

Please compare the costs and LOS of acute care transfers cases to the post-acute transfer cases. The analysis of our data shows that the post-acute transfer payment policies should also be applied to the acute transfer cases. Thank you.

Sincerely,

Lynn-Marie D. Wozniak

Lynn-Marie D. Wozniak, MS, RHIT
Manager, Health Policy & Information
NEXT WAVE
24 Madison Ave. Ext.
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518-452-3351 (p)
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Submitter : Mrs. Lynn-Marie Wozniak **Date:** 06/22/2005

Organization : NEXT WAVE

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1500-P-569-Attach-1.DOC

Submitter : Mr. David Pearson **Date:** 06/21/2005

Organization : Texas Organization of Rural & Community Hospitals

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

In the latest proposed rule regarding the Inpatient Prospective Payment System, CMS would only provide continued CAH status for necessary providers that are building replacement facilities at another location and can demonstrate their construction plans began before December 8, 2003. As you are well aware, applying this kind of a change retroactively virtually assures that little or no hospitals will be able to take part.

The seemingly arbitrary and restrictive date also takes important decisions out of the hands of hospital trustees and their local communities. It places in jeopardy many relocation projects that were started in the year and a half since the passage of the Medicare Modernization Act. Lastly, it leaves no flexibility to relocate a hospital when it becomes absolutely necessary due to worn down infrastructure.

Rather than throw the baby out with the bath water, we would suggest that the CMS Regional Office staff retain the ability to determine a CAHs future status by using a set of constructive parameters, while ensuring that certain obvious guidelines cannot be breached. Otherwise, only a minor portion of those hospitals that meet the federal mileage requirement will ever truly have an opportunity to serve their communities long term.

Here are a few of the metrics that CMS staff could use to differentiate between plans to improve access through a replacement facility and tactics meant to exploit the program in order to gain a competitive advantage through relocation:

True age and condition of current facilities ? By using records from the Hill-Burton program, hospital-reported depreciation and more, it would be fairly easy to verify the true age of a hospital, piece meal improvements not withstanding. Age is the number one issue for most rural hospitals. Most communities are still using all or some of their original building and though most do appear well taken care of, they simply don?t meet with today?s healthcare standards.

Life safety and other code issues ? Another verifiable cause of most construction projects is the need to meet life safety and other state and federal code violations. Numerous hospital remodeling projects can and do end up being more costly and disruptive than a newly constructed facility.

Clearly defined boundaries ? Another factor that often leaves very little discomfort is a hospital?s sole community status or district location. When a CAH in question is the only hospital in a given non-MSA county or tax district, it can sometimes be significantly less than 35 miles to the next nearest hospital. Yet, this same CAH may remain almost completely isolated due to a county or district boundary that in rural areas clearly separate one market from another.

Ability to improve or increase access ? Although a tad less objective, a hospital?s desire to better serve its local community must be taken into account somehow. Populations move and transportation routes can change, which means business patterns will invariably need to change as well. We cannot expect a facility to continue operating in an area that limits access and thereby poses an increased risk to patients.

Other intangible opportunities ? The government shouldn?t place limits that would restrict a hospital?s ability to reduce costs by taking advantage of a benevolent gift (such as land) or business incentives (economic development funds). Under these scenarios, most proposed reconstruction wouldn?t substantially decrease the distance to other area provides and might in fact lead to a level of self-sufficiency that would allow for a return to PPS status over time.

TORCH is hopeful that a much less restrictive method of ongoing endorsement can be worked out. Several Critical Access Hospitals in Texas have stated that if they are unable to rebuild within the next several years and also preserve their CAH designation, they will likely close their doors. Please develop a fair process that prevents future abuse.

CMS-1500-P-450-Attach-1.DOC

E Comment
Attachment 450

363
CAH/Reloc

Written comments sent to Centers for Medicare and Medicaid Services (CMS), HHS electronically via http://www.cms.hhs.gov/regulations/ecomments on 6/21/05:

Hefter
Hartstein
Collins
Mark
Smith

Comments on CMS–1500–P
VII. Proposed Changes for Hospitals and Hospital Units Excluded from the IPPS
B. Critical Access Hospitals (CAHs)
3. Proposed Policy Change Relating to Designation of CAHs as Necessary Providers
a. Determination of the Relocation Status of a CAH
b. Relocation of a CAH Using a Waiver to Meet the CoP for Distance

In the latest proposed rule regarding the Inpatient Prospective Payment System, CMS would only provide continued CAH status for necessary providers that are building replacement facilities at another location and can demonstrate their construction plans began before December 8, 2003. As you are well aware, applying this kind of a change retroactively virtually assures that little or no hospitals will be able to take part.

The seemingly arbitrary and restrictive date also takes important decisions out of the hands of hospital trustees and their local communities. It places in jeopardy many relocation projects that were started in the year and a half since the passage of the Medicare Modernization Act. Lastly, it leaves no flexibility to relocate a hospital when it becomes absolutely necessary due to worn down infrastructure.

Rather than throw the baby out with the bath water, we would suggest that the CMS Regional Office staff retain the ability to determine a CAHs future status by using a set of constructive parameters, while ensuring that certain obvious guidelines cannot be breached. Otherwise, only a minor portion of those hospitals that meet the federal mileage requirement will ever truly have an opportunity to serve their communities long term.

Here are a few of the metrics that CMS staff could use to differentiate between plans to improve access through a replacement facility and tactics meant to exploit the program in order to gain a competitive advantage through relocation:

- True age and condition of current facilities – By using records from the Hill-Burton program, hospital-reported depreciation and more, it would be fairly easy to verify the true age of a hospital, piece meal improvements not withstanding. Age is the number one issue for most rural hospitals. Most communities are still using all or some of their original building and though most do appear well taken care of, they simply don't meet with today's healthcare standards.

- Life safety and other code issues – Another verifiable cause of most construction projects is the need to meet life safety and other state and federal code violations. Numerous hospital remodeling projects can and do end up being more costly and disruptive than a newly constructed facility.

- Clearly defined boundaries – Another factor that often leaves very little discomfort is a hospital's sole community status or district location. When a CAH in question is the only hospital in a given non-MSA county or tax district, it can sometimes be significantly less than 35 miles to the next nearest hospital. Yet, this same CAH may remain almost completely isolated due to a county or district boundary that in rural areas clearly separate one market from another.

- Ability to improve or increase access – Although a tad less objective, a hospital's desire to better serve its local community must be taken into account somehow. Populations move and transportation routes can change, which means business patterns will invariably need to change as well. We cannot expect a facility to continue operating in an area that limits access and thereby poses an increased risk to patients.

- Other intangible opportunities – The government shouldn't place limits that would restrict a hospital's ability to reduce costs by taking advantage of a benevolent gift (such as land) or business incentives (economic development funds). Under these scenarios, most proposed reconstruction wouldn't substantially decrease the distance to other area provides and might in fact lead to a level of self-sufficiency that would allow for a return to PPS status over time.

TORCH is hopeful that a much less restrictive method of ongoing endorsement can be worked out. Several Critical Access Hospitals in Texas have stated that if they are unable to rebuild within the next several years and also preserve their CAH designation, they will likely close their doors. We don't say this to sound alarmist, but rather to stress the importance of developing a fair process that can also prevent any future abuse of the Critical Access Hospital program.

If you have any further questions please contact David Pearson, Vice-President of Advocacy & Communications for the Texas Organization of Rural & Community Hospitals at 512-873-0045 or dpearson@torchnet.org.

364

Submitter : Ms. Andrea Serra

Date: 06/21/2005

Organization : Gaston Memorial Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-455-Attach-1.DOC

E Comment
Attachment 455

364

Q-Data

June 21, 2005

Dear Sir:

The ability of hospitals and our vendors to comply with the requirements for timely and accurate data submission is challenged by miscommunication, technical ambiguities, and other issues. Therefore, the final FY '06 inpatient PPS should establish a clear documentation and communications process for this purpose. Further, hospitals should not be penalized when technical issues specific to the CMS or Quality Improvement Organizations (QIOs) hinder our ability to meet specific data requirements.

- An explicit, step-by-step process for data submission should be established—including exact specifications, all edits or audits to be applied, and other related information. Hospitals and vendors must be privy to such parameters to ensure timely data submission. Further, CMS should communicate any changes to submission file requirements no less than 120 days prior to the effective/implementation date. No changes should be permitted once a submission quarter has begun, as this puts process integrity at risk.

- For greater reporting accuracy, a test process for validating data file submissions and measuring calculations should be established. Hospitals and submission agents should be provided with a test file in the appropriate format for internal verification *prior* to testing a submission. The process should permit submission of test file(s) to verify file formats, accuracy of data calculations, and other audit criteria related to data submission. An appropriate test process should be permitted each time changes in data submission or measure specifications are prescribed.

- In the proposed rule, there is no mention of a minimum sample size for hospitals that elect to sample. Consequently, if hospitals that do *not* sample elect to submit all of their qualifying cases for a given study (i.e., 425 pneumonia cases for a given quarter) and three get "rejected," will they still meet the data requirements—or, must such hospitals correct the case errors so that *every* one gets into the warehouse? Under our reading of the proposed rule, it appears that they do not—so long as such hospitals have met the minimum number of cases required by the "aligned" JCAHO/CMS sampling requirements, however they are established.

- An explicit, step-by-step validation process should be established—including clear definitions, all applicable skip logic, all edits or audits to be applied, and other related information. Hospitals must know exactly *what* is being validated so they may adhere to the specifications during the data collection process. Under the current process, by the time hospitals receive feedback on one quarter's validation, they have already moved onto the next quarter's data collection and can not make changes quickly enough to impact the next quarter. If the validation

specs and requirements were clear and well- documented, hospitals could be proactive. Any changes must be communicated clearly and within a timeframe sufficient for hospitals to react and changes their attendant processes. Any modifications to the technical processes be published 120 days prior to the effective/implementation date.

- The validation process should incorporate *only* data associated with the ten specified measures. Under the current system, a hospital that submits multiple data sets may earn an *overall* quality score of 80 percent; however, if errors occur more frequently in the subset required for the annual payment update, the quality of such data may be considerably *lower*. In this way, payments risk being based on inconsistent calculations and inaccurate data.

- Further, we believe that hospitals should be notified of any validation rule changes at least 120 days prior to the hospital data abstraction period. The validation rules applied by CMS as of June 6, 2005 are, in fact, retroactive to the July—September 2004 data. CMS validated the three test LDL measures for the AMI clinical focus group. Consequently, hospitals are receiving mismatches for not collecting this optional data. The validation documentation for the July 1, 2004 discharges is dated April 29, 2005. Since the data was submitted at the end of January, hospitals have not had sufficient time to make the appropriate change.

- Under the proposed rule, CMS only allows ten days for a hospital to appeal its validation; however, the agency fails to specify whether the reference is to "business" or "calendar" days. Neither case offers sufficient time for hospitals to respond. Allowing hospitals 30 calendar days to appeal their validation findings would be adequate.

- Many hospitals report having received inconsistent communications relating to the "data reporting for annual updates" provision of the Medicare drug law (MMA). All communications and directives regarding this initiative should be centralized and disseminated to all stakeholders (hospitals, vendors, and QIOs) simultaneously. Such a strategy would simplify and standardize message generation. It would also eliminate the confusing and often contradictory communications typical of the current process, which requires state QIOs to interpret a given communication before forwarding it to hospitals.

Andrea K. Serra, CHE
Vice President
Gaston Memorial Hospital
2525 Court Drive
Gastonia, N. C. 28054

Submitter : Mr. Kyle Kramer **Date:** 06/21/2005

Organization : American College of Cardiovascular Administrators

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached.

CMS-1500-P-476-Attach-1.DOC

E-Comment Attachment 476

365

American Academy of Medical Administrators

Developing Excellence in Healthcare and Leadership

701 Lee Street • Suite 600 • Des Plaines, IL 60016-4516
Phone: (847) 759-8601 • Fax: (847) 759-8602 • email: info@aameda.org • www.aameda.org

AMERICAN COLLEGE OF CARDIOVASCULAR ADMINISTRATORS

June 21, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates
Docket Number: CMS –1500-P

To Whom It May Concern:

The American College of Cardiovascular Administrators appreciates the opportunity to submit comments related to the 2006 Hospital Inpatient Prospective Payment System (IPPS), published recently in the April 25, 2005 *Federal Register*. Our comments are submitted on behalf of all cardiovascular programs and administrative professionals across the United States.

The American College of Cardiovascular Administrators (ACCA) is a specialty group of the American Academy of Medical Administrators (AAMA), which is comprised of over 3,000 members representing all sectors of the healthcare administrative field. Specifically, the ACCA/AAMA is a nonprofit professional society of individuals involved in the administration of cardiovascular and other specialty services at hospitals and clinics across the United States whose purpose is to develop and refine concepts and practices in the field of cardiovascular and other specialty healthcare administration and to promote the advancement of its members in knowledge, professional development, and personal achievements through continuing education, research, and advocacy in healthcare management. Our members are the primary personnel responsible for the implementation and management of issues – technology and otherwise – impacting cardiovascular programs across the country.

We appreciate the considerable effort you and your staff members have put into the development and improvement of the inpatient prospective payment system (IPPS) and point specifically to efforts aimed at the acknowledgement of emerging technologies such as drug-eluting stents and advanced implantable defibrillators – traditional and bi-ventricular. We further recognize the significant complexities associated with gathering reasonably accurate cost data on outpatient procedures, specifically technology costs.

DRG Assignment for ICD Implantation

On page 50 of the proposed rule CMS provides an analysis showing the three ICD DRGs with and without hospital procedure code 37.26. The problem with the analysis is hospital procedure code 37.26 contains three separate procedures, of varying intensity: electrophysiology study, intraoperative device interrogation and non-invasive programmed stimulation. This means code 37.26 represents a coding problem (three very different codes in one) – not a payment problem. Until the coding issue is addressed, the real impact on payment can not be determined. Currently there is no data on how the three procedures vary with respect to hospital charges. In a meeting attended by industry, CMS coding experts acknowledged that the structure of hospital procedure code 37.26 results in flawed charge data. CMS says it is not appropriate to have all three procedures in code 37.26

drive to higher paying DRGs. It is equally inappropriate to have all three driving ICD related implant procedures to lower paying DRGs.

By our calculations, the proposed changes would cause 75 percent of all ICD implant procedures to code into DRG 515, the lowest paying DRG for ICD procedures. This represents a dramatic change from 2004 DRG coding data, which suggests that 44 percent of ICD implant procedures code into DRG 515. While this change will result in dramatic savings for CMS, hospitals will suffer measurable decreases in their ability to cover costs associated with the implantation of devices such at cardiac resynchronization defibrillators (CRT-D). Under DRG 515, these more expensive devices will not be fully covered and hospitals will incur real losses in the treatment of Medicare patients. CMS's earlier recognition of data from the SCD-HeFT trial would seem to indicate that ICD therapy on a prophylactic basis for a certain subset of patients is appropriate medical therapy. However, this proposed coding change will lead to this significant medical advance in the management of patients with increased risks for sudden cardiac death financially unfeasible for hospitals.

New Technology Add-on Payments

In addition to the coding changes mentioned above, CMS proposes to eliminate the new technology add-on payment that has been associated with the implantation of CRT-D devices over the past year. CMS has determined that this category of devices does not meet the criteria for new technology. However, this change, when combined with the coding issues associated with DRG assignment for ICD implantation, creates a substantial financial issue for hospitals implanting CRT-D devices. In 2003, 21 percent of ICD implants for Medicare patients were coded as CRT-D. With ongoing advancements in the management of heart failure patients via these devices, it is expected that the total number of CRT-D implants will continue to increase. As such, it is recommended that CMS alter its view on new technology, specifically for heart failure devices, and reinstate this payment for the coming year.

Repair of Atrial Septal Defects

CMS proposes a change in the logic associated with grouping of patients undergoing repair of atrial septal defect (ASD) with prosthesis, closed technique (35.52) from DRG 108 to DRG 518. In CMS's examination of the grouping of left atrial appendage devices, CMS noted a significant difference in charges and length of stay for patients with percutaneous ASD repair versus open in DRG 108. CMS feels the resources for the percutaneous repair are more similar to procedures in DRG 518: Percutaneous Cardiovascular Procedures without Coronary Artery Stent or Acute Myocardial Infarction. In 2003, 163 facilities reported 694 Medicare cases of percutaneous ASD repair.

ACCA/AAMA acknowledges the fact that resource intensity for patients undergoing percutaneous ASD repair is less than that of open repair. However, ACCA/AAMA does not accept that costs associated with percutaneous repair are akin to procedures presently coding into DRG 518. The ASD closure device alone is significantly more costly than technologies utilized in the treatment of patients presently coding into DRG 518. In addition to the cost of the closure device itself, most institutions have found that the device is best deployed with concurrent utilization of intracardiac echocardiography. The combination of these two technologies and other necessary support structures for ensuring safe and effective patient care easily surpasses DRG 518's allocated reimbursement. As such, ACCA/AAMA recommends that CMS rescind the recommendation for regrouping of percutaneous ASD closure until better data can be gathered and a more appropriate reimbursement calculation can be developed.

Intracoronary Interventional Procedures

CMS proposes to split DRGs 516 and 526 into four new DRGs with recognition of complexities and comorbidities. Specifically, CMS proposes to create the following DRG classifications for intracoronary interventional procedures:

- DRG 547: Percutaneous CV Procedure with AMI with CC
- DRG 548: Percutaneous CV Procedure with AMI without CC
- DRG 549: Percutaneous CV Procedure with Drug Eluting Stent with AMI with CC
- DRG 550: Percutaneous CV Procedure with Drug Eluting Stent with AMI without CC

ACCA/AAMA has encouraged the creation of coding strategies that acknowledge case complexity and patient acuity. As such, we are supportive of this strategy. However, we are concerned about the fact that this system of coding does not fully acknowledge procedures that involve multiple vessels and multiple lesions. This is especially true at a time when interventional cardiologists are willing to take on more complex patients in the interventional laboratory and as a result, technology utilization is increasing on a per case basis. We appreciate the fact that CMS is pursuing the implementation of six new procedure codes to account for multi-vessel coronary intervention and multiple stent insertion within one vessel. We understand that no payment changes are proposed for these codes and that they will be used to track resource consumption for future payment. We will watch closely for CMS's analysis and consequent utilization of this data.

Summary

Again, ACCA/AAMA appreciates the opportunity to provide our commentary on the 2006 CMS IPPS proposal. ACCA/AAMA remains fully supportive of prospective payment for hospital inpatient services, and commends CMS for its ongoing efforts to ensure adequate reimbursement for all clinical services. Moreover, we recognize the extremely complex issues involved in establishing appropriate reimbursement for procedures performed in the inpatient setting. As such, ACCA/AAMA remains committed to working with CMS and other affected parties to ensure that hospitals remain able to provide access to high quality cardiovascular care involving cutting-edge technologies in all settings of care. Finally, ACCA/AAMA supports CMS's efforts to ensure that Medicare beneficiaries have continued access to high quality, efficient, and effective cardiovascular services.

Sincerely,

R. Kyle Kramer, FAAMA, FACCA
Vice Chair, AAMA Board
Chair, ACCA Health Policy Committee

the American College of Cardiovascular Administrators
is a specialty group of the
American Academy of Medical Administrators

Xc: Renee Schleicher, CAE
ACCA/AAMA Board of Directors

3646

Submitter : Mr. John DeSantis **Date:** 06/21/2005

Organization : Key West HMA, Inc. d/b/a Lower Keys Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1500-P-480-Attach-1.DOC

E Comment
Attachment 480

Q Data

366

June 16, 2005

Centers for Medicare and Medicaid
Department of Health and Human Services
Attn: CMS-1500-P
P.O Box 8011
Baltimore, MD 21244-1850

Re: Hospital Quality Data" file code CMS-1500-P, as recommended by the Proposed Rule in the May 4, 2005 Federal Register

Dear Sir or Madam:

Lower Keys Medical Center is a Sole Community Provider in Key West, Florida. We service an isolated population in a rural island chain and provide care that has awarded us a 94% on our 2003 JCAHO survey, and Quality Service scores of 98% and above. We have significant concerns about the use of the QNet 3rd quarter 2004 Validation Assessment score in determining our FY2006 Medicare rates (full market basket update).

Deleted: This letter is in reference to Hospital Quality Data. It is written as recommended by the Proposed Rule in the May 4, 2005 Federal Register.¶
¶

The QNet process is relatively new and requires significant human resources. Rural areas characteristically are underserved; sufficient qualified, experienced personnel to respond to all of the demands of CMS, state agencies and the QIO are difficult to obtain. In this situation, due to a misaddressed request for 3rd quarter 2004 Validation data, we stand to be punished with reduced Medicare payments despite the continuance of high quality care to the residents of this island community.

Despite notifying our QIO of the appropriate addressee for correspondence related to this initiative, their requests continued to go to a different department, and therefore the appropriate attention to the Validation request could not be given. We have explained this to our QIO and asked for the opportunity to send in the requested records late. We formally appealed the 3rd quarter Validation Results and sent the records at that time.

They asked that our next quarter's reports (4th quarter 2004) be sent in as much "before" the deadline as possible. We have complied and submitted the 4th quarter's information nearly 1 month ahead of deadline.

Nearly 16% of the services we provide are to a non-paying, indigent population. Medicare represents 38% of our business and a decrease in our rate would create a considerable impact on our ability to provide a quality, progressive health option to a community that, based upon its location, has few to no other options for acute care.

For instance, if a necessary provider CAH relocated a few miles outside of a city's population center to an area that was close to an interstate highway exit, the impact of being close to the exit and outside of the population center would be impossible to analyze prospectively. Most importantly, the 75% threshold focuses on the services provided instead of identifying the health needs that would not be addressed without the facility in question. The fact that a facility provides services does not mean that the services are not readily available elsewhere. Once again, it is MVRMC's understanding that the CAH designation, was created to ensure that facilities would have the resources necessary to continue providing health services in underserved areas.

Finally, MVRMC concurs with the requirement that necessary provider CAH facilities wishing to relocate more than 500 yards from existing sites, demonstrate that they had plans to relocate prior to December 8, 2003. On December 8, 2003, the public was notified through the Federal Register that the "necessary provider exception" would sunset on January 1, 2006. After January 1, 2006, facilities may not receive the CAH designation through the state certification process. However, facilities that meet the federal CAH designation criteria will still be eligible for CAH designation after January 1, 2006.

Since notice was not published until December 8, 2003, MVRMC agrees that necessary provider CAHs with plans to relocate prior to December 8, 2003, should be allowed to do so after January 1, 2006, so long as certain requirements are met (as recommended above). However, necessary provider CAHs without plans to relocate after that date should be restricted from doing so (outside of the 500 yard radius) since they were notified over two (2) years in advance that the necessary provider exception would sunset on January 1, 2006.

In summary, MVRMC strongly supports the notion that clear restrictions should be established regarding the replacement and relocation of necessary provider CAH facilities. Opponents of this notion have argued that the CAH designation for existing necessary provider CAHs should be "grandfathered" and necessary provider CAHs should be allowed to relocate freely so long as the clinical and size requirements are met. Without restrictions, necessary provider CAHs could move to sites adjacent to other facilities, including other CAHs. This outcome is inconsistent with the original intent of the CAH designation and would result in misuse of federal funds.

Thank you for considering our comments. MVRMC would appreciate the opportunity to supply additional information, respond to questions or provide anecdotes if necessary.

Sincerely,

JOHN KEE,
Chief Executive Officer

369

+ CATHOLIC HEALTH INITIATIVES

Berea Hospital

WI / DC
WI / Gen

Hefter
Hartstein
Miller

June 10, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Comments on **WAGE DATA CORRECTIONS**

Dear Dr. McClellan:

We appreciate the opportunity to comment on the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates, published in the Federal Register on May 4, 2005. We are commenting on the policy discussed at page 23384 of the May 4, 2005 Federal Register regarding retroactive changes to the federal fiscal year 2005 (FY 2005) wage index.

The policy discussed at page 23384 states that, pursuant to section 903(a)(1) of Pub. L. 108-173, which allows the Secretary to make retroactive changes to items and services if failure to apply such changes would be contrary to the public interest, the Centers for Medicare and Medicaid Services (CMS) is proposing a retroactive correction to the wage data used to compute the FY 2005 wage index for hospitals that meet certain criteria. The criteria are: 1) the fiscal intermediary or CMS made an error in tabulating a hospital's FY 2005 wage index data; 2) the hospital informed the fiscal intermediary or CMS, or both, about the error, following the established schedule and process for requesting corrections to the FY 2005 wage index data; and 3) CMS agreed before October 1 that the fiscal intermediary or CMS made an error in tabulating the hospital's wage data and the wage index should be corrected by the beginning of FY 2005, but CMS was unable to publish the correction by that date. The discussion at page 23384 also states that CMS published a correction to its FY 2005 inpatient prospective payment final rule on December 30, 2004 that included the corrected wage data for four hospitals that meet the above criteria and that the corrections were effective January 1, 2005.

We very much agree that a retroactive correction to the FY 2005 wage index is appropriate and appreciate the Secretary exercising his authority to make that retroactive correction. For reasons discussed below, however, we request that the policy be amended to delete the requirement that CMS must have agreed before October 1, 2004 that it made an error in tabulating a hospital's data.

St. Joseph Hospital (provider no. 18-0010) and St. Joseph East (provider no. 18-0143) are both located in the Lexington, KY core-based statistical area ("CBSA"). For both hospitals, the fiscal intermediary made an error in tabulating the hospitals' FY 2005 wage index data (based on the hospitals' cost reports ending June 30, 2002), and the hospitals informed the fiscal intermediary and CMS of this error following the established schedule and process for requesting corrections to the FY 2005 wage data. Accordingly, both hospitals meet the first two criteria proposed by CMS for a retroactive correction to the FY 2005 wage index data.

The hospitals received a letter dated October 15, 2004 from James Hart, Deputy Director of the Division of Acute Care for CMS, stating that CMS had reviewed this wage data matter and that it agreed that it was necessary to correct the hospitals' wage data. The letter also states,"[t]he corrected wage data will be retroactive to October 1, 2004, and will be published in an upcoming correction notice and/or joint signature letter." Because this letter is dated October 15, 2004, it does not technically meet the third criterion proposed by CMS at page 23384. As a practical matter, we believe that CMS had determined prior to October 1, 2004 that the wage data for provider nos. 18-0010 and 18-0043 should be corrected, but did not issue its letter stating so until October 15, 2004. Note that prior to October 1, 2004 there were numerous conversations between CMS, PricewaterhouseCoopers (which was acting as the representative for the St. Joseph Hospitals on this matter) and the St. Joseph Hospitals. In these conversations, CMS verbally agreed that the fiscal intermediary had incorrectly tabulated the wage index data for the St. Joseph Hospitals' wage index data and the correction should be effective October 1, 2004.

We believe, however, that the circumstances described above justify a retroactive correction to the FY 2005 wage data pursuant to section 903(a)(1) of Pub. L. 108-173, because the failure to apply such changes would be contrary to the public interest. The fact that CMS agreed to make the wage data change retroactive to October 1, 2004 is sufficient reason to implement the change as of that date. Moreover, these wage data corrections should have been implemented as part of the established process for requesting corrections to the wage index data, which would have made them effective October 1, 2004. Accordingly, we suggest that the criteria published at page 23384 of the Federal Register be amended to delete the requirement that CMS must have agreed before October 1, 2004 to correct the wage data.

We also want to confirm our understanding that the wage data correction for provider nos. 18-0010 and 18-0143 will result in a retroactive wage index correction to October 1, 2004 for all acute-care hospitals in the Lexington, KY CBSA. In our opinion, a change to the wage data for provider nos. 18-0010 and 18-0143 that did not affect the wage index for the entire CBSA would be inequitable and contrary to the public interest.

Again, we very much appreciate the opportunity to comment on the proposed policy and CMS's effort to make retroactive corrections to the FY 2005 wage index when those corrections are in the public interest.

Sincerely,

Della Deerfield
Vice-President/Finance

cc: Scott Raab, Office of Senator Mitch McConnell

Town of Manchester

41 Center Street • P.O. Box 191
Manchester, Connecticut 06045-0191
www.ci.manchester.ct.us

STEVEN R. WERBNER, GENERAL MANAGER

Transfer

Hefler
Hartstein
Walz
Hart

June 20, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Post-acute Care Transfers; Proposed Changes to the Hospital Inpatient Prospective Payment System and FY'06 Rates; Proposed Rule

Dear Administrator McClellan:

I am writing to comment on the Centers for Medicare and Medicaid Services' (CMS) draft rule on the Medicare Hospital Inpatient Prospective Payment System, as published in the May 4, 2005 *Federal Register*. We are particularly concerned about CMS' reported request to expand the number of DRGs subject to the post-acute transfer policy from the current 30 to 223.

The current Medicare transfer payment policy requires that cases assigned to one of 30 DRGs be paid as *transfers* when patients are discharged to psychiatric or rehabilitation hospitals or units, children's, long-term care, or cancer hospitals, and skilled nursing facilities or home health agencies. Under this policy, payment is *per diem.*

I am strongly opposed to the transfer policy to encompass additional classes of patient cases. This would weaken the incentives inherent in the inpatient PPS. A new transfer policy covering 223 DRGs would effectively uproot an incentive-based system fueled by per-case control, to one inordinately focused on per diem costs. Patient care will clearly be impacted by such a decision.

Again, I reiterate my strong opposition to any expansion of the inpatient transfer policy, and believe that such a move would most assuredly not be in the best interests of patients or providers. The proposed policy would undermine clinical decision-making and penalize hospitals for providing patients with the most appropriate care in the most

appropriate settings. Hospitals are already facing great financial difficulty and, in fact, many hospitals are failing.

Changes such as these can only hurt more and citizens in need of care will be denied the necessary care they require and are entitled to. Please do not support these proposed changes.

Thank you for this opportunity to comment on the proposed inpatient PPS rule.

Sincerely,

Stephen T. Cassano

Stephen T. Cassano
Mayor

Karl J. Krapek

371

June 21, 2005

Transfers

Hefter
Hartstein
Walz
Hart

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS- 1500 – P
P. O. Box 8011
Baltimore, MD 21244-1850

Re: **Post-acute Care Transfers; Proposed Changes to the Hospital Inpatient Prospective Payment System and FY'06 Rates; Proposed Rule**

Dear Administrator McClellan:

I want to comment on the Centers for Medicare and Medicaid Services' (CMS) draft rule on the Medicare Hospital Inpatient Prospective Payment System, as published in the May 4, 2005 *Federal Register*. As a hospital director, I am particularly concerned about CMS' reported request to expand the number of DRGs subject to the post-acute transfer policy from the current 30 to 223.

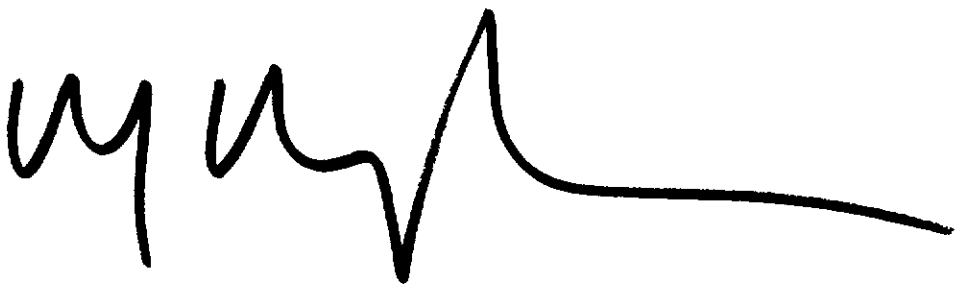
The current Medicare transfer payment policy requires that cases assigned to one of 30 DRGs be paid as transfers when patients are discharged to psychiatric or rehabilitation hospitals or units, children's, long-term care, or cancer hospitals, and skilled nursing facilities or home health agencies. Under this policy, payment is per diem.

I strongly oppose expanding the transfer policy to encompass additional classes of patient cases. We believe this would fundamentally weaken the incentives inherent in the inpatient PPS. A new transfer policy covering 223 DRGs would effectively uproot an incentive-based system fueled by per-case control, to one inordinately focused on per diem costs.

The proposed policy would undermine clinical decision-making and penalize hospitals for providing patients with the most appropriate care in the appropriate settings.

Thank you.

Best regards,



Karl J. Krapek

372

MILFORD HOSPITAL

Hosp Red.
Labor S
Transfers

Hecter
Hartstein
Kenly
Miller
Knight
Seifert
Treitel
Walz
Hart

June 24, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1500-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1500-P; Medicare Program; Proposed Changes to Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Rates

Dear Sir or Madam:

Milford Hospital appreciates the opportunity to provide these comments regarding the Centers for Medicare and Medicaid Services (CMS) proposed rule: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates [CMS-1500-P].

Hospital Redesignations and Reclassifications (Pages 23376 – 7)

Under Section 1886(d)(8)(E) of the Act, an urban hospital can apply for redesignation as a rural hospital. Under the proposed rule, the "hold harmless" provisions that occur under section 1886(d)(8)(B) and section 1886(d)(10) when a hospital is granted reclassification, will now be applied when hospitals are approved for redesignation. Milford Hospital supports this appropriate extension of the "hold harmless" protection, which is particularly important to many Connecticut hospitals. Milford Hospital thanks CMS for addressing this issue in the proposed rule.

Other Provisions

There are several provisions of the proposed rule that remain harmful to many Connecticut hospitals. Milford Hospital opposes the following provisions:

- Reductions to the labor share;
- Expansion of the transfer policy; and

Of particular concern is the proposed expansion of the transfer provision, which is projected to result in a reduction in Medicare funding to Milford Hospital of $180,000 in FFY 2006, a reduction this hospital simply cannot afford.

Finally, we ask that CMS consider a minimum guaranteed rate of increase 2% for hospital providers and a one-time increase of 3.8% to correct for the consistent under-forecasting of the hospital market basket that occurred in seven of the last eight years. Granting such an increase, while not correcting for the past under funding, will offer great relief by bringing the current rates to their proper level. Setting a minimum increase of 2% will prevent what happened last year when 48 hospitals in the country were paid less in 2005 than 2004; 14 of the 48 were in Connecticut. If the

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various proposed changes go into effect for FFY 2006, nine hospitals in Connecticut will receive less in 2006 than they received in 2005. We believe CMS should develop and implement a minimum increase for hospitals similar to that developed for Health Plans (i.e. 2% minimum annual increase).

We appreciate your consideration of these comments.

Sincerely,

Joseph Pelaccia

Joseph Pelaccia
Vice President, Finance

SAINT BARNABAS
HEALTH CARE SYSTEM
Newark Beth Israel Medical Center

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RONALD J. DEL MAURO
President and Chief Executive Officer
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PAUL A. MERTZ
Executive Director

Hefler
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June 23, 2005

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

Subject: Labor-Related Share

To Whom it May Concern:

I am writing on behalf of Newark Beth Israel Medical Center to express our opposition to the changes that the Centers for Medicare & Medicaid Services (CMS) has proposed in the FY 2006 Medicare inpatient PPS regulation governing the labor-related share of Medicare payments to hospitals. The proposed regulation calls for reducing the labor-related share from 71.1 percent to 69.7 percent for hospitals located in areas with a wage index greater than 1.0 and would cost our hospital approximately $331,000 in lost Medicare revenue.

Three years ago, CMS proposed increasing the labor-related share for all hospitals from 71.1 percent to 72.5 percent. The agency, however, expressed concern over the harmful impact this would have on rural hospitals and withdrew the proposal in favor of further analysis of the methodology it used to compute this proposal. While CMS was performing this analysis, Congress passed legislation that set the labor-related share at 62 percent for hospitals with a wage index of 1.0 or less to increase payments to most rural hospitals.

In proposing to reduce the labor-related share for FY 2006 for hospitals with a wage index greater than 1.0 – primarily urban hospitals – CMS now is using the same methodology it rejected three years ago. We do not understand why a methodology rejected three years ago is now considered valid. If that methodology is now, in fact, considered valid, CMS's decision not to raise the wage index as originally proposed three years ago resulted in urban hospitals being underpaid by Medicare since that time.

Since this change will decrease Medicare revenue for all affected hospitals – those whose wage index is greater than 1.0 – CMS proposes achieving budget neutrality by redistributing this money by increasing the standardized amount for all hospitals. This approach will result in a financial windfall for *all* hospitals with a wage index of 1.0 or less – that is, for most rural hospitals. If CMS believes that 69.7 percent is the true, appropriate figure for labor-