STATE OF LOUISIANA
DEPARTMENT OF HEALTH AND HOSPITALS

Kathleen Babineaux Blanco
GOVERNOR

LOUISIANA
Department of HEALTH and HOSPITALS

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

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HARTSTEIN

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.

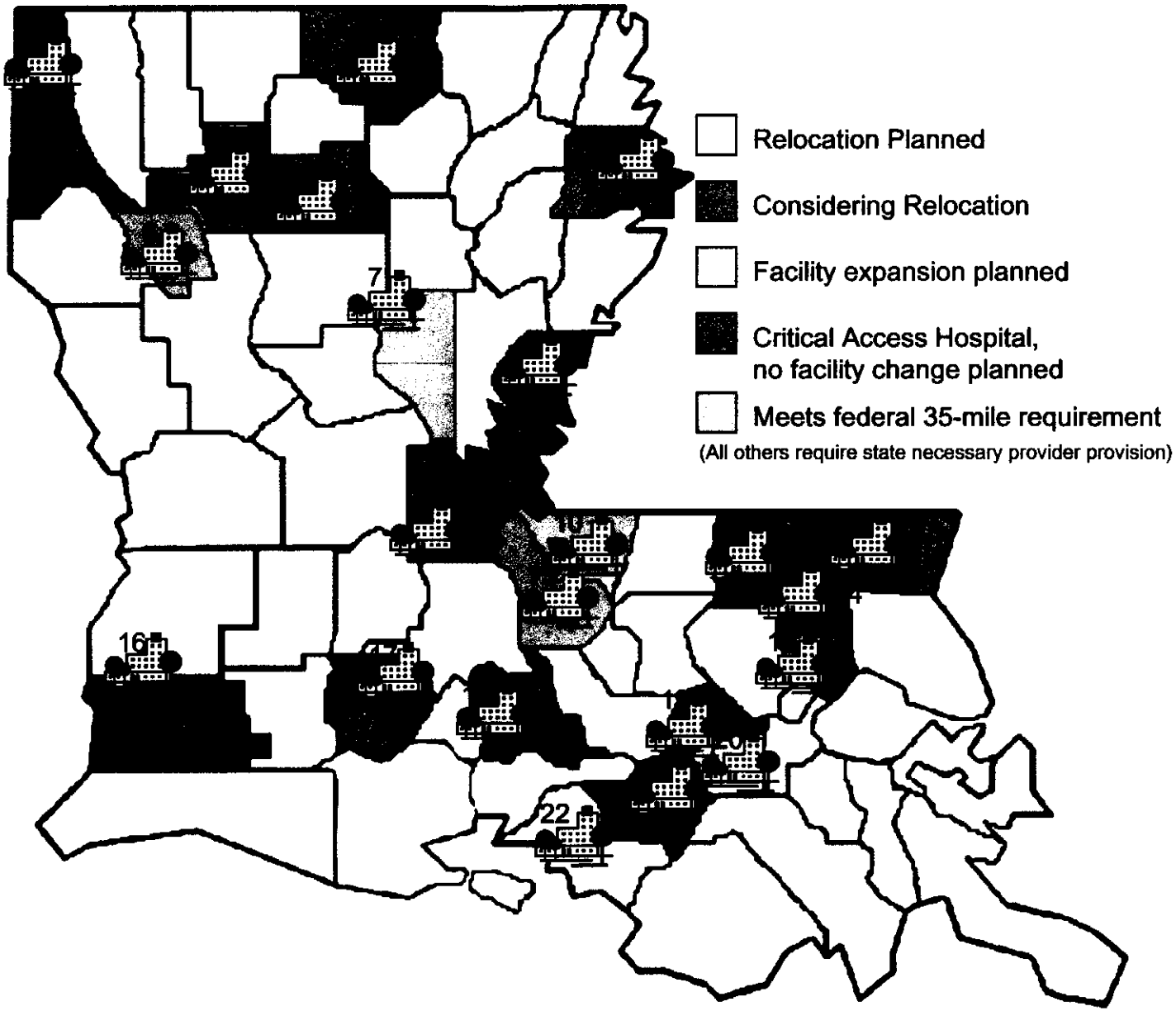
Sincerely,

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

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LTC/DRG

June 22, 2005

Mark B. McClellan, M.D., Ph.D,
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Ave, SW
Washington, DC 20201

Attention: **CMS-1500-P**

Dear Administrator McClellan:

Sisters of Mercy Health System (Mercy) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates"* (IPPS), 70 Fed. Reg. No. 85 (May 4, 2005). MERCY is a 19-hospital system operating in Missouri, Kansas, Oklahoma, and Arkansas.

Mercy is very appreciative that CMS is proposing a 3.2% PPS rate increase for federal fiscal year 2006. As you know well, it is critical for healthcare to be able to recruit and retain qualified healthcare professionals. This requires the ability to provide competitive wages versus other career opportunities available. Additionally, as noted by the proposed add-on for technology; the non-labor cost of providing care continues to escalate at levels well above general inflation. With Medicare representing Mercy's largest payer of care provided, increases are paramount to our continued provision of quality healthcare.

The primary focus of this letter is to comment on the proposed changes to the regulations for the following issues:

- DRG Reclassifications
- Post-Acute Care Transfer Payment Policy
- Outlier Payment Threshold
- DSH Adjustment Data

- New Technology Applications
- Critical Access Hospitals
- LTC-DRGs

I. DRG RECLASSIFICATION

CMS proposes several DRG coding and classification changes based on an analysis of the FY 2004 MedPAR file, updated through December 2004. The following are comments and opinions regarding code and DRG changes.

A. CMS proposes to remove code 37.26 from the list of cardiac catheterizations for DRG's 535 and 536. If a defibrillator is implanted and an EPS performed with no other type of cardiac catheterizations, then the case would be assigned to DRG 515. Code 37.26 is not to be reported separately when a defibrillator is inserted, according to coding guidelines. We understand CMS's reasons for removing code 37.26 from DRG 535 and 536 based on the average charge, however we **do not agree** with this methodology. The average charge for DRG's 535 and 536, with 37.26 only and without cardiac catheterization, is respectively 18% and 2% higher than DRG 515's average charge. Based on the chart on page 23317, almost 15% of 535 **and** 536 would fall to 515. The case weight difference between DRG 515 and 535 and 536 is 31.7% and 20%, respectively. We doubt that our resource consumption for these cases moving from 535/536 to 515 will decline at a similar pace. We believe further analysis is required or an appropriate case weight adjustment before code 37.26 is removed from DRG's 535 and 536.

B. Mercy commends CMS on their analysis to accommodate new coronary artery stent codes to differentiate between the number of vessels treated as well as the number of stents inserted. The recommended DRG restructuring to show complex versus noncomplex procedures appears to be appropriate. However, based on the presence of coronary stents in relation to certain additional diagnoses, we believe coding errors and omissions in the MedPAR database could have skewed CMS's analysis. Doing a study without completely identifying the proper codes can bias the statistics gathered and affects the validity of the conclusions. We have the following comments/questions regarding the codes:

1. Congestive heart failure – is it the intent to include only *congestive* heart failure, or any heart failure. If *any* heart failure is the criteria, then codes 428.2 through 428.9 should also be included. If it was intended to only include *congestive* heart failure, then the hypertensive heart failure codes as listed in the Federal Register (e.g., 402.01, 402.11, 402.91, etc.) do not include the term *congestive* and it is questioned whether they should be included.
2. Arteriosclerotic cardiovascular disease is stated to be "represented by code 429.2." However, in the coding world, arteriosclerotic cardiovascular

disease is more likely to be coded to the 414.0x category. We believe using 429.2 is not what CMS intended here.

3. Cerebrovascular disease – some of the codes listed in the Federal Register appear to be incorrect. For instance, there is no code 430.0; the correct code is 430. In addition, the code noted as 436.0 is an invalid code and should be code 436. It is noted that only codes that are titled "with cerebral infarction" are included. We feel additional codes should be added to capture cerebrovascular disease *without* cerebral infarction, and would include codes 433.00, 433.10, 433.20, 433.30, 433.80, 433.90. 434.00, 434.10, and 434.90. In addition, cerebrovascular disease could be extended to include codes which involve TIA diagnoses and these would include codes 435.0, 435.1, 435.2, 435.3, 435.8, and 435.9. Other codes which show cerebrovascular disease include those in the 437 category (Other and ill-defined cerebrovascular disease). We feel these should have been included as well.
4. Regarding the secondary diagnosis codes of acute MI, we believe that the fifth digit of "2" should also be included for all of the listed codes. The fifth digit of "2" represents those cases where there is a subsequent admission within the 8 week period following an initial MI. Because patients could go home following the MI and then come back to the hospital for a stent, the fact that there was an MI within the previous 8 week time period may be pertinent, depending on what the focus of the analysis might have been.
5. The renal failure codes failed to include code 586 – Renal failure. Additionally, code 585.0 is an invalid code and should be code 585 – Chronic renal failure.

C. We agree with CMS's proposal to modify joint replacement codes to incorporate new codes for revisions of joint replacement.

D. An issue regarding DRG 518 is not addressed in this proposed rule but should be considered by CMS. When a patient is admitted with coronary artery disease and an MI occurs after admission, the MI cannot be coded as principal diagnosis according to coding guidelines. Then, if the patient has a PTCA (but no stent placed), the case groups to DRG 518 – Percutaneous cardiovascular procedure without coronary artery stent or AMI (RW 1.7509). Since the patient did have an MI during this admission, it seems logical that the case should group to DRG 516 – Percutaneous cardiovascular procedures with AMI (RW 2.6457). This would result in appropriate payment to cover the resources needed to address the MI.

II. POSTACUTE CARE TRANSFERS

CMS proposes to expand the post-acute care transfer policy. Two options are discussed however it appears CMS is promoting the second option. Option 1 would include all DRGs within the post-acute care transfer policy. CMS believes this option would provide consistent treatment of all DRGs however a significant number of DRGs have lengths of stay less than 3 and thus receive the full DRG payment in the

first two days of the stay. Option 2 would expand the post-acute care transfer policy from 30 to 223 DRGs in FFY 2006. Under Option 2, the proposed criteria necessary for a DRG to be included in this policy changes from the current criteria is as follows. The current policy requires a DRG meet the criteria below for the two most recent years data is available. The proposed policy does not require this two year stipulation.

CURRENT	PROPOSED
- DRG must have at least 14,000 post-acute care transfer cases.	- DRG has at least 2,000 discharges to post-acute care.
- At least 10% of its post-acute care transfers occurring before the geometric mean length of stay	- At lease 20% of its cases are discharged to post-acute care.
- DRG has a geometric mean length of stay of at least 3 days.	- DRG has a geometric mean length of stay of at least 3 days.
- DRG has a decline in its geometric mean length of stay of at least 7% during the most recent 5-year period.	- If either DRG of a paired set of DRGs (based on the presence or absence of a comorbidity) meets the first three criteria above, both paired DRGs are included.
- If either DRG of a paired set of DRGs (based on the presence or absence of a comorbidity) meets the first three criteria above, both paired DRGs are included.	

CMS believes this proposed change would expand the application of the post-acute care transfer policy to DRGs that have both a relatively high volume and a relatively high proportion of post-acute care utilization. Option 2 would result in $880 million less in Medicare payments to hospitals or a 1.1 percent decrease.

We believe that CMS should not implement an expansion of the post-acute care transfer policy. While Section 1886(d)(5)(J)(iv) of the Social Security Act authorizes CMS to expand the post-acute care transfer policy to additional DRGs based on high discharge volumes to post-acute care facilities, we believe CMS's definition of "high volume" is arbitrary at best. We do not understand how "high volume", currently meaning a minimum of 1,400 cases per DRG (14,000 x 10%), proposes to mean a minimum of 40 cases per DRG (2,000 x 20% x 10%). The original intent of this policy was to avoid providing an incentive for a hospital to transfer patients to other facilities early in a patient's stay to minimize costs and still receive the full DRG payment. CMS's significant change in criteria continues to assume providers "game" the system on an even broader scale. This impacts the Medicare discharges of our urban facilities by 50% and as much as 75-80% of our rural facilities. **The estimated financial impact on our teaching facility alone is over a half a million dollar reduction in Medicare reimbursement.**

Above all, this policy penalizes hospitals that ensure that Medicare patients receive care in the most appropriate setting. In addition, it undercuts the fundamental principle of the

PPS, which is that some cases will cost more than the DRG payment, while others will cost less, but on average, the overall payments should be adequate. It also is important to recognize that to the extent there still are cost reductions associated with discharging patients to post-acute care facilities, such reductions will be reflected in lower DRG weights during the DRG recalibration process.

III. OUTLIER PAYMENT THRESHOLD

If the costs of a particular Medicare case exceed the relevant DRG operating and capital payment (including and DSH, indirect medical education (IME), or new technology add-on payments) plus a fixed-loss cost threshold, the hospital will receive an outlier payment. This payment equals 80% of the case's cost above the threshold calculation.

CMS proposes to increase the fixed-loss cost threshold for outlier payments from $25,800 to $26,675. This represents a 3.4% increase from the FFY 05 level. Outlier payments are funded through a 5.1% reduction in the PPS standardized payment amount. Therefore, CMS should set the outlier cost threshold at a level that it believes will result in outlier payments that equal 5.1% of total DRG payments. However, CMS estimates that outlier payments represented only 3.5% of total DRG payments in FFY 04. CMS further believes that FFY 05 outlier payments will be approximately 4.4%of actual total DRG payments. This is .7 percentage point lower than the 5.1% projected in setting the FFY 05 outlier threshold. This means less total Medicare payments to hospitals. The estimated reduction in outlier payments to our system exceeds $500,000.

Based on CMS's estimates for FFY 04 and 05, it appears the outlier should not be increased or even reduced for FFY 06.

IV. DSH ADJUSTMENT DATA

Section 951 of Public Law 108-173 requires CMS to arrange to furnish the data necessary for hospitals to compute the number of patient days used in calculating the disproportionate patient percentages. This provision is not specific as to whether it applies to the patient day data used to determine the Medicare fraction or the Medicaid fraction. CMS is interpreting this section to mean they will arrange to furnish hospitals both sets of data; the Medicare fraction data from CMS' records and the Medicaid fraction data from the State Medicaid Agency's records. The Medicare fraction data historically is based on the Federal fiscal year. A hospital could request the data based on the hospital's fiscal year and accept the resulting DSH percentage for that year, whether more or less favorable.

Specifically, CMS proposes to make the Medicare fraction data available for either the Federal fiscal year or, if the hospital's fiscal year differs from the Federal fiscal year, for the months included in the two Federal fiscal years that encompass the hospital's cost reporting period. This will allow the hospital to review both sets of data and determine

which fiscal year yields a higher DSH %. There will be no cost to hospitals to obtain the Medicare fraction data. Currently there is a charge by CMS to hospitals for this data.

We applaud and agree with CMS for proposing to make the Medicare fraction data available to hospitals for both Federal and hospital fiscal years. We also agree with eliminating the charge for this data. Both are long overdue.

V. NEW TECHNOLOGY APPLICATIONS

CMS established a methodology that would provide additional payments to hospitals for new technologies that are not yet reflected in the DRG payment system. However, for Federal Fiscal Year (FFY) 2005, the additional payment was limited to only three new technologies. For FFY 2006, an additional payment is proposed for only **one** new technology, the "Kinetra Implantable Neurostimulator", and this is currently receiving an add-on payment. Mercy is concerned that CMS is not considering these new technologies in a timely manner. We believe CMS should also incorporate a capital cost factor to the current add-on payment for operating costs. Mercy urges CMS to study and review their current procedures and criteria for approving new technology applications. We encourage CMS to consider a payment mechanism that will more adequately compensate providers for "state of the art" medical care.

New technology must meet three criteria under the DRG system to qualify for an additional payment. The additional payment is based on the hospitals cost for the new medical service or technology. Medicare pays the lesser of a) 50% of the difference between the cost of the case with the new technology and the DRG payment, or b) 50% of the cost of the new technology.

Mercy urges CMS to increase the payment for new technology add-on payments from 50% of the additional cost of the service or device to 80% of the cost. We believe this is in line with the Conference Committee Agreement accompanying the Medicare Modernization Act which states, "the Secretary should consider increasing the percent of payment associated with the add-on payments up to the marginal rate used for the inpatient outlier." We believe the 80% represents the appropriate balance for ensuring that hospitals are not excessively at financial risk for expensive cases.

VI. CRITICAL ACCESS HOSPITALS

The proposed rule provides that any Critical Access Hospital (CAH) designated as a "necessary provider (NP)" by the State is prohibited from building a replacement facility unless: (1) It's within 250 yards or on land owned before 12/08/03, (2) construction plans were started before 12/08/03, and (3) the new facility will provide care to at least 75% of current patients using at least 75% of existing staff (75% rule). The penalty for violating these regulations is an automatic loss of both CAH certification and cost-based reimbursement. Over 50% (600) of all CAH's are "necessary providers".

CMS has taken an ill advised step which will result in rural communities being unable to obtain quality medical care. The proposed regulations are a broad over-reach of CMS authority and place a ban on new construction for almost half of all small rural hospitals in the United States. This is problematic for the following reasons:

It was not the intent of Congress that CMS would prohibit or hinder communities from replacing facilities that provide quality health care to rural America. Many of the small hospitals in the rural United States were financed under the Hill-Burton act and are now forty to fifty years old. These aging facilities are simply not capable of providing high quality, cost efficient service without the Necessary Provider Designation. One of the primary reasons for this situation is the Prospective Payment System (PPS) adopted by CMS formerly HCFA almost twenty-five years ago. It is apparent that this system has unfairly penalized low volume providers. Furthermore, the PPS has meant that many rural hospitals have not been able to adequately fund depreciation expenses over a long period of time. These measures and rules have already had the effect of nearly guaranteeing these facilities no longer have the capacity for capital expenditures sufficient to replace most rural hospitals. As a result, rural hospitals have not been able to keep up with their urban and suburban counterparts who were increasingly paid more for the same service than rural hospitals. Rural hospitals also have the burden of a much larger percentage of Medicare population than urban hospitals. Thus, every tweak in the PPS system fell more heavily on rural hospitals because of this fact.

The CMS proposed regulations are an over-reach to a potential problem that can be easily managed without placing a ban on all new construction. Many CAHs are located on either small campuses or on campuses that adequately served the rural community population decades ago. CMS fails to understand that rural communities have changed and that the current hospital location and physical plant may not adequately meet the community's needs. These decisions allow for superior service and access and are not a means to compete against PPS facilities. To assume differently is to grossly misunderstand rural America, something that CMS has done we feel. If in fact the situation would arise that the CAH moved just to have a more competitive advantage over a rival PPS hospital, the 75% rule would prevent that from happening. CMS has failed to understand the safety net nature of rural hospitals and rural doctors. This is especially important for Medicare beneficiaries that many times have no where else available for comprehensive healthcare services.

The proposed rule will force CAHs to allocate funds to renovate structures that no longer meet either the needs or the demands of modern health care. As inefficiencies are realized, CMS will be forced to provide more money to assets to maintain an aging and declining healthcare infrastructure in rural America. Ironically, the CMS proposal to ban a local community's ability to rebuild on an adjacent or nearby location will cost Medicare more over time, not less. The higher labor costs of operating in a retrofitted building more than offset the slightly cost of rebuilding. The proposal then displays a short sighted thinking process by the rule makers and a dramatic misunderstanding of the health care setting in rural areas.

The CMS proposed ban on construction is based on its bias against cost based reimbursement rather than on any established fact. CAHs in so far as replacement and/or relocation should be treated as any other hospital by CMS. This "difference" is not based in law but rather in CMS bias against small rural hospitals and cost based reimbursement. The proposed ban on major construction projects developed after December 8, 2003 is an over reaction against a potential problem that can be appropriately managed with current CMS policy. As mentioned earlier we support the long-standing 75% rule that simply states that if a hospital relocates, it must serve 75% of the same community as previously served to be considered the same provider. We think this alone would solve the grossly exaggerated claim that most CAHs want to move to be in a more competitive position with their nearest PPS competitor. Second, CMS seems to be in a panic mode concerning the growth of the CAH program. This was specifically intended by Congress. The growth of the program is limited by the number of rural hospitals that reasonable have twenty-five or fewer beds. Every reasonable estimate puts this potential universe at less than 1,500 hospitals nation-wide. Since more that 1,100 hospitals have already converted to CAH status. That leaves less than 400 hospitals even potentially eligible for this designation. Attention should be paid to the total cost of the program (approximately $3B annually) and the additional cost as compared with all these CAHs being PPS hospitals (less than $800M according to MedPac figures) compared with the total hospital budget this year for CMS of better than $239B. This makes the total CAH expenditure less than 0.01% of the total annual CMS hospital budget. In this context the argument becomes one that is philosophical rather than substantive. Obviously, CMS does not favor cost-based reimbursement even though it is mandated by Congress. This Congressional mandate is fostered by the abject failure of the current PPS payment system to adequately reimburse rural hospitals for vital health services provided to Medicare beneficiaries.

The CMS proposed regulations reverse a long standing policy. Designation as a CAH necessary provider is associated with its current Medicare provider agreement which should remain intact unless the CAH fundamentally changes its business or is terminated by Medicare for cause. It is a longstanding policy that the provider agreement describes the legal entity and the services provided – not the physical structure or location. It should also be noted that CMS was required to approve each state's plan for designating necessary providers. Because of the constant change in health care, this plan should be revisited by both the state and CMS on a regular basis, probably every three to five years.

Finally, this proposed rule transfers to CMS control over local rural health care never envisioned by Congress. This change would be a loss of local and state control never seen before. If allowed to stand, it would be a threat to all hospitals and all communities, small and large. This change would give CMS unprecedented authority to dictate the structure of local health systems and control access to health care. This constitutes an unnecessary intrusion into the economic development of rural communities. If allowed to go into effect this rule would do significant harm to rural America's healthcare system, bring to bear unforeseen strain on the country's urban healthcare system and establishes a precedent of regulatory intrusion directly counter to the intent of Congress.

Based on the information presented above, our recommendation is that any CAH be allowed to replace or relocate their facility and maintain their status as a CAH as long as that facility can satisfy the 75% rule. We support the 75% rule that simply states that when a hospital relocates it will be servicing the same community and will be operating essentially the same services with essentially the same staff. We think this alone would solve the grossly exaggerated claim that most CAHs want to move to be in a more competitive position with their nearest PPS competitor.

Specifically, we absolutely oppose any and all deadlines for actions related to Critical Access Hospital (CAH) replacement or relocation in the Inpatient Prospective Payment System (IPPS) final rule. The proposed "75% threshold" is appropriate and sufficient to assure that a replacement or relocation CAH facility continues to meet the intent of its original Necessary Provider designation, i.e. that the "CAH serves at least 75 percent of the same service area that it served prior to its relocation, provides at least 75 percent of the same services that it provided prior to the relocation, and is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees."

VII. LTC-DRGs

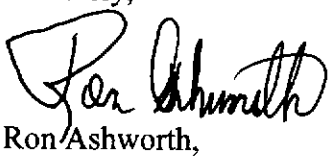
Mercy understands the LTC-DRG reclassifications, however; we continue to be concerned with the current regulations restricting the reimbursement for patients admitted from a Host hospital to an LTC. Mercy currently leases space in three of its hospitals to an LTC provider. The LTC provider has been instrumental in providing a level of care to LTC patients that Mercy otherwise could not have provided had the patient remained in an acute care setting. The intensity of care required of an LTC patient is not economically feasible to replicate in an acute care setting. Mercy continues to request CMS consideration of MedPac's recommendation to implement a clinically-based criteria for admission to an LTC. This would be more consistent with the admission criteria utilized in other care settings. The admission criteria instituted by CMS will render these three facilities economically non-viable within 2 years. This will have a detrimental impact to the almost 800 patients who receive care annually in these three LTCs. Additionally, it will cost Mercy in excess of $7 million annually to provide the increased level of care required of the LTC patients with no additional reimbursement from CMS.

VIII. CONCLUSION

Thank you for this opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above.

If you have questions concerning these comments, please feel free to contact Bill Colletta at (314) 364-3525.

Sincerely,



Ron Ashworth,
President and Chief Executive Officer
Sisters of Mercy Health System

Cc: Jim Jaacks
Randy Combs
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Via Federal Express

DRG/GEN
NT

June 22, 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

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

Dear Dr. McClellan:

Cordis Corporation is pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Medicare Hospital Inpatient Prospective Payment System (PPS) and Fiscal Year 2006 Rates, published on May 4th, 2005, in the Federal Register. Cordis Corporation is a member of the Johnson & Johnson family of companies and a leading manufacturer of cardiovascular, endovascular and neurovascular advanced medical technologies. Our comments cover two areas: (1) Hospital Reimbursement for Drug-Eluting Coronary Stents (DES) and (2) the proposed DRG assignment for extracranial carotid stenting.

Summary of Comments

- Cordis supports CMS' proposal to maintain a separate DRG structure for cases involving the insertion of drug-eluting coronary artery stents.

- Cordis supports CMS' proposal to split out DRGs 516 and 526 in FY 2006 based on the presence or absence of a secondary diagnosis on the existing complications and co-morbidities (CC) list. The MedPAR database shows clear differentiation in the average charges for acute myocardial infarction (AMI) patients with and without CCs.

- We are encouraged that the proposed reimbursement differential between comparable DES and bare metal stent (BMS) cases has increased over the FY 2005 rule. However, we remain concerned that the DRG relative weights underestimate the true costs of performing DES procedures, especially for cases involving treatment of multiple vessels and the insertion of multiple DES.

- We congratulate CMS for creating 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 disease treatment (codes 00.40, 00.41, 00.42 and 00.43), effective October 1, 2005. We agree with CMS that the agency should evaluate hospital charge data underlying these new procedure codes to determine whether new DRGs based on multiple vessel treatment and/or insertion of multiple stents are warranted.

- Cordis proposes that CMS create two new DRGs for carotid stenting cases split on the presence or absence of complications or co-morbidities.

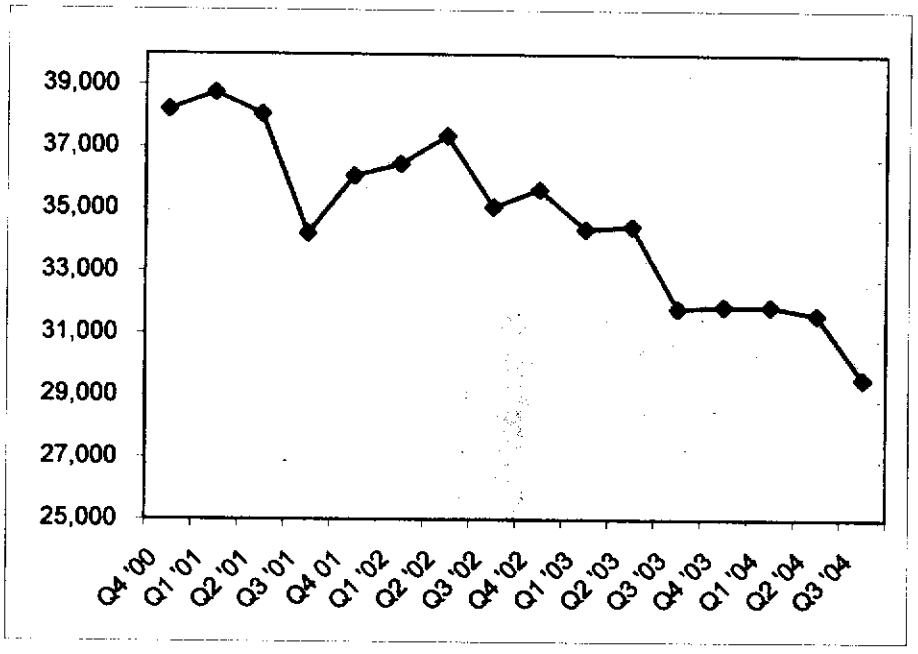
I. HOSPITAL REIMBURSEMENT FOR CORONARY DES

Cordis is a pioneer in developing bare metal and drug-eluting stents, and received approval from the Food and Drug Administration (FDA) on April 24, 2003 for the CYPHER™ Sirolimus-eluting stent. As you know, drug-eluting stents offer important clinical benefits to patients who would otherwise experience restenosis and the need for either additional PCI (percutaneous coronary intervention) procedures or coronary artery bypass. Many interventional cardiologists predict that 30-50% of patients receiving coronary artery bypass grafting (CABG) may be shifted to less invasive drug-eluting stent procedures.

The FY 2004 MedPAR database documents the continued conversion of CABG to DES. Figure 1 below shows the downward trend in quarterly Medicare CABG discharges during the Medicare fiscal years 2001 through 2004. Because of the seasonal variation in procedures, it is helpful to compare comparable quarters on a year over year basis. *There were 34,443 CABG discharges in the MedPAR database in the second quarter of FY 2003, immediately prior to DES introduction. In contrast, there were only 31,617 CABG cases in the corresponding quarter for FY 2004, an 8.2% decrease in volume.* While there has been a general downward trend in the number of CABG surgeries since 2000, this trend has clearly accelerated with the introduction of DES technologies.

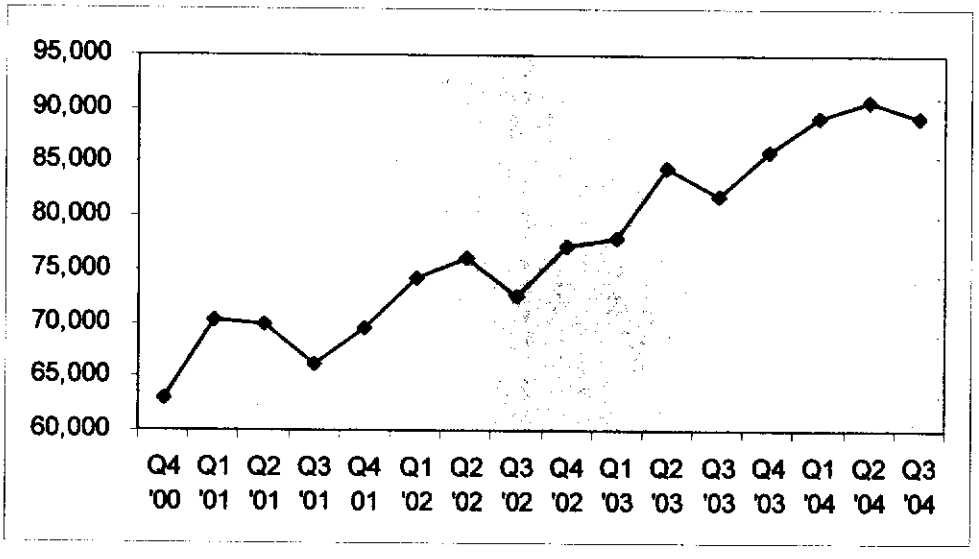
There has been a corresponding increase in stenting discharges over this same time period. Figure 2 below documents the increasing trend in stenting procedures by quarter for fiscal years 2001 through 2004. *There were 84,602 stenting discharges in the MedPAR database in the second quarter of FY 2003. This grew to 90,656 cases in the corresponding quarter for FY 2004, a 7.2% increase in volume.*

Figure 1 – Medicare CABG Discharges by Quarter FY 2001 - 2004



Note: Discharges in DRGs 106, 107 & 109

Figure 2 – Quarterly Medicare Stenting Discharges – FY 2001-2004



Note: Discharges in DRGs 516, 517, 526 & 527 (majority of cases in DRG 516 are stenting

Drug-eluting stents not only represent a significant advance in patient care but also represent a significant advance in the economics of treating coronary artery disease. In fact, results of the CYPHER™ SIRIUS trial, a 1,058-patient U.S. clinical trial, show that payers will be able to recoup virtually all costs associated with the stent within one year (without taking into account savings from reduced CABG surgery) as a result of

substantial reductions in the need for retreatment and rehospitalizations caused by restenosis despite the substantially higher costs of the drug-eluting stents. For every 100 patients in the SIRIUS trial that were treated with the CYPHER™ stent, there were 19 fewer revascularization procedures and 25 fewer hospital re-admissions than with conventional stents. Importantly, three other prospective, randomized, double-blinded clinical trials with the CYPHER™ stent in an additional 700 patients (C-SIRIUS, E-SIRIUS, SES-SMART) and numerous real-world registries with the CYPHER™ stent in over 12,000 patients confirm these impressive results.

Based on an independent economic analysis of the SIRIUS trial performed by Dr. David Cohen[1], in-patient hospital costs were approximately $2,800 higher with the CYPHER™ stent than with the conventional stent (at a price premium of $2,000 per stent for the CYPHER™ stent versus the bare metal stent and 1.4 stents per patient), but the follow-up medical costs were $2,500 lower per patient than those for the conventional stent group. *These cost off-sets do not include the cost reductions to the health care system derived by a shift from more expensive CABG procedures. Taking these savings into account, the CYPHER™ stent is expected to produce overall cost savings to the health care system.*

A. Temporary DES DRGs and Proposed DRGs Based on CC List for AMI Cases

We are encouraged that CMS has proposed to maintain a separate DRG structure for cases involving the insertion of drug-eluting coronary artery stents. Since FY 2003 this structure has allowed hospitals to obtain incremental reimbursement for the more costly Medicare patients receiving the DES technology compared to bare metal stent (BMS) devices. Although the overall utilization of BMS is declining, it is premature to eliminate the temporary DES DRGs until such time that BMS represent an inconsequential percentage of the total discharges. Since current use of DES exceeds utilization that is reflected in MedPAR data, combining DES and BMS at this time would unfairly reduce payments for DES procedures.

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 the following 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
DRG 550: Percutaneous Cardiovascular Procedure with DES with AMI w/out CC

As exhibited in the proposed rule, there is a clear differential in the average hospital charges for AMI patients with and without CCs. Cordis supports the creation of the four new DRGs for FY 2006 that would differentiate reimbursement for these sets of AMI patients. However, we are not convinced that the proposed "with CC" and "without CC" structure should be the permanent solution for all the coronary stent DRGs. For example, the FY 2004 MedPAR data do not support a similar CC/non-CC split in the non-AMI DRGs (517 and 527), where over 70 percent of the total coronary stent discharges occur.

[1] Of Beth Israel – Deaconess Medical Center and the Harvard Clinical Research Institute.

We, therefore, agree with CMS that this new modified structure proposed for FY 2006 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." (Federal Register, Page 23320)

B. Hospital Reimbursement Differential for DES Procedures

We are encouraged that the proposed reimbursement differential between comparable DES and BMS cases has increased over the FY 2005 rule. As exhibited in Table 1 below, the base reimbursement differential for the DES DRGs in FY 2005 was $1,632 (DRGs 526 vs. 516) and $1,082 (DRGs 527 vs. 517) respectively. The differentials between comparable stent cases have grown to $2,007 (DRGs 549 vs. 547), $2,122 (DRGs 550 vs. 548) and $1,315 (DRGs 527 vs. 517) respectively. Taking into account the relative volume of the procedures and the fact that over 70 percent of the cases are in DRGs 527 and 517, the weighted average differential is only $1,511.

Table 1 -- Stent DRG Reimbursement in FY 2005 and FY 2006 Proposed Rule

DRG	FY 2005 Base Payment*	DRG	Proposed FY 2006 Base Payment*	% of Total Coronary Stent Cases
516	$13,151	**547**	$14,503	*8%*
		548	$10,774	*3%*
517	$10,491	**517**	$10,578	*19%*
526	$14,784	**549**	$16,510	*10%*
		550	$12,896	*6%*
527	$11,523	**527**	$11,892	*54%*
Differential (526 vs. 516)	***$1,632***	*Differential (549 vs. 547)*	***$2,007*** *(18% volume)*	***Weighted Average Differential: $1,511***
		Differential (550 vs. 548)	***$2,122*** *(9% volume)*	
Differential (527 vs. 517)	***$1,082***	*Differential (527 vs. 517)*	***$1,315*** *(73% volume)*	

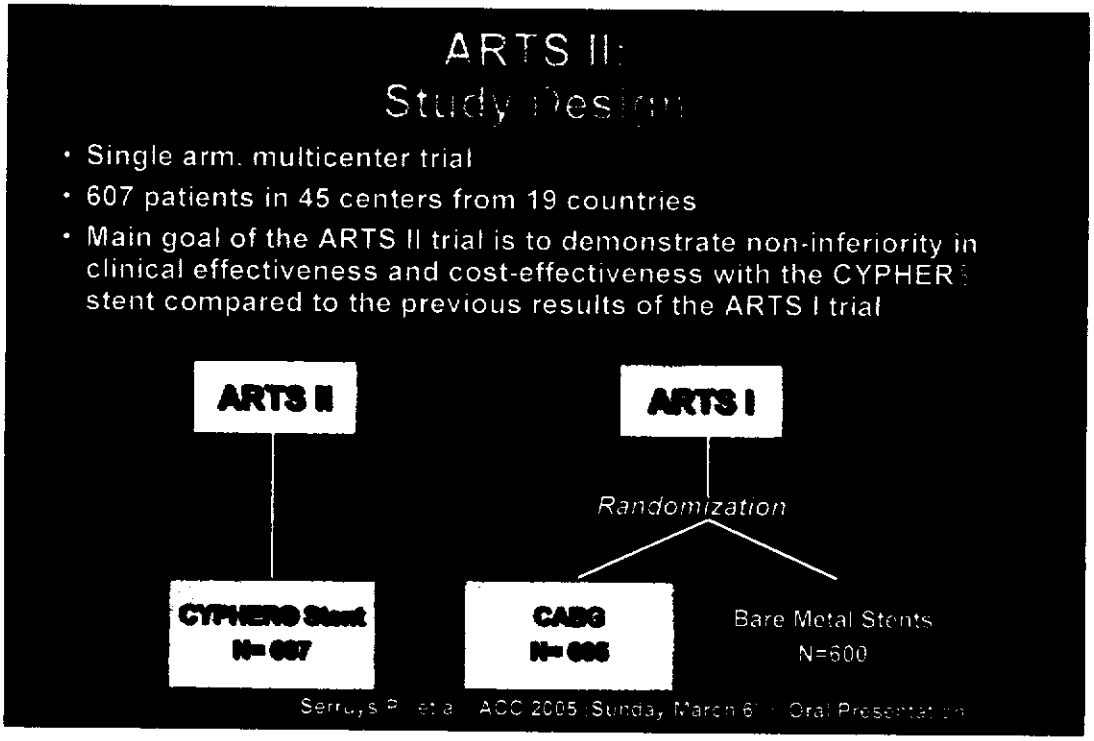
** Reimbursement calculated using the published standardized amounts for large urban areas. Assumes a wage index of 1.00 and no other add-on payments.*

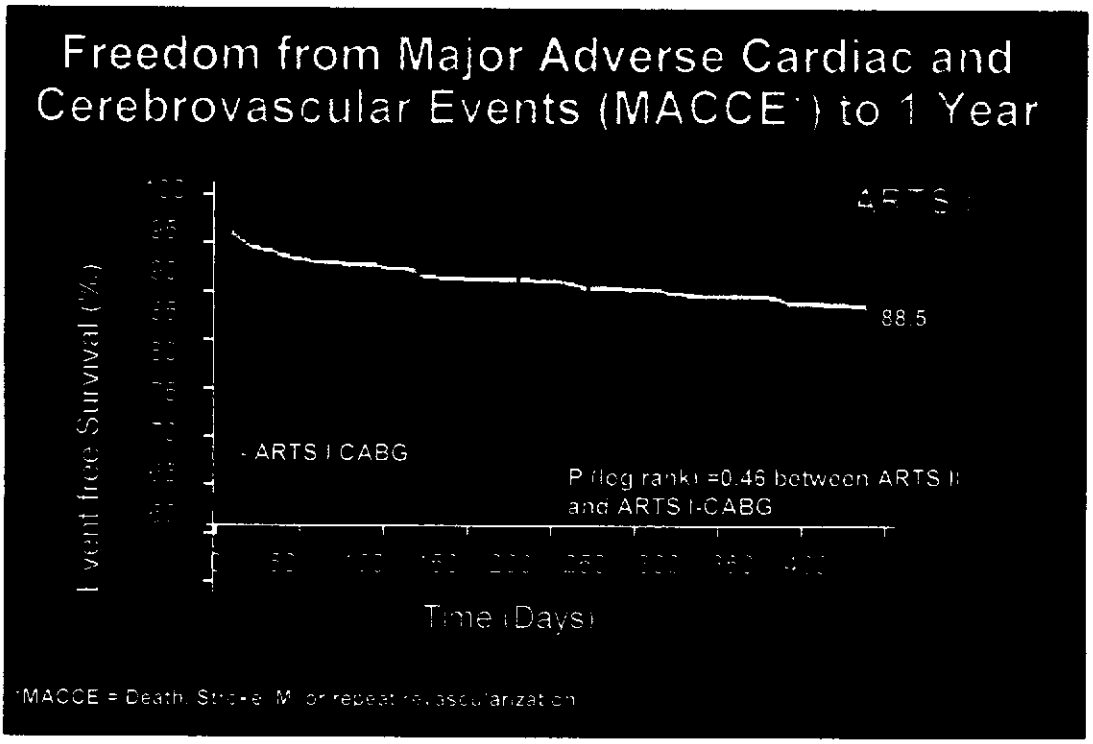
Although we are encouraged by the improvement in the differential, we remain concerned that the DRG relative weights significantly underestimate the true costs of performing DES procedures, especially for cases involving multiple vessel disease and the insertion of multiple DES. This shortfall may provide a financial disincentive to hospitals to perform multi-vessel coronary revascularization procedures using this minimally invasive approach compared with the alternative CABG surgery. It may also encourage the use of a less effective technology (BMS) or a hybrid combination (DES and BMS) of stents for Medicare beneficiaries in need of multiple DES. We are aware that CMS is concerned whenever reimbursement levels discourage the use of the most clinically appropriate treatment, which is another reason for reconsidering differentiating multi-vessel or multiple stent procedures from less complex procedures in the future.

The approximate average selling prices for DES and BMS devices are $2400 and $800 respectively. *At an incremental cost of $1600 per DES device over non-DES stents (which is highly cost-effective or cost-saving from a payer perspective), the weighted average incremental DRG payment of $1,511 does not even pay for one DES per procedure.* When the incremental DES costs using a mean stent use per patient of 1.5 are considered, the incremental reimbursement appears even more deficient. At 1.5 DES per procedure, the incremental per procedure costs are $2,400. We remain concerned that the DES DRG rates, as proposed, could result in a significant financial loss for hospitals that perform DES procedures and possibly continue to discourage access to this new breakthrough technology or adversely influence clinical practice.

C. New Multi-Vessel and Multi-Stent Procedure Codes

Cordis sponsored the ARTS II registry, which is a multi-center, 600 patients, European study of multi-vessel stenting with the primary end-point of MACCE (death, stroke, MI and revascularization). The one-year results of this study were recently presented at the American College of Cardiology Scientific Sessions, March 2005. As shown in the slides below, at one-year freedom from major adverse cardiac and cerebrovascular events (MACCE) was virtually identical for patients treated with CYPHER Sirolimus-eluting stents when compared to coronary bypass surgery patients treated in ARTS I (89.5% vs.88.5%, p=0.46) despite the fact that the patients treated with the CYPHER stent were at considerably higher risk of complications than those treated with CABG. These impressive data are causing physicians to consider the many benefits associated with stenting before recommending the best treatment option for their patients. These benefits include a less invasive procedure, which causes less pain, anxiety and morbidity, a shorter length of hospital stay and an earlier return to work or daily living activities.





We applaud CMS' initiative in the proposed rule 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). Cordis appreciates the effort exhibited by CMS staff to work collaboratively with the industry on the creation of such codes. It is crucial that CMS track the hospital resources involved in such cases and provide commensurate DRG reimbursement.

We remain concerned that hospitals initially may not code accurately for coronary stent procedures in FY 2006 given that CMS will be creating four new coronary stent DRGs and adding eight new procedure codes for MVS and multi-stent procedures. While we support these additions, it adds a new level of complexity to the overall DRG and coding structure for coronary stent procedures that could be confusing in the initial implementation. As such, we encourage CMS to work closely with the Coding Clinic at the American Hospital Association on hospital education efforts for these new codes. Cordis also plans extensive hospital education projects on the new codes and coronary stent DRGs for the upcoming FY 2006 update. Overall, we believe that the eight new procedure codes will provide valuable data to CMS as it considers new DRG reimbursement categories for multi-vessel treatment and multi-stent insertion. It is important that hospitals are educated to adequately provide CMS with these data.

<u>The Importance of the New Codes Given Resource Differences for MVS Cases</u>
The importance of the eight new procedure codes is highlighted by the significantly higher hospital charges for MVS DES cases in DRGs 526 and 527 versus non-MVS DES

cases in the FY 2004 MedPAR database. These data suggest that approximately 20 percent of DES cases entail treatment of multiple vessels, as signified by ICD-9-CM procedure code 36.05 (Multiple Vessel Percutaneous Transluminal Coronary Angioplasty) and that these cases have significantly higher charges than the cases without multi-vessel disease. As exhibited in Table 2 below, the hospital charge difference for the MVS cases in both DRGs 526 and 527 is close to $11,000 higher than the non-MVS cases. Given these charge differences, it is crucial that CMS closely evaluate the new codes to consider the new DRGs for these cases.

Table 2 – Charge Differences for Multi-Vessel Stenting (MVS) Cases versus Non-MVS

	DRG 526		**DRG 527**	
	# of Cases	**Average Charges**	**# of Cases**	**Average Charges**
All Cases	56,013	$45,545	193,549	$35,792
Cases with 36.05	10,730 (19%)	$54,392	38,633 (20%)	$44,329
Cases w/out 36.05	45,283 (81%)	$43,438	154,916 (80%)	$33,662
Charge Difference for MVS Cases		**+$10,944**		**+$10,677**

II. EXTRACRANIAL CAROTID STENTING DRG ASSIGNMENT

Cordis once again thanks CMS for deciding last year to create new ICD-9 CM procedure codes for intracranial and extracranial stenting and angioplasty (codes 00.61 through 00.65). Each of these codes describes an important percutaneous alternative to a current surgical approach and/or unmet clinical need. These codes will allow for tracking of outcomes and costs associated with these procedures and will help provide Medicare beneficiaries access to new technologies.

Extracranial carotid stenting with emboli protection (procedure code 00.63) offers a promising alternative to surgical endarterecomy of the carotid artery for high-risk surgical patients. Results from the SAPPHIRE trial indicate that the procedure is not inferior to, and in some respects is significantly superior to, surgical endarterectomy in patients at high surgical risk. Specifically, when strokes occur with stenting and emboli protection as opposed to open carotid endarterectomy, they tend to be minor rather than major and approximately 2/3 resolve.

Furthermore, there is a significantly *lower* rate of repeat revascularization with stenting than open endarterectomy as well as a significantly *lower* rate of cranial nerve palsies at 2 years in our randomized controlled SAPPHIRE trial. These data have recently been reviewed with CMS. For many of these patients, existing co-morbidities and/or anatomical features make carotid stenting the only treatment option. Therefore, it is important to assign these cases to a DRG(s) that adequately covers all or a significant portion of the costs of performing these procedures. In the absence of adequate payment, many high-risk surgical patients without alternative treatment options may not have access to the procedure because hospitals may be unwilling to absorb another new procedure with its concomitant costs.

CMS is proposing to use proxy codes to evaluate the costs and DRG assignments for carotid artery stenting because codes 00.61 and 00.63 were only approved for use at the beginning of FY 2005 and MedPAR data are not yet available on these codes. The agency is proposing code 39.50 (Angioplasty or atherectomy or other noncoronary vessels) in combination with procedure code 39.90 (Insertion of nondrug-eluting peripheral vessel stents) in DRGs 533 and 534 as the proxy codes for coronary artery stenting.

After carefully considering potential alternatives, Cordis recommends that CMS create two new DRGs for carotid stenting cases based on the presence or absence of complications or co-morbidities. As exhibited in Table 3 below, the carotid stenting discharges, as signified by the presence of codes 39.50 and 39.90, in DRGs 533 and 534 have respective charge differentials of $9,058 and $7,195 above cases without codes 39.50 and 39.90.

Table 3 – Charge Differences for Carotid Stenting versus Non-Carotid Stenting Cases, FY 2004 MedPAR Database

DRG	Coding Status	Discharges	Average Standardized Charge
533	All Discharges	35,730	$21,286
533	Discharges without codes 39.50 and 39.90	33,992	$20,845
533	Discharges with codes 39.50 and 39.90	1,738	$29,903
534	All Discharges	37,457	$15,166
534	Discharges without codes 39.50 and 39.90	35,911	$14,870
534	Discharges with codes 39.50 and 39.90	1,546	$22,065

These differentials are likely understated as the 2004 MedPAR data were collected 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 unlikely that hospitals included the cost of the carotid stenting devices in their FY 2004 charges. The already significant differential between carotid and non-carotid stenting cases will likely grow more pronounced in the FY 2005 MedPAR database as hospitals begin to include the charges for the FDA-approved carotid stent cases in their claims to CMS. Without a change in the DRG structure for carotid cases, hospitals will perform these cases at a significant financial lose. Therefore, we believe that two new DRGs to differentiate the more costly carotid stent cases is the most logical approach to ensure that Medicare beneficiaries have access to this important treatment alternative in FY 2006.

CONCLUSION

We appreciate the opportunity to comment on the proposed rule. Once again, we appreciate the diligence of the Coverage, Coding and Payment staff, who have been very helpful and proactive in their consideration of the CYPHER Stent and other important new technologies. If you have any questions on these comments, please contact me.

Brian G. Firth MD, Ph.D, MBA
Vice President Medical Affairs and Health Economics Worldwide
Cordis Corporation, a Johnson & Johnson Company.

cc. Marc Hartstein
Kathy Buto

269

DRG/Gen

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

June 24, 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

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

Dear Dr. McClellan:

Guidant Corporation, Medtronic and St. Jude Medical appreciate the opportunity to submit joint comments on Section II.4.a., Automatic Implantable Cardioverter/Defibrillators, of the Centers for Medicare and Medicaid Services (CMS) Proposed Rule on the Medicare Hospital Inpatient Prospective Payment System for FY 2006 (CMS-1500-P). We appreciate, as well, the meeting between CMS and Industry held on May 25, 2005, to discuss our concerns regarding Section II.4.a. and have enclosed the presentation made to CMS to supplement our comments. In addition to this joint comment letter, each organization will comment separately to payment and policy issues contained in the Proposed Rule.

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

Along these lines, our comments focus on four areas:

1. Concern and recommendation
2. Procedural diversity in current coding resulting in poor and insufficient data
3. Restructuring current coding
4. Resource coherence

1. Concern and recommendation

For FY 2006, we ask that CMS not 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 CMS clarifies the definition and usage of 37.26 and accumulates adequate data to determine whether a modification of the defibrillator DRGs is justified.

As CMS has noted in previous DRG revisions, a full-scale electrophysiologic study (EPS) qualifies as a cardiac catheterization. However, the data show that cardiac defibrillator cases with code 37.26 alone have lower average charges than those with other cardiac catheterization codes. This almost certainly reflects coding problems in the use of 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. It is not appropriate to modify the DRGs based on charge data that includes such disparate procedures. The solution to a coding problem is to fix the coding, not to alter DRG assignment.

2. Procedural diversity in current coding resulting in poor and insufficient data

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, Vol. 68 (August 1, 2003): 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. 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, are also essential in determining the need for a defibrillator as well as the appropriate device type. 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 basic problem 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 at least part of FY 2004, the timeframe for the MedPAR file used in the analysis, code 37.26 may reflect four different procedures:

- Device interrogation without arrhythmia induction
- Noninvasive programmed stimulation (NIPS)
- Full-scale diagnostic EPS
- Intraoperative induction and device testing

While these procedures share some features, they 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 (EP) laboratory but is non-invasive. EPS must also be performed in an EP laboratory but is invasive and requires special disposable catheters. 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 only showed lower average charges than other procedures with cardiac catheterization.

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 laboratory 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 less resource intensive procedures are no longer part of 37.26. Moving bedside interrogation out of 37.26 was a good first step. CMS should continue 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.

Reinforcing with 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 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.

Coders were instructed to no longer use 37.26 for bedside interrogations (Coding Clinic, Third Quarter 2003, p.23) effective November 1, 2003. Although this was early in FY 2004, new guidelines take time to disseminate among coding staff and to be reflected in encoding systems. Moreover, it was not until the FY 2005 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 is likely that the FY 2004 MedPAR data for 37.26 is further skewed by the presence of bedside interrogations, a low resource procedure that is no longer coded to 37.26.

Enclosed is a table summarizing the procedures, current coding structure and proposed structure.

During the May 25 meeting, CMS acknowledged the inconsistencies among coders in the use of 37.26 and the need for more specific codes to permit distinction between the procedures currently coded under 37.26. When one code embodies several disparate procedures with varying purposes, sites of service, and intensity, the resultant data are not representative of any one of the procedures. Until the specific resources associated with each unique procedure can be identified, we believe it is premature to undertake a critical DRG change that will have a significant financial impact on hospitals and potentially impede patient access to therapy. We recommend that CMS not proceed with the proposed modification at this time.

3. Restructuring current coding

At the invitation of CMS staffers, a coding proposal creating a new ICD-9-CM procedure code for NIPS, removing it from 37.26 was previously submitted. To address other areas of coding confusion with the use of 37.26 for testing performed with defibrillator implantation, the coding proposal also featured new and revised inclusion and exclusion notes to identify what intraoperative testing should be considered integral to device implantation and how this testing is distinct from EPS.

The coding proposal was initially sent on February 11, 2005, for consideration by the ICD-9-CM Coordination and Maintenance Committee. At the May 25 meeting with CMS, we discussed the need to include this proposal on the agenda for the September 29, 2005, Committee meeting. We will follow-up separately to ensure this item is included on the meeting agenda.

Code 37.26 currently captures a variety of procedures that differ clinically and in resource intensity. Creating one or more new codes to clearly identify these procedures will provide accurate charge data for future DRG refinements. However, using current data that encompasses four disparate procedures to modify the defibrillator DRG logic is not appropriate.

4. Resource coherence

The proposed modification of the defibrillator DRGs would result in a dramatic shift of cases from DRGs 535 and 536 to DRG 515. The average charge data clearly do not support the reassignment of DRG 535 cases with code 37.26 and without a cardiac catheterization to DRG 515. Based on the CMS analysis of MedPAR data, approximately 43% of DRG 535 cases (average charges, $98,900) would shift to DRG 515 (average charges, $83,660) – a 15% ($15,240) disparity in average charges – indicating a significant difference in resource intensity. The proposed rule states "while the cases in DRG 535 with code 37.26 and without a cardiac catheterization have higher average charges than the average charges in DRG 515, these cases have lower average charges than the average charges for overall cases in DRG 535". This statement appears to minimize the significant difference in charges between the DRG 535 cases with EPS only and the average charges for all cases in DRG 515. It also ignores the greater similarity of the average charges between DRG 535 EPS only cases ($98,900) and those for all cases in DRG 536 ($94,454). DRGs are intended to reflect

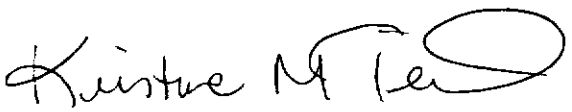
cases with similar patterns of resource intensity. Assigning DRG 535 cases with EPS only to DRG 515 is inconsistent with DRG logic and does not result in grouping of cases of similar resource intensity. CMS should not reclassify the DRG 535 cases with EPS only to DRG 515.

Conclusion

CMS should withdraw the proposed DRG modification and address this coding problem with a coding solution before implementing critical changes to the current defibrillator DRG structure.

We thank CMS for the opportunity to comment on this important issue and look forward to working collaboratively on the coding changes for 37.26 and on future refinement and restructuring of the current defibrillator DRGs to maintain clinical and resource coherence.

Sincerely,



Kristine Teich
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cc: Marc Hartstein

Enclosures (2)

Procedure	Electrophysiologic Study (EPS)	Non-Invasive Programmed stimulation (NIPS)	Intraoperative Induction	Bedside Check
Description	Invasive, diagnostic, with induction or attempted induction of arrhythmia to determine appropriate device or medical therapy (i.e. ICD, ablation, pharmaceuticals)	Non-invasive induction of an arrhythmia after implant to test device and reassess its settings	Induction of an arrhythmia during implant to test device and determine therapeutic settings	Non-invasive, no induction of arrhythmia, confirms device settings and downloads data for analysis
When performed	Before device implant	Follow-up after device implant	At time of device implant	Prior to discharge
Where performed	In EP or Cath Lab	In EP or Cath Lab	In OR (with device implant)	Bedside
Code contributing to FY 2004 data	37.26	37.26	FY 2004 change to 37.94. The descriptor change added "EPS" to the inclusion note on 37.94 which, along with published guidelines, was supposed to alert people *not* to code intraoperative testing separately. The confusion is more that intraoperative testing does not constitute true EPS and the descriptor change blurred that distinction.	Instructions were issued in November 2003 with some procedures being coded as 37.26 for the initial month FY 2004 change to 89.59 an interim code. FY 2005 change to 89.49
Proposed Changes	Remain 37.26 Proposal for September 2005 ICD-9-CM Coordination and Maintenance Meeting	Change to 37.20 Proposal for September 2005 ICD-9-CM Coordination and Maintenance Meeting	Clarify immediately via published statements Revise descriptor Proposal for September 2005 ICD-9-CM Coordination and Maintenance Meeting	Remain 89.49

IPPS Proposed Rule FY 2006

II 4a. Automatic Implantable Cardioverter / Defibrillator

Discussion with Centers for Medicare and Medicaid Services

Presented by: Guidant, Medtronic and St. Jude Medical

May 25, 2005

Agenda

- FY 2006 IPPS Proposal by CMS
  - Data and Rationale
- Current Coding
  - Diversity of Procedures
- Industry Concern with Proposal
- CMS Efforts to Address Coding
- Industry Coding Proposal
- Recommendation
- Summary

FY 2006 IPPS Proposal by CMS

- Proposal has been made to
  - Remove 37.26 (Cardiac electrophysiologic stimulation and recording studies or (EPS)) from the list of cardiac catheterizations for DRGs 535 and 536
- If a defibrillator is implanted and EPS only is performed the case would be assigned to DRG 515

CMS Decision Based On

- Coding confusion and potential mis-assignment of intraoperative testing to 37.26
  - Supported by coding inquiries
    - CMS attempted to address at October 2004 ICD-9-CM Coordination and Maintenance Committee Meeting
- FY 2004 MedPAR data analysis
  - Average standardized charges and average length of stay associated with 37.26 only claims were much lower as compared to
    - Cardiac cath alone
    - Cardiac cath with EPS

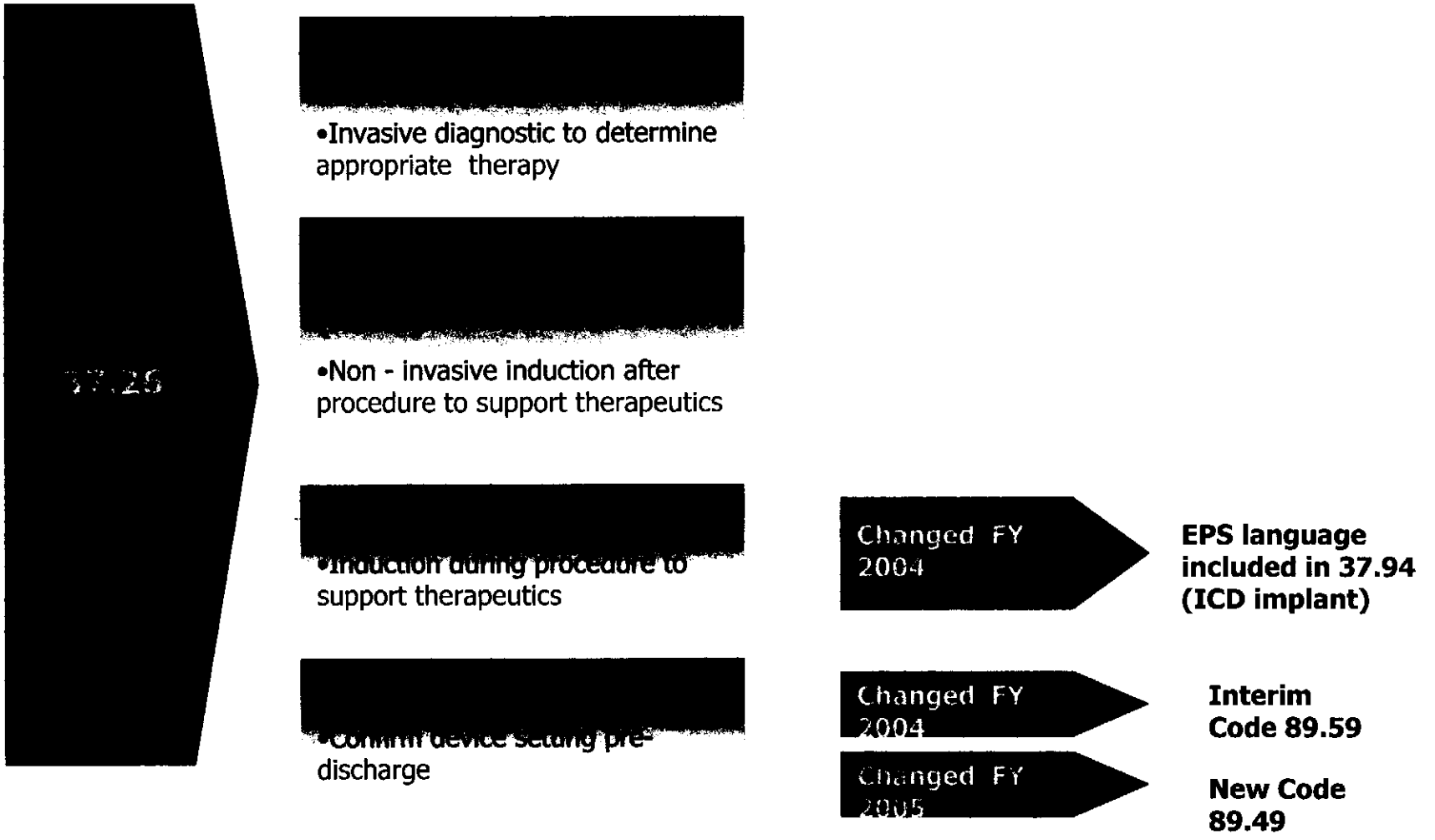
FY 2004 Data from Proposed Rule

DRG	Cases	ALOS	Average Standardized Charges
DRG 535 Cardiac Cath w/out 37.26	5,060	10.63	$ 127,130.79
DRG 535 With 37.26 only	5,264	5.61	$ 98,900.13
DRG 535 Cardiac Cath and 37.26	1,794	9.44	$ 115,701.09
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
DRG 515	25,236	4.32	$ 83, 659.76

Conclusion by CMS

- ALOS and standard charges for 535 and 536, EP study only, are closer to 515
- "...consider that there may be some coding problems in the use of code 37.26, we believe it is appropriate to propose a modification to these DRGs"
- CMS concern appears to be driven by possible use of 37.26 for intraoperative testing
  - Additional concern by industry is 37.26 is one code for varying procedures, each with a different intent and resource consumption

Diversity of Procedures



Diversity of Procedures

- Diversity of coding and description causes confusion
  - Code description for 37.94 is unclear with addition of EPS language
    - Changed for FY 2004
    - Confusion would have contributed to FY 2004 data collection
  - AICD bedside check
    - Changed for FY 2004 and FY 2005
    - Confusion would have contributed to FY 2004 data collection also
  - 37.26 remains a single code describing two very different procedures
    - EPS - invasive diagnostic procedure
    - NIPS – non-invasive procedure to support optimal device therapy

Diversity of Procedures

- Diversity of coding and description results in poor and insufficient data
  - FY 2004 data reflects possible coding of bedside check, intraoperative testing, EPS and NIPS
    - 37.94 and bedside check interim coding changes coincide with FY 2004
    - Period of data collection and analysis for FY 2006 DRG changes
  - While intraoperative testing, NIPS and EPS functionally capture induction of an arrhythmia that is where the similarity ends
    - Purpose of procedure, resources, and methodology are inherently very different
    - Would expect their charges to be different as well

Industry Concern with Proposal

- Appears there is agreement on
  - Possible miscoding of intraoperative testing using 37.26
- In addition
  - Possible inclusion of some AICD bedside check
  - NIPS coding and confusion
    - Documented in Coding Clinic as well as industry inquiries
- Coding questions have been numerous around 37.26 and associated procedures
- Industry believes the solution to a coding problem is to fix the coding, not to alter current DRG assignment

Industry Concern with Proposal (Con't)

- Coding problems should be addressed first
  - Disparate procedures are currently assigned to a broad code, 37.26
    - EPS and NIPS should have each have a unique code to clarify procedure and adequate data collection
  - No general understanding that 37.94 is inclusive of intraoperative testing and 37.26 should not be coded separately
    - Clarification is required to ensure procedure is coded appropriately
  - Procedural differences are difficult to comprehend
  - Coding descriptions and instructions have not been made clear
- DRG decisions should not be made on disparate procedure coding
  - Once coding is addressed, allow for sufficient data collection on which to make better payment and DRG decisions

CMS Effort to Address Coding

- AICD beside check code changed effective FY 2004 and again in FY 2005
- October 2004 attempt to modify 37.94 and use of 37.26 with AICD insertion
  - Intent to revise current coding description (37.94) is appropriate
  - Additional recommendation to add "code also" language to CRT-P, CRT-D and ICD was not clear
    - Would not have eliminated confusion when to code 37.26
      - Unfortunately derailed entire proposal
- Recommendation would not have addressed confusion and disparate coding

Industry Coding Proposal

- In follow-up to Oct. 2004 meeting Medtronic contacted CMS to propose a clearer coding structure
  - New codes, along with information and clarification, would eliminate coder confusion
  - Specific codes, unique to the varying procedures, results in
    - specific procedural data
    - data to support better decision making on defibrillator DRGs
- Proposal was not included on March 2005 ICD-9-CM Coordination and Maintenance Meeting Agenda

Industry Coding Proposal

- Issue clarification of 37.94 via Coding Clinic
  - Eliminates 37.26 from being coded for intraoperative testing
    - Industry will assist in development
    - Industry will support in our own coding materials
  - Clarification can be made immediately and would not be constrained by official implementation dates of October and April

Industry Coding Proposal (Con't)

At September 2005 ICD-9-CM Coordination and Maintenance Meeting

- Present recommendation made previously to:
  - Maintain 37.26 for the invasive EPS procedure
  - Add code 37.20 for NIPS
  - Change 37.94 to eliminate EPS language
- Clarify, via Coding Clinic, various procedures, how to recognize and code
  - Industry, Associations can work with Coding Clinic to present clarification on the procedures and appropriate coding
    - Might there be other venues available ?

Recommendation

- Do not change procedures currently assigned to DRGs 535 and 536
  - Do not remove 37.26 (EPS) from the list of cardiac catheterizations
  - Proposed change is based on poor coding and insufficient data
- Implement industry proposed coding changes to more accurately reflect the procedure performed
- Allow for appropriate data collection timeframe
- Gather and review resultant data which more accurately reflect charges and length of stay of the specific procedure

Recommendation

- Supports ...
  - Addressing CMS concern and goals to evaluate possible resource changes resulting from expanding NDC
    - Comparison of FY 2003 to FY 2004 data demonstrates trend toward DRG 515 (92% increase)
  - Changing practice patterns of EP study, intraoperative and NIPS due to primary prevention patients
    - Unique coding would enable better understanding and decision making
  - Accommodating shift in patient populations
  - Minimizing number of DRG changes over time

Summary

- Do not remove 37.26 (EPS) from the list of cardiac catheterizations for DRGs 535 and 536
- Implement recommended coding changes
- Allow for appropriate timeframe of data collection
  - Specific codes for procedures
  - Patient population changes
- Review data to support rationale for logical decision making
- Collaborate with Industry and HRS to re-evaluate DRG structure
  - Better data will support better decision making by all parties

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Medtronic
SOFAMOR DANEK

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Kelly
Hu

June 24, 2005

Mr. Marc Hartstein
Division of Acute Care
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 HIPPS and FY 2006 Rates; Proposed Rule
New Technology Applications
DRG Reclassifications (DRG 546)

Dear Mr. Hartstein:

Medtronic Sofamor Danek appreciates the opportunity to comment on the FY 2006 proposed rule for the Hospital Inpatient Prospective Payment System, published in the Federal Register on May 4, 2005. Our comments pertain to the new technology add-on payment application for INFUSE® Bone Graft when used in tibia fracture repairs, the expiration of the new-tech add-on payment for INFUSE for spine fusion, the creation of DRG 546, and the new-tech add-on application for the Charite artificial lumbar disc.

New Technology Add-on Application for INFUSE® Bone Graft/Open Tibia Fractures

Medtronic Sofamor Danek is disappointed that CMS proposed to deny the new technology re-application for the open tibial fracture indication of INFUSE Bone Graft, which was approved by the FDA in April 2004. CMS denied the initial application in FY 2005 on the basis that a "substantially similar" product had been on the market since 2001 and INFUSE therefore could no longer be considered new because the 2-3 year period of eligibility for the two "substantially similar" therapies had elapsed.

Our reapplication to CMS for FY 2006 and subsequent presentations to CMS in direct meeting and at the New Technology Substantial Improvement Town Hall in February 2005 made a number of arguments to respond to CMS' finding of "substantial similarity" and to support approval of the INFUSE/tibia re-application in FY 2006. Most significantly, we noted that:

- In the FY 2005 final rule, CMS appeared to conclude that INFUSE was a substantial improvement over previously available treatments.

- The CMS regulations included no formal definition of "substantial similarity." We therefore proposed a three-part test to CMS to clarify the meaning of "substantially similar." This test consisted of the following elements (all of which must be met):

- The follow-on technology or service must use the same or a similar mechanism of action to achieve the therapeutic outcome.
- The technology or service must be indicated for use in the same population, for the same medical conditions.
- The technology must achieve the same level of substantial improvement.

- On the basis of our proposed test, INFUSE and OP-1 Implant could not be considered "substantially similar" because the products were not indicated for use in the same population (and in fact were indicated for distinctly different and non-overlapping patient populations) and because there was no published or demonstrated evidence to suggest that OP-1 Implant achieved the same or a comparable level of clinical benefit as INFUSE.

- Because INFUSE for open tibial fractures was new, met the payment inadequacy criterion, represented a substantial improvement over previously available therapies, and could not be considered "substantially similar" to OP-1 or any other product, Medtronic believed it met all the requirements for add-on payment status and recommended approval.

In the proposed rule, CMS did not agree with Medtronic's proposed test to define "substantial similarity." CMS noted that our first criterion (i.e., same mechanism of action) "has some relevance in determining whether two products are substantially similar," (Federal Register, May 4, 2005, page 23359) but CMS rejected the remaining two criteria proposed by Medtronic. CMS instead stated: "[W]e believe that whether cases involving different products are assigned to the same DRGs is a more relevant consideration than whether the products have the same specific indications." Based on this interpretation of "substantial similarity," CMS again proposed to deny add-on payment for the INFUSE tibial indication.

We appreciate that the policy of "substantial similarity" raises a number of complex issues, but at the same time we respectfully disagree with CMS' position on these issues and with the agency's proposed denial of INFUSE. We have two significant concerns.

First, by denying the INFUSE application on the basis of "substantial similarity," CMS has essentially redefined the eligibility requirements for add-on payment. We note that the preamble to the September 7 2001 final rule discusses substantial similarity only in terms of attaching subsequent products to approved add-on payments. It does not describe a process through which applications may be denied add-on payment solely on the basis of substantial similarity. Moreover, there is no language in the actual text of the regulation defining the term or describing how it will be used.

Medtronic is concerned that by denying the INFUSE application on the basis of substantial similarity, CMS has not given the technology full consideration against the three established criteria for add-on payments – i.e., newness (as determined by date of market availability), payment inadequacy, and substantial improvement. When evaluated relative to these criteria, we believe INFUSE for open tibia fractures clearly qualifies for add-on payment (including substantial improvement over OP-1 Implant and available treatments for acute open tibial fractures).

We believe clarification is necessary from CMS to ensure that all applications for new-technology add-on payments are assessed against – and only against – the established eligibility criteria as described in regulation. If CMS wishes to expand the eligibility requirements to include (and fully define) "substantial similarity," we believe it is most appropriate to do so formally through the public notice and comment process. Until such time, we believe denial based on a finding that the technology is "substantially similar" to another product and therefore no longer new is inappropriate.

Second, we do not concur with CMS' position that assignment to the same DRGs is a more relevant consideration than whether the products are indicated for separate patient populations. We believe the specific indications for a product are in fact an important consideration in determining whether DRG weights

appropriately reflect the costs of a new technology. Services or technologies that have narrow indications and represent only a fraction of the cases in a DRG are not likely to have a significant impact on the overall weighting of the DRG. An expansion of indications – leading to wider utilization of the product – will have a larger impact on the weighting and overall payment for the DRG. In such instances, the DRG weights that reflect only the previous narrower indications will not appropriately reflect the costs of the technology with wider utilization. In addition, new indications in different patient populations may have significantly different costs than existing indications. We therefore believe new indications of existing technologies should receive full consideration for add-on payment even if previous indications were assigned to the same DRG. Granting add-on payment will provide appropriate reimbursement while additional data accrue in MedPAR to recalibrate the DRG based on the weighting of the expanded indication.

The key consideration for CMS when a new indication occurs in the same DRG once again should be whether the technology meets the three established criteria for add-on eligibility – i.e., newness (based on date of market availability), payment inadequacy, and substantial improvement. Again, we emphasize that these are the established criteria. While it is true that many technologies that have permeated the DRG through previous indications likely would not qualify for add-on payment because it would be difficult to meet the cost criterion, Medtronic believes that there will be cases where new indications of existing technologies will meet the three criteria and should receive an add-on payment. Under the three existing criteria, we believe INFUSE meets the qualifications for add-on payment status. We do not believe the utilization of rhBMPs in DRGs 218 and 219 that is reflected in the FY 2004 MedPAR file fully account for the costs of INFUSE with the new tibial indication.

To summarize, Medtronic continues to support the underlying premise that CMS' payment policy should not bestow an advantage to the first product that comes to market and receives an add-on payment. Our proposed three-part test for substantial similarity is most appropriate in situations involving products approved by the FDA subsequent to the initiation of an add-on payment for an earlier-to-market therapy. This ensures a level playing field for "substantially similar" technologies. Beyond those situations, we believe the most appropriate way to determine eligibility for add-on payments is through the three existing criteria established in regulation. Based on these criteria, we believe INFUSE is eligible for and merits add-on payment status.

The new technology add-on payment is critical to patient access and early adoption of new technologies. In October 2003, INFUSE® Bone Graft received a new technology payment for spinal fusion. The following month represented the single highest volume growth for the product, suggesting a very strong correlation to the new technology funding. Given the proposed denial by CMS for additional payment specific to acute tibia fractures, we remain concerned that Medicare patients may not have appropriate access to this technology. We respectfully urge CMS to approve the add-on payment in the final rule.

Expiration of New-Technology Add-On Payment for INFUSE Bone Graft/Spine Fusion

The proposed rule for FY 2006 notes that the new-technology add-on payment for the INFUSE spine fusion indication will expire at the end of FY 2005. As the payment expires, Medtronic Sofamor Danek would like to take this opportunity to thank CMS for approving the add-on and granting a total of two years of payment. INFUSE is truly a breakthrough technology for the treatment of degenerative disc disease and related back disorders. The add-on payment has contributed significantly to patient access and broader physician adoption of this important new treatment. We appreciate CMS efforts on the add-on payment.

DRG 546: Curvature of the Spine or Malignancy

Medtronic Sofamor Danek supports the creation of DRG 546 for spinal fusions except cervical with a principal diagnosis of curvature of the spine or bone malignancy. The addition of this DRG, with its higher weight, will help reimburse hospitals more adequately for the resources utilized in treating patients with significant spinal

deformities and other problems. Medtronic would like, however, to mention a few codes not included on the proposed list of diagnoses that deserve consideration for inclusion:

213.2 Benign neoplasm of bone and articular cartilage; vertebral column, excluding sacrum and coccyx
238.0 Neoplasm of uncertain behavior of other and unspecified sites and tissues; Bone and articular cartilage
239.2 Neoplasms of unspecified nature; Bone, soft tissue, and skin
721.7 Spondylosis and allied disorders; Traumatic spondylopathy
724.3 Other and unspecified disorders of back; Sciatica
732.8 Other specified forms of osteochondropathy
756.19 Anomalies of spine; Other

In addition, three codes included on the list of principal diagnoses can only be coded as secondary diagnoses based on the current coding guidelines. Thus, codes 737.41 - 737.43 cannot be used to group cases to the proposed DRG 546 as they will never be coded as the principal diagnosis. The GROUPER will need to be modified to accept these secondary diagnoses codes.

The proposed rule indicates that CMS may consider other changes to the spine fusion DRGs in the future. Medtronic looks forward to working with CMS on these issues, and to incorporating the views of all the major spinal specialty societies on proposed modifications to the DRGs.

New Technology Add-On Application for Charite Artificial Disc

Medtronic Sofamor Danek takes no position on CMS' decision whether to grant add-on payment status for Charite. However, if CMS approves Charite for add-on status, Medtronic Sofamor Danek believes granting an add-on payment – rather than reassigning the technology to DRGs 497 and 498 – is the most appropriate way to recognize the costs of Charite until the DRGs can be appropriately recalibrated to reflect the costs of this technology. The purpose of the new tech add-on program is to provide a cost-based bridge to compensate hospitals for additional costs related to new technology. Until further data become publicly available, we believe it would be premature to reassign spinal disc prostheses to DRGs 497 and 498. This is fully consistent with CMS' position not to consider changes to DRGs 497 and 498 to account for multi-level spine fusion until sufficient data became available in MedPAR under the new multi-level spine fusion procedure codes. In addition, the spine fusion DRGs are well-established based on several years of utilization and accrual of cost experience. Without a fuller understanding of the expected resource use of cases with spinal disc prostheses, we are concerned that reassignment of spinal discs to DRGs 497 and 498 may have the potential to cause an inappropriate reduction in future weights for spinal fusion. We would look forward to working with CMS on future analyses when adequate MedPAR data become available on the new codes for artificial discs.

Conclusion

Medtronic thanks CMS for the opportunity to comment on the hospital inpatient proposed rule for FY 2006 and we appreciate your consideration of the issues raised in this letter. If you have questions, please feel free to contact me at (901) 399-2110.

Sincerely,

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Senior Manager, Reimbursement Planning
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June 24, 2005

Mr. Marc Hartstein
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Department of Health & Human Services
Attn: 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 Rates
New Technology Applications

Dear Mr. Hartstein:

Medtronic is the world's leading medical technology company, providing lifelong solutions for individuals with chronic disease and enhancing the lives of Medicare beneficiaries. Medtronic Neurological appreciates the opportunity to comment on the proposed hospital inpatient PPS rule for FY 2006, published in the *Federal Register* on May 4, 2005. The following comments are specifically related to Medtronic's new technology application for the Restore Rechargeable Implantable Neurostimulator. The comments below are reflective of our long history working directly with CMS on numerous decisions involving medical technology. It is our sincere hope the comments will clarify issues raised in the proposed rule and assist CMS in making its final decision on Restore.

Overview of Proposed Rule Findings on Restore

CMS deferred issuing a preliminary decision on Restore in the proposed rule because FDA approval of the device had not yet been received. CMS noted reservations about whether the technology could be considered new and requested public comments on the newness, cost, and substantial improvement aspects of the Restore application.

Distinction Between Rechargeable and RF Neurostimulators

CMS raised a number of questions in the proposed rule regarding the newness of rechargeable neurostimulation therapy. In particular, CMS' concerns related to the differences between radio frequency (RF) neurostimulators and fully implantable rechargeable neurostimulators. CMS stated:

> "Although we recognize the benefits of a more easily rechargeable neurostimulator system, we believe that the Restore® device may not be sufficiently different from predecessor devices to meet the newness criterion for the new technology add-on payment. ...Similar products have been on the market since 1999. ...[T]hese technologies are already represented in the DRG weights and are not considered new for the purposes of the new-technology add-on payment provision. ...We welcome comments on this issue, specifically regarding how the Restore® device may or may not be significantly different from previous devices."

CMS also commented in the proposed rule on a previous new technology add-on payment application for Renew™ spinal cord stimulation (SCS).

> "In the FY 2003 final rule, we discussed and subsequently denied an application ... for Renew SCS because 'Renew SCS was introduced in July 1999'...[T]his system only requires one surgical placement and does not require additional surgeries to replace batteries as do other internal SCS systems' ...Renew SCS is identified by the same ICD-9-CM procedure code [as Restore® (03.93)] ...Both systems rely on rechargeable batteries and in the case of the Renew SCS the energy is transmitted through the skin from a radiofrequency source for the purpose of recharging. ... [Medtronic] contends that [Restore®] is superior to the Renew device because Renew requires an external component that uses a skin adhesive that is uncomfortable and inconvenient...leading to patient non-compliance..."

We believe rechargeable technology is new and distinctly different from radio frequency and non-rechargeable spinal cord stimulation. The key difference between RF and rechargeable, fully implantable pulse generators is the power source. The power source for RF systems is external to the body, rather than internal or implanted in the body. RF systems involve two main components: a transmitter and antenna that are worn externally and a receiver that is surgically implanted. The external transmitter sends RF signals through the antenna on the skin to the subcutaneously implanted receiver. The RF implanted receiver itself is not a power source; rather it receives RF signals from the external transmitter. The transmitter is powered by a 9 volt battery which requires frequent replacement by the patient.

Because the RF power source is external to the body, it must be worn continuously to receive stimulation. When the transmitter and antenna are removed from the area over the implanted receiver, stimulation ceases immediately and pain returns. This can be challenging because patients are unable to use the system while showering, bathing, or swimming. This can be a significant problem for patients whose pain is so debilitating that activities of daily living are exceedingly difficult or impossible without stimulation. Not only can it be difficult to sleep with external components, but therapy may be affected as components may shift during sleep causing the antenna and transmitter to misalign with the receiver, interrupting stimulation and pain relief. Many patients experience skin irritation and contact sensitivity at the site of the receiver placement, which can compromise therapy when pain prevents matching the antenna to the receiver.[1]

[1] Alo KM, Pain Practice, 2003

Fully implantable rechargeable neurostimulation devices such as Restore® offer an advanced power source through an internal rechargeable battery located in the implanted pulse generator. Whereas RF systems utilize an external power source, rechargeable pulse generators utilize an internal power source – a rechargeable lithium battery. Patients are able to recharge the internal power source by placing an external patient recharger over the unit for a short period.

In a study by Stultz,[2] patients with implantable pulse generators (IPG) reported greater improvements in quality of living, ability to walk, lift, carry, stand, climb stairs and bending. The study found significant correlation between functional and VAS changes, relative to changes in quality of life. In addition, the Stulz found that obese patients reported difficulty securing the antenna over the receiver.

In a second study by DeVulder, et al., patients who had higher energy requirements and received an implantable pulse generator (IPG) rather than an RF system continued to use energy at a higher rate than those with RF systems.[3] Additionally, IPG patients reported lower or weaker medication use, while 53% of RF patients required concurrent use of stronger medications (opioids).

The table below provides a summary of the distinct differences between RF systems and rechargeable implantable pulse generators.

Radio Frequency	Rechargeable
• External Power Source	• Internal Power Source
• NOT rechargeable	• Rechargeable
• Therapy ceases immediately when power source (transmitter) removed from site	• Short (3-6 hours) recharge period once every 3-6 weeks
• Patients unable to shower or swim with transmitter and antenna	• Therapy provided 24/7 with very few limitations
• Very low patient compliance	• High patient compliance

Based on this information, we believe rechargeable, fully implantable neurostimulators are in fact new and different from RF and non-rechargeable neurostimulators.

Newness Criterion for Add-On Payment

The CMS definition of newness is as follows (42 CFR 412.87(b)(2)):

> "A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration)."

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[2] Stultz, Mark: Quality of Life, Function, and Pain Relief Attributed to Two Types of Spinal Cord Stimulations Systems: Results of a Patient Survey. Pain Digest 1999; 9:348-352

[3] Devulder J, DeLaat M, VanBastelaere M et al:Spinal Cord Stimulation:A valuable treatment for chronic failed back surgery patients. J Pain Symptom Manage 1997; 13: 296-301

Restore® received FDA approval as a PMA-S on April 8, 2005 and became available for commercial distribution in April 2005. A copy of the approval letter is included in the Appendix.

Two additional companies manufacture dual array rechargeable neurostimulators. Advanced Bionics Corporation, a subsidiary of Boston Scientific, was granted FDA approval on April 27, 2004 for Precision™ Spinal Cord Stimulation System. Advanced Neuromodulation Systems (ANS) received FDA approval on December 10, 2004 for Genesis® RC Dual (IPG) Neurostimulation System, and FDA approval on March 15, 2005 for Eon ™ Neurostimulation System. We believe CMS would consider these products to be "substantially similar" to Restore and would therefore include them in the add-on payment if approved.

The earliest availability of implantable rechargeable neurostimulators was the Precision™ Spinal Cord Stimulation System, manufactured by Advanced Bionics Corporation, which received FDA approval on April 2004.

The ICD-9-CM Coordination and Maintenance Committee recognized implantable dual-array rechargeable neurostimulators as a new and distinct technology by issuing a unique new procedure code (86.98) that will become effective in FY 2006.

Based on the recent FDA approval dates and the issuance of a new ICD-9-CM procedure code for FY 2006, implantable rechargeable neurostimulators are not reflected in the current DRGs and fall within CMS' defined 2-3 year window to be considered new.

Substantial Improvement of Restore Rechargeable Implantable Neurostimulator: Advanced Power Source and Higher Functionality

Neurostimulation is designed to deliver electrical stimulation to the spinal cord to block the sensation of pain. This technology is based upon the gate theory for pain control, developed by researchers Ronald Melzack and Patrick Wall. The current technology standard for neurostimulators utilizes internal sealed batteries as the power source to generate the electrical current. These internal batteries have finite lives, and require replacement when their power has been completely discharged. The replacement procedure involves a surgery, where the depleted neurostimulator is replaced with a new one. The average life expectancy of neurostimulators for the treatment of chronic pain is approximately three years, but can vary widely depending on the amount of energy required to achieve adequate pain relief. Energy usage varies by patient, and patients requiring high energy are limited in their options for neurostimulation.

The Restore® rechargeable implantable neurostimulator represents the next generation of neurostimulator technology. The rechargeable battery allows the physician to set the voltage parameters in such a way that fully meets the patient's requirements to achieve adequate pain relief without fear of premature depletion of the neurostimulator. The expected life of Restore® is nine years, compared to an average life of three years for conventional neurostimulators. This represents a significant improvement in the therapy as patients who

require can use the necessary power settings to achieve pain relief, and undergo fewer neurostimulator replacement procedures.

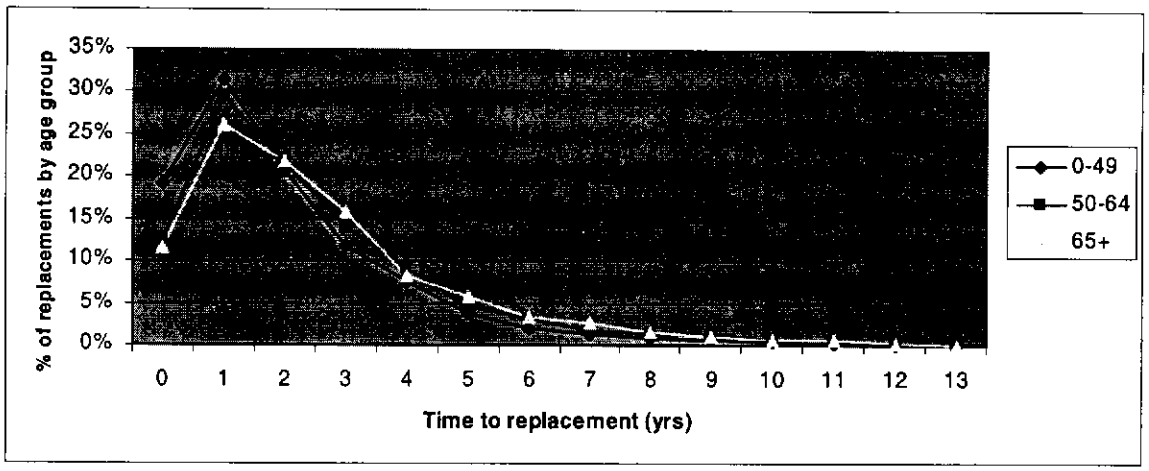
One of the most significant benefits of rechargeability is the ability to provide continuous, effective neurostimulation to patients who require high amounts of energy to manage their pain and who would otherwise need to undergo frequent and multiple replacements of a non-rechargeable device to meet their therapy needs. Medtronic estimates that 30 percent of all neurostimulator patients have complex pain patterns that require high energy to achieve adequate pain relief. These patients are candidates for a rechargeable device. Sixteen percent of this population is 65 or older. Medtronic's estimate is based on two extensive data sources: (1) Medtronic's device registration system, and (2) a randomized controlled study currently underway.

Medtronic's device registration system includes data on over 70,000 implants (including 14,000 replacements). This system allows us to identify the likely prevalence of patients who suffer from severe or complex pain who would benefit from advancements in rechargeable neurostimulation. An analysis performed on patients requiring a replacement indicates that roughly 33% of all replacements occur within two years of initial implant. These patients are clear candidates for a rechargeable device. For all ages, the mean number of months to replacement was 31.5 months. For ages 65+, the mean number of months to replacement was 30.3 months. The table on the next page illustrates the average time to replacement and the extent to which current non-rechargeable neurostimulators may not serve patients as well as rechargeable technology.

Medtronic is conducting a post-market study comparing the effectiveness of spinal cord stimulation to current medical management in a Failed Back Surgery Syndrome (FBSS) population. This study is an international, randomized, multi-center, single blind study which has just completed the enrollment of 100 subjects (1:1 randomization). Twenty seven subjects (n=27) have reached the 3-month endpoint. All patients in the SCS arm receive a non-rechargeable device. This study is an excellent opportunity to assess the power needs of FBSS patients. Roughly 30% of the 27 subjects will need their non-rechargeable devices replaced in less than 30 months. These patients would be appropriate candidates for a rechargeable device due to the energy use and resulting replacement intervals of a non rechargeable system.

Typically, the primary reasons for device replacements are higher energy requirements, pain patterns that have become increasingly more complex, end of battery life, and infection (5% or less).

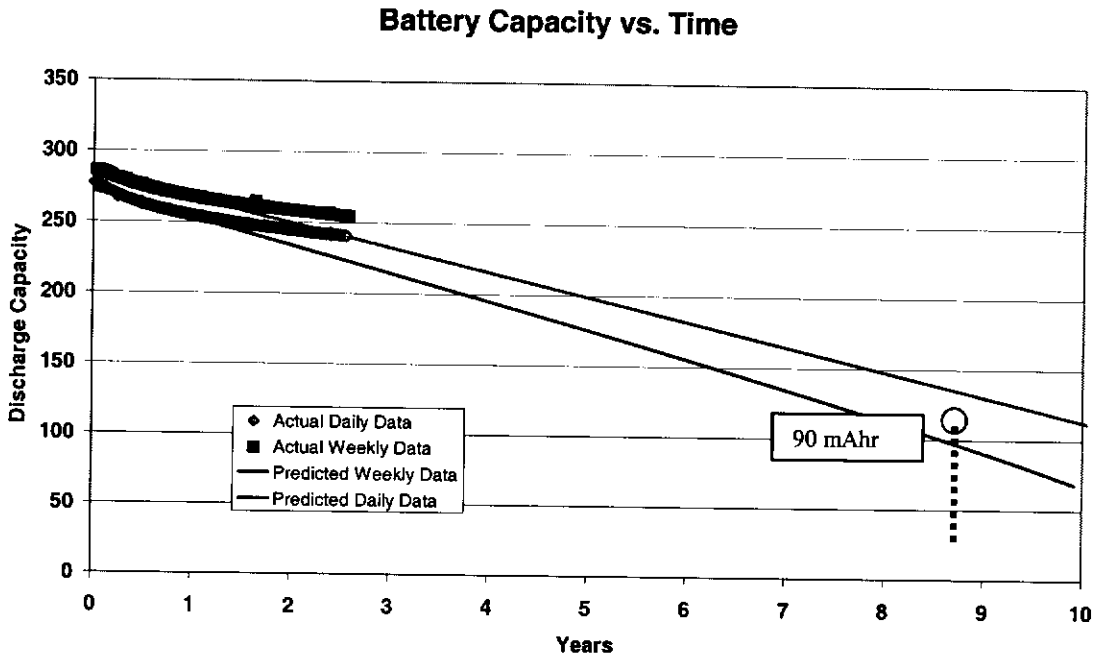
Medtronic Replacement Data
Years to Neurostimulator Replacement by Age at Replacement (2000-Current)



Battery Life Data

The Restore® 9-year battery life is demonstrated by a combination of 32 months (2^+ years) of actual test data and conservative battery modeling. These two pieces of information are displayed in the figure below and show that the battery will retain at least 90 mAhrs capacity through 9 years of service.

The battery model was built using accelerated data and is validated by an ongoing real-time testing program, as is typically done with batteries for long-term medical device applications. Conservative assumptions are used to predict long-term battery performance. It is well known from the literature and from our own characterization studies that capacity losses tend to decrease with increasing time and cycle number. Thus, our linear models, which tend to overestimate losses at long times and high cycle numbers, are a very conservative means of extrapolation.



The Medtronic device registration system and analysis of the ongoing randomized controlled study support our estimate that approximately 30% of all neurostimulator patients require higher energy, and are candidates for a rechargeable device. Until the availability of rechargeable devices, physicians were forced to choose between frequent surgery to replace non-rechargeable neurostimulators or compromise symptom relief to extend life of the battery. Researchers attempted to develop ways of extending battery life. In one study, North et al.[44] attempted to program the device to extend the life of non-rechargeable devices (analogous to a physician prescribing 100mg q.d.of a drug, but then telling the patient to take only 60mg a day for fear of running out of the drug). Rechargeable devices allow patients with higher energy requirements to receive the appropriate dose of stimulation without regard to battery conservation and avoidance of frequent surgeries for replacement.

Reduction in Replacement Procedures

Rechargeability eliminates the need to replace devices in high energy users. The chief benefit of reduced replacement procedures is the decline in the number of complications that would otherwise be associated with replacement surgery. The complications listed in clinical literature of spinal cord stimulation are very consistent. Not all complications listed are associated with the implant procedure itself. The complications of implanting a neurostimulator are expected to be the same at initial implant as they are for replacement.

[4] North, R, Brigham D, Khalessi A, Calkins S, Piantadosi S, Campbell D, Daly M, Day P, Barolat G, Taylor R: Spinal Cord Stimulator Adjustment to Maximize Implanted Battery Longevity: A Randomized, Controlled Trial Using a Computerized, Patient-Interactive Programmer. International Neuromodulation Society 2004; 7:13-25

The complications commonly cited in clinical literature related to an implantable neurostimulator include:[5] [6]

- Infection
- Seroma
- Pain over implant
- Allergic reaction
- Hardware malfunction
- Battery failure
- Skin erosion

The most common complication related to the implant of a neurostimulator is infection. The rates of infection range from 0-12% in clinical literature, with an average infection rate of 5%. The site of infection most generally cited is the pocket where the neurostimulator is implanted into the body. One particular study published in 2004 suggests that the surgical infection risk for neurostimulators is the same as other implanted devices including drug infusion pumps, cardiac devices and cerebrospinal fluid shunts. The study further provides the estimated infection rates for ICDs from 1 to 7%, and states, "Infections were more common after battery end-of-life device replacement than after the initial implantation."[3]

We do not have any internal data that systematically tracks complication rates for the Medicare population as compared to the general population of spinal cord stimulation patients. Further, in our review of the clinical literature, we did not find any such stratification in the patient population cited. We would anticipate that the complications listed in clinical literature are generalizable to the Medicare population.

More Responsive Therapy for Patients with Complex Pain (High-Energy Users)

The Restore® rechargeable system offers a number of unique characteristics which provide additional functionality and more responsive theryapy beyond that of previous non-rechargeable neurostimulation systems, including; rechargeability, full implantability, increased number of electrodes, increased programming capabilities, physician prescribed dosage parameters and patient selectable electrode configurations to allow better treatment of pain, advance diagnostics, and data storage.

Rechargeable pulse generators accommodate more electrode contacts for broader stimulation coverage and greater programming flexibility to address lead migration. Higher functionality of the system is available through the utilization of two eight-electrode leads rather than two four-electrode leads utilized by current non-rechargeable implantable neurostimulator

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[5] Turner JA, Loeser JD, Deyo, RA, Sanders SB. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. *Pain*, 2004; 108: 137-147

[6] Cameron, T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *Journal of Neurosurgery: Spine*, 2004; Volume 100: 254-267

technology. Stimulation provided through sixteen electrodes provides broader coverage and minimizes the potential for lead migration, one of the most common complications associated with neurostimulation.

The use of rechargeable pulse generators enables high energy patients to be treated with an implanted generator rather than an external power source. Previous options for patients requiring high energy settings to achieve relief of their pain symptoms include; frequent surgical replacements of a non rechargeable, implantable pulse generator, utilization of an RF system that is not fully implantable, nor rechargeable, or conserving battery life by turning the therapy "off" or reducing the energy consumed, resulting in the inability to receive the full benefit from the therapy in order to conserve battery life (i.e. extending battery life at the cost of enduring more pain).

The availability of additional electrodes allows the physician the option of activating more of the electrodes by reprogramming the neurostimulator rather than replacing the leads through surgical intervention. Previously, surgical intervention was required to correct lead migration. Patients benefit from a substantial reduction in surgical replacement procedures and avoid common complications associated with surgical procedures.

Finally, rechargeability provides a more responsive therapy for patients with complex pain (high energy utilization). Patients with complex pain and high energy needs exhibit multifocal, progressive, complex pain symptoms of mixed origin, and their pain patterns tend to change with postural changes.

Patient Selection

The Medicare National Coverage Determination (NCD) for Electrical Nerve Stimulation (160.7) requires that the implantation of a neurostimulator be used "only as a late resort (if not a last resort) for patients with chronic intractable pain". It further requires that other treatment modalities "have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient". In addition, the NCD has been interpreted to require that, in order to determine if neurostimulation will be effective, every potential patient undergo a three to seven day trial period. During and after the trial period, the physician is able to match the appropriate therapy to the patient by evaluation of the power settings required to obtain adequate pain relief during the trial screening period. Medtronic has developed a definitive tool to assist physicians in choosing the appropriate neurostimulator based on the patients energy requirements and pain patterns as identified during the trial period. Many other important factors also need to be taken into consideration. For example, based on the location(s) of the pain, the physician can determine the amount of coverage required on the spinal cord to provide the most efficacious therapy. The more electrodes that are required, the higher the energy requirements of the patient. Thus if the patient is experiencing complex pain, (i.e. pain in more than one location), they will have much higher energy needs than a patient experiencing simple pain (i.e. pain in one location).

Some patients also experience pain migration, where the pain spreads from one location to another (i.e. pain originating from the toe and migrating up the leg, or pain moving from one

leg to the other). This can require utilization of a different set of electrodes and therefore increase the power requirements on the neurostimulator. In addition, many patients require increased power settings over time compared to those at initial implant, either due to the progression of the underlying cause of the pain or to neuronal plasticity (i.e. increased tolerance to spinal stimulation).

The following table identifies typical device selection considerations by type of pain. All systems other than Restore® are varieties of non-rechargeable implantable neurostimulators. Additionally, only Medtronic products are included in this table.

Typical Device Selection by Type of Pain

Pain Classification	Unilateral	Bilateral	Complex
Associated Indications	Single Limb Pain, CRPS	FBS, CRPS-2, Radiculopathies, Arachnoiditis, Peripheral neuropathy	CRPS-1, FBS, Radiculopathies, Arachnoiditis
Characteristics	Monoradicular, stable	Stable, bifocal	Multifocal, progressive, complex symptoms, more dermatomes involved, pain pattern changes with postural changes, mixed origin
Systems to Consider	Itrel 3, Synergy Compact+ (Versitrel)	Synergy Compact+ (Versitrel), Synergy Plus+ (Synergy), Restore	Restore

Ongoing Medtronic research and development is targeted at both rechargeable and non-rechargeable neurostimulation and we anticipate non-rechargeable neurostimulators will remain a robust segment of the market. Our most recent non-rechargeable device, SynergyPlus+ was recently approved by the FDA on June 15th. Please find information regarding SynergyPlus+, as well as our overall non-rechargeable and rechargeable product portfolio, in the attached Appendix.

Add-on Payment Amount and Coding

CMS proposed a maximum add-on payment amount of $10,568 if approved. This amount is based on projected pricing information provided to CMS by Medtronic prior to receipt of FDA approval and market release of Restore®. On April 15, 2005, Medtronic submitted revised pricing to CMS based on post-launch actual pricing. The system pricing was reduced from $21,135 to $18,640. Based on the change, we calculate a new maximum add-on payment amount of $9,320 if the application is approved.

A new ICD-9 code – 86.98, Insertion or replacement of dual array rechargeable neurostimulator pulse generator – will become effective October 1, 2005 to identify rechargeable dual-array neurostimulators. If approved, the presence of this code would trigger payment of the add-on.

Conclusion

Medtronic appreciates the opportunity to comment on the proposed rule provisions regarding the Restore Rechargeable Implantable Neurostimulator. We believe Restore meets all the criteria to qualify for an add-on payment. In sum:

- Rechargeable devices are distinctly different from RF and non-rechargeable spinal cord stimulation systems. The key factor in this determination is the power source, which delivers a much more effective therapy for patients with high energy requirements.

- The technology is new, falling within the 2-3 year window of initial market availability and eligibility for add-on. The costs of the technology are not reflected in the DRGs, and a unique procedure code has been assigned to rechargeable neurostimulators for tracking and payment purposes effective FY 2006.

- The technology is inadequately paid, exceeding the case-weighted threshold of the DRGs to which the technology is assigned (included in Appendix).

- The technology represents a substantial clinical improvement, conferring a better power source and higher functionality to provide more responsive therapy for patients with complex pain and high.

We appreciate your consideration of these comments and the additional information provided in this letter. Add-on payment status will significantly improve Medicare patient access to this important advancement in spinal cord stimulation technology and we kindly urge CMS to approve the application. Please contact me if you have any further questions.

Sincerely,

Marilyn Halseth

Marilyn Halseth
Reimbursement Manager
Medtronic Neurological

Appendix

1. Copy of FDA Approval
2. Synergy Plus information
3. Cost Threshold
4. Product Portfolio

Restore® New-Tech DRG Charge Analysis

- **Medtronic Analysis**
  - Modeled anticipated charges for Restore
    - Analysis of FY2003 MedPAR data on non-rechargeable neurostimulators
    - Hospital acquisition cost (IMS Hospital Supply Index)

- **Thresholds to Demonstrate Payment Inadequacy**
  - DRG 499: $24,828
  - DRG 500: $17,299
  - DRG 531: $38,748
  - DRG 532: $24,650
  - Per Table 10 in the FY 2005 final rule

Analysis of FY2003 MedPAR Data

- FY2003 MedPAR provides charge information for spinal cord stimulator implant procedures involving non-rechargeable neurostimulators
  - Cases identified by the presence of ICD-9-CM procedure code
    - 03.93 – Insertion or replacement of spinal neurostimulators
  - Cases located in four DRGs
    - DRG 499: Back and neck procedures except spinal fusion with CC
    - DRG 500: Back and neck procedures except spinal fusion without CC
    - DRG 531: Spinal procedures with CC
    - DRG 532: Spinal procedures without CC

Spinal Cord Stimulation System Implants in FY 2003 (Non-Rechargeable)

Procedure	DRG	# of Cases	2003 MedPAR Charges		Case Weighted Threshold			
			Unadj. Mean Charges	Mean Standardized Charges (per CMS calc.)	Published Threshold (from CMS Table 10)	Case Weighting Percentage	Case Weighted Threshold	Operating CCR
	499	**327**	**$41,555**	**$34,506**	**$24,828**	**21.2%**	**$5,275**	**.37**
Spinal Cord Stimulation System Implant	**500**	**572**	**$34,580**	**$29,265**	**$17,299**	**37.2%**	**$6,430**	**.39**
	531	**233**	**$39,037**	**$32,336**	**$38,748**	**15.1%**	**$5,866**	**.37**
	532	**407**	**$34,401**	**$27,956**	**$24,650**	**26.5%**	**$6,519**	**.37**
Total – Case Adjusted		1,539	$36,689	$30,497			$24,090	.38

Anticipated Average Mean Standardized Charges

Description		FY 2003	
Mean Non-Rechargeable Neurostimulator Average Sales Price[1]	1	$10,203	
Cost of Restore Neurostimulator and External Patient Recharger	2	$21,135	
Difference in Cost of Technology	3	$10,932	2 - 1
Case Adjusted Operating CCR	4	.38	
Conversion of Cost to Charges – Anticipated Increase in Charges	5	$28,768	3 / 4
Mean Standardized Charges	6	$30,497	
Anticipated Average Mean Standardized Charges for Restore	7	$59,265	5 + 6
Case Weighted Threshold	8	$24,090	
Difference	9	$35,175	7 – 8

[1]Source – 2003 IMS Hospital Supply Index Product Data – IMS collects purchase order data from 350 hospitals and projects that data to all 4,800 hospitals to create their database. Non-rechargeable neurostimulator average sales price was used to derive the relevant device cost component in the existing DRG data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2005

Lucy Tan, RAC
Principal Regulatory Affairs Specialist
Medtronic, Inc.
710 Medtronic Parkway NE
Minneapolis, Minnesota 55432-5604

Re: P840001/S74
Restore™ Rechargeable Neurostimulation System
Filed: October 12, 2004
Amended: October 20, 2004, March 25, 2005 and April 1, 2005

Dear Ms. Tan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for the Restore™ Rechargeable Neurostimulation System which consists of the following components:

- Restore™ Implantable Neurostimulator, Model 37711;
- External Patient Recharger System, Model 37752 (Recharger (INS), Model 37751 and Antenna, Model 37791, Recharge Belt, and Desk-Top Charger, Model 37742);
- External Patient Programmer, Model 37742;
- External Patient Programmer Antenna, Model 37092;
- Restore Software Application, Model 8870;
- External Neurostimulator (ENS), Model 37021;
- Snap-Lid Connector (Screening) Cable, Model 3550-31;
- 1 x 8 Lead Kit (Standard Electrode Spacing), Model 3777;
- 1 x 8 Lead Kit with Percutaneous Extension, Model 3877;
- 1 x 8 Lead Kit (Compact Electrode Spacing), Model 3778;
- 1 x 8 Lead Kit with Percutaneous Extension, Model 3878;
- 1 x 8 Extension, Model 37081; and,
- Lead Accessory Plug and Closed Boot Kit for INS, Model 3550-29.

The Restore™ Rechargeable Neurostimulation System is indicated as an aid in the management of chronic, intractable, unilateral or bilateral pain associated with the following:

- Failed Back Syndrome or Low Back Syndrome or Failed Back;
- Radicular Pain Syndrome or Radiculopathies resulting in pain secondary to Failed Back Syndrome;

- Post Laminectomy Pain;
- Unsuccessful Disk Surgery;
- Degenerative Disk Disease (DDD)/ Herniated Disk pain refractory to conservative and surgical interventions;
- Peripheral Causalgia;
- Epidural Fibrosis;
- Arachnoiditis or Lumbar Adhesive Arachnoiditis;
- Complex Regional Pain Syndrome (CRPS) or Reflex Sympathetic Dystrophy (RSD) or Causalgia; and,
- Multiple Back Surgeries.

Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible and before commercial distribution of your device you must submit an amendment to this PMA with copies of all approved labeling in final form. The labeling will not routinely be reviewed by FDA staff when PMA supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.

Rockville, Maryland 20850

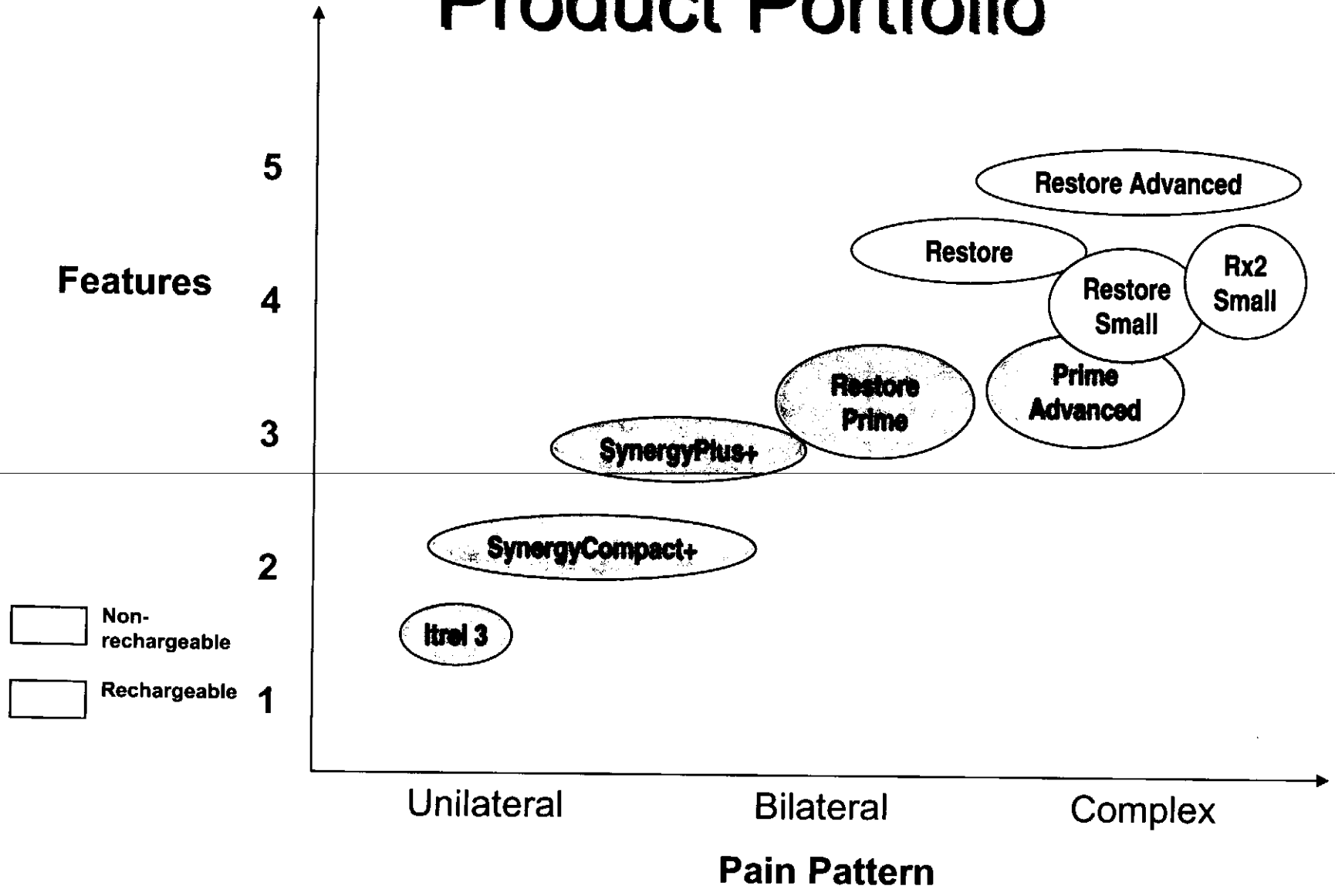
If you have any questions, please contact Kristen A. Bowsher, Ph.D. at (301) 594-1296.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2005-2008 Medtronic SCS Product Portfolio



Medtronic
When Life Depends on Medical Technology

News Release

Medtronic Media Contacts:

Robert Carson, Investor Relations, 763-505-2705
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Medtronic Boosts Portfolio Of Implantable Pain Therapies With Latest FDA Approval

Release of Synergy Plus+™ enhances therapy options for people with chronic pain

MINNEAPOLIS - June 15, 2005 - Medtronic, Inc. (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) approval and U.S. availability of its SynergyPlus+™ neurostimulation system for chronic pain.

SynergyPlus+ is the newest "pain pacemaker" to join Medtronic's family of implantable chronic pain therapies. It was designed to give patients more control over the delivery of stimulation that blocks pain signals from reaching the brain while performing a variety of daily activities. This advancement allows the world leader in pain management technology to better meet the growing needs of chronic pain patients and their physicians.

Approximately 25 percent of the U.S. population, more than 70 million people, experience some form of chronic pain. Many of these people remain unaware of the range of available treatment options. It is estimated that chronic pain accounts for an estimated $100 billion per year in medical costs, including 515 million lost workdays and 40 million physician visits.

SynergyPlus+ has the greatest number of program options (up to 26) available of any non-rechargeable neurostimulation system on the market today. Using a small, hand-held "remote control" programming device, patients can choose among multiple settings that are preset by a physician to address pain levels associated with different daily tasks, such as standing, walking or laying down.

"Because chronic pain affects each person differently, it's important to have a range of therapies designed specifically to treat the individual needs of any patient," said Dr. Alon Mogilner, Director of Functional and Restorative Neurosurgery, North Shore University Hospital, New York. "SynergyPlus+ is the right choice for many of my patients who require low to moderate levels of stimulation to control their pain."

The device's array of program options provides a level of therapy customization that may result in fewer physician follow-up visits, which can otherwise be required to ensure that the most effective amount of stimulation is delivered over time. In addition, SynergyPlus+ is the only system with diagnostic capabilities that allow physicians to assess the way patients use the system to fine tune delivery of pain-blocking stimulation.

About Chronic Pain

Defined as pain that persists or recurs for more than six months, chronic pain can be caused by a variety of injuries and diseases, and most commonly affects the lower back and legs. Left untreated or under-treated, chronic pain can destroy a person's quality of life. Beyond the physical disability that often results, it can lead to difficulty holding a job, low self-esteem, strained relationships, depression, and suicide.

About the SynergyPlus+™ Neurostimulation System

SynergyPlus+ is the next generation of Medtronic's Synergy™ system, the neurostimulation device that helped legendary performer and comedian Jerry Lewis overcome nearly 40 years of chronic pain due to decades of performing physical comedy routines.

The SynergyPlus+ system is indicated as an aid in the management of chronic, intractable unilateral or bilateral pain of the trunk and/or limbs that is associated with: failed back syndrome, low back syndrome or failed back, radicular pain syndrome, post laminectomy pain, multiple back operations, unsuccessful disc surgery or degenerative disc disease, peripheral causalgia, epidural fibrosis, arachnoiditis or lumbar adhesive arachnoiditis, and Complex Regional Pain Syndrome (CRPS).

For more information on chronic pain and Synergy Plus+, visit www.tamethepain.com or call 800-510-6735.

About Medtronic Neurological Pain Therapies

The SynergyPlus+ system is the latest advancement to join the Medtronic portfolio of neurostimulation and pump pain therapies. Medtronic offer a variety of pain therapies that are currently available to clinicians specializing in the management and treatment of chronic pain, including Restore™, the longest-lasting and most powerful rechargeable neurostimulation system available.

Medtronic also offers a line of intrathecal pain-control pumps, called SynchroMed EL® and SynchroMed® II, which release medication at programmable rates to an area around the spinal cord.

Medtronic's neurostimulation therapy has already achieved worldwide medical acceptance for the management of chronic, intractable, unilateral or bilateral pain associated with many pain-related conditions.

About Medtronic

Medtronic, Inc., (www.medtronic.com) headquartered in Minneapolis, is the world's leading medical technology company, providing lifelong solutions for people with chronic disease.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's Annual Report on Form 10-K for the year ended April 30, 2004. Actual results may differ materially from anticipated results.

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June 24, 2005

DRG/GEN
NT
ICD-9-CM

Hefter
Hartstein
Walz
Treitel
Brooks
Kelly
Hue
Fagan
Gruber

Mr. Marc Hartstein
Division of Acute Care
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 HIPPS and FY 2006 Rates; Proposed Rule
DRG Reclassifications
New Technology Applications
Changes to ICD-9-CM Coding System

Dear Mr. Hartstein:

Medtronic appreciates the opportunity to provide comments on the proposed hospital inpatient PPS rule for FY 2006, published in the *Federal Register* on May 4, 2005. Medtronic is the world's leading medical technology company, providing lifelong solutions for individuals with chronic disease and enhancing the lives of Medicare beneficiaries. The comments below are reflective of our long history working directly with CMS on numerous decisions involving medical technology.

Automatic Implantable Cardioverter Defibrillators

The proposed rule would restructure the current non-operating room procedures that are assigned to cardiac defibrillator DRGs. Under the proposal, procedure code 37.26 (Cardiac electrophysiologic stimulation and recording studies (EPS)) would be eliminated from the list of cardiac catheterizations currently assigned to DRGs 535 and 536. These cases would be assigned to DRG 515. The rule proposes no change to DRG 515 (Cardiac Defibrillator Implant Without Cardiac Catheterization).

We recommend that CMS reconsider this proposal and retain 37.26 on the list of cardiac catheterization procedures which map to DRGs 535 and 536. The basic problem 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.

Following Medtronic's attendance at the October 2004 ICD-9-CM Coordination and Maintenance Committee, we contacted CMS to offer assistance in sorting through the coding difficulty with EPS. During our discussion in early January, CMS staff welcomed our offer to help resolve the problem and develop a proposal. To arrive at a coding proposal that would be logical to coders and procedurally coherent, Medtronic enlisted a coding expert and an electrophysiologist to develop a recommendation for the March 2005 meeting. Despite meeting the deadline for submission, CMS notified Medtronic that the recommendation would not be considered on the agenda. Instead, the topic has been included in the proposed rule as a payment issue rather than the coding issue that underlies it.

In a consensus industry response to the proposed rule (dated June 23, 2005), as well as an industry meeting with CMS on May 25, 2005, we raised the coding concerns that affect the FY 2004 MedPAR data. In brief, these concerns are as follows:

- 37.26 is a single code describing two very different procedures (EPS and NIPS). While intraoperative testing, NIPS, and EPS functionally capture induction of an arrhythmia, that is where the similarity ends. The purpose of the procedure, resources, and methodology are inherently very different and would therefore contribute a different level of average charges to the FY 2004 data.

- CMS expressed concern that 37.26 may have been inappropriately coded for some intraoperative testing procedures. This most certainly would drive average charges down if intraoperative procedures were coded as 37.26.

- A separate bedside check code was established beginning in FY 2004, but due to a November 2003 notification in Coding Clinic, a month or more of claims data could also be contributing to the FY 2004 data.

Based on the disparate procedures contributing to the data, it is premature to make a decision to change the defibrillator DRGs. Rather, distinct coding should be established for NIPS and EPS as well as reclarification that intraoperative procedures should not be coded using 37.26. Sufficient time should be allowed for appropriate data collection reflecting the unique procedures. The data that result should more accurately reflect charges and length of stay of the specific procedures. Reviewing the data after an appropriate collection timeframe would be a more appropriate approach to determine whether or what structure of DRG modification is necessary.

In addition to FY 2004 data being populated by disparate procedures with disparate resource consumption, the proposal does not align with the average charge data presented by CMS. If CMS's goal is to align average charges to provide appropriate payment to hospitals, the FY 2004 data does not support the CMS proposed changes either. In focusing only on the procedural change of eliminating EPS-only procedures from the current non-operating cardiac catheterization procedures, the average charges have not been taken into consideration. The following chart, which shows average charges for all cases and for EPS-only service procedures, indicates that moving procedures from DRG 535 to DRG 515 is not reflective of similar resource

consumption and average charges. Instead, the FY 2004 data average charges for EPS-only procedures under DRG 535 align more appropriately with DRG 536. Despite this analysis of charges, CMS's proposal would move almost 50% of the cases to DRG 515.

DRG	Average Charge	Average Charge EPS Only
535	$ 113,175.43	$ 98,900.13
536	$ 94,453.62	$ 85,390.88
515	$ 83,659.76	

In summary, we recommend that CMS reconsider this proposal and retain 37.26 on the list of cardiac catheterization procedures which map to DRGs 535 and 536 until correct codes are established to differentiate the procedures and average charges. We believe the charge analysis does not support reassigning implants with EPS-only to be reassigned from DRG 535 to 515.

Medtronic will follow-up with CMS to make our previous coding recommendation available for consideration on the September 29, 2005 meeting of the ICD-9-CM Coordination and Maintenance Committee.

New Tech Add-on Payment for Endovascular Grafts for Thoracic Aortic Aneurysms

Medtronic is actively involved in bringing an endovascular prothesis for the repair of thoracic aortic aneurismal disease to market. In fact, Medtronic recently announced the completion of enrollment in its Valor Trial. We believe this technology provides a new and safer option for patients suffering from a life-threatening illness. While the all-cause mortality associated with open surgical repair of thoracic aortic aneurysms has been reported at greater than 30%, early data from U.S. clinical trials and experience in Europe indicate that the all-cause mortality associated with endovascular repair is lower than 22%, a substantial clinical improvement over current surgical practice.

For this reason, as stated in previous correspondence with CMS (March 15, 2005), Medtronic supports the Gore, Inc. application for New Technology Add-On Payment for these devices and believes that when its Talent Thoracic Endovascular Stent Graft is approved by the FDA, it should equally qualify for this Add-On payment under the terms of CMS's September, 2001 Final Rule concerning "substantially similar" technology.

We are concerned, however, that the proposed rule placed a time limitation on when a device would need to gain FDA post-market approval in order to qualify for consideration of being "substantially similar." We believe that such a limitation would be in direct conflict with CMS's original intent not to "bestow an advantage to the first applicant representing a particular new technology." Rather, any new technology which meets the criteria set forth by CMS for "substantially similar" should qualify for the New Tech Add-On so long as that technology gains FDA post-market approval any time during the period for which the New Tech Add-on is in effect. We respectfully request that in the Final Rule, this apparent error be corrected.

Drug Eluting Stents

Medtronic Vascular would like to commend CMS for continuing to maintain a separate reimbursement structure for discharges involving the insertion of drug-eluting coronary artery stents (DES). This structure will allow the continued collection of data with which to support a more accurate reimbursement rate to hospitals for the more costly DES cases.

We would also like to commend CMS for proposing 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. As exhibited in the FY 2004 MedPAR file, there is a clear differential in the average hospital charges for AMI patients with and without CC and the four new DRGs for FY 2006 will allow more appropriate payment to hospitals on a case by case basis. Similarly, we agree 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."

Medtronic is especially pleased that CMS acted 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. Medtronic looks forward to working with the agency as the data from these new multi-vessel/multi-stent codes becomes available.

Carotid Artery Stenting

As the agency notes in the Proposed Rule, CMS established codes for carotid artery stenting procedures (CAS) on October 1, 2004. Medtronic 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.

However, we also believe that the carotid artery stent cases in DRGs 533 and 534 have average charges that are significantly higher than the average charges for all cases within these DRGs. Based on our analysis of the MedPAR data, the difference 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 underpayment for carotid stenting cases in these DRGs. This potential underpayment for carotid stenting procedures is likely understated as the 2004 MedPAR data does not include any FDA approved devices – only 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 in charges between carotid and non-carotid cases assigned to these DRGs 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.

Given the significant difference in charges for carotid stent procedures relative to the DRGs to which they are assigned, 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 of the 2004

data, 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 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.

Continuation of New-Technology Add-On Payment for Kinetra

The proposed rule for FY 2006 notes that the new-technology add-on payment for Kinetra will be extended through FY 2006. Kinetra remains within the two- to three-year period to be eligible for add-on payments. Medtronic appreciates and concurs with the extension of the add-on payment. The add-on payment for Kinetra has contributed significantly to patient access to deep brain stimulation for the treatment of Parkinson's disease and broader physician adoption of this important new technology.

Expiration of New-Technology Add-On Payment for CRT-D

The proposed rule for FY 2006 notes that the new-technology add-on payment for CRT-D will expire at the end of FY 2005. As the payment expires, Medtronic would like to take this opportunity to thank CMS for approving the add-on and granting one year of payment. CRT-D is a breakthrough technology for the treatment of certain patients with heart failure. The add-on payment has contributed significantly to patient access and broader physician adoption of this important new treatment.

Implementation of ICD-10

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, the number of available codes under ICD-9 is rapidly dwindling and the availability of new codes has been raised in public meetings as a potential basis for CMS to deny applications for new codes. Medtronic 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. 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 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. Medtronic 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. Medtronic strongly urges CMS to move forward with implementation of ICD-10 as quickly as possible.

Thank you for your consideration of these comments.

Sincerely,

Jeff Farkas
Director, Health Policy & Payment
Medtronic, Inc.

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June 23, 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:

This letter is written on behalf of the Committee on Healthcare Financing ("Committee") with respect to the cited rulemaking (the "Proposed Rule"). The Proposed Rule would implement changes to the hospital inpatient prospective payment systems and fiscal year 2006 rates and have a substantial and, in our view, critical impact on the Department of Health and Human Services ("Department") Critical Access Hospital ("CAH(s)") program. It was published in the May 2005 Federal Register.

For your information, the Committee is an association of national investment and mortgage bankers and bond insurers, which actively participate in a substantial majority of both conventionally and federally supported financings for healthcare facility development throughout the United States. Such financings include major urban teaching hospitals, as well as facilities qualified under the CAH program. With respect to its participation in federal programs, since the early 1970s our members have worked closely with the Department of Housing and Urban Development with respect to its Section 242 financing program for the construction and rehabilitation of hospital facilities and with the Department with respect to its Hill Burton programs. A list of Committee members is attached.

Please know that the Committee has carefully watched the development of the CAH program since its inception and has found it to be an invaluable tool for assuring the availability of capital to finance the construction, replacement and rehabilitation of healthcare facilities that would assure the availability of accessible, affordable and quality healthcare in America's rural communities. Consistent with Congress' intent in creating the CAH program, our members have found the CAH program to be a particularly effective means for accessing low interest rate capital, or for that matter capital *per se,* in rural communities where capital for these purposes is

not readily accessible. We conclude that without a flexible and workable CAH program, capital for assuring quality and state of the art healthcare in many rural communities will be conspicuously absent.

With respect to the Proposed Rule, please know that the Committee has worked with the National Rural Health Association ("NRHA") over the years on various matters affecting rural healthcare capital formation and in light of its expertise in rural healthcare matters have carefully reviewed NRHA's letter to the Department dated June 23, 2005, with respect to the Proposed Rule. We are writing to indicate our strong concurrence with the concerns regarding the negative impact of the Proposed Rule on CAH capital formation expressed in those comments and urge the Department to adopt the changes set forth in the NRHA letter.

We appreciate the opportunity to submit this letter of support. Please do not hesitate to contact the undersigned at 202-293-8200 if you have any questions or require any additional information.

Very truly yours,

COMMITTEE ON HEALTHCARE FINANCING

By: _____
Michael E. Mazer
As Counsel to the Members of the Committee

MEM: cs

Enclosures

cc: Hilda Heady
Alan Morgan
Edward Shapoff
Joseph Marion

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NATIONAL RURAL HEALTH ASSOCIATION

June 23, 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 National Rural Health Association (NRHA) 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**. We appreciate your ongoing commitment to rural health care, and the NRHA looks forward to working with you in our mutual goals of improving access and quality of health care for all rural Americans.

The NRHA is a national nonprofit membership organization that provides leadership on rural health issues. The association's mission is to improve the health of rural Americans and to provide leadership on rural health issues through advocacy, communications, education and research. The NRHA membership is made up of a diverse collection of individuals and organizations, all of whom share the common bond of an interest in rural health.

Of particular concern to NRHA is the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding replacement or relocation of a Critical Assess Hospital (CAH) that have been designated as a Necessary Provider (NP).

Or comments are as follows:

CAH Replacement Facilities

1.) **We strongly oppose all deadlines for actions related to Critical Access Hospital (CAH) replacement or relocation in the Inpatient Prospective Payment System (IPPS) final rule.**

2.) **The proposed "75% threshold" is appropriate and sufficient to assure that a replacement or relocation CAH facility continues to meet the intent of its original Necessary Provider designation,** i.e. that the "CAH serves at least 75 percent of the same service area that it served prior to its relocation, provides at least 75 percent of the same services that it provided prior to the relocation, and is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees."

Our basis for this position is as follows:

1. The Proposed Regulation transfers to the Centers for Medicare and Medicaid Services (CMS) control over the basic structure of local rural health care, a loss of local control never before seen, and if allowed to stand, a precedent that threatens all hospitals and all communities.

2. It was clearly not the intent of Congress in the Medicare Modernization Act that a Critical Access Hospital (CAH) designated as a Necessary Provider be perpetually prohibited from replacing or relocating their facility, facilities that are often 40 to 50 years old.

3. Many rural hospitals are located on a small campus in the middle of residential neighborhoods with relocation being the most appropriate, and sometimes only, alternative since there is no room to expand on the existing site.

4. The proposed rule will force CAHs to allocate funds to renovate structures that no longer meet either the needs or the demands of modern health care. As inefficiencies are realized, CMS will be forced to provide more money through cost-based payment to maintain an aging and declining healthcare infrastructure in rural America. Ironically, the CMS proposal to ban a local community's ability to rebuild on an adjacent or nearby location will cost Medicare more over time, not less. The higher labor costs of operating in a retrofitted building more than offset the slightly higher initial cost of rebuilding. The proposal displays a short sighted thinking process by the rule makers and a dramatic misunderstanding of the health care setting in rural areas.

5. Many rural hospitals are in 40 to 50 year buildings with antiquated floor plans, construction and utilities. Newer facility designs promote patient safety and quality of care that would be, as a practical matter, prohibited by the proposed rule. Forcing hospitals to continue in facilities after they become outdated is an inappropriate and avoidable risk for rural communities.

6. A ban on major construction projects developed after December 8, 2003 is an over reaction against a potential problem that can be appropriately managed by the portion of CMS's proposed rule that would require assurance that, after the construction, the CAH will be servicing the same community and will be operating essentially the same services with essentially the same staff.

7. The CMS ban is based on the misguided belief, not tested in law and a break with CMS's past policy that the relocation of a CAH can be treated differently than the relocation of any other hospital. There is no basis in law that the relocation within a community of a CAH with Necessary Provider status constitutes a cessation of business and loss of its provider agreement and number.

8. A CAH's Necessary Provider designation is associated with its current Medicare provider agreement that remains intact unless the CAH fundamentally changes its business (e.g., ceases its current operations) or is terminated by Medicare. It is a longstanding policy that the provider agreement describes the legal entity and services provided—not the physical structure or location.

On June 6, 2005, the NRHA facilitated a conference call between a sample of CAH hospital CEOs, to provide specific examples of the impact this proposed regulation is having on their facilities. See **Attachment A** for a detailed account of their examples.

Occupational Mix Adjustment

CMS proposes to continue adjusting 10% of the wage index by an occupational mix adjustment. CMS noted last year some confusion and inconsistency with the data accumulated in the first occupational mix survey. We recognize this survey process was new to providers, intermediaries and CMS, and agree that there is likely a great deal of inconsistency in the way different hospitals completed the survey.

We encourage CMS to revisit this process immediately and gather new data within the next year, rather than waiting two more years before obtaining such data. At the same time, more detailed instructions should be issued to clarify the types of data reported, and how occupational data should be recorded on the survey form. CMS notes that a **Federal Register** notice will be published outlining changes to the survey process, and we look forward to reviewing this notice.

Post acute Care Transfers

CMS once again proposes to expand the post acute care transfer (PACT) policy. In describing the proposed expansion CMS notes that, of 507 active DRGs, 220 have lengths of stay of less than 3.0 days and 64 have fewer than 100 short-stay transfer cases. CMS proposes to include the remaining 223 DRGs under the PACT policy. Based on revised data posted to the CMS website, we understand there are now 231 DRGs proposed to be included under the PACT policy. We do not believe the proposed changes are in compliance with Section 1886(d)(5)(J) of the Act. This section requires that DRGs included under this policy must have "a disproportionate use of post discharge services."

While CMS notes that each of the selected DRGs had at least 2,000 PACT cases, CMS does not explain how this represents a "disproportionate use" of post discharge services. The plain meaning of the word "disproportionate" would indicate that, for a DRG to be included under the PACT policy, the usage of post discharge services would have to be outside the norm. CMS previously published criteria that somewhat accomplished this goal, by requiring 14,000 PACT cases for a DRG to be included under the policy. By excluding the 220 DRGs with lengths of

stay of less than 3.0 days, CMS effectively proposes to include every other possible DRG under the policy that had 100 or more transfer cases.

To demonstrate that it has met the intent of the law, CMS should publish a complete list of all DRGs showing how many total cases each DRG had and how many of those cases included usage of post discharge services. The usage rate should also be computed for each DRG, as well as the overall average usage rate. We believe a usage rate at least one standard deviation above this average should be set as a minimum before a DRG is made subject to the PACT policy. We do not believe any change is needed in the current PACT policy. However, if CMS does propose such a change, we believe the clear intent of the law is to limit the PACT policy to DRGs with a disproportionate use of post discharge services, something CMS does not demonstrate with its proposal.

Further, we do not believe that CMS is required to implement changes to the PACT policy as actual reductions in Medicare spending. We request CMS make the postacute transfer policy a budget neutral policy, such that any reductions in Medicare spending through revisions to this policy be paid to providers through an increase in the PPS update factor.

Sole Community Hospitals and Medicare Dependent Hospitals

CMS proposes to modify the budget neutrality adjustment applied to hospital-specific payment rates for SCHs and MDHs to no longer consider changes in the wage index when applying the budget neutrality adjustment to hospital-specific payment rates. However, CMS fails to quantify the impact of this proposal. We request more detailed information regarding the impact of this change on fiscal 2006 payments, as well as the impact if this change was imposed retroactively.

DSH Adjustment Data

We appreciate the efforts CMS is making to comply with Section 951 of the Medicare Modernization Act, which required that CMS make certain DSH adjustment data available by December 8, 2004. CMS notes that a future **Federal Register** notice will publish more details on this issue. Due to the significance of this issue and the time that has already elapsed since December 8, 2004, we request that CMS expedite its efforts to make such data available.

Geographic Reclassifications

CMS proposes to update 42 CFR 412.103(a)(1) to use Rural-Urban Commuting Area codes to identify hospitals located in rural census tracts. However, it was difficult to locate these codes by going to the website identified in the proposed regulations. We request further clarification concerning these codes or a more detailed website reference to link to the codes.

Rural Hospitals Redesignated as Urban

As a result of the most recent labor market changes, some counties that were previously considered rural were redisignated as urban. Per the MMA, a rural county that is adjacent to one or more urban counties is considered to be located in the urban MSA to which the greatest number of workers in the county commutes, if certain conditions are met. These are known as "Lugar Counties." Thus, some CAHs are now located in Lugar counties and are unable to meet the rural location requirement, even through they were in full compliance at the time they were designated as critical access.

In response, CMS proposes that CAHs in counties that were designated Lugar counties effective October 1, 2004 because of the new labor market definitions will be allowed to maintain their CAH status until September 30, 2006. NRHA supports this continued transition to allow for the opportunity for these facilities to reclassify.

Budget neutrality and RCH demonstration

The NRHA supports the decision of CMS to achieve budget neutrality for the rural community hospital demonstration by adjusting the total of all PPS payments. This is a fair and reasonable means of balancing the modest cost of this demonstration.

Evaluation of the RCH demonstration

The NRHA looks forward to seeing the evaluation/assessment of the RCH program. We offer our assistance to the contractor awarded this task. We are concerned that all possible benefits and costs be considered, which we believe will require input from experts knowledgeable of special rural circumstances.

Registered Nursing: page 23375

The NRHA is deeply disturbed by the unsupported statement that hospitals are accounting for the shortage of physicians by hiring more registered nurses. We know of no instance of this occurring. The statement implies a practice of downgrading care, especially since it uses "registered nurses," not even nurse practitioners (who deliver primary care). We ask that this statement be stricken from the final rule.

Conclusion:

We believe at this time, it is important to address for the public record, a much larger issue concerning CMS's internal misunderstanding of the CAH program in general.

Through CMS actions regarding the CAH program over the past four years, it appears that the agency internally perceives the growth of the CAH program incorrectly. **This growth of the CAH program was specifically intended by Congress. Furthermore, the growth of the program is limited by the number of rural hospitals that reasonable have twenty-five or fewer beds.** Every reasonable estimate puts this potential universe at less than 1500 hospitals nation-wide. More that 1100 hospitals have already converted to CAH status., leaving fewer than 400 hospitals even potentially eligible for this designation. Attention should be paid to the total cost of the program (approximately $3B annually) and the additional cost as compared with all these CAHs being PPS hospitals (less than $800M according to MedPAC figures) compared with the total hospital budget this year for CMS of better than $239B.

The NRHA appreciates the opportunity to submit these comments on the proposed rule. Please do not hesitate to contact Alan Morgan, Interim Executive Director at 703-519-7910 if you have any questions about these comments.

Sincerely,

Hilda R. Heady

Hilda Heady
President

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June 24, 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:

St. Jude Medical, Inc. is pleased to comment 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).

St. Jude Medical is dedicated to the design, manufacture, and distribution of cardiovascular medical devices of the highest quality, offering physicians, patients, and payers outstanding clinical performance and demonstrated economic value. The Company's product portfolio includes cardiac resynchronization therapy (CRT) devices, implantable defibrillators (ICDs), pacemakers, specialty catheters, vascular devices, and heart valve replacement and repair products.

Our comments will address the following issues: reclassification of the defibrillator DRGs; new technology add-on payment; refinement of complications/comorbidities list; MedPAR data; external data; and the MedPAC recommendations.

Modification to the Defibrillator DRGs ("DRG Reclassifications")

These comments reflect similar concerns and recommendations that have been included in a joint letter submitted June 23, 2005, by Guidant Corporation, Medtronic, and St. Jude Medical on the proposed modification to the defibrillator DRGs.

CMS has proposed to remove hospital procedure code 37.26 (cardiac electrophysiological and recording studies [EPS]) from the list of cardiac catheterization procedures that lead defibrillator cases to DRGs 535 or 536. If a defibrillator is implanted with EPS and no other type of cardiac catheterization, the case would be

assigned to DRG 515. We ask CMS to withdraw this proposal. 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.

CMS has noted in previous DRG revisions that a full-scale electrophysiological study (EPS) qualifies as a cardiac catheterization. However, the data show that cardiac defibrillator cases with code 37.26 alone have lower average charges than those with other cardiac catheterization codes. This almost certainly reflects coding problems in the use of 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. It is not appropriate to modify the DRGs based on charge data that includes such disparate procedures. The solution to a coding problem is to fix the coding, not to alter DRG assignment.

Similarity of EPS and Cardiac Catheterization

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, Vol. 68 (August 1, 2003): 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. 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, are also essential in determining the need for a defibrillator as well as the appropriate device type. 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.

Inconsistency Among Coders in the Use of 37.26

The CMS data analysis show that cases with 37.26 only had lower average charges than other cardiac catheterization procedures. The problem with the analysis is that code 37.26 is used for procedures other than full-scale diagnostic EPS; all with lesser

intensity. During at least part of FY 2004, the timeframe for the MedPAR file used in the analysis, code 37.26 may reflect four different procedures:

- Device interrogation without arrhythmia induction
- Noninvasive programmed stimulation (NIPS)
- Full-scale diagnostic EPS
- Intraoperative induction and device testing

While these procedures share some features, they 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 (EP) laboratory but is non-invasive. EPS must also be performed in an EP laboratory but is invasive and requires special disposable catheters. 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 only showed lower average charges than other procedures with cardiac catheterization.

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 laboratory 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 less resource intensive procedures are no longer part of 37.26. This will result in a discrete code (37.26) to clearly identify full-scale diagnostic EPS.

Reinforcing with 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 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.

Coders were instructed to no longer use 37.26 for bedside interrogations (Coding Clinic, Third Quarter 2003, p.23) effective November 1, 2003. Although this was early in FY 2004, new guidelines take time to disseminate among coding staff and to be reflected in encoding systems. Moreover, it was not until the FY 2005 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 is likely that the FY 2004 MedPAR data for 37.26 is further skewed by the presence of bedside interrogations, a low resource procedure that is no longer coded to 37.26.

During the May 25 meeting, CMS acknowledged the inconsistencies among coders in the use of 37.26 and the need for more specific codes to permit distinction between the procedures currently coded under 37.26. When one code embodies several disparate procedures with varying purposes, sites of service, and intensity, the resultant data are not representative of any one of the procedures. Until the specific resources associated

with each unique procedure can be identified, we believe it is premature to undertake a critical DRG change that will have a significant financial impact on hospitals and potentially impede patient access to therapy. Creating one or more new codes to clearly identify these procedures will provide accurate charge data for future DRG refinements. However, using current data that encompasses four disparate procedures to modify the defibrillator DRG logic is not appropriate.

Reclassification of EPS only Cases to DRG 515

The proposed modification of the defibrillator DRGs would result in a dramatic shift of cases from DRGs 535 and 536 to DRG 515. The average charge data clearly do not support the reassignment of DRG 535 cases with code 37.26 and without a cardiac catheterization to DRG 515. Based on the CMS analysis of MedPAR data, approximately 43% of DRG 535 cases (average charges, $98,900) would shift to DRG 515 (average charges, $83,660) – a 15% ($15,240) disparity in average charges – indicating a significant difference in resource intensity. The proposed rule states "while the cases in DRG 535 with code 37.26 and without a cardiac catheterization have higher average charges than the average charges in DRG 515, these cases have lower average charges than the average charges for overall cases in DRG 535". This statement appears to minimize the significant difference in charges between the DRG 535 cases with EPS only and the average charges for all cases in DRG 515. It also ignores the greater similarity of the average charges between DRG 535 EPS only cases ($98,900) and those for all cases in DRG 536 ($94,454). CMS should not reclassify the DRG 535 cases with EPS only to DRG 515 due to the distinct difference in resource utilization.

Recommendation

CMS should withdraw the proposed DRG modification and address this coding problem with a coding solution before implementing critical changes to the current defibrillator DRG structure.

New Technology Add-On Program

St. Jude Medical believes 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. We are committed to continuing to work with CMS to improve the program so that it most effectively meets the goal of earlier patient access to new medical technologies.

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 are also concerned with the apparent inconsistency in the application of the "substantial similarity" provision regarding the eligibility of competing products for add-on payments.

The Advanced Medical Technology Association (AdvaMed) has submitted detailed comments on these and other concerns with the new technology add-on payment program. We fully support the AdvaMed comments and request that you consider the AdvaMed comments as you review applications for the final rule.

Refinement of Complications and 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.

Release of MedPAR Data

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. St. Jude Medical 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.

External Data

St. Jude Medical 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.

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. 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. We note 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. We echo 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. St. Jude Medical, 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. We also agree that any approach to

significantly modify the IPPS 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. St. Jude Medical believes that CMS should complete these projects before considering whether to implement the MedPAC proposals. St. Jude Medical 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.

We thank you for the opportunity to provide comments and look forward to continuing to work with you on these important issues. If you or your staff has questions, please feel free to contact me at swalker@sjm.com or 651-481-7638.

Sincerely,

Susan Walker
Director, Reimbursement

BATTLE CREEK HEALTH SYSTEM
300 North Avenue • Battle Creek, Michigan 49017
269/966-8000

Oaklawn Hospital

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June 24, 2005

Via Hand Delivery

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1500-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Dr. McClellan:

These comments are being jointly filed by Battle Creek Health System and Oaklawn Hospital, the two remaining providers in Calhoun County, Michigan, which comprises the newly established Battle Creek (12980) Core-based Statistical Area ("CBSA").

Before October 1, 2004, Calhoun County was a part of the Kalamazoo-Battle Creek Metropolitan Statistical Area. For fiscal year 2004, the Kalamazoo-Battle Creek wage index was 1.0500. For fiscal year 2005, the final wage index for the Battle Creek CBSA plummeted to 0.9345 (before consideration of the blended rate). This 11 percent decrease was the highest decrease experienced by any hospital that was redistricted from one metropolitan area into a newly created metropolitan area throughout the United States, with the exception of Madison County, Indiana. However, the Madison County hospitals were designated as a part of a Combined Statistical Area ("CSA") that also included Indianapolis, and those hospitals, we understand, have been reclassified into the Indianapolis CBSA for wage index purposes effective October 1, 2004. As such, Calhoun County was the most negatively impacted metropolitan area for federal fiscal year 2005 of any of the newly designated single county metropolitan areas that were split off from an existing MSA as a result of the adoption of the 2000 CBSA based Census designations.

According to CMS's own data from 2004, only 45 urban hospitals experienced a wage index decrease of more than 10 percent as a result of the new metropolitan area designations. See 69 *Fed. Reg.* at 49,032. However, according to CMS, these were primarily hospitals that were moved to rural areas. The Centers for Medicare & Medicaid Services (CMS) very generously provided hospitals that were redistricted out of metropolitan areas into rural areas hold-harmless protection for three years to give those hospitals the opportunity to either seek geographic reclassification or adjust to a lower wage index level. Hospitals that were moved to new urban areas that experienced these high-end reductions, such as the Battle Creek CBSA hospitals, received no such hold harmless protection. Although the Battle Creek hospitals were given a blended rate based on 50 percent of the Kalamazoo wage index and 50 percent of the new Battle Creek wage index for federal fiscal year 2005, that transition protection expires September 30, 2005.

We believe that the hospitals that experienced a wage index decrease of more than 10 percent, regardless of whether the decrease resulted from these hospitals being relocated into rural areas, should also receive hold-harmless protection. There is no justifiable basis for treating these hospitals differently, simply on the basis that they remained urban. CMS protected hospitals that were relocated to rural areas no matter how small their potential wage index drop. Hospitals that remained in urban areas, but that nonetheless experienced dramatic wage index decreases should be treated comparably to the hospitals that were relocated out of urban areas. As such, we urge CMS to provide hold-harmless protection to all hospitals that experienced a wage index decrease of more than 10 percent, regardless of whether the hospital remained urban or rural.

If CMS does not accept this hold harmless proposal, we request that CMS extend the blended rate to hospitals that experienced a wage index decrease of more than 10 percent for at least another two years to further ameliorate the impact of the new metropolitan area changes.

Alternatively, CMS could resolve this problem by treating Kalamazoo and Battle Creek as a CSA. Specifically, CMS could determine that a single county MSA that was redistricted out of a nearby metropolitan area and incurred a decrease in the raw wage index for federal fiscal year 2005 of at least 10 percent, to be considered a part of a CSA with the metropolitan area to which they were previously associated. In the case of Battle Creek, we specifically propose that the Kalamazoo and Battle Creek CBSAs be considered a CSA such that the two hospitals in Calhoun County could seek a group reclassification for wage index purposes to the Kalamazoo-Portage CBSA and satisfy the same CSA criterion. As a further alternative, instead of treating the two CBSAs as a single CSA, CMS could consider hospitals in this situation as exempt from satisfying the "same CSA" requirement at 42 C.F.R. § 412.234.

It should be noted that Oaklawn Hospital has obtained a wage index reclassification to Lansing as of October 1, 2005, but this provides Oaklawn Hospital with only very limited relief compared to the Kalamazoo wage index, which both hospitals have received for several years.

We believe that CMS has the authority to implement any of the changes suggested above under Social Security Act § 1886(d)(5)(I)(i), which provides the Secretary with broad authority to make adjustments and exceptions under the inpatient prospective payment system.

We appreciate the opportunity to bring these comments to your attention and would be pleased to provide any additional statistical analyses or other data in support of our request. Thank you for your consideration of these proposals.

Sincerely,

Patrick Garrett
President/CEO
Battle Creek Health System

Rob Covert
President/CEO
Oaklawn Hospital

cc: Baker Healthcare Consulting, Inc.

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SSM HEALTH CARE

Transfers Impact

Hefter
Wahlstein
Walz
Hart
Kraemer

June 23, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 1500 – P
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. SW
Washington, DC 20201

RE: Postacute Care Transfers

Dear Administrator McClellan:

On behalf of SSM Health Care, we appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Medicare Hospital Inpatient Prospective Payment System (PPS), as published in the May 4, 2005 *Federal Register*. We are particularly concerned about CMS' proposal to expand the number of DRGs subject to the postacute 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 a subacute level of care prior to the published geometric mean length of stay ("geometric mean") for the assigned DRG. Under this policy, payment for services provided before the transfer is made on a per diem basis solely because the patient recovered and was discharged to a lower level of care sooner than the average for that DRG.

The Medicare regulations have historically recognized that patients do not all recover at the same rate. The methodology for developing and recalibrating base payment rates considers the historical range of lengths of stay within each DRG, including stays shorter than the geometric mean.

SSM Health Care strongly opposes expanding the transfer policy to encompass additional classes of patient cases. We believe this would fundamentally weaken the incentives inherent in the inpatient PPS, converting it to a per-diem system for those patients without rebasing the payment rates to fairly compensate providers for the cost of care to patients whose rate of recovery requires discharge after the geometric mean. It reduces the Medicare cost of care for a subset of patients without considering the

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effect of that reduced reimbursement on the ability of providers to provide care to all of their Medicare patients. Health care standards are in place to ensure that patients are not discharged prematurely.

The estimated negative financial impact to our health care system of this proposal to expand the number of DRGs subject to the postacute transfer policy is in excess of $11 million. A decrease in reimbursement of that magnitude would undermine clinical decision-making and penalize hospitals for providing patients with the most appropriate care in the most appropriate settings. This most assuredly would not be in the best interests of the patients or providers.

We respectfully request that the proposal to expand the transfer policy to additional DRGs be withdrawn unless corresponding changes in the base payment methodology make the combined changes budget neutral.

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

Faithfully,

William C. Schoenhard

William C. Schoenhard, FACHE
Executive Vice President/COO

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AANN
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DRG 16EN
(stroke)

HEFTER
HARTSTEIN
Brooks
FASAN
Gruber
Kelly
Hue

June 16, 2005

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

Dear Colleagues,

The American Association of Neuroscience Nurses is the professional society representing nurses who care for individuals with neurological conditions. A significant number of our 3800 members work with patients who have a diagnosis of stroke. We provide education and training resources to those nurses and have multiple forums for them to discuss their practice issues. Many of our members have operational and programmatic responsibilities for care delivery systems and they are very concerned about the reimbursement challenges inherent in the current system. As the science of care has changed, the reimbursement structure has not; resulting in disincentives to receiving or delivering optimal care. This is particularly relevant as it relates to reperfusion therapy. We are asking CMS to support changes to Medicare hospital inpatient reimbursement for advanced stroke treatment in FY2006.

The peer-reviewed literature supports the assertion that those who receive reperfusion therapy have better outcomes, including a higher level of functionality, requiring less long-term care and nursing home services. The net impact is a reduction in cost over the course of treatment. The scientific statement on Acute Stroke treatment indicates that reperfusion with rt-PA (in appropriate patients) is supported by Level 1A evidence. Unfortunately, hospitals who make this valuable treatment available incur much higher costs due to the infrastructure, resources and protocols needed to provide the therapy. In the current reimbursement scheme, hospitals that provide this therapy are at a distinct financial disadvantage. Patients may not be receiving optimal care as a result.

We join our colleagues in the Brain Attack Coalition urging you to support changes to the Medicare hospital impatient reimbursement program for advanced stroke treatment in FY 2006. We believe that patient outcomes will be enhanced and that costs per case will be ultimately reduced.

Thank you for your tireless efforts on behalf of Medicare beneficiaries and in particular your support for enhancing stroke care by enhancing the payment programs. If we can be of further assistance, please don't hesitate to contact me.

Sincerely,

Cynthia Blank-Reid, MS

Cynthia Blank-Reid, MSN RN CEN
President, AANN
Cindy.Blank-Reid@tuhs.temple.edu

Cc: Brain Attack Coalition
Jean A. Rose-DeRenzy, RN, MS, CN; BAC Liaison

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SMITH HEFTER HARTSTEIN

June 23, 2005

BY FEDERAL EXPRESS - tracking number 7911 1487 5698

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

RE: Comments to Proposed Changes to the Hospital Inpatient Prospective Payment Systems, File Code CMS-1500-P
Implementation of § 951 of Pub. L. 108-173
DSH Adjustment Data (70 Fed. Reg. 23306, 23434-36)

Dear Sirs:

This responds to CMS' invitation to comment on the proposed rule implementing section 951 of the Medicare Modernization of Prescription Drug Act of 2003 ("MMA"), Pub. L. 108-173. DSH Adjustment Data, 70 Fed. Reg. 23306, 23434-36 (May 4, 2005). Section 951 of the MMA and the proposed rule address two areas of concern for Medicare providers that receive the Medicare disproportionate share hospital ("DSH") payment adjustment.

Since 1990, Southwest Consulting Associates ("SCA") has been providing management consulting services, specifically regarding the DSH payment, to many hospitals across the country. SCA presently performs DSH consulting services for over 400 hospitals in 35 states. SCA submits these comments on behalf of its client hospitals.

I. COMMENTS REGARDING CMS' PROPOSED IMPLEMENTATION OF MMA SECTION 951 AS IT RELATES TO THE 'MEDICAID FRACTION.'

SCA believes that CMS should allow hospitals to obtain the MedPAR Limited Data Set ("MedPAR LDS") free of charge and without waiting for an appeal to a fiscal intermediary or the Provider Reimbursement Review Board ("PRRB" or "Board"). We also believe that this proposed rule falls short of compliance with the requirements of section 951 of the MMA. 70 Fed. Reg. at 23434-35. MMA section 951 mandates that effective December 8, 2004, "the Secretary shall arrange to furnish to [PPS hospitals] the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage under [the PPS statute] for that hospital for the

current cost reporting year." As discussed in the notice of the proposed rule, 70 Fed. Reg. at 23434, the "disproportionate patient percentage" is defined in section 1886(d)(5)(F) of the Social Security Act as the sum of two fractions, the "Medicare fraction" and the "Medicaid fraction." Accordingly, the plain language of section 951 requires the Secretary to "arrange to furnish" to PPS hospitals "the data necessary for such hospitals to compute the number of patient days used in computing" the Medicare fraction, including the supplemental security income ("SSI") data needed to compute the patient days that go into the numerator of that fraction. *See* MMA § 951.

There are two basic elements to the computation of the Medicare fraction that is used to calculate the disproportionate patient percentage. The first element is the number of "patient days" attributable to patients who were entitled to benefits under Medicare Part A and the federal SSI program. Social Security Act § 1886(d)(5)(F)(vi)(I); 70 Fed. Reg. at 23434. These patient days are included in the numerator of the Medicare fraction. *Id.* The second element is the total number of "patient days" attributable to patients who were entitled to Medicare Part A benefits. Social Security Act § 1886(d)(5)(F)(vi)(II); 70 Fed. Reg. at 23434. These patient days are included in the denominator of the Medicare fraction. *Id.*

1.1 CMS' PROPOSAL DOES NOT MEET THE STATUTE'S REQUIREMENTS.

By simply supplying hospitals with the MedPAR LDS data, as suggested in the proposed rule, CMS would be providing a hospital with data that the hospital can only use to identify patients and patient days that were included in CMS' calculation of the Medicare fraction. See 70 Fed. Reg. at 23434-35. As CMS implicitly acknowledges in the notice of the proposed rule, this disclosure would only permit a hospital to "compare and verify" CMS' calculation with whatever data a hospital may have in its records. 70 Fed. Reg. at 23434. This proposed approach does not meet the requirements of MMA section 951 for the reasons noted below.

The plain language of MMA section 951 requires the Secretary to arrange to furnish hospitals with the data they need to perform their own computations of the patient days attributable to Medicare patients who were entitled to SSI. In order to perform this computation, a hospital needs access to SSI entitlement data for all of the hospital's Medicare patients, not just those that CMS matched to the SSI data file that CMS receives from the Social Security Administration ("SSA").

First, as CMS knows, hospitals do not presently have SSI data to compare against CMS' calculation of the Medicare fraction because hospitals do not have access to the SSA data that would be needed

to verify a patient's entitlement to federal SSI benefits. Indeed, Congress would not have needed to enact the MMA's requirement that the Secretary arrange to furnish SSI entitlement data to PPS hospitals if hospitals otherwise have access to the SSI data needed to compute the patient days in the numerator of the Medicaid fraction. In fact, this is apparently one of the principal purposes, if not the sole principal purpose, of the requirement in MMA section 951. With the exception of Medicare-eligibility data pertaining to certain dual-eligible Medicaid recipients (as discussed below), virtually all other data needed to compute the Medicare and Medicaid fractions is either in hospitals' own records or is otherwise available from most State Medicaid agencies.

Second, a hospital cannot accurately compute the number of patient days that should be included in the numerator of the Medicare fraction based only upon the SSI entitlement information reflected in CMS' calculations of the Medicare fraction. This information is insufficient for a hospital to compute an accurate percentage because CMS' calculations are systemically flawed and, as a result, the numerator of CMS's calculations is systematically understated.

Witnesses from CMS and SSA recently gave testimony under oath establishing that CMS' calculations of the Medicare fraction are systemically flawed in several respects that systematically reduce the resulting SSI ratios. This testimony and other related documents are part of PRRB case numbers 96-1822, 97-1579, 98-1827 and 99-2061 which were heard by the PRRB in September 2004. The unrebutted testimony of CMS' staff and the current and former SSA employees establishes the following flaws (among others) in CMS' calculation of the Medicare fraction:[1]

a) CMS' Match Is Systemically Flawed.

CMS' calculations of the Medicare fraction fail to properly identify all Medicare patients who receive SSI benefits because CMS' match process uses patient identifiers (e.g., the 'HICAN') that are not individual-unique and may change over time.

By way of example, the unrebutted evidence presented to the PRRB in the Baystate case identified several Medicare beneficiaries who were included in the denominator of CMS' calculation of the Medicare fraction, who were receiving federal SSI case benefits

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[1] The Provider's evidence has been supplied to the PRRB. We note, however, that the fiscal intermediary in that case, Mutual of Omaha, was represented by the counsel for the Secretary, in the HHS Office of the General Counsel. All transcripts and evidence adduced in connection with that case were produced to the Secretary's counsel, are in the possession, custody and control of the agency, and are incorporated herein by reference.

during the periods of their inpatient hospital stays, and who were included in SSA's annual tapes, but who were not included in the numerator of CMS' calculation of the Medicare fraction.[2] The omission of these SSI days shows that CMS failed to match its inpatient hospital utilization records for these patients against the SSI data in SSA's annual tapes.

William Anthony Dean ("Dean") testified before the PRRB that he is CMS' principal MEDPAR programmer and the individual within CMS who has been responsible since 1995 for running the program(s) that are used to match the inpatient hospital stay records in the MedPAR file with the SSI data in the SSI tapes that SSA annually supplies to CMS. Dean testified in September 2004 that CMS matches the health insurance claim account number ("HICAN") in the MedPAR records against a Title II claim account number ("CAN") and a social security number (with an "A" suffix added at the end) in the SSI data file.[3]

An individual's HICAN often does not contain his or her own social security number.[4] So, the HICAN in a MEDPAR file will not match to the social security number with an "A" suffix added at the end from the SSI data file.

Further, while an individual's HICAN is often the same as his or her Title II CAN, these numbers change over time, as when an individual marries or is divorced.[5] As a result, CMS' match process fails to match some inpatient hospital utilization records against the annual SSI data file. This will occur whenever CMS has a MedPAR record reflecting a current HICAN and tries to match that record against an SSI file that reflects an older Title II CAN that was in use at some point in the 42-month date range covered by the SSI file.[6] These false negatives occur because CMS does not use the individual-unique social security number to match records,[7] and because SSA supplies only one Title II CAN for each individual and SSA's program generally includes the oldest Title II CAN within a 42-month date range.[8] Thus, even Dean admitted in testimony before the PRRB that CMS' match

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2 *See* Provider's Post Hearing Brief at 76-78 (and testimony cited therein).

3 *See* Provider's Post Hearing Brief at 51-55 (and testimony cited therein).

4 *See* Provider's Post Hearing Brief at 44-45 (and testimony cited therein).

5 *See* Provider's Post Hearing Brief at 30-31, 44-45 (and testimony cited therein).

6 *See* Provider's Post Hearing Brief at 53-55, 76-78 (and testimony cited therein).

7 *See* Provider's Post Hearing Brief at 51-55 (and testimony cited therein).

8 *See* Provider's Post Hearing Brief at 30-33 (and testimony cited therein).

process systemically fails to match some records in cases like this.[9]

SSA also testified it performs a monthly match of SSI recipients to CMS data. This monthly match is performed in order to adjust monthly SSI checks for recipients who have been admitted or discharged from a skilled nursing unit. One SSA staff who testified was appalled that CMS was not matching the SSI data by the social security number with a secondary match using name and date of birth in a similar manner as SSA's process.

A different problem was also brought to light through the evidence discovered in the PRRB case. SSA, when transmitting the SSI records to CMS, was not sending all records for each recipient. SSA was submitting only one record; however, for various reasons, a person may have more than one SSI record for a given time frame. When SSA discovered the error in 1996 they began sending all records for each person. However, CMS testified that because these multiple records were thought to be duplicates, CMS incorrectly eliminates all but one of the records for each person. The removal of these records causes the SSI data to not be matched correctly, thus understating the SSI fraction.

b) CMS' Calculations Systemically Omit SSI Entitlement Data Due To CMS' Early Cut-Off.

As discussed in the PRRB case, CMS' calculation of the numerator of the Medicare fraction also is systemically understated because of an early cut-off date for the SSI data that CMS uses in its calculation of the Medicare fraction.[10] For example, CMS has admitted that for at least one patient stay days were counted as Medicare days in CMS's MEDPAR data, and that zero SSI days were counted for that stay in CMS' MEDPAR data.[11] The SSI days associated with this stay were omitted from CMS' MEDPAR data because the individual's SSI payments appear to have been temporarily in suspense when SSA prepared the annual SSI tape but were activated just one month later, retroactive to the individual's hospital stay.[12] If CMS had used the SSI data in SSA's later tapes to update its calculation, the SSI days associated with this stay would have been properly accounted for in both the numerator and the denominator of the SSI fraction.

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9 *See* Provider's Post Hearing Brief at 54-55 (and testimony cited therein).

10 *See* Provider's Post Hearing Brief at 39-41, 75-76 (and testimony cited therein).

11 *See* Provider's Post Hearing Brief at 75-76 (and testimony cited therein).

12 *Id.*

The evidence before the PRRB shows that SSA furnishes a tape of SSI entitlement records to CMS sometime around March of each year.[13] Each tape covers the first six months of the current calendar year (i.e., the tape collects actual data for January - March and projects 3 months of data for April - June) and the prior three calendar years.[14] (We note that CMS has recently begun having SSA perform an earlier run of the SSI data that can only cause the SSI fractions to decease due to excluding even more retroactive grants of benefits). Thus, CMS ultimately receives three annual SSI tapes for any given federal fiscal year; but, only the first annual tape (i.e., the tape received in or around March of the next year), is used to compute the Medicare fraction.[15] CMS currently computes the Medicare fraction in the Spring following the end of a federal fiscal year, based on the annual SSI tape produced by SSA some months earlier. The second annual SSI tape for a given fiscal year is matched against some later MedPAR runs for that year,[16] but that updated data is never used to update CMS' calculation of the Medicare fraction, and the third and latest annual SSI tape is never matched against any MedPAR files for that year.[17]

SSI benefits are only rarely terminated retroactively but are commonly granted or reinstated retroactively.[18] Retroactive grants or reinstatements of SSI benefits occur when initial applications are denied and later granted on appeal, when terminations are reversed on appeal, and when benefits that are temporarily in suspense or on hold are later granted or reinstated retroactively.[19] In some of these types of cases, an individual's benefits may be retroactively granted or reinstated for a prior period of hospitalization after the time when CMS computes the Medicare fraction for a federal fiscal year (in the following Spring).[20] Retroactive corrections to the SSI data would be reflected in the subsequent SSI tapes furnished to CMS (which is probably why SSA sends more than 3-years' data every

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13 *See* Provider's Post Hearing Brief at 27 (and testimony cited therein).

14 *See* Provider's Post Hearing Brief at 28-29 (and testimony cited therein).

15 *See* Provider's Post Hearing Brief at 46-48 (and testimony cited therein).

16 *See* Provider's Post Hearing Brief at 46-48 (and testimony cited therein).

17 The tenth and last MEDPAR run for any given federal fiscal year is performed in the third December after the end of the fiscal year. For example, the last MEDPAR run for fiscal year ended September 30, 1992 would be the MEDPAR run performed in December 1994.

18 *See* Provider's Post Hearing Brief at 39-41 (and testimony cited therein).

19 *Id.*

20 *See, e.g.,* Provider's Post Hearing Brief at 75-76 (and evidence cited therein, discussing the patient stay identified as Master ID number 13111).

year), but CMS does not use the updated SSI records to update its calculations of the Medicare fraction.

1.2 CMS SHOULD ADOPT A PROCESS BY WHICH HOSPITALS MAY HAVE INPATIENT HOSPITAL UTILIZATION RECORDS MATCHED BY A CMS CONTRACTOR AGAINST UPDATED AND COMPLETE SSI ENTITLEMENT RECORDS USING APPROPRIATE MATCH CRITERIA ACCEPTABLE TO THE HOSPITAL, INCLUDING INDIVIDUAL-UNIQUE SOCIAL SECURITY NUMBERS.

For the foregoing reasons, we suggest that in order to properly implement section 951 of the MMA, CMS should establish a process by which hospitals may have their own match performed against updated and complete SSI entitlement data. This match could be performed by a CMS contractor, but hospitals should have the ability to use the appropriate primary and alternative match criteria (e.g., social security numbers, then HICANs, Title II CANs, or names, gender and dates of birth,) in the match process. The denominator of this match would be all days entitled to Medicare Part A (i.e. the Medicare Part A PS&R). As discussed in the case,[21] such an alternative data match was proposed to CMS in connection with the Baystate appeal to the PRRB and is discussed in the last section of the Post-Hearing Brief filed in that case.

In response to Baystate's alternative data match proposal, the agency initially posed a host of reasons why SSA could not, or allegedly would not, disclose updated SSI records to CMS or would not permit CMS (or a contractor of CMS) to disclose to a hospital the patient-level detail data resulting from a match of that data with inpatient hospital utilization records.[22] We note, however, that SSA's counsel wrote a letter to the CMS Administrator dated July 9, 2004, which stated that SSA would produce updated SSI records to CMS for the specific purpose of facilitating such an alternative data match, and with the understanding that the patient-level detail resulting from a match would be produced to the hospital by CMS or its contractor.[23] Thus, SSA's written communication to the Administrator makes it clear that nothing in the Privacy Act or in other federal law would preclude SSA from furnishing CMS with the data that would be needed to implement this proposal.

Further, to the extent that CMS' own routine uses would not cover disclosure to a hospital of the patient-level data concerning the results of such a match (and we believe that they do), now is the time for CMS to adopt an appropriate routine use to accommodate

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[21] *See* Provider's Post Hearing Brief at 73-74, 107-09 (and evidence cited therein).

[22] *See* Provider's Post Hearing Brief at 73-74 (and evidence cited therein).

[23] *See* Provider's Post Hearing Brief at 74 (and Provider Exhibits 142 and 143).

this proposal. Due to the systemic flaws in CMS's match process, and the systemic omission of SSI data resulting from the early cut-off in CMS' match process, the Secretary cannot comply with the requirements of section 951 of the MMA merely by furnishing a hospital with the results of CMS' data match. This data systemically understates the SSI days in the numerator of the Medicare fraction, and, therefore, it is not sufficient to permit a hospital to accurately compute the number of patient days in the numerator of the hospital's Medicare fraction.

II. COMMENTS REGARDING CMS' PROPOSED IMPLEMENTATION OF MMA SECTION 951 AS IT RELATES TO THE 'MEDICAID FRACTION.'

We agree with CMS that the best methodology to obtain Medicaid eligibility is to continue working directly with the individual states. We also appreciate the recognition that a few states are reluctant to work with providers on providing eligibility data. While the language in the proposed rule may be helpful in working with those few states, definitive regulations may be needed if states are still reluctant to provide the data necessary for the DSH calculation.

We would like to point out that states should be supplying all relevant information to providers for the purpose of determining which patients can be included in the DSH calculation. Simply providing whether a patient is eligible for Medicaid is not sufficient for determining whether a patient may be included in the DSH calculation. The following items are also needed from the State:

- Eligibility for the patients' actual dates of service
- Whether the patient has met spend down requirements (if applicable)
- What type of Medicaid benefits did the patient receive:
  - State funded or federal funded
  - State Model (a.k.a. separate) SCHIP (if applicable)
  - Inpatient or non-inpatient
  - Medicaid benefits where the patient is dual-eligible

Therefore, we request that CMS emphasize with the States that the above data elements must be supplied in order for the providers to appropriately remove days not allowable for the Medicare DSH calculation. If CMS fails to do so, the fiscal intermediaries should not be permitted to remove days because a provider cannot determine if a Medicaid eligible day does not qualify for the DSH calculation (i.e. state funded or non-inpatient benefits).

In addition, per the 2005 final regulations, providers must identify and remove all dual-eligible days from the DSH calculation. However, CMS has not provided a practical process for a provider to examine each patient for Medicare Part A

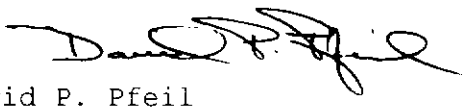
eligibility. Most fiscal intermediaries are requiring hospitals to look up a sample of patients in all 9 regions of the Common Working File (CWF) using the patient's Social Security Number and 4 BIC identifiers. This translates into looking up each patient in the CWF 36 times (9 times 4). For a medium-sized hospital, this would require over 100,000 inquiries into the CWF.

SCA has attempted to discover a computerized method of querying the CWF and found a vendor who could do this work. However, the original quoted price was $0.75 per account.

Since Congress has mandated that CMS provide the data necessary for the DSH calculation, we request that CMS provide a process where providers can submit a large volume of records to the CWF and electronically check for Medicare Part A eligibility instead of forcing providers to perform inquires one by one so that providers can more readily conform to the 2005 dual-eligible final rule.

We appreciate the opportunity to comment on the 2006 proposed regulations. If you have any question concerning the above comments, please call me at (972) 732-8100.

Sincerely,



David P. Pfeil
President

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June 24, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

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

Dear Administrator McClellan:

The Society of Interventional Radiology (SIR) is a national specialty association with over 4,000 members that represents the majority of practicing vascular and interventional radiologists in the United States, along with other physicians and allied health professionals interested in interventional radiology.

SIR appreciates the opportunity to comment upon the Proposed Rule, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates as published in the May 4, 2005 *Federal Register.* SIR's comments are directed to the following topics in the proposed rule:

- MDC 1 (Diseases and Disorders of the Nervous System) – Stroke
- MDC 1 (Diseases and Disorders of the Nervous System) – Unruptured Cerebral Aneurysms
- MDC 5 (Diseases and Disorders of the Circulatory System) – Carotid Artery Stent
- MDC 6 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) – Kyphoplasty
- FY 2006 Applications for New Technology Add-On Payments.

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MDC 1 (Diseases and Disorders of the Nervous System) – Stroke [Page 23315]

SIR commends CMS' efforts to update the Inpatient Prospective Payment System (PPS) to better describe stroke treatment and its associated costs.

In the proposed rule, CMS presented two options for better capturing the costs and use of thrombolytic therapy in the treatment of ischemic stroke. The first option was to modify DRG 14 (Intracranial Hemorrhage or Cerebral Infarction) to read "Ischemic Stroke Treatment with a Reperfusion Agent" and to include only those stroke cases treated by thrombolytic therapy reported with code 99.10 (Injection or infusion of thrombolytic agent). All other stroke cases would go into the renamed DRG 15 (Nonspecfic CVA and Precerebral

Occlusion Without Infarction) to "Hemorrhagic Stroke or Ischemic Stroke without a Reperfusion Agent." The second option was to leave DRG 14 and DRG 15 alone and create a new DRG entitled "Ischemic Stroke with a Reperfusion Agent."

SIR would support either of the proposed options as both better account for the use of thrombolytics and the associated costs in the treatment of stroke. Coding and reporting accuracy should be improved since "stroke" is clearly identified in the DRGs' descriptions. Additionally, there should be better hospital charge capture when thrombolytic therapy is used for ischemic strokes. These options provide a framework for new stroke treatment options (e.g., thrombus retrieval devices). We encourage CMS to revisit this issue as these new technologies diffuse into clinical practice.

MDC 1 (Diseases and Disorders of the Nervous System) – Unruptured Cerebral Aneurysms [Page 23316]

SIR appreciates CMS' ongoing attention to unruptured cerebral aneurysms.

SIR and other organizations commented to the agency nearly two years ago in favor of a specific DRG for treatment of unruptured aneurysms. At the time, we were concerned that the resources associated with unruptured aneurysms were not fully appreciated in DRG 1 or DRG 2. CMS' subsequent analysis of 2004 MedPAR data demonstrate the presence of higher charges associated with unruptured aneurysms in DRG 1 ($53,455) and DRG 2 ($34,028) than all cases in DRG 1 ($51,466) and DRG 2 ($30,346). We recognize that this differential may not justify the creation of a new DRG at this time, but it does identify an issue worthy of further evaluation. As more current data become available, we would appreciate the opportunity to revisit this issue with CMS.

MDC 5 (Diseases and Disorders of the Circulatory System) – Carotid Artery Stent

SIR recommends that CMS revisit the existing DRG structure once new data on carotid stenting become available to ensure that the DRGs are appropriately descriptive and the rates include device costs.

The SIR agrees that sufficient data regarding carotid artery stenting (CAS) may not exist currently for DRG rate setting. Procedure codes for carotid stenting were created only as of last year. Medicare's coverage of carotid stenting was limited to procedures performed in clinical trials; it is unlikely that the claims processed under this limited indication included device costs.

CMS soon should be in possession of enough data on CAS for DRG rate setting. In May, CMS announced broader Medicare coverage of carotid stenting for certain specified patients. The clinical trial coverage option remains for those patients not included in the recent coverage decision. Also, CMS should have an additional year's worth of data based on the CAS procedural codes.

It is imperative that the DRG rates reflect CAS device costs. Preliminary MedPAR data presented in the proposed rule suggest higher charges for patients receiving a carotid stent. This is to be expected and the DRG rates should be determined accordingly.

MDC 6 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) – Kyphoplasty

SIR recommends a delay in specific DRG rate setting for kyphoplasty and vertebroplasty until more hospital charge data become available.

It is the position of SIR that vertebroplasty and kyphoplasty offer equivalent clinical response in the treatment of painful compression fractures refractory to medical therapy. Kyphoplasty offers no advantages over vertebroplasty with respect to pain relief, vertebral height restoration, and complication rate. SIR, however, does recognize that kyphoplasty is more resource intensive than vertebroplasty.

Specific procedure codes for vertebroplasty (81.65) and kyphoplasty (81.66) came into being only last year. Prior to the creation of specific codes for the respective procedures, both were coded under a general code (78.49 – Other repair or plastic operation on bone) applicable to a range of procedures unrelated to vertebroplasty or kyphoplasty. From the MedPAR data presented in the proposed rule, it is unclear what impact specific vertebroplasty and kyphoplasty codes will have on the base DRG rates and whether it will be significant to warrant specific DRG rate setting. SIR also has concerns regarding potential incentives introduced if DRG rates differ for clinically comparable services.

FY 2006 Applications for New Technology Add-On Payments– Endovascular Repair of the Thoracic Aorta [Page 23362]

Endovascular repair of the descending thoracic aorta meets CMS' requirement of a substantial clinical improvement for new technology add-on payments. Therefore, SIR recommends that CMS extend such payments to thoracic aorta stent-grafts.

Endovascular repair of thoracic aortic aneurysms offers high technical successes with lower morbidity and mortality in comparison to traditional open surgery. Endovascular repair has one-third the hospital stay and results in the patient returning to normal activities in half the time of open thoracotomy repair. For more information regarding the specific benefits offered by endovascular repair, please see our attached statement to the February 23, 2005 Townhall Meeting.

Thank you, again, for the opportunity to comment on the 2006 proposed rule for the hospital prospective payment system. If you have questions or require additional information, please contact Michael R. Mabry, SIR's Assistant Executive Director for Policy, at (703) 691-1805, ext. 201 or mabry@sirweb.org.

Sincerely,

Michael E. Edwards, MD
SIR Councilor for Health Policy & Economics

Attachment
SIR Statement to Town Hall Meeting on New Technology
Add-on Payments for FY 2006

February 17, 2005

Tzvi M. Hefter
Division of Acute Care
Mail Stop C4-07-05
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop C1-09-06
Baltimore, Maryland 21244

Re: Statement of the Society of Interventional Radiology (SIR) – Medicare Program; Town Hall Meeting on the Fiscal Year 2006 Applications for New Medical Services and Technologies Add-on Payments Under the Hospital Inpatient Prospective Payment System

The Society of Interventional Radiology (SIR), on behalf of its over 4,000 members, appreciates the opportunity to provide commentary in support of Medicare payment for endovascular repair of thoracic aortic aneurysms (TAA).

Endovascular repair of TAA meets CMS's requirement of a substantial clinical improvement as compared to currently available treatment options. Endovascular repair of TAA offers high technical successes with lower morbidity and mortality in comparison to traditional open surgery. Specific outcome comparisons between endorepair and surgery are described in the body of our statement.

Background

Aneurysmal disease and dissection of the thoracic aorta are serious life threatening conditions. Thoracic abdominal aneurysms typically affect the elderly, particularly those who smoked heavily and have comorbid conditions such as hypertension, coronary artery disease, and obstructive pulmonary disease. In fact, of the 2,058 deaths attributed to TAA and/or dissection reported by the National Center for Health Statistics in 2001, nearly 86 percent were aged 65 or older.[1] Most TAAs are asymptomatic until rupture. Approximately 30 percent of TAA patients die within five years, this rate increases with the size of the aneurysm. Patients with thoracic dissections fared worse.

Conventional treatment of TAA consists of open thoracotomy with graft replacement of the diseased section of the aorta. Despite advancements in the procedure, operative mortality rates and serous morbidity (e.g., paraplegia, renal failure, stroke, prolonged ventilatory dependence) range from 5 to 10 percent, even when performed by experienced surgeons.[2] Post-operative hospital length of stay is typically up to 10 days, with several days spent in the intensive care unit (ICU) and some time post-operatively on ventilator-assistance. The patient is able to return to work within two to three months.

Endovascular Repair of Thoracic Aortic Aneursyms

Technique

Dake et al first described the feasibility of endovascular repair of TAA in 1994.[3] Since then, there have been advances in technique and stent-graft design leading up to commercially available devices. Pre-operative planning requires precise imaging and measuring to assure appropriate patient and device selection. Endovascular repair requires anesthesia (general or conscious sedation) and a femoral arterial exposure through which the necessary guidewires, catheters and the device are introduced under fluoroscopic/angiographic guidance. The device is advanced from the femoral artery, through the iliac artery, into the abdominal aorta, finally positioned within the treatment area of the thoracic aorta. Once proper positioning of the device within the thoracic aorta has been confirmed by fluoroscopy/angiography, the device is deployed. Balloon dilation may be used following device deployment to ensure proper "seating" and sealing of the device against the vessel wall. Additional stent-graft components (modules), depending on anatomy and device design, may be deployed in a similar manner to provide adequate coverage of the aneurysm and/or to treat endoleaks. The femoral arteriotomy is closed, resulting in a small groin incision.

Results

Endovascular repair of TAA has been found to have comparable results as open surgery; particularly in high-risk patients.[4] the technical successes related to stent-graft deployment exceeds 90 percent. Endorepair has mortalities in the zero to 4 percent range and major complications (e.g., paraplegia) in zero to 1.6 percent of patients.[5]

Last month, Makaroun et al published the results of the phase II multicenter trial of the GORE TAG thoracic endoprosthesis.[6] This study of 142 patients had a technical success rate of 98 percent, low ICU stays (average 2.6 days, median one day), short total hospital stays (average 7.6 days, median three days), and operative mortality of 1.5 percent. Follow-up for the study was 24 months, during which time there were no TAA ruptures and aneurysm-rated and overall survival were 97 percent and 75 percent, respectively.

CMS's Significant Improvements in Patient Outcomes Offered by Endovascular Repair of Thoracic Aortic Aneurysms vs. Open Surgery

CMS has a process for identifying and ensuring adequate payment for new services and technology under Medicare. This process requires the new technology or service to demonstrate "significant clinical improvement". The December 20, 2004 *Federal Register* on page 78467 provides outcome criteria to determine such improvement. These criteria are highlighted below and addressed with respect to TAA endorepair.

Reduced Mortality Rate

Thoracic aortic aneurysm and dissection are life-threatening conditions with significant mortality rates approximating 30 to 50 percent for five-years. Open surgical thoracotomy has serious mortality and morbidity rates of five to 10 percent in the best of hands. Conversely, for endovascular repair, the mortality and morbidity rates range from zero to less than two percent.

Reduced Rate of Device-Related Complications

Endovascular repair has a high technical success rate in excess of ninety percent. Major device-related complications are extremely rare. Makaroun reported to the FDA's Circulatory Device Panel that the GORE TAG endograft had a 94 percent freedom of major device related events.[7] Endoleaks are the most common minor complication with most spontaneously resolving without the need for additional interventions. The marked reduction in procedure-related complications comes from the considerably less invasive nature of this procedure compared with open TAA repair.

Decreased Rate of Subsequent Diagnostic or Therapeutic Interventions

Endovascular repair results in fewer major adverse events than surgery (defined as requiring therapy and post-hospitalization (24 to 48 hours) or required major therapy and unplanned increase in care/hospitalization resulting in permanent adverse sequelae or death).[7] Moreover, endovascular repair avoids prolonged ventilator support in the ICU that can be required after an open thoracotomy repair. Follow-up imaging will be life-long, like endovascular AAA repair, but also like open TAA repair. These patients will require annual imaging (most often CTA) to assess for TAA growth, endoleak, graft migration or failure. Like with TAA patients having open repair, the potential for extension of aneurysmal disease into non-treated segments of the aorta will require monitoring.

Reduced Recovery Time

Endovascular repair of TAA or dissection requires approximately one-third of the ICU days and total hospital days as required for surgery.

Decreased Pain, Bleeding, or Other Quantifiable Symptoms

Endovascular repair involves a small groin incision through which the device is introduced, rather than the 12-inch chest incision associated with thoractomy repair. The patient avoids ventilator and heart bypass assistance, and blood transfusions are not typically required with endovascular repair. Endovascular repair had lower rates of bleeding, pulmonary, renal, wound, and neurological complications than surgery.[7]

More Rapid Beneficial Resolution of the Disease Process Treatment

Various studies have found that endovascular repair has comparable outcomes compared with thoracotomy repair. Patients having endovascular repair were able to return to normal activities in 30 days compared to 78 days for surgery. [7]

Decreased Number of Future Hospitalizations or Physician Visits

The combination of fewer major adverse events and complications along with a shorter overall hospital stay should result in less future hospitalizations and physician visits. However, as mentioned previously, TAA patients will require periodic imaging monitoring irrespective of treatment approach.

SIR appreciates the opportunity to provide this written statement in favor of endovascular repair of thoracic aneurysm and dissection. If you have any questions or require additional information, please contact Michael R. Mabry, SIR's Assistant Executive Director for Policy at (703) 460-5561 or mabry@sirweb.org.

Sincerely,

Janette D. Durham, MD, MBA
President

Cc: Michael Treitel, CMS
Meredith Walz, CMS
Peter Lauer, CAE, SIR

Citations

1. http://www.cdc.gov/nchs/data/statab/mortfinal2001_workI.pdf
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3. Dake, MD Transluminal placement of endovascular stent-grafts for the treatment of descending thoracic aortic aneurysms.
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4. Gowda RM, Misra D, Tranbaugh RF, Ohki T, Khan IA. Endovascular stent grafting of descending thoracic aortic aneurysms. Chest. 2003 Aug; 124(2):714-9. Review.
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6. Makaroun MS, Dillavou ED, Kee ST, Sicard G, Chaikof E, Bavaria J, Williams D, Cambria RP, Mitchell RS. Endovascular treatment of thoracic aortic aneurysms: Results of the phase II multicenter trial of the GORE TAG thoracic endoprosthesis. J Vasc Surg. 2005 Jan; 41(1):1-9.
7. http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4085T1.htm

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JUN 24 2005

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BY:.....

June 22, 2005

Centers for Medicare and Medicaid Services
Attention: CMS- 1500-P
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington DC 20201

RE: CMS-1500-P, Medicare Program

To Whom It May Concern:

On behalf of Peach Regional Medical Center, a Critical Access Hospital (CAH) located in Fort Valley, Georgia, we appreciate the opportunity to submit comments on the proposed rules.

250 yard rule

My major concern involves the state's authority to grant "necessary provider status" to hospitals. I understand that this authority will expire January 1, 2006. However there is a provision which allows any CAH that is designated as a "necessary provider" in its state's rural health plan prior to January 1, 2006 to maintain that designation. However CMS' proposed rule would prevent CAH's with the necessary provider designation from rebuilding more than 250 yards from their current location.

While our hospital has been deemed a "necessary provider" by the state effective 2001, we are in the process of planning for a replacement facility. We have obtained an option to purchase some land for a replacement hospital. I have recently encountered some issues that must be taken into consideration. Please read below.

601 Blue Bird Boulevard • P.O. Box 1799 • Fort Valley, GA 31030 478/825-8691

Given that most Critical Access Hospitals have aging and ailing plants (our hospital is 51 years old), it is essential that CAH's retain the ability to build replacement hospitals now and in the future. And it is also imperative that CAH's and their communities retain some amount of autonomy in determining where the replacement facilities will be located. Communities change drastically with the passing years and a hospital once located in the growth areas of the county may now (50 years later) find themselves located in a part of the county that is some distance from the concentration of the county's population where there is little industry, poor roads, etc. Again CAH's and their communities must retain some autonomy in deciding where to relocate their replacement hospitals.

Another point that must be considered is that of available infrastructure. CAH's are often located in smaller, poorer counties that do not have the necessary infrastructure in place to support their replacement hospital. For instance, sewer and waste water lines may not be run and may not be available due to costs issues. This will also dictate where replacement hospitals can be built.

Geography alone will also dictate where sites may be available. CAH's do not have an abundance of cash on hand in most cases. So it stands to reason that any additional costs need for site preparations are prohibitive to the CAH. Again, CAH's and their communities must retain some autonomy in deciding where to locate their replacement hospitals.

I urge CMS to rescind this overly restrictive policy and allow necessary provider CAH's to relocate as needed to improve the care of and meet the needs of their communities.

Necessary Provider Status Relocations

CMS has proposed a rule that a CAH, that moves beyond the 250 yards, must have purchased the land before December 8, 2003 OR the hospital must then prove that the replacement hospital was "under development" as of December 8, 2003.

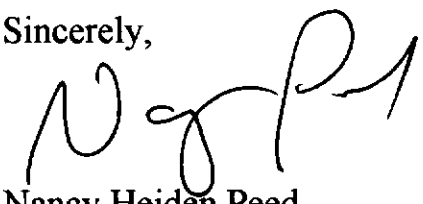
Again, I am in the process of building a replacement hospital. We certainly have been planning for this since before December 8, 2003, however this is a huge endeavor for a CAH, and the process takes time. There are demographic studies to complete, review and analyze. Debt capacity studies must be completed. Budgets must be prepared and funding must be

obtained. All of these things must be done BEFORE land is optioned with appropriate zoning, architectural plans are drawn, bids for construction are accepted or funding is secured.

I believe the date restrictions as proposed by CMS are unreasonable. I ask that CMS revisit this issue and design a process that allows for replacement hospitals for the CAH's.

I sincerely appreciate the opportunity to submit these comments on the proposed PPS rule for FY 2006. If you have any questions, please call me at 478.825.8691.151.

Sincerely,



Nancy Heiden Peed
Chief Executive Officer

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Federation of American Hospitals

June 24, 2005

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS Proposed Rule with Comment Period, Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates, Federal Register (May 4, 2005):

Dear Dr. McClellan:

The Federation of American Hospitals ("FAH") is the national representative of privately owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay and long-term care hospitals in urban and rural America, and provide a wide range of ambulatory, acute and post-acute services. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed rule ("NPRM") regarding changes to the hospital inpatient prospective payment system and fiscal year ("FY") 2006 rates. Attached as Exhibit A to this letter, FAH has set forth a list of all major issues commented upon in this letter (and the corresponding page number where discussion of each issue begins).[1]

[1] Please note that FAH has made every effort to follow the numbering system utilized for presenting the NPRM in the May 4, 2005 Federal Register. Therefore, in several cases where no comments are being submitted in response to specific sections of the NPRM, the section numbering of these comments will not be consecutive.

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Part II of the NPRM

B - DRG Reclassifications

1. General

The FAH has no comment with regard to the General section.

2. Pre-MDC: Intestinal Transplantation

The FAH agrees with not pursuing further DRG modification for intestinal transplantation at this time, based on the data provided in the proposed rule.

3. MDC 1 (Diseases and Disorders of the Nervous System)

a. Strokes

The FAH strongly supports the proposed modifications for tissue plasminogen activator ("tPA") administration for severe stroke patients based on the higher than average charges associated with this patient population. Regardless of the number of patients represented in MedPAR, CMS previously has made DRG reclassifications when appropriate, regardless of volume. For example, one topic readdressed for FY 2006, Intestinal Transplantation, was reclassified in FY 2005 based on a review of five cases from the previous fiscal year. This year's proposed rule indicates, based on the most recent MedPAR data, that this procedure affected only four patients for the entire fiscal year. Thus, CMS should make modifications to the stroke DRGs to reflect the higher costs associated with tPA.

In response to CMS's comments regarding the potential underreporting of tPA administration based on the absence of DRG impact, the FAH and its members are advocates of complete, accurate and consistent coding. We will continue to strive for this level of excellence as the industry prepares to see an increased use of high cost new technologies and pharmaceuticals that can impact patient care and associated resources.

b. Unruptured Cerebral Aneurysms

The FAH agrees with CMS's proposal based on the minimal difference in charges within the affected DRGs.

4. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Automatic Implantable Cardioverter/Defibrillator

On page 23317 of NPRM, CMS provides an analysis showing the three ICD DRGs with and without hospital procedure code 37.26. The analysis of procedure code 37.26 contains three separate procedures, of varying intensity; electrophysiology study, intraoperative device interrogation and non-invasive

programmed stimulation. The inclusion of these three procedures with varying intensity does not allow for the necessary analysis from a resource utilization perspective. Until the coding issue is addressed, the real impact on payment can not be determined.

FAH respectfully requests that CMS withdraw the proposed ICD DRG revision to provide the opportunity for the necessary ICD-9-CM procedure codes to occur. Based on the current coding guidelines, code 37.26 is not being reported at the time of initial device insertion or replacement. Although we have concerns with this guidance, the guideline does provide the opportunity to resolve this issue prior to any actual reclassification of the applicable DRGs.

b. Coronary Artery Stents

The FAH agrees with the new ICD-9-CM codes for vessels and number of stents used for treatment. However the FAH would like to see appropriate reimbursement beginning in FY 2006 consistent with the additional expense for multiple stents. Based on data from one of our member organizations, an average of 1.5 stents are used per patient.

The FAH also agrees with the proposed complications/co-morbidities (CC) revisions for DRG 516 and 526 to capture the additional expense for treatment of common and resource intensive cardiovascular and cerebrovascular CCs.

c. Insertion of Left Atrial Appendage Device

The FAH agrees with moving left atrial appendage device procedures out of DRG 108 and into DRG 518 based on significantly lower average charges and length of stay as compared to the majority of cases within the current classification.

d. External Heart Assist System Implant

The FAH agrees with CMS's decision not to make any changes to DRGs 103 or 525 at this time, based on the data provided with the proposed rule.

e. Carotid Artery Stent

The FAH agrees with this proposal.

f. Extracorporeal Membrane Oxygenation (ECMO)

The FAH agrees with reassigning ECMO cases to DRG 541, with a revised DRG title of "ECMO or Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis except Face, Mouth and Neck Diagnoses with Major O.R." Based on the data provided with the proposed rule, the average ECMO charges are more closely aligned with average charges and length of stay within DRG 541.

5. MDC 6 (Diseases and Disorders of the Digestive System): Artificial Anal Sphincter

The FAH agrees with the proposal. However, we encourage CMS to continue to monitor procedure codes 49.75 and 49.76 and the DRG codes to which they are assigned.

6. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Hip and Knee Replacements

The FAH agrees with the proposal to reclassify initial joint replacement procedures and joint revisions within separate DRGs. There is increased resource intensity for joint revision procedures versus initial replacements. This is supported by the data in the proposed rule, which reveals that the average joint revision charges are $7,000 higher than original joint replacements.

b. Kyphoplasty

The FAH agrees that the topic should be readdressed when charge data is available to analyze this specific procedure.

c. Multiple Level Spinal Fusion

The FAH notes an error in the proposed rule for multiple spinal fusion codes. The proposed rule includes DRG revisions for principal diagnosis assignment for curvature of the spine and malignancies. Specifically, the list of principal diagnoses includes curvature of the spine conditions, codes 737.41 - 737.43. These codes cannot be used as a principal diagnosis because the codes represent curvatures of the spine associated with other conditions. Pursuant to current coding guidelines, the other conditions must be coded first. As a result, none of these codes should ever be coded as a principal diagnosis. Also, code 732.8 for adult osteochrondrosis was not on the list of included codes.

7. MDC 8 (Infectious and Parasitic Diseases (Systemic or Unspecified Sites)): Severe Sepsis

The FAH strongly requests reconsideration of changes to the current sepsis classification. Although CMS states that the current definition of severe sepsis is not specific enough at this time in terms of "clinical coherence or resource utilization" to warrant any changes, changes to the coding guidelines are already impacting the provider community. Specifically, coding guidelines have been revised based on clinical definitions, which in turn affected the DRG classification for sepsis. In many instances these DRGs are insufficient for the hospital resources provided.

The FAH recommends a recalibration of DRGs impacted by severe sepsis with respiratory failure when a patient is placed on mechanical ventilation. This proposal

is based upon the resources consumed when a patient is maintained on mechanical ventilation for respiratory failure when the patient also has severe sepsis. According to the ICD-9-CM Code Book tabular and 4Q 2003 Coding Clinic pp 79-81, "*For patients with severe sepsis, the code for the systemic infection (038.x) or trauma should be sequenced first, followed by either code 995.92, Systemic inflammatory response syndrome due to infectious process with organ dysfunction, or code 995.94, Systemic inflammatory response syndrome due to noninfectious process with organ dysfunction. Codes for the specific organ dysfunction should also be assigned.*" As a result of this coding guideline, respiratory failure cannot be sequenced as the principal diagnosis because it is considered an organ dysfunction of the patient's sepsis. The resources consumed for a patient with severe sepsis who is placed on mechanical ventilation are significantly higher than a patient with severe sepsis who is not placed on mechanical ventilation. There is currently no DRG for sepsis that identifies the increased utilization of mechanical ventilation to appropriately represent the resources expended for these patients.

The FAH recommends changes to DRG 416 and/or 475 based upon the impact of this coding advice. We recommend a DRG reclassification of severe sepsis with mechanical ventilation within DRG 475 with a revised title to read "Respiratory System Diagnosis or Severe Sepsis with Ventilator Support". Another option would be to create a new DRG for "Severe Sepsis with Mechanical Ventilation" with the appropriate reimbursement assigned to this DRG for resources consumed when a patient with severe sepsis is maintained on mechanical ventilation for organ dysfunction of respiratory failure.

8. MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders): Drug-Induced Dementia

The FAH is concerned by CMS's reluctance to reclassify drug-induced dementia into more appropriate DRGs. If a patient is admitted with dementia due to an adverse effect of a drug, code 292.82, drug-induced would be coded as the principal diagnosis and the E code for the specific drug would be coded as a secondary diagnosis, grouping this patient into one of the alcohol and drug abuse DRGs (521-523). The adverse effect of a drug should not be considered alcohol or drug abuse. We recommend that CMS evaluate all implications of not reclassifying this condition, from both a patient and payer perspective. We recommend further review of this issue and subsequent classification to more appropriate DRGs.

9. Medicare Code Editor (MCE) Changes

The FAH requests CMS to reconsider making the necessary ongoing revisions to the Newborn Age Edit and other pediatric data. CMS states that the issue will not be addressed because CMS does not have the level of expertise to develop pediatric edits. If CMS intends to keep edits such as this in place, the agency is obligated to maintain and update these edits as is necessary. If CMS continues its current stance, this edit should be removed from the Medicare Code Editor.

10. Surgical Hierarchies

The FAH agrees with the proposed changes based on the data provided.

11. "CC List"

a. Background

The FAH has no comments on this background discussion of the complications and comorbidity list.

b. Comprehensive Review of the CC List

The FAH recognizes that CMS is considering utilizing costs instead of charges to determine whether a diagnosis is considered a CC. Although we cannot predict on a diagnosis by diagnosis basis how this would affect the hospital industry, we can determine the average difference in cost by the 121 DRG pairs. Until we have further indication from CMS on this proposal, we cannot make an accurate prediction of overall impact.

The FAH strongly recommends the development of a task force/technical committee to help with future revisions to the CC List. Currently, there is a variance between the number of codes submitted by hospitals via the electronic claim submission process and the number of codes processed by CMS. It is impossible to properly refine the CC list using MedPAR data due to this restriction. The FAH agrees that revisions are needed, but this should be done through a formalized open-door task force represented by experts from both the clinical and financial spectrum. As part of this taskforce, the FAH also suggests analyzing cases where multiple CCs are present for purposes of determining the need for a refined DRG system.

c. CC Exclusion List for FY 2006

The FAH agrees with the revised CC Exclusion List based on the information provided.

12. Review of Procedure Codes in DRGs 468, 476, and 477

a. Moving Procedure Codes from DRG 468 or DRG 477 to MDCs

The FAH has no comment with regard to this sub-topic.

b. Reassignment of Procedures among DRGs 468, 476 and 477

The FAH agrees that no modifications for FY 2006 are necessary based on the information provided.

c. Adding Diagnosis or Procedure Codes to MDCs

The FAH has no comment with regard to this sub-topic.

13. Changes to the ICD-9 Coding System

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

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in the committee language for the MMA, recommended that the secretary of Health and Human Services (HHS) undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology as required under the 2000 Benefits Improvement and Protection Act.

To date, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. We believe that without a change to ICD-10 soon, there could quickly be a significant data crisis in the U.S. This coding crisis will affect the efficiency of the current coding process, adding significant operational costs. Additionally, failure to recognize this looming problem will only impede the efforts to achieve the benefits of the President's goal of assuring the use of electronic health records by 2014. The FAH therefore urges speedy adoption of ICD-10 upgrades.

14. Other Issues: Acute Intermittent Porphyria

The FAH agrees with CMS's proposal not to modify for this metabolic disorder at this time, based on the minimal difference in average charges and length of stay.

C - DRG Weights

The FAH believes using length of stay and charges as an alternative method for determining if a new complication/co-morbidity (CC) methodology is consistent with general DRG methodology. However a comparison or a change to a system such as AP-DRGs or APR-DRGs would provide a severity measure and would have to be further analyzed based on the CMS proposed rule.

D - LTC-DRGS

- **Proposed FY 2006 IPPS Rule Changes**

In its May 4, 2005 proposed IPPS rule, CMS proposes various updated LTC-DRG reclassifications and relative weights for LTCHs for FY 2006. These changes include recalibration of LTCH PPS DRGs and changes in LTC-DRG classifications, in accordance with Section 123 of Public Law 106-113 and LTCH PPS regulations at 42 C.F.R. §§ 412.500, *et seq.* CMS proposes to use the IPPS GROUPER Version 23.0 for FY 2006 to process LTCH PPS claims occurring from October 1, 2005 through

September 30, 2006. The updated GROUPER Version 23.0 includes LTC-DRGs that correspond to the DRGs under the IPPS or acute care hospitals.

In assessing the impact of the proposed LTC-DRG reclassifications and relative weights for LTCHs based on the proposed Version 23.0 of the CMS GROUPER, CMS estimates that the proposed changes will result in a decrease in aggregate LTCH payments of approximately 4.7%, when compared to the previous Version 22.0 of the CMS GROUPER applicable to FY 2005. Based on the explanations provided by CMS for this decrease in overall LTCH payments of approximately 4.6% to 4.7%, FAH believes that the LTCH PPS program is out of compliance with the Congressional mandate that the LTCH PPS maintain budget neutrality with respect to LTC-DRG relative weights.

- **Summary**

The FAH believes that the currently proposed aggregate decrease in LTCH payments of approximately 4.7% is inconsistent with the statutory mandate that LTCH PPS DRG relative weights be recalibrated in a budget neutral manner. The current proposed rule departs from the statutorily mandated principle of budget neutrality in that the LTC-DRG recalibrations and revisions fail to take into account the same budget neutrality factors that are annually taken into account for the underlying inpatient hospital PPS DRGs on which the LTCH PPS DRGs are based and with which such LTCH PPS DRGs are inextricably linked. Given the common statutory language and ancestry of the LTCH PPS and IPPS programs, and the lack of any distinguishing language in the legislative histories of the two programs, the FAH believes that CMS is required to follow the same principles of budget neutrality when recalibrating and revising LTCH PPS DRGs as when CMS is recalibrating and revising the IPPS DRGs on which the LTCH PPS DRGs are based.

- **Rationale for Proposed Changes**

CMS indicates in the proposed FY 2006 IPPS rule that one reason for the decrease in overall LTCH payments is that "[w]hen we compared the version 22 (FY 2005) LTC-DRG relative weights to the proposed version 23 (FY 2006) LTC-DRG relative weights, we found that approximately 72 percent of the LTC-DRGs had higher relative weights under version 22 in comparison to the proposed version 23. We also found that the version 22 LTC-DRG relative weights were, on average, approximately 16 percent higher than the proposed version 23 LTC-DRG relative weights." *See* 70 Fed. Reg. at 23667.

In addition, CMS observed that based on an analysis of the most recent available LTCH claims data from the FY 2004 MedPAR file: "the proposed average LTC-DRG relative weight decreases [are] due to an increase of relatively lower charge cases being assigned to LTC-DRGs with higher relative weights in the prior year. Contributing to this increase in these relatively lower charge cases being assigned to LTC-DRGs with higher relative weights in the prior year are improvements in coding practices, which are typically found when moving from a reasonable cost based payment system to a PPS.

The impact of including cases with relatively lower charges into LTC-DRGs that had a relatively higher relative weight in the version 22.0 (FY 2005) GROUPER is a decrease in the average relative weight for those LTC-DRGs in the proposed GROUPER version 23.0." *Id.*

A failure by CMS to address these reasons for decreasing LTCH payments resulting from lower relative DRG rates is inconsistent with the existing statutory and regulatory requirements mandating LTC-DRG reweighting budget neutrality.

- **Proposed LTC-DRG Reclassifications and Relative Weights for LTCHs for FY 2006 Are Out of Compliance With Statutory Requirements that the LTCH PPS Maintain Budget Neutrality**

When Congress first proposed an LTCH PPS, Congress stated:

> "The Secretary –
>
> (B) Shall consider several payment methodologies, including the feasibility of expanding the current diagnosis related groups and Prospective Payment System established under Section 1886(d) of the Social Security Act to apply to payments under the Medicare program to long term care hospitals."

Section 4422(a)(2) of Balanced Budget Act of 1997, Public Law No. 105-33.

Two years later, Congress stated:

> "(a) The Secretary of Health and Human Services shall develop a per discharge Prospective Payment System for payment for inpatient hospital services of long term care hospitals described in Section 1886(d)(1)(B)(iv) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B)(iv)) under the Medicare program. Such system shall include an adequate patient classification system that is based on diagnosis related groups (DRGs) and that reflects the differences in patient resource use and cost, and shall maintain budget neutrality."

Section 123(a), Public Law No. 106-113 (November 29, 1999).

Congress then further mandated that the Secretary provide, beginning with cost reporting periods on or after October 1, 2002, "for payments for inpatient hospital services furnished by long term care hospitals under Title XVIII of the Social Security Act (42 U.S.C. § 1395 *et seq.*) in accordance with the system described in Subsection (a)." *Id.*, at Section 123(c). Based on Section 123 of Public Law No. 106-113, and as with IPPS-DRGs, Congress very clearly required that an LTCH PPS system be based on

DRGs that reflect differences in patient resource uses and costs, and maintain budget neutrality.

A year later, Congress modified certain aspects of its mandate for an LTCH PPS, but importantly, did not modify its requirement that LTCH PPS DRGs be maintained in a budget neutral fashion. In pertinent part, Congress stated:

> "In developing the Prospective Payment Systems for payment for inpatient hospital services provided in long term care hospitals . . . the Secretary of Health and Human Services shall examine the feasibility and the impact of basing payment under such a system on the use of existing (or refined) hospital diagnosis-related groups (DRGs) that have been modified to account for different resource use of long term care hospital patients as well as the use of the most recently available hospital discharge data. The Secretary shall examine and may provide for appropriate adjustments to the long term hospital payment system, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment . . ."

Section 307(b) of Benefits Improvement and Protection Act of 2000, Public Law No. 106-554.

Moreover, Congress stated that if the Secretary was unable to implement an LTCH PPS under Section 123 of the BBRA by October 1, 2002, the Secretary was authorized to implement an LTCH PPS, basing payment under such a system, while using existing inpatient hospital DRGs, modified where necessary to account for the different resources used by long term care hospital patients. *See*, Section 307(b)(2) of BIPS, Public Law No. 106-554.

In this statement of Congressional intent, no change was made to the requirement established earlier that the LTCH PPS DRGs be maintained in a budget neutral fashion. Moreover, the Secretary was authorized to provide for appropriate adjustments to the long term hospital payment system which historically had been associated with the inpatient PPS system, including adjustments to DRG weights, area wage adjustments, geographic reclassification, etc., and which were required to be treated as budget neutral items for purposes of the acute hospital IPPS.

In the August 11, 2004 IPPS final rule for FY 2005, CMS stated, in pertinent part:

> ". . . Section 123 of Public Law No. 106-113 requires that the LTCH PPS, among other things, shall include an adequate patient classification system that is based on DRGs and that reflects the differences in patient resources and costs, and shall maintain budget neutrality.

69 Fed. Reg. at 48999 (Aug. 11, 2004).

CMS has similarly for many years been applying a similar budget neutrality adjustment factor to the IPPS standardized amount, pursuant to Social Security Act Section 1886(d)(4)(C)(iii). In particular, CMS has been applying such budget neutrality adjustment factor on an annual basis to ensure that the proposed DRG recalibration and wage index updates and changes are budget neutral. For example, with respect to FYE 2005, CMS stated: "Budget neutrality is determined by comparing aggregate IPPS payments before and after making the changes that are required to be budget neutral. For example, reclassifying and recalibrating the DRGs, updating the wage data, and geographic reclassifications." *See* 69 Fed. Reg. at 28374 (May 18, 2004).

The governing statute referred to by CMS in its annual proposed IPPS rules states that:

> "(A) The Secretary shall establish a classification of inpatient hospital discharges by diagnosis related groups and a methodology for classifying specific hospital discharges within these groups. . . .
>
> (B) For each such diagnosis related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups.
>
> (C)(i) The Secretary shall adjust the classifications and weighting factors established under Subparagraphs (A) and (B), for discharges in fiscal year 1988 and at least annually thereafter, to reflect changes in treatment patterns, technology . . . and other factors which may change the relative use of hospital resources. . .
>
> > (iii) Any such adjustment under clause (i) for discharges in a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection for discharges in the fiscal year are not greater or less than those that would have been made for discharges in the year without such adjustment...."

Social Security Act Section 1886(d)(4).

Although the statutory provision cited above applies specifically to hospitals covered under the IPPS, the principles espoused by Congress in crafting this language

were and are no different than the principles espoused by Congress in mandating that the Secretary of Health and Human Services establish an LTCH PPS. Indeed, given the dearth of other Congressional guidance in the form of codified statutes for LTCH PPS, one can only logically assume that Congress intended the Secretary to establish LTCH PPS on a budget neutral basis going forward in the same vein as was established for the acute hospital IPPS.

CMS, itself, has recognized in a final IPPS rule that the DRGs used under IPPS for acute care hospitals and the patient classification system utilized under LTCH PPS are closely linked:

> ". . . Since the patient classification system utilized under the LTCH PPS is based directly on the DRGs used under the IPPS for acute care hospitals, in that same final rule, we explained that the annual update of the long term care diagnosis related group (LTC-DRG) classifications and relative weights will continue to remain linked to the annual reclassification and recalibration of the [acute] DRGs under the IPPS." [Emphasis added.]

68 Fed. Reg. at 45374 (Aug. 1, 2003).

Immediately thereafter, CMS indicated that even though the LTCH PPS annual payment rate update cycle would be changed from July 1 through June 30, instead of October 1 through September 30, since LTCH DRGs are so closely based on IPPS DRG updates, LTCH DRGs and LTC-DRG classifications and relative weights will continue to be effective for discharges occurring on or after October 1 through September 30 each year. Furthermore, only one paragraph later, CMS again recognizes that:

> "Section 123 of Public Law 106-113 specifically requires that the PPS for LTCHs be a per discharge system with a DRG based patient classification system reflecting the differences in patient resources and costs in LTCHs while maintaining budget neutrality."

Id.

The statutes mandating LTCH PPS and acute hospital IPPS, respectively, each require there to be a per discharge system with a DRG based patient classification system reflecting the differences in patients' use of resources and relative costs, while maintaining budget neutrality. *See* Social Security Act Section 1886(d)(4) and Section 123 of Public Law 106-113. No matter how hard one tries, one cannot differentiate the letter and spirit of the IPPS governing statute from the language of Section 123 of Public Law 106-113 requiring LTCH PPS to be a per discharge system, while maintaining budget neutrality.

CMS has also explained in discussing the general overview of development of the LTC-DRG relative weights in August 2003 that it would "adjust the LTCH PPS standard federal Prospective Payment System rate by the LTC-DRG relative weights in determining payment to LTCHs for each case. . . ." 68 Fed. Reg. at 45375 (Aug. 1, 2003). CMS then reiterated that a relative weight for each LTC-DRG represents the resources needed by an average inpatient LTCH case in that LTC-DRG. Such a characterization is no different than the explanation Congress included in Section (d)(4) of Social Security Act Section 1886, the statute governing IPPS. In other words, there is no statutory or other logical basis for applying budget neutrality principles to DRG recalibrations under acute hospital IPPS, but not doing so under the LTCH PPS.

- **CMS should implement a "dampening" policy to mitigate the impact of wide swings in LTC-DRG relative weights during the LTCH PPS transition period**

The proposed reductions in LTC-DRG relative weights have a significant impact on overall LTCH payments and individual LTCH facilities. Any significant fluctuation in payments, downward or upward, can be destabilizing for Medicare providers, particularly as they transition to a new payment system.

As a unique provider type, LTCHs do not see a broad spectrum of patients in their facilities with many different diagnoses. There are 550 LTC-DRGs which are based on a large set of DRGs used in the IPPS. Of these LTC-DRGs, 172 are categorized as low-volume for LTCHs and have less than 25 cases annually. Consequently, a much narrower group of only 378 LTC-DRGs and relative weights are employed on a regular basis compared to the IPPS. With this narrower set of LTC-DRGs, a majority of discharges can be concentrated in only those groups with declining weights. If the LTCHs do not have offsetting discharges in other LTC-DRGs with proposed weight increases, they will have difficulty balancing their current ability to specialize in certain unique care areas with future Medicare payment incentives.

The LTCH PPS, in its third year of implementation, is still in transition; the initial five-year phase-in will end in September 2006. During this time of transition, LTCH coding and data are still undergoing improvement. In fact, the December update of the 2004 MedPAR file used to establish the proposed weights only reflects the claims from the second year of the LTCH PPS. While coding practices are improving, we are concerned that the proposed LTC-DRG relative weights do not yet fully reflect the nature and type of services, staff, and other resources we provide for our patients. However, the FAH believes the dramatic reduction in over 70 percent of the LTC-DRG relative weights is reflective of transitional concerns and not a trend in LTCH patient case-mix. CMS has put significant efforts into smoothing the transition to the LTCH PPS, and the reductions in the LTC-DRG relative weights disrupt this transition.

The FAH therefore recommends that CMS implement an additional transitional adjustment to mitigate the impact of the reductions in LTC-DRG relative weights. The reduction in over 70 percent of LTC-DRG relative weights from FY2005 to proposed FY2006 has a substantial impact on the FAH's member LTCHs. We encourage the

Secretary to exercise his discretion to maintain a smooth transition to the LTCH PPS and establish a dampening policy for LTC-DRG relative weights similar to that employed with Ambulatory Payment Classifications (APCs) in the Outpatient Prospective Payment System (OPPS) (Federal Register Vol. 67, No. 212, pp. 66749-66750). We believe this adjustment to the relative weights would follow CMS' and Congress' intentions to smooth the transition to the LTCH PPS from cost-based reimbursement.

Under the dampening policy, all proposed FY2006 LTC-DRG relative weights with decreases or increases of 10 percent or more would be adjusted. The dampening policy would reduce the proposed change for those FY2006 LTC-DRG relative weights meeting this 10 percent threshold by one half of the difference between the FY2005 LTC-DRG relative weight and the FY2006 LTC-DRG relative weight. This would reduce wide swings in LTC-DRG relative weight value from year-to-year while LTCHs are implementing changes in response to the new payment system.

CMS established a similar policy for the OPPS during the first years of hospitals' transition to this prospective payment system. The dampening policy was created due to concerns during the early years of the OPPS about changes in pass-through payments for drugs and devices, miscoding, restructuring of APCs, and use of data from a period following implementation of the OPPS. We believe this last point is particularly germane to the LTCH PPS. As we stated previously, the December update of the 2004 MedPAR file represents only the second year of the LTCH PPS. For many LTCHs, many cost report years begin in September, consequently the 2004 MedPAR represents the first full year of data. As the transition matures and unfolds, more data will become available, and coding will improve; thereafter, we do not believe a dampening policy will be necessary.

A dampening policy would reduce the de-stabilizing effect of LTC-DRG relative weight changes of 10 percent of more for LTCHs. The policy would ensure that CMS' and Congress' previous commitments to a smooth LTCH PPS transition continue and LTCHs have the ability to maintain their current levels of high quality care to medically complex beneficiaries.

E – New Technology Applications

1. Background

   The FAH has no comment on the background discussion.

2. Public Input Before Publication of This Notice of Proposed Rulemaking on Add-On Payments

   The FAH has no comment on this subsection of the NPRM..

3. FY 2006 Status of New Technology Approved for FY 2005 Add-On Payment

   a. Infuse (Bone Morphogenetic Proteins (BMPs) for Spinal Fusions)-

The FAH agrees with CMS's proposal to discontinue the add-on payment in FY 2006 based on new technology guidelines.

b. InSync Defibrillator System (Cardiac Resynchronization Therapy With Defibrillation (CRT-D))

The FAH agrees with the CMS proposal to eliminate the add-on payment based on new technology guidelines. However, we ask that CMS evaluate cases involving this device prior to publishing the FY 2006 IPPS final rule to ensure that the average standardized charges for these cases are comparable to the current DRG classifications.

c. Kinetra Implantable Neurostimulator for Deep Brain Stimulation

The FAH supports the continuation of add-on payments for this new technology.

4. FY 2006 Applications for New Technology Add-On:

a. INFUSE Bone Graft (Bone Morphogenetic Proteins (BMPs) for Tibia Fractures):

The FAH agrees with CMS's intention to avoid extending add-on payments for similar technologies. However, standardized criteria are needed to properly evaluate if there are clinical differences in new technologies. For example, although a similar product was approved for the treatment of tibia fractures, the indication for that similar product was for non-union of a fracture. OP-1 Putty is indicated for use with acute fractures. Each of these indications represents separate diagnoses, and therefore separately affected payment. As a result, the cost of this new technology has not been realized within the applicable DRGs for acute fractures. FAH believes additional review of this new technology is warranted.

b. Aquadex System 100 Fluid Removal System:

The FAH agrees with this change based on new technology guidelines.

c. CHARITE Artificial Disc

The FAH is in support of this new technology if it provides a significant clinical benefit over existing technologies.

d. Endovascular Graft Repair of the Thoracic Aorta

The FAH is in support of new technology approval if it provides a significant clinical benefit over existing alternative technologies.

e. Restore Rechargeable Implantable Neurostimulator

The FAH is in support of new technology approval if it provides a significant clinical benefit over existing alternative technologies.

f. Safe-Cross Radio Frequency Total Occlusion Crossing System (Safe-Cross)

The FAH is in support of new technology approval if it provides a significant clinical benefit over existing alternative technologies.

g. Trident Ceramic Acetabular System

The FAH agrees with denying add-on payment based on new technology guidelines. However, we encourage CMS to consider incorporating this new technology within the current and future restructuring of joint replacement and revision DRGs.

h. Wingspan Stent System with Gateway PTA Balloon Catheter

The FAH agrees with CMS' proposal to reject new technology consideration at this time pending FDA approval.

Part III of the NPRM – Wage Index

B – CBSAs

The FAH agrees with CMS's previous decision to allow urban hospitals that became rural under the new definitions to maintain their assignment to the Metropolitan Statistical Area (MSA) where they were previously located for the three year period of FYs 2005, 2006 and 2007. The FAH has become aware of at least one situation where a new hospital is scheduled to open later this year in a geographic area that is now considered rural but was urban under the previous definitions. We recommend that the policy be clarified to allow a new hospital in an area that is now rural, but would have been urban under the prior classifications, to also benefit from the three year transition period that has been granted to existing hospitals. Such hospitals were planned with the expectation of higher Medicare payments based on an urban wage index and should be equally protected from the reduction in the wage index that affects existing hospitals in the same geographic areas. Such hospitals should be entitled to receive the benefit of the three year transition for the remainder of the three year period of FYs 2006 and 2007.

C - Occupational Mix Adjustment

The FAH has reviewed the table on page 23369 of the NPRM showing the Medicare Occupational Mix Survey Results. We note that there appears to be some data omitted from the table, specifically data pertaining to laboratory employees. We assume that this was an oversight on the part of CMS and request that the full set of data be published in the Final Rule.

More generally, the FAH continues to have serious concerns about the validity and reliability of the occupational mix data that CMS has collected. We believe that problems with the data are pervasive and cannot be rectified until a new survey is performed. As expressed in the FAH's comments on the FY 2005 Proposed IPPS Rule, dated July 12, 2004, we believe that the data is flawed due to the limited time for the survey and the lack of opportunity for CMS to review thoroughly. Specific areas of major concern with the data include the following:

a. Errors in the survey dates – It appears that over 8% of the providers have incorrect date fields in the survey.

b Significant variances in hours reported on worksheet S-3 of the cost report and the occupational mix survey – 56% of hospitals' total man-hours varied by greater than 10% and 32% varied by greater than 20%.

c. Employees appear to be inconsistently classified between hospitals. Specific areas of concern include Dietary Technicians, Medical Assistants, RNs, Pharmacists, Physical Therapists and Occupational Therapists.

d. Hospitals were allowed to complete the survey for a 4-week period during their peak season, which will not likely be representative of the hospitals' actual annual staffing mix. It appears that greater than 25% of hospitals used this option.

The FAH submitted a detailed explanation of its concerns about the occupational mix survey data as Exhibit C to its FY 2005 comments. For convenience, the FAH is resubmitting these comments, which remain pertinent, as Exhibit B to this letter. Although we certainly recognize that CMS is bound by statute to implement the occupational mix adjustment, we still believe that the administrative burden on providers and fiscal intermediaries, and the difficulties in obtaining accurate data, make the occupational mix adjustment undesirable. The FAH again urges CMS to approach Congress and seek a repeal of this requirement.

Considering the problems with the initial survey, our membership is very pleased that CMS intends to revise the occupational mix survey, improve the data collection process and collect a full year's data. We hope that CMS will, when developing the new survey, review the detailed comments that the FAH developed last year, attached hereto as Exhibit B, which include numerous suggestions for improvement. Significant among these suggestions are:

a. All of the definitions should be carefully reviewed to ensure that they are clear and precise.

b. Ideally, hospitals should have at least six months notice of the survey design prior to the start of the collection period.

c. A very thorough fiscal intermediary review process, with significant oversight by CMS, should be put into place. Considering the challenges in collecting accurate data, this review process should be more extensive than the review process currently used for wage index data.

D - Wage Data

CMS has proposed a significant change by requiring that, beginning with the FY 2007 wage index, hospitals and fiscal intermediaries must ensure that pension, post-retirement health benefits, and other deferred compensation plan costs for the wage index are developed in accordance with the provisions set forth in PRM - I, sections 2140, 2141 and 2142. This is a substantial change from past practice, wherein hospitals have been reporting pension costs in accordance with Generally Accepted Accounting Principles (GAAPs). As CMS has noted, the PRM instructions "combine GAAPs, Medicare payments principles, and other Federal labor requirements," but they actually modify and are not consistent with GAAP.

CMS has proposed this change without giving any rationale for this departure from prior practice. The FAH respectfully requests that CMS hold off in implementing this proposed change and, instead, publish the rationale for this change in policy. The FAH requests that providers be given an additional opportunity to comment on this issue, once CMS has made public its reasoning for the change.

F - Wage Index

The FAH notes that CMS has made a modification in the calculation of the wage index, without specifically pointing it out or giving any explanation. This change was made in step 4 of the Computation of the Proposed FY 2006 Unadjusted Wage Index on page 23373 of the proposed rule in the Federal Register. The change pertains to the calculation for Overhead Wage-Related Cost Allocation to Excluded Areas. This calculation is made up of three steps:

1. Determine the ratio of overhead hours to revised hours.

2. Compute overhead wage-related cost by multiplying the overhead hour's ratio from step 1 by wage-related costs.

3. Multiply the overhead wage-related costs by the excluded hour's ratio.

The change in the calculation occurred in step 1. For 2006, the calculation for revised hours was changed to subtract excluded areas (Lines 8 and 8.01). This change results in a higher ratio for step 1, which results in an increase in the overhead cost allocated to excluded areas. This change ultimately lowers the hospital's average hourly rate.

The FAH requests that CMS explain the basis for the change and how a proper allocation can be achieved using the formula set forth in the proposed rule. Providers

should be given a further chance to comment on this revision to the methodology before it is implemented.

We believe that this methodology revision will have a significant impact on the wage indexes for some hospitals. The change in the calculation has caused confusion among hospitals as to the correct wage index amounts. This confusion could lead hospitals to make bad decisions related to the withdrawal of wage index reclassifications. Accordingly, we request that CMS implement a policy similar to last year's and allow hospitals to withdraw or reinstate their geographic reclassification applications within 30 days of the date that the Final Rule is published. (See further discussion below under Out-Migration Adjustment.)

G - Blended Wage Index

The FAH fully supports CMS's proposal to continue to adjust only 10% of the wage index factor for occupational mix. For the reasons discussed above and in Exhibit B, the FAH shares CMS's concerns about the accuracy of the data, believes that the data collected in the original occupational mix survey is seriously flawed, and believes that the use of such data is resulting in a distortion to the wage index. We agree that the use of a transition period, until more accurate data can be collected, is an appropriate way to address the data problems. The FAH applauds CMS's decision to appeal the decision in *Bellevue Hospital Center v. Leavitt* and urges CMS to vigorously pursue that appeal as far as it pertains to the implementation of the occupational mix factor.

H - Hospital Redesignations and Reclassifications

Cancellation of Reclassification from Urban to Rural: Under current law, 42 U.S.C. § 1395ww(d)(8)(E), an urban hospital may submit an application to be treated as rural if it meets certain criteria. One of the criteria is that the hospital would qualify as a Sole Community Hospital (SCH) if it were treated as rural. The Secretary has promulgated a regulation at 42 C.F.R. § 412.103 to carry out this statutory mandate. Pursuant to § 412.103(f), such reclassifications remain in effect without need for re-approval unless there is a change in the circumstances under which the classification was approved. Further, pursuant to § 412.103(g), in order to cancel such a reclassification, a hospital must submit a written request to CMS not less than 120 days prior to the end of its current cost reporting period, and the cancellation of the reclassification to rural will become effective with the beginning of the hospital's next cost reporting period.

The FAH has become aware of situations where a hospital may lose its SCH status due to the growth of another hospital's inpatient services in its service area, but may not learn of this change, which depends on data from another hospital becoming available, until it is too late to submit a request to cancel its rural reclassification for the following fiscal year. This will result in not only the hospital losing the higher payments that result from SCH status, but also being paid under the lower rural wage index for an additional fiscal year until it can timely submit a request for cancellation of its rural reclassification. The FAH believes that § 412.103(f) is not clear on this point. While it states that the rural reclassification will remain in effect until there is a change in

circumstances, it is not clear whether the loss of SCH status will result in immediate termination of the reclassification contemporaneously with the effective date of the loss of SCH status, or whether a hospital in this situation would still be required to request cancellation of its rural reclassification 120 days prior to the beginning of its fiscal year, pursuant to § 412.103(g).

The FAH requests that CMS clarify this regulation to verify that a hospital reclassified pursuant to 42 U.S.C. § 1395ww(d)(8)(E) and losing its SCH status could immediately switch to its regular urban wage index. If that is not the intent of the current regulation, then the FAH requests that CMS modify the regulation accordingly. Further, because Medicare dependent hospitals must be classified as rural, any clarification or modification in regulations should address both SCHs and Medicare dependent hospitals. Since the provisions of the regulation regarding duration and cancellation of the rural reclassification are not mandated by the statute, CMS has the authority to make this change if it is necessary.

Expiration of Section 508 Reclassifications: Pursuant to Section 508 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173 (MMA), certain hospitals are entitled to reclassifications to areas with higher wage indexes for a three year period ending April 1, 2007. Based on CMS policy as the FAH understands it, a hospital that is entitled to a Section 508 reclassification would not be simultaneously entitled to a reclassification pursuant to 42 U.S.C. § 1395ww(d)(10).

The FAH believes that this may result in the unfair treatment of hospitals when the Section 508 reclassifications expire on April 1, 2007. We would like to clarify how CMS will treat Section 508 hospitals when its provisions expire. It is the FAH's understanding that Section 508 hospitals will revert to the wage index for the geographic area where they are located on April 1, 2007. The FAH seeks clarification as to whether such hospitals will be entitled to geographic reclassification pursuant to the provisions of Section (d)(10) for the remainder of FY 2007. Will the Medicare Geographic Classification Review Board deny the application of a hospital that applies for a Section (d)(10) reclassification for FY 2007 while still subject to a Section 508 reclassification? If so, such hospitals will be subject to a lower wage index than that to which they might otherwise be entitled for the remaining six months of FY 2007.

The FAH respectfully requests that, unless the provisions of Section 508 are extended by Congress, CMS allow Section 508 hospitals to apply for and be granted reclassification for FY 2007, assuming they meet the criteria, even though they may be subject to a Section 508 reclassification during the first half of FY 2007. Such hospitals should be permitted to be reclassified pursuant to Section (d)(10) effective April 1, 2007 when the provisions of Section 508 expire. Because the deadline for applying for Section (d)(10) reclassification for FY 2007 is September 1, 2005, CMS should clarify this in the Final Rule for FY 2006.

I – Out -Migration Adjustment

Hospitals that qualify for an out-migration adjustment and do not waive the application of the adjustment are not simultaneously entitled to reclassification pursuant to Sections 1886 (d)(8) or (d)(10). Because of significant changes to the wage index that took place in FY 2005, CMS allowed hospitals to withdraw or reinstate their geographic reclassification applications within 30 days of the publication of the FY 2005 Final Rule. By doing so, CMS acknowledged that changes made between the proposed and final rules could affect whether a hospital was better off accepting the out-migration adjustment or whether it would be more advantageous for a hospital to waive the out-migration adjustment and pursue geographic reclassification.

Although the changes to the wage index are not as extensive for FY 2006, the FAH believes there is still a likelihood that revisions made between the proposed and final rules may impact a hospital's choice of whether to accept the out-migration adjustment or whether to apply for geographic reclassification. Accordingly, we request that CMS implement a policy similar to last year's and allow hospitals to withdraw or reinstate their geographic reclassification applications within 30 days of the date that the Final Rule is published.

The FAH also notes that for FY 2006, the second year of the out-migration adjustment, CMS is applying adjustments that are identical in amount to the adjustments given to qualifying hospitals in FY 2005. It appears that hospitals will receive the same adjustment in each of the three years of eligibility for the out-migration adjustment. We do not believe that the governing statute, Section 505 of the MMA, requires that the adjustments be identical for all three years. The statute only requires that the adjustment be granted for a three year period.

The FAH believes that it is not logical or fair to freeze the amount of the adjustment for three years. Because of changes in the wage index each year, some hospitals will be receiving out-migration adjustments even though the wage index for their geographic area is now higher than the wage index for the county to which their residents are commuting. Likewise, there may be hospitals which would be entitled to a higher out-migration adjustment if it was recalculated based on the new wage indexes for FY 2006. The three year eligibility period for the out-migration adjustment is similar to the three year eligibility period for geographic reclassifications, but the wage indexes for the latter change each year despite the guaranteed three year reclassification. The FAH recommends that CMS revise its policy so that the out-migration adjustment will be recalculated each year based on updated wage data and the new wage indexes.

J - Wage Index Data Corrections

Contrary to its previous policy, CMS has proposed that wage index corrections could be effective retroactively under certain limited circumstances, i.e., situations involving an error by the fiscal intermediary or CMS that the hospital could not have known about before its review of the final wage index data file. The FAH agrees in part

with this proposal, because hospitals should not be forced to endure lower payments due to circumstances created by errors made by the fiscal intermediary or CMS.

We strongly recommend, however, that such retroactive adjustments should only be made in situations where the adjustments would result in higher wage indexes for the hospitals affected. Hospitals that have accepted payments and planned their finances based on what they believed to be correct DRG payments should not be penalized retroactively if CMS discovers errors that were made by it or by the fiscal intermediary that should have resulted in lower wage indexes for those hospitals. Likewise, when CMS makes positive adjustments retroactively as described in the proposed rule, there should be no concomitant retroactive reduction to other hospitals that originally would have had lower wage indexes if the error had not been made.

The FAH also supports CMS's proposal to correct the FY 2005 wage index retroactively in certain limited circumstances. According to the proposed rule, these retroactive corrections will be made in situations where (1) errors were made by CMS or the fiscal intermediary in tabulating the wage index data, (2) these errors were brought to the attention of CMS or the fiscal intermediary in the course of the established process for development of the FY 2005 wage data, and (3) CMS agreed by October 1, 2004 that these errors should be corrected but was unable to publish said corrections by the beginning of the federal fiscal year. While we support this proposal, the FAH disagrees that it should be limited to only four hospitals. There are other hospitals that were given entitlement to wage index corrections pursuant to the notice published in the December 30, 2004 Federal Register, and FAH believes that the other hospitals, whose wage indexes were improperly lowered due to no fault of the hospitals, should also be entitled to corrections retroactive to October 1, 2004.

Part IV of the NPRM

B- Rebasing and Revising the Hospital Market Basket

CMS is proposing to rebase the hospital inpatient market basket from FY 1997 to FY 2002 using FY 2002 Medicare cost report data as well as 1997 data from Bureau of Economic Analysis, U.S. Department of Commerce that has been aged to 2002. The estimated market basket increase for FY 2006 is 3.2 percent. Given that the actual market basket increase for FY 2005 is 4.1 percent (compared to the estimated increase of 3.3 percent contained in the final FY 2005 rule), we are concerned that CMS is again underestimating the market basket increase. This underestimation concern is underscored by the awareness that over the last eight fiscal years, CMS underestimated the market basket increase 7 times.

Accordingly, given the essential role that the market basket increase estimate has on the Medicare hospital inpatient rate update, we urge CMS to thoroughly review the methodology used to make this determination.

3. Labor-Related Share

Based on the proposed rebased and revised hospital inpatient market basket for FY 2006, as well as on related definitional changes noted in the FY 2003 IPPS NPRM, CMS is proposing to revise the labor-related share used to determine the proportion of the national PPS base payment rate to which the area wage index is applied. The change would be effective for cost reporting periods beginning on or after October 1, 2005.

Currently the labor-related share is 71.1 percent. CMS is proposing to reduce this proportion to 69.7 percent. While this proposed change will have no impact on hospitals with an area wage index of 1.0 or less, such a change will have a progressively adverse impact on hospitals with an area wage index of greater than 1.0. The impact will be proportional to the size of the area wage index (AWI) – the greater the AWI is above 1.0, the greater the adverse impact.

We note that in the FY 2003 IPPS NPRM, CMS proposed increasing the labor-related share from 71.1 percent to 72.5 percent. In the final FY 2003 IPPS rule, however, CMS indicated that it had decided not to proceed with the proposed change. CMS did not provide an explicit reason. CMS did note its concern with the adverse impact such a change would have on rural hospitals. It also noted that it planned to conduct additional research. At the time, CMS simply said that it would conduct further analysis to determine the most appropriate methodology before proceeding.

Now, CMS is again proposing a change in the labor-related share – this time a decrease, which will obviously not adversely impact rural hospitals. Yet, CMS still has not developed a more appropriate methodology, despite having conducted additional research. Instead, CMS proposes to use the same methodology it has used in the past, notwithstanding its statement in the FY 2003 IPPS final rule, that it "would conduct further analysis to determine the most appropriate methodology before proceeding."

Our question is, what has changed that would now make this old methodology an "appropriate methodology" when in 2002 it was implicitly deemed to be an inappropriate methodology?

We urge CMS to again withdraw the proposed change in the labor-related share until "the most appropriate methodology" is revealed.

Part V of the NPRM

A - Postacute Care Transfers

Thirty (30) DRGs are currently included in the Postacute Care Transfer Policy. Under the current criteria for the Postacute Care Transfer Policy, the minimum number of postacute care cases within any particular DRG must equal or exceed 14,000. In addition, at least 10% of a hospital's postacute transfers within a particular DRG must occur before the geometric mean length of stay, and the geometric mean length of stay within any particular DRG must equal or exceed three (3) days. Furthermore, if a DRG is not already included in the policy, a decline in its geometric mean length of stay during the most recent five-year period must equal at least 7%.

In its FY 2005 proposed IPPS rule, CMS proposed relatively modest changes to these criteria to assure that a handful of DRGs covered by the Postacute Care Transfer Policy continued to qualify for treatment under the policy. CMS, after receiving comments on these proposed changes, rejected the proposed changes to the criteria, and instead instituted a very modest "grandfathering" policy to retain these few DRGs within the transfer policy.

For FY 2006, CMS is now proposing a significant expansion of the Postacute Care Transfer Policy that is inconsistent with statutory directive, unnecessary, unwarranted and contrary to patients' and hospitals' best interests.

CMS has now proposed:

- Lowering the minimum number of postacute care transfer cases to qualify for treatment under the Postacute Care Transfer Policy from 14,000 to 2,000 (a reduction of over 85%).

- Requiring that only 20% of all cases within a DRG be referred to postacute care settings.

- Continuing to require that 10% of all discharges within a DRG to postacute care must be prior to the geometric length of stay for the DRG.

In addition, the current policies of (1) requiring at least a three day geometric mean length of stay, and (2) requiring any "paired set" of DRGs (based on the presence or absence of comorbidities) both be included under the Postacute Care Transfer Policy if either one qualifies under the other criteria, are being retained.

The FAH strongly opposes the proposed change to the Postacute Care Transfer Policy, including the restatement of the criteria for qualifying DRGs under the policy, as well as the expansion of the policy from approximately thirty (30) DRGs to 231 DRGs (as indicated on CMS's web site in a Table posted subsequent to the publication of the proposed rule, which indicated that 223 DRGs would be subject to the policy). Simply stated, the changes that CMS is now proposing to make completely disrupts, if not destroys, the entire premise of the original rule, and bears no relation to the substance of the directive given to the Secretary of Health and Human Services by Congress when it authorized a Postacute Care Transfer Policy. Basically, what CMS has now proposed is to include all DRGs under the policy that are somehow not disqualified under the most lenient qualifying criteria possible.

The FAH opposes this proposed expansion to the Postacute Care Transfer Policy, as well as the restatement of the qualifying criteria for that policy, for the following reasons:

- **The proposed changes to the qualifying criteria are inconsistent with the governing statute.**

The Postacute Care Transfer Policy initially implemented by the Secretary of Health and Human Services was authorized pursuant to Social Security Act section 1886(d)(5)(J). The governing standard for selecting DRGs for inclusion under the policy (initially for ten DRGs, and later authorized to consist of an expanded number) stated that the Secretary could select diagnosis related groups "based upon a high volume of discharges classified within such groups and a disproportionate use of post discharge services described [elsewhere in the statute]." 42 U.S.C. § 1395ww(d)(5)(J)(iii)(I). When CMS implemented the Postacute Care Transfer Policy several years ago, it defined "high volume" DRGs as having at least 14,000 postacute care discharges within a DRG. Presumably, Congress agreed with CMS' selection of the 14,000 case level as being "high volume" since Congress has not altered its statutory directive regarding "high volume" DRGs since that time, even though Congress has since amended its directive. Also presumably, CMS had reasons for selecting the 14,000 postacute care discharge level as an indication of a "high volume" DRG. The FAH understands that this number could have been pegged slightly higher or slightly lower and still met whatever criteria CMS was using to define "high volume" DRGs, but suddenly reducing the definition of "high volume" DRGs from an annual postacute care discharge level of 14,000, to a discharge level of 2,000, cannot possibly, under any definition, continue to meet Congress's intent in authorizing the Secretary to select "high volume" DRGs for coverage under the Postacute Care Transfer Policy. The reduction from 14,000 cases to 2,000 cases represents a reduction of over 85% in the number of discharges to postacute are settings required to qualify a DRG under the policy.

Moreover, given that there are far more than 2,000 hospitals in the United States, CMS is apparently adopting a definition of "high volume" to mean that any given hospital could warrant as little as one discharge to postacute care within a particular DRG, in a given one or two-year period, yet that discharge would still be covered under this policy. Looking at the nation as a whole, under any standard, 2,000 postacute care discharges within a DRG is not the type of "high volume" that Congress authorized the Secretary to address.

Likewise, Congress authorized the Secretary to include only those DRGs that evidenced a "disproportionate use of post discharge services." Yet, CMS is now proposing to establish a criterion whereby if 20% of discharges within a DRG are discharged to a qualifying postacute care setting, any postacute care discharge within that DRG will be treated as a "transfer" and not a discharge, at tremendous potential economic disadvantage to the "transferring" hospital. The proposed rule provides no rationale, calculation or basis for determining that 20% of discharges within a DRG to postacute care settings constitutes a "disproportionate use" of postacute care settings. Indeed, the 20% level appears arbitrary, given that CMS has identified the range of postacute care setting utilization for DRGs that presently qualify under the Postacute Care Transfer Policy as ranging from a low of 15% to a high of 76%. Given that many of the percentages at issue range above 35%, 40% or even 50%, to suggest that 20% of discharges within a DRG constitutes a disproportionate use of postacute care settings without any real explanation or context is unsupported and wholly arbitrary.

To place the issue into more of a realistic context, the FAH also posits that if the 20% disproportionate use standard and 2,000 "high volume" case standards are adopted, the "average" hospital in the United States could treat five (or fewer) patients over five years within a particular DRG, discharge on average only one of those patients to a postacute care setting, and all admissions nationwide within that DRG would be placed at risk of greatly reduced payment under the Postacute Care Transfer Policy.

The requirement that to qualify a DRG under the policy, only 10% of all discharges to postacute care must be prior to the geometric mean length of stay for the DRG also is problematic in the context of the other newly proposed criteria. The FAH recognizes that by definition, this means that up to 90% of all discharges within a DRG are not short stay discharges to postacute care settings. Once again, the 10% standard in the context of the other newly proposed criteria, is unsupported by any reasonable study, calculation or statutory intent. The newly proposed "disproportionate use" standards bear no resemblance to the requirement imposed by Congress that only those DRGs which evidence a disproportionate use of postacute care transfer settings should be included in the Postacute Care Transfer Policy.

The FAH believes further that the proposed inclusion of 231 DRGs within the Postacute Care Transfer Policy is substantially out of line with Congressional intent. The FAH questions how can over 40% of all active DRGs be deemed to be "disproportionate" to the remainder of the DRGs?

- **The proposed changes to criteria are arbitrary.**

The FAH believes that the rationale used by CMS to explain its proposed changes to the Postacute Care Transfer Policy is unacceptably arbitrary. CMS explains that it looked at 550 DRGs, eliminated 26 that had been deactivated and another 17 that included no cases in the fiscal year 2004 MedPAR files. These 43 DRGs were therefore excluded from the Postacute Care Transfer Policy since to include them would have no economic effect, CMS reports. CMS then indicates that of the remaining 507 DRGs, 220 of these have geometric mean lengths of stay that are less than three days; thus, for these 220 additional DRGs, application of the Postacute Transfer Policy for these DRGs similarly would have no effect. Of the remaining 287 DRGs, 64 were excluded because they had fewer than 100 short stay transfer cases. CMS explained that since these DRGs did not have a high volume of short stay discharges to postacute care facilities, these DRGs were excluded from the policy.

The FAH believes that in performing this analysis, CMS has departed from the standards established by Congress for the Postacute Care Transfer Policy, and has arbitrarily decided to include all DRGs that were not excluded from the policy because of a lack of economic impact. The FAH believes that to suggest that because a particular DRG has more than 100 short stay transfer cases, it may therefore not be included in the group excluded from the policy, seems unrealistic. The FAH believes that the process used by CMS in identifying the 231 DRGs that it now proposes to cover under the Postacute Care Transfer Policy and the criteria selected to qualify those DRGs, is also somewhat like the case of the tail wagging the dog. That is, CMS appears to have

selected 231 DRGs, then found criteria to match. Instead of modifying the criteria slightly to address known concerns, CMS appears to have disregarded the existing criteria, and is now recommending fundamental changes to the Postacute Care Transfer Policy, without any new or revised guidance from Congress.

If CMS has specific concerns regarding specific DRGs, as has been expressed in the past concerning split DRG pairs, the FAH believes that CMS should directly address those concerns. For example, in the FY 2005 IPPS rule, CMS adopted a grandfathering policy to retain certain split DRG pairs under the Postacute Care Transfer Policy, even after the split, for some period of time, to assure that both DRGs of the pair were covered by the policy. The FAH believes that this is a more rational and less arbitrary approach to addressing the split pair problem, since it removes, rather than creates, incentives for economically driven coding. Perhaps such grandfathering could be extended or even made permanent for those DRGs for which there continues to be a high volume of post acute care transfers and a disproportionate use of short inpatient stays followed by discharges to postacute care transfer settings.

- **Expansion and wholesale redefinition of the transfer policy violates the original premise of PPS.**

A significant expansion of the transfer policy violates the original premise and basis of the inpatient prospective payment system. When PPS was adopted in 1983, transfer cases with short length of stay (inliers) were left in the database used to determine the DRG weights and thus payment for each DRG. By leaving the inlier transfer cases in the database, the DRG weights were thereby reduced from what the weights and payments would have been had CMS chosen to exclude the inlier transfers and pay such inliers on another basis (such as a transfer policy). The basic concept of DRG PPS is that some cases will be more costly than the average (excluding outliers) and some cases will be less costly (inliers). By adopting a far more inclusive Postacute Care Transfer Policy, CMS is saying that there will be no transfer cases paid using the DRG that are less costly. The original premise of inpatient PPS was that payment would be made on a per discharge basis. The adoption of a per diem payment system for transfer cases violated the original premise of a discharge payment system. The proposal to now expand the transfer policy six-fold, therefore violates the original premise and basis of the prospective payment system since inlier transfer cases are already included in the computation of the DRG weights and payment rates.

The foundation of PPS is to reward hospitals for efficient behavior. One indicator of efficient behavior is shorter hospital stays. Broad expansion of the transfer policy will undermine, if not eviscerate, the incentive to act efficiently because hospitals suffer a financial penalty for doing so.

- **Expansion and/or redefinition of the Postacute Care Transfer Policy should be delayed pending anticipated significant changes to DRGs in the near future.**

The FAH believes that CMS should carefully consider the benefit to all concerned derived from delaying implementation of so dramatic an expansion to the Postacute Care Transfer Policy pending the anticipated, sweeping changes to DRGs expected in the near future. CMS has indicated that it plans to make sweeping changes through recalibrations and refinements to IPPS DRGs based on MedPAC's recommendations that DRGs more properly account for differences in case intensity, severity and resource use, especially as between specialty hospitals and general acute care hospitals. The CMS Administrator, Mark B. McClellan, M.D., Ph.D, testified recently before Congress that "CMS is analyzing MedPAC's recommendations to improve the accuracy of the payment rates for inpatient hospital services and expects to adopt significant revisions in FY '07".

Adoption of MedPAC's recommendations with regard to improving the accuracy of payment rates for inpatient hospital services provided by specialty hospitals, on the one hand, and more traditional general acute care hospitals, on the other, could significantly alter the DRG payment system in very basic and material ways. As such, the transfer policy provisions would be significantly affected as a direct consequence of these changes to DRGs.

The FAH believes that CMS should now refrain from making a massive and rather unsettling change to the transfer policy provisions in FY 2006, when significant and material changes are planned with respect to inpatient DRGs for FY 2007 or soon thereafter. Rather, CMS should evaluate its transfer policy proposal in light of the planned analysis of MedPAC's recommendations on specialty hospitals and the recalibration, refinement and overall restructuring, if necessary, of IPPS DRGs. If significant changes are made for FY 2007, or soon thereafter, with respect to more fully capturing differences in the severity of illnesses for particular DRGs, such changes may well address many issues that are currently wrapped up in how postacute care setting discharges are being handled. Some of the issues on which CMS can only be guessing now, and which therefore have resulted in somewhat arbitrary criteria for establishing what constitutes a postacute care transfer under the transfer policy, may be better explained, or even explained completely, when placed in the context of refined DRGs that more accurately address differences in severity of illness.

- **Expansion of the transfer policy may create a perverse incentive for hospitals to extend the length of stay.**

The proposed broad expansion of the transfer policy to other DRGs is not good health care policy because it may create an incentive for hospitals to extend the length of stay to one day short of the geometric mean length of stay. CMS has proposed to pay a per diem for days below the geometric mean length of stay. The per diem is two times for the first day in recognition of added costs of the first day of stay. Such a per diem policy could create an incentive for hospitals to retain Medicare patients until one day short of the geometric mean length of stay since the hospital would then receive the full DRG payment. Such a perverse incentive should not be built into the Medicare prospective payment system. CMS should be adopting health policies that will ensure that the Medicare patient receives the most appropriate care across the various health care sites of services without undue payment influences. With prospective payment systems now in

place, or soon to be in place, for SNF, inpatient rehabilitation, psychiatric and home health, expansion of the transfer policy is even more inappropriate, since payment influences have already been minimized with the adoption of such prospective payment systems.

The FAH believes that CMS has decided to redefine an expanded transfer policy without fully considering the arguments presented here against such expansion and redefinition. In addition, this would create significant and costly administrative burdens on the providers, thus resulting in cost increases to the healthcare system.

- **Expansion of the transfer policy is unfair.**

The expansion of the transfer policy is unfair to areas of the country that have shorter than average lengths of stay. Even when a Medicare patient is transferred for legitimate treatment purposes, these hospitals are penalized with lower reimbursement simply because they may have better practice patterns and shorter lengths of stay.

- **Significant expansion of the transfer policy creates an administrative nightmare for hospitals.**

The proposed expansion of the transfer policy related to patients who receive home health services within three days of discharge will create an administrative nightmare for hospitals. To correctly code the patient status code (discharge status), hospitals are required to keep track of what happens when a patient is discharged to another setting. This process becomes administratively cumbersome for patients who are discharged to home and subsequently receive home care services as illustrated in the following example: A patient is discharged to home (with LOS shorter than CMS GMLOS) with no plan for further treatment. Two days later the patient's physician decides that they should begin receiving home care, but does not notify the hospital. The hospital is now at financial and legal risk. The original payment must now be adjusted to reflect the per diem methodology rather than payment based on the DRG. To track these patients, hospitals must contact the patient and/or the physician's office to determine if the patient has received home health services within three days of discharge. This means that every patient who is discharged to home with one of the Post Acute Transfer DRGs must be contacted three days after discharge and before the claim can be submitted. This creates a tremendous administrative burden for hospitals because of the increased number of patients subject to the transfer policy and necessitates frequent payment and claim readjustments for fiscal intermediaries and providers who submitted the claims upon the patient's discharge. It also causes a delay in reimbursement for those facilities that hold the claims until the hospital can validate whether the patient discharged home with no plans to receive home care did receive home care within three days of discharge. Moreover, difficult as it is for hospitals to track such developments involving 30 DRGs, extension of the Postacute Care Transfer Policy to 231 DRGs would pose an almost insurmountable administrative burden and financial and legal risk to hospitals.

The FAH opposes this expansion and further recommends that CMS restrict the home care provision within the transfer policy to those patients who upon discharge from the acute care facility already have a plan for home care services to begin within three days of discharge.

- **Expansion of the transfer policy penalizes hospitals for ensuring Medicare patients receive care in the most appropriate setting.**

There have been significant advances in health care delivery since the inception of inpatient PPS. One of the key advances of this decade with regard to patient care is the ability of hospitals to be responsive to each patient's medical needs and treat those needs in the most appropriate care setting. Clearly, it is in the patients' interest to move them to less intensive care settings where appropriate. These advances are in turn accounted for appropriately with the reclassifications and recalibrations of the DRG relative weights that are performed annually.

- **Expanding the transfer provision will have a drastic financial impact.**

Extensive expansion of the transfer provision would have a drastic negative financial impact on hospital providers. This would occur just as the hospital industry has recovered from the impacts of BBA and as they prepare for current and future challenges, which include: nursing shortages, preparing for bio-terrorism and aging of the baby boomers.

- **A transition period should be provided if CMS proceeds with the proposed changes to the Postacute Care Transfer Policy.**

The FAH has stated its firm opposition to the proposed changes to the Postacute Care Transfer Policy. However, if these sweeping changes are adopted, the FAH firmly believes that the proposed changes should not be adopted on a full and immediate basis. CMS, itself, has recognized (at 70 Federal Register 23661) that the proposed changes will have a drastic impact on acute hospitals. CMS estimates that the impact of the proposed changes will be 1.1% of acute inpatient hospital Medicare revenue, approximately 880 Million dollars, a tremendous hit to hospitals' reimbursement structures and operating margins if adopted in any one year. FAH requests, therefore, that if CMS ultimately adopts these unnecessary and unwarranted changes to the Postacute Care Transfer Policy, CMS should provide at least a three (3) year transition period within which to fully implement the changes, in order to "soften" the financial impact the changes will impose.

- **Savings from transfers have already been considered in the annual Congressional update, and the adoption of an expanded transfer policy would adversely impact future cost of delivery.**

The current payment system has proven to be appropriately balanced between patient care and cost control. The expansion of the transfer provision to 231 or all DRGs could penalize hospitals for providing the most appropriate care in the most appropriate setting. In addition, the cost control incentives in the current system focus on the cost of the whole stay versus the cost by day. These incentives along with advances in medical

technology and treatment have resulted in lower lengths of stay and an increase in the quality of care. The cost savings that have occurred, with shorter length of stays from transfers included, have already been considered by Congress each year. Historically, under PPS, hospitals have been limited to payment updates below the hospital market basket (inflation). Thus, the adoption of a transfer policy would unfairly penalize hospitals for responding positively to the incentives built into the original PPS, where payment was made on a per-discharge basis and where cost savings have already been factored into the annual update.

In addition, a shorter length of stay frees up beds and nursing resources. This focus will become more critical as the baby boom generation ages and needs more healthcare services.

A policy that creates disincentives for providers to manage the total cost of the stay could result in a growth in the length of stay which puts a strain on the system, could magnify the nursing shortage, and could require a greater investment in capital for physical plants.

- **The institution of prospective payment in other settings has provided safeguards against excessive costs.**

When the BBA was enacted and the original transfer provision was implemented, all of the patient care settings, other than acute care, were under a cost-based system. However, at this time, these settings are either fully under (or will soon be under) prospective payment systems, which means payments are fixed and the program has virtually no risk of excessive payments if patients are transferred to post-acute settings. All but SNF are based on an admission or an episode of care as in home health. Postacute care setting providers therefore have an incentive not to accept acute patients who are discharged early. This would appear to provide significantly more of a safeguard than the cost-based system was providing.

In addition, the expansion of the transfer policy:

- Will require multiple per diem payment policies; and
- Will require increased audit work.

B – Hospital Quality Data

The FAH supports the concept that hospitals should voluntarily provide the public information about their performance regarding patient care. FAH member hospitals were among the first in the nation to report such data on the CMS website in late 2003, which was prior to the passage of the Medicare Modernization Act (MMA) establishing a financial incentive to do so.

The FAH understands and appreciates the arduous task it has been for CMS over the last year to create the infrastructure necessary to collect and report hospital quality

data and to reconcile this activity with Medicare payment policy. Among other significant tasks, it has required that CMS work with the Joint Commission on Healthcare Organizations (JCAHO) to create one set of identical definitions between the two organizations. It has required hospitals and vendors to reprogram their software and report the correct information, sometimes on an accelerated schedule. And it has imposed substantial demands on the CMS contractor that operates Quality Net Exchange, given that over 4,000 hospitals reported their quality data last July in order to qualify for the full market basket payment.

While the FAH recognizes and is thankful for the several changes that CMS has made over the course of fiscal year 2005 to improve and simplify the processes involved, building this infrastructure has not occurred without bumps in the road. One such "bump," the CMS process for conducting the chart audit validation of the data, has been a significant one, and will be the focus of our comments since it is the requirement most directly related to the methodology CMS has proposed for hospitals to receive a full update in their prospective payment rate for fiscal year 2006.

- **Do Not Use Third Quarter 2004 Validation Results for Determining Full Update**

The NPRM indicates that, for the FY 2006 payment update, CMS will rely heavily on data from the third quarter of 2004. As proposed, a hospital will need a minimum score of 80 percent reliability, using data from the third quarter of 2004, to receive full market basket payment in FY06.

For a number of reasons, detailed below, the process for conducting and communicating the results of the third quarter 2004 validation results has been fraught with difficulty. These problems indicate that the agency and its contractors are not fully ready to conduct the validation analysis and report it back to hospitals in an accurate and timely manner. Until most of these problems identified below are addressed and resolved, hospitals' reimbursement should not be tied to a process that has been so rife with inaccuracies and confusion. Moreover, even if CMS and its contractors are able to demonstrate improved competency and consistency in the validation process, the FAH continues to have concerns about several aspects of the methodology used in the validation process. These concerns are also detailed below.

On May 6, 2005, via a CMS SDPS Memorandum, CMS staff reported that all hospitals would have access to their complete data validations results on June 6, 2005. Knowing that they had to have at least a passing rate of 80 percent on the validation matching process to receive full payment in FY06, FAH member hospitals were fully prepared for receiving and analyzing their results on June 6.

On June 6, hospitals in several states reported that they had accessed their validation results on Quality Net Exchange and found that they had uniformly failed their validation reliability test (i.e., received a matching score of less than 80 percent). Since these hospitals had passed validation in prior quarters, many were distressed to learn this outcome but immediately began pulling patient records to begin the appeals process—a

10-day window following June 6. Very quickly, several hospitals discovered that the patient medical records that had been compared to the hospital's patient medical records by the Clinical Data Abstraction Center (CDAC) were actually for different patients—patients never admitted to their hospital. Problems were reported in at least 6 states and the District of Columbia (CT, GA, LA, MD, TN, and TX). Apparently, the CDAC sent these hospitals individual patient data for the wrong patients, i.e. individuals that had never been patients in these respective hospitals.

The patient privacy violation further compounded the problem. Hospitals were notified by an email the morning of June 7, 2005, from Qnetsupport@ifmc.sdps.org informing these hospitals that "In most instances the retrieved (validation) reports contain patient information from other providers." The email instructed hospitals that in order to protect the confidentiality of these patients, any downloaded and/or printed third quarter 2004 validation reports must be destroyed by shredding, burning, or deletion from "your network and/or workstation and empty the recycle bin." The email indicated that an attachment to the email contained a form entitled, "Certification of Destruction and Non-Use or Disclosure" that had to be signed by a hospital official and faxed to the Quality Net Help Desk "as soon as possible". Unfortunately, no form was attached to the email, although hospitals subsequently received the form. Clearly, this process created a new compliance activity that hospitals did not expect or anticipate. It remains unclear whether or how compliance with the completion of this form will affect the hospital's validation results or consideration of full payment.

CMS indicated that corrected validation results would be provided to hospitals by 5:00 p.m. central time on June 7; however, results were not made available until 8:26 p.m. central time, which meant that most hospitals did not see this notice and view their results until June 8 at the earliest. Many hospitals also found the actual validation reports to be confusing and difficult to interpret. QIOs provided conflicting information regarding how to interpret the results.

There also appear to be continuing problems with the CDAC abstracting optional data elements that are not required to be used in the validation process, resulting in inaccurate failure rates. The entire validation process has unfortunately produced unnecessary stress and frustration for all those involved—CMS staff, CMS contractors, performance measurement vendors and hospitals. In time, the FAH has little doubt that the system will improve; but, at present, it should not result in reimbursement determinations.

This rather lengthy summary of the third quarter 2004 validation process is necessary to illustrate the continuing technical problems that have yet to be resolved. When these problems are combined with the methodological issues detailed below, the FAH strongly recommends that CMS ensure that the chart audit validation process is fully operational and accurate *before* it links additional hospital payment to its results. Furthermore, it should be noted that the initial legislation contained in MMA, Section 501(b), Pub. L. 108-173, required that hospitals *submit* data on 10 quality indicators in order to receive the full update. The law did not specify that an additional chart audit

validation test be created or that it be tied to providers' receipt of the full market basket payment.

- **Address Several Methodology Issues in the Chart Audit Validation Process**

JCAHO-CMS Data Not Aligned until January 1, 2005: The FAH remains extremely concerned that CMS has proposed using third and fourth quarter 2004 data to conduct the chart audit validation process. Specifically, it was not until January 1, 2005 that CMS and JCAHO completely aligned their common definitions so that the ten measures were identical. Prior to January 1, 2005, JCAHO provided specific skip logic in the software programming used by vendors to submit the data that did not match the data needed by the CDAC to conduct the validation test. As a result, various hospitals failed the validation analysis inappropriately. While CMS has made several attempts to resolve the problem, it was not until January 1, 2005 that hospitals and performance measurement system vendors became confident that alignment issues had been eliminated as a major contributor to hospitals failing the reliability test. (In fact, it was not until the third quarter of 2004 that CMS and JCAHO agreed to align acute myocardial infarction (AMI), heart failure and pneumonia measures.) Therefore, the FAH strongly recommends that the first quarter that should be subject to validation testing for the purposes of determining payment is the first quarter of 2005, when all stakeholders can be confident that identical data were submitted to JCAHO and CMS, and that the CMS contractors completing the validation audits were using the same data definitions and algorithms used by the hospitals in the data collection process.

Sample Size and Mix Used in Validation is Inadequate: As the FAH commented in its letter to CMS last year regarding the inpatient FY05 PPS rule, we continue to recommend that the CDAC include more than five patient medical records per quarter in its validation analysis. We continue to have concerns, as well, with the fact that records can be randomly selected for five patients with one of three medical conditions. Under this sampling methodology, it is possible that all five selected cases may share the same medical condition, e.g., acute myocardial infarction. AMI happens to have five measures, whereas pneumonia has three and heart failure has only two measures. A hospital with five AMI cases would have a significantly greater number of data elements that would be used to calculate its validation rate, making it easier to meet the 80 percent pass rate than a hospitals with five cases of pneumonia and/or heart failure where there are a lesser number of data elements used to calculate the validation rate. To create a level playing field across hospitals, we recommend that CMS design a sampling methodology that increases the number of patient medical records used in the analysis and results in hospitals providing patient medical records across all three conditions. This sampling change would create a more equitable basis for comparing hospital performance.

Independent Appeals Process Lacking: The FAH has two concerns regarding the proposed validation appeals process. Our first concern is the fact that there is no independent review process for a hospital's appeal. The CDAC conducts the initial validation reliability test. If a hospital appeals the decision, the Quality Improvement

Organization (QIO) forwards the appeals request back to the CDAC, the same organization that conducted the analysis the first time. There is no opportunity for an independent review of the data. The FAH strongly recommends that CMS address this significant shortcoming in the program.

Our second concern is in regard to the role of the QIO in the appeals process. CMS documents describe two conflicting roles for the QIOs—one that is judgmental and one that is merely administrative in regards to facilitating the appeals process. The proposed rule indicates that the QIO will review the appeal with the hospital and "if the QIO review agrees with the hospital's original abstraction, the QIO will forward the appeal to the CDAC for a final determination. If the QIO does not agree with the hospital's appeal, then the original results stand." However, the CMS flow chart entitled, "Hospital Data Validation Process" effective with discharges from July 1, 2004 forward, located on the Quality Net Exchange website, indicates that the QIO role is not judgmental but administrative. The flowchart states, "QIO and hospital discuss CDAC finding" and "QIO sends appeal form with rationale for appeal to CDAC for follow-up." The FAH recommends that CMS clarify the QIO's role in the appeals process and that it not be permitted to deny a hospital's appeal to the CDAC.

- **Other Comments**

Submitting Electronic Data/Implications of Electronic Medical Record: The FAH welcomes the opportunity to provide comments on submitting electronically produced data on quality measures. The FAH is clearly in favor of using standardized electronic medical records (EMR) and other forms of electronic data transmission as the primary means for submitting quality data to CMS and other entities. We support building a single national data base of quality measures that could be used by all stakeholders—public and private payers, regulators, accreditors, consumers, and providers. In theory, electronic submission will increase the accuracy of the data and lower administrative costs. Unfortunately at the present time, the business case for investment in EMR is not by any means clear. There are a number of legal, administrative, financial, regulatory, and technical barriers to widespread EMR adoption. Without vast and immediate progress toward eliminating these barriers, submission of quality data via EMRs is, quite possibly, years away. Proposed Congressional legislation and the excellent work being conducted by the Office of the National Coordinator for Health Information Technology along with the actions of a wide variety of private-sector initiatives, clearly underscore the desire to remedy such barriers. Comprehensive action, with input from all stakeholders, will be necessary to allow hospitals to routinely submit quality data directly from EMRs within the next 10 years.

Access to Quality Net Exchange Hospital Data: There continues to be a significant barrier for hospitals in administering and complying with MMA's 501(b) provisions. Currently, only personnel from individual hospitals can view their data on Quality Net Exchange. Individuals who oversee quality programs but are employed by a hospital system, rather than a specific hospital owned by the system, cannot view individual hospital data on Quality Net Exchange, even though the hospital is owned by the system. This problem exists for small and large systems, both non-profit and

investor-owned. Similarly, the JCAHO-approved measurement systems vendor for a particular hospital cannot view the data it collects for a hospital on Quality Net Exchange.

As the FAH recommended in its comment letter last year, CMS should permit individuals employed by hospital systems and individuals employed by the measurement systems vendor for a hospital to view an individual hospital's data on Quality Net Exchange. In all cases, individuals employed by a hospital system or contracted with a vendor are charged with assisting individual hospitals to successfully participate in the Hospital Quality Alliance and the provisions of 501(b). They can help ensure that individual hospitals comply with all aspects of the program, from the validation process to complying with the preview period, and fully participate on reporting additional voluntary measures. However, they cannot do this efficiently or effectively without the ability to view individual hospital data on Quality Net Exchange. In its August 2004 final rule, CMS stated that they agreed with this recommendation "in principle," and that CMS "believes we can resolve the legal issues satisfactorily and we anticipate implementation of mechanism to allow this type of access in the fall of 2004." However, the FAH is not aware that CMS has proposed or implemented a solution to this problem at this time.

Communication and Education with Hospitals: While CMS has instituted some periodic communications with hospitals and vendors, we strongly recommend that these continue, and that the quality of such briefings improve. For example, we recommend that conference calls held with vendors and hospitals have the ability to mute listeners so that participants can clearly hear CMS and JCAHO officials. We also recommend that the answers to questions that CMS staff provides on such calls be provided in written form and distributed to the QIOs, hospitals and vendors in a timely fashion following the conference calls. In its August 2004 final rule, CMS agreed to improve communications, and indicated that it would look for ways to educate hospitals by using its QIOs. To date, however, the FAH is not aware of specific QIO efforts to communicate with hospitals in a more timely manner regarding the Hospital Quality Alliance or the provisions of 501(b) in MMA.

F – IME Adjustment

1. Background

The FAH has no comments on the Background subsection.

2. IME Adjustment for TEFRA Hospitals Converting to IPPS Hospitals

CMS proposes to clarify and codify its policy of assigning an indirect medical education ("IME") intern and resident full time equivalent ("FTE") cap for those hospitals converting after 1996 from TEFRA (PPS exempt) to IPPS. The FAH fully supports this proposal, but requests that CMS clarify that the proposed regulation applies to excluded psychiatric and rehabilitation units as well as hospitals. For instance, the

FAH recommends the proposed rule change apply in situations where a TEFRA hospital or TEFRA unit converts to an IPPS hospital.

CMS noted in this section of the proposed rule that, in certain limited situations, a provider may rightfully no longer have access to the data (oftentimes from 1996) necessary to compute a new IME FTE cap. In those situations, the FAH requests that CMS make it clear that fiscal intermediaries are expected to cooperatively work with providers to calculate (or impute as necessary) a fair and equitable IME FTE cap using any and all available data (including alternative data and data from subsequent periods).

The FAH requests that CMS amend the proposal to make it clear that any new IME FTE cap for a hospital/unit that was PPS exempt will be based on the count of FTEs rotating both within the hospital and in qualifying non-hospital sites. The FAH believes this was CMS's intent, because the preamble indicates that the new FTE cap will be "based on the FTE count of residents during the cost reporting period(s) used to determine the hospital's direct GME FTE cap . . . ." 70 Fed. Reg. at 23433. Significantly, in 1996, the direct graduate medical education ("GME") rules clearly allowed for the inclusion of nonhospital rotations in the FTE count, but the IME regulation did not provide for the inclusion of nonhospital rotations until October 1997. The text of the proposed regulation suggests that the new IME FTE cap will be computed in accordance with the IME regulation. The FAH simply requests clarification that the new FTE cap will include any and all qualifying nonhospital rotations. This makes sense since a cap is being generated based on the 1996 GME FTE cap. The 1996 GME FTE cap would have included qualifying nonhospital rotations.

3. Section 1886(d)(8)(E) Teaching Hospitals That Withdraw Rural Classification

The FAH supports CMS's proposed regulation to rescind any permanent increase to the IME FTE cap for a hospital that rescinds its election to be treated as a rural hospital under Section 1886(d)(8)(E). The FAH agrees with CMS that increased IME FTE caps should be forfeited if a hospital does not remain a rural hospital under the 1886(d)(8)(E) election. Essentially, any other rule would allow a hospital to elect treatment as a rural hospital for as little as one year, secure a permanent increase to the IME FTE cap, and then return to being treated as an urban hospital. The Secretary should not permit any such usage of the Section 1886(d)(8)(E) election.

On the other hand, the FAH agrees with CMS that hospitals which become urban as a result of the OMB-revised labor area designations have no control in the matter. These hospitals should not lose the 130 percent adjustment to their IME FTE cap or their increased caps resulting from the addition of new residency programs. See infra Section V. I of this letter (discussion of this issue under GME comments).

G – DSH Adjustment Data

Part V.G of the NPRM, beginning at 70 Fed.Reg. 23434, proposes that CMS will modify the existing process to establish the SSI portion of a hospital's DSH payment adjustment by furnishing:

> MedPAR LDS data for a hospital's patients eligible for both SSI and Medicare at the hospital's request, regardless of whether there is a properly pending appeal relating to DSH payments. We are proposing to make the information available for either the Federal fiscal year or, if the hospital's fiscal year differs from the Federal fiscal year, for the months included in the two Federal fiscal years that encompass the hospital's cost reporting period. Under our proposal, the hospital could use these data to calculate and verify its Medicare fraction, and to decide whether it prefers to have the fraction determined on the basis of its fiscal year rather than a Federal fiscal year. The data set made available to hospitals would be the same data set CMS uses to calculate the Medicare fractions for the Federal fiscal year. [*Id.* at 23435 (emphasis added).]

The FAH seeks clarification with regard to several aspects of this proposal. First, CMS's intent seems clear from the language of the notice that hospitals may "decide" whether to have their SSI percentage calculated on a federal fiscal year or hospital fiscal year basis, whichever is most advantageous to the hospital. Unfortunately, the proposal also seems to suggest that data will be provided on an either/or basis. For hospitals to have a meaningful choice of calculation methodology, the FAH requests that CMS provide requesting hospitals with data for both hospital and federal fiscal years. In this regard, the proposal also seems to intend that hospitals can elect from year to year whether they will calculate and report the SSI percentage based on a federal or hospital fiscal period. CMS should make clear whether hospitals will be required to report their SSI percentage calculation consistently from year to year based on a federal or hospital fiscal year basis.

Second, hospitals have requested the MedPAR LDS data through the course of PRRB appeals to verify the accuracy of the SSI percentages posted in Federal Register notices. The proposed rule does not address the situation where a hospital may identify errors in the MedPAR LDS provided data.[2] That is, the hospital has evidence that a Medicare Part A beneficiary was also entitled to SSI benefits and this beneficiary was omitted in error from the CMS provided MedPAR LDS data file. The FAH recommends

[2] The proposal also does not address the situation where a hospital requests SSI data, but does not receive that data until after the cost report must be filed. CMS should make clear that intermediaries will be required to accept any updated data providers receive from CMS before a cost report is settled, or after such a report is settled through a reopening request.

that CMS provide explicit instructions that Medicare fiscal intermediaries are to include Medicare Part A days beyond what was included in the MedPAR LDS in its cost report Medicare SSI ratio as long the hospital can provide adequate documentation to support the Medicare beneficiary's entitlement to SSI benefits at the time of their hospital stay. This handling of the Medicare fraction will be comparable to the current CMS regulation with respect to the Medicaid fraction where the burden is on the provider to document patient Medicaid eligibility. As a result, this equivalent burden would apply to the Medicare Part A SSI entitlement days requested by the hospital to be included in addition to the MedPAR LDS provided days.

Third, CMS has not proposed changes to the Medicare DSH regulation at 42 C.F.R. § 412.106 to accommodate the proposal to provide hospitals with the requisite data to allow a choice of fiscal year methodology. To comply with the statutory mandate of section 951 of Pub. L. 1080-173 (MMA), it would appear the regulation needs a conforming amendment. In particular, subsection 412.106(b)(3) now provides:

> If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

This regulatory language does not allow the kind of hospital choice of federal or hospital fiscal year contemplated by the proposal and should be amended to allow for such choice.

Finally, with respect to the Medicaid fraction of the DSH adjustment factor, CMS states:

> [W]e believe there is no need to modify the Medicaid State plan regulations to require that State plans verify Medicaid eligibility for hospitals. However, should we find that States are not voluntarily providing or verifying Medicaid eligibility information for hospitals, we will consider amending the State plan regulations to add a requirement that State plans provide certain eligibility information to hospitals. [*Id.* at 23436.]

The FAH recommends that CMS provide a formal process for hospitals to report States that are not voluntarily providing or verifying Medicaid eligibility information. The establishment of a formal, systematic process to report State non-compliance will provide a comprehensive process as opposed to CMS just "finding out" about potential State non-compliance issues.

One suggested format for this reporting mechanism is the establishment of an area on the CMS website that permits hospitals to submit State Medicaid eligibility non-compliance issues for DSH percentage calculation purposes. This new portal could

become a clearinghouse for reported problems. All reported problems would be publicly available information accessible by all hospitals and the State Medicaid Plans themselves. CMS would monitor these reported problems and take corrective action as deemed appropriate.

H - Geographic Reclassifications

3. Urban Group Hospital Reclassifications

a. Proximity

In the proposed rule, at page 23437, CMS has proposed to revise the criteria for meeting the proximity requirement for urban hospitals seeking reclassification as a group. Under the current rule, as established through the FY 2005 rulemaking, "hospitals located in counties that are in the same Combined Statistical Area (under the MSA definitions announced by the OMB on June 6, 2003); or in the same Consolidated Metropolitan Statistical Area (CMSA) (under the standards published by the OMB on March 30, 1990) as the urban area to which they seek redesignation qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation." CMS states that the purpose of this policy, which included criteria from both the old and new OMB definitions, despite the switch to the new OMB classifications, was to preserve the rights of urban counties to reclassify. CMS now proposes to eliminate the use of the 1990-based CMSA standard in this determination, as it believes it is no longer necessary.

The FAH supports the removal of the 1990-based criteria and agrees that it is no longer necessary. However, we believe that CMS has fallen short of its goal in protecting the right of urban hospitals to reclassify as a group by only adopting, in the criteria for defining proximity, Combined Statistical Areas (CSAs) from the new OMB classifications without including the CBSAs that are used for wage index purposes. The FAH urges CMS to modify its policy to allow hospitals located in counties that are in the same CBSA, as well as CSA, as the county to which they seek redesignation to be considered to have met the proximity requirement. By failing to include CBSA's in the proximity criteria, CMS has excluded one group of hospitals, those located in Palm Beach County, Florida, from being able to reclassify to the Fort Lauderdale-Pompano Beach-Deerfield Beach, FL Division of the Miami CBSA. The FAH assumes that it was not the intention of CMS to exclude this one county group. Since CBSAs are actually more refined classifications than CSAs, we believe that inclusion of CBSAs in the proximity criteria would be consistent with CMS's policy goals to both transition to the new labor market area definitions and to protect hospitals from unintended unfavorable consequences.

The FAH also strongly encourages CMS to utilize its discretion to incorporate the CBSA criteria in the determination of applications for urban group reclassification for FY 2006. Such a revision of policy for the upcoming federal fiscal year would be consistent with CMS's allowance of a special adjustment for hospitals that failed to qualify for reclassification for FY 2005 due to the elimination of the

standardized cost criteria for FY 2006 reclassifications. *See* 69 Fed. Reg. at 49104 (Aug. 11, 2004).

b. Exclusion of New Hospitals from Group Reclassifications.

Pursuant to 42 C.F.R. § 412.234(a)(1), for urban hospitals seeking redesignation as a group to another urban area, all hospitals in the county must apply. It has come to the FAH's attention that CMS has taken the position, not found in the applicable regulations, that a new provider in the county cannot benefit from the group reclassification, but will receive the wage index of the geographic area where that hospital is located. We understand that this unpublished policy applies both to newly-constructed hospitals, as well as hospitals with new ownership that have applied for a new Medicare provider number, rather than assume the provider number of the seller.

The FAH believes that such a policy is unfair to new hospitals, putting them at a competitive disadvantage with the other hospitals in the county. Further, since such reclassifications last for three years, a new hospital will be forced to accept a wage index lower than all other hospitals in its area for up to the three year period. The FAH urges CMS to reconsider this policy and, at a minimum, to explain its reasons and include it in the regulations.

I – Graduate Medical Education

1. Background

The FAH has no comment on the Background subsection.

2. Direct GME Initial Residency Period ("IRP") Section 413.79(a)(10)

FAH strongly supports CMS's proposed revision to the "simultaneous" match policy. That is, the FAH agrees that so long as the resident matched to a specialty program requiring a clinical base year before the start of residency training, the IRP should be set using the period of board eligibility associated with the specialty program in which the resident has matched and is expected to begin training in the second year program. CMS indicated that this revision best reflects its original intent in revising the IRP rule effective October 1, 2004. Thus, the FAH recommends that CMS clarify that this proposal will likewise apply effective October 1, 2004.

Further, with respect to the October 1, 2004 effective date, the FAH seeks clarification of how the IRP is set for a resident that begins training based on a simultaneous match at or before the start of the academic year beginning on July 1, 2004. This match would result in clinical base year training from July 1, 2004 through June 30, 2005, which is already past the October 1, 2004 effective date. Then, the second year specialty training would begin on July 1, 2005. The FAH requests that CMS clarify that the IRP would be set using the second year specialty even though the actual simultaneous match originally occurred prior to October 1, 2004. Indeed, the IRP issue does not even arise until the third or fourth year of training, which would be well after October 1, 2004. Further, the IRP is set based on the second year specialty, and training in the second year

occurred after October 1, 2004. Finally, the provider would only be submitting documentation of the simultaneous match in years potentially impacted by the .50 IRP weighting, which would be well after October 1, 2004 (e.g., as part of the audit of cost reporting periods 6/30/06, 6/30/07, etc.). For these reasons, the IRP should be set using the second year of specialty training even though the match occurred prior to October 1, 2004.

3. New Teaching Hospitals' Participation in Medicare GME Affiliated Groups (Section 413.79(e)(1)

The FAH supports CMS's proposal to allow new urban teaching hospitals that qualify for an adjustment to their FTE caps under Section 413.79(e)(1) to affiliate so long as the new urban teaching hospital receives an increase to its IME and GME caps under the affiliation. We agree that this proposal adds needed flexibility for new urban teaching hospitals that receive an FTE cap for the first time under Section 413.79(e)(1).

4. GME FTE Cap Adjustment for Rural Hospitals (Section 413.79(c) and (k))

The FAH strongly agrees with CMS's clarification in this section that hospitals that become urban as a result of the new OMB labor market areas would nevertheless be permitted to retain the adjustments they received for new programs as long as they were rural at the time they received them. Further, the FAH strongly agrees with CMS that the 30 percent increase to the FTE caps for rural hospitals should not be rescinded if a rural hospital becomes urban as a result of the OMB labor market area designations.

Finally, the FAH also strongly agrees with CMS's interpretation permitting urban hospitals with rural track training programs to retain the adjustment they received for such programs at Section 413.79(k), even if the "rural" tracks, as of October 1, 2004, are now located in urban areas due to the new OMB labor market areas. The FAH agrees with CMS that Congress intended to allow the adjustment for rural tracks to remain permanent as long as the rural track training programs continue, even if once-rural tracks are now urban due to new labor market area boundaries. Congress clearly intended to encourage the training of physicians in the rural tracks identified by the statute.

J – Provider Based Entities

The FAH clearly understands and supports the requirement in 42 C.F.R. § 413.65(g)(7) that a hospital that is the main provider must provide a "Written Notice Of Beneficiary's Financial Obligation" ("Notice") to Medicare patients that are treated in a hospital outpatient department ("HOD") or a hospital-based entity ("HBE") where the HOD or HBE is not located on the main provider's campus. Our concern is the application of the Notice requirement when a Medicare beneficiary is treated in an outpatient department of a provider-based remote location of a hospital ("RLH") that is not located on the main provider's campus.

In a RLH, the volume of Medicare patients that receive treatment in outpatient settings on the campus of the RLH, such as emergency and radiology services, is generally very large. Providing the Notice under these circumstances, which generally must include either the coinsurance amount or an estimate based on typical or average charges for the outpatient visit to all Medicare beneficiaries in these departments, is administratively quite burdensome. Also, giving the Notice in this type of setting is confusing to the beneficiary, since outpatient services rendered on the campus of the RLH are viewed by the beneficiary to be no different than services rendered on the main campus of any hospital, where a Notice is not required under the current rules and the beneficiary would expect to incur a coinsurance liability for the outpatient visit as well as for any physician service rendered.

We understand that the intent of this requirement is to avoid patient confusion or lack of clarity as to the setting in which services are being provided, and consequently the patient's financial liability for the services. In fact, CMS revised its initial proposed rule on the Notice to limit the requirement to departments or entities which are not on the campus of the main provider, because a patient receiving services on the main campus is aware that he or she is in a hospital setting and understands the financial obligations that will be incurred for those services. (See, 65 Fed. Reg. 18520, April 7, 2000.) It would be consistent with this intent if a RLH that is located off the campus of the main provider were required to provide the Notice in any HOD or HBE located off the campus of the RLH, but not when patient services are rendered on the campus of the RLH, since it is only in off-campus locations that beneficiaries may be unclear as to whether the location is part of a hospital or a non-hospital entity.

Therefore, the FAH recommends that CMS modify the beneficiary Notice requirement to not require RLHs to give the Notice to beneficiaries who access outpatient services on the campus of a RLH, but keep the requirement for off campus services provided by a RLH.

If that recommendation is not acceptable, in the alternative we recommend that CMS apply the Notice obligation only to small RLHs, such as facilities with less then twenty-five (25) beds, where the public could potentially be unclear as to whether the facility is a hospital. Requiring the smaller RLHs that could be perceived as non-hospital entities to give the Notice prior to rendering outpatient services would ensure that Medicare beneficiaries understand that they are receiving services in a hospital.

Both of these recommendations are based upon the fact that an HOD or HBE located on the campus of a RLH, or located in a larger hospital that is a RLH, would clearly be perceived as a hospital by the public, and the beneficiary would not be misled as to the type of facility and the site of service. The recommendations are consistent with CMS's rationale for excluding from the requirement an HOD or HBE located on the campus of the hospital that is the main provider.

We compliment CMS for the technical and clarifying changes to the "Location" requirement, but noticed that the proposed regulation section 413.65(e)(3) appears to be unclearly written. The "Location" requirement set forth in 413.65(e)(3) specifies that a

facility or organization not located on the main campus of the potential main provider can qualify for provider-based status only if it is located within a 35-mile radius of the campus of the hospital or CAH that is the potential main provider, except when the requirements of paragraph (e)(3)(i), (e)(3)(ii), or (e)(3)(iii) are met. We believe the proposed change as set forth on page 23464, "The facility or organization meets the requirements in paragraph (e)(3)(i), (e)(3)(ii), (e)(3)(iii), (e)(3)(iv), or, in the case of an RHC, paragraph (e)(3)(v) of this section, and the requirement in paragraph (e)(3)(vi) of this section...", is somewhat unclear as to whether the facility must meet all listed requirements in sections (e)(3)(i), (e)(3)(ii), (e)(3)(iii), and (e)(3)(iv) even if the facility is located within a 35-mile radius of the campus of the hospital or CAH that is the potential main provider.

The FAH recommends that CMS clarify that the "Location" requirement may still be met either by being within a 35 mile radius of the campus of the main provider or by meeting one of the other criteria in section (e)(3).

L – Specialty Hospitals

1. Administrative Review of Specialty Hospitals

FAH commends CMS for indicating its intention to closely review the issue of whether so-called "specialty hospitals" qualify as "hospitals" under section 1861(e) of the Social Security Act. This statutory section requires hospitals to be primarily engaged in furnishing inpatient services. However, recent studies by the Medicare Payment Advisory Commission ("MedPAC") and CMS imply that at least surgical and orthopedic specialty hospitals may not meet this standard, due to the inability to identify any appreciable volume of inpatient cases. Accordingly, we share CMS' concern that many specialty hospitals may not satisfy this standard. For this reason alone, it is appropriate for CMS to review this issue closely.

FAH strongly believes that CMS' Medicare certification process, whether administered directly through state agency surveys or the deeming authority of private accrediting entities, should focus on ensuring that this standard is satisfied during all initial certification and recertification reviews. While this process is necessary for all hospitals, CMS' particular concern with regard to specialty hospitals is appropriate and warranted.

However, FAH is concerned with the manner in which CMS is implementing its administrative review and enrollment suspension. Based on CMS' June 9, 2005 Fact Sheet, it is clear that the administrative suspension of processing enrollment applications will not apply to a significant number of specialty hospitals which are not currently approved to serve Medicare patients. We reach this conclusion based upon the following Fact Sheet statement:

> "The suspension does not apply to those specialty hospitals that have prior to June 9, 2005, submitted an enrollment application or have requested an advisory

opinion from CMS concerning whether they were subject to the moratorium under section 507 of the MMA."

We understand this to mean that all specialty hospitals that currently have an advisory opinion request pending will have those requests held in abeyance and will be allowed to move forward with the normal Medicare certification process. Facilities that served Medicare beneficiaries during the section 507 moratorium period may still desire a response to their advisory opinions, so that they may be paid for related services for which claims are now being held. Based on the recent GAO report, we understand the number of facilities in this group may be around 25, although we understand the number may actually now be higher.

The second, and more troubling, aspect of the Fact Sheet statement applies to new specialty hospitals that opened during the section 507 moratorium and do not qualify for grandfathering status as "under development." Based upon our reading, any such facility that filed an enrollment application with Medicare prior to June 9, 2005 in anticipation of the moratorium's expiration will not be subject to the administrative suspension. We are deeply troubled by this approach, as it creates a loophole that is likely to permit a significant number (*i.e.*, at least 50, but probably higher) of new specialty hospitals to become Medicare participants before the certification rules and related processes receive the close scrutiny they clearly need and deserve.

To address these concerns, FAH requests that CMS apply the suspension of processing enrollment applications to all specialty hospitals until its review is completed and appropriate revisions are adopted. Given the concerns expressed with the current enrollment process, it would be unwise for CMS to allow a significant number of facilities to enter the program through the current process. We believe CMS has the statutory authority to implement our request for both groups of specialty hospitals identified in the Fact Sheet's statement. To do otherwise would be to allow a significant increase in volume of specialty hospitals during a time when CMS has recognized that its enrollment process may be flawed.

2. Proposed DRG Refinements

Also with regard to specialty hospitals, significant attention, led by the Medicare Payment Advisory Commission ("MedPAC"), has recently focused on Medicare payment refinements as a possible means to address the concerns presented by specialty hospitals. The FAH understands that the current DRG system has aged and, as a result, begun to show limitations that require careful study and adjustment. We believe that MedPAC's recent report provides a meaningful analysis in this regard and identifies several potential solutions worthy of consideration, in particular, its recommendation regarding reform of the flawed outlier payment methodology. However, the impact of MedPAC's recommended solutions, when considered individually and collectively, must be studied closely and modeled over time before any definitive move is made toward implementation. The FAH strongly urges CMS to proceed deliberately through this process, given the detailed nature of the existing system and the even greater complexities that are presented by MedPAC's various proposed refinements. In our

view, the most important objective of any DRG refinements must be to improve the system in a way that is logical, sound, and that can be administered fairly for all hospitals with minimal disruptions. Above all, refinements must not undermine the underlying premise of a prospective payment system that rewards efficient behavior and is based on the law of averages.

3. FAH Whole Hospital Exception Rulemaking Petition

As indicated above, FAH is supportive of CMS' decision to review its procedures for enrolling specialty hospitals in Medicare and to consider refinements to the DRG system. However, neither of these actions will ever resolve the core problem with physician-owned specialty hospitals, which is the fundamental anti-competitive impact that results from physician-owners or investors self-referring to their specialty hospitals. Expert studies have shown that the inherent conflict of interest in ownership and self-referral results in the "cherry picking" of patients as well as several other undesirable outcomes. We do not believe that refining the DRG system, which would present broad-based changes with implications well beyond the problem MedPAC expects it will address, is the magic potion to resolve the specialty hospital problem.

For these reasons, we are concerned that HHS has denied FAH's rulemaking petition requesting changes to the whole hospital exception regulation. Given the significant recent focus on specialty hospitals, we strongly believe that CMS should engage in rulemaking to assess and analyze the available data from the sole perspective of whether the intent of the physician self-referral prohibition is being well served by the agency's current regulatory interpretation. The public would benefit from a focused agency review of the available data and a discussion of how the data affects its regulatory interpretation.

It appears the HHS denial is premised on legal advice that it does not have statutory authority to act as we request. During HHS' deliberations on the petition, FAH provided ample support for why the Department clearly has statutory authority to make our requested changes should it conclude they were warranted after notice and comment rulemaking. However, we are disappointed that the HHS denial letter summarily rejects our position without any substantive response to our arguments regarding the agency's legal authority.

We continue to believe strongly that the Department has the regulatory authority to create additional standards for specialty hospitals under the physician self-referral statute that protect against the infusion of conflict of interest that physician-owners bring into the normal physician referral process. In fact, recent CMS public statements at the EMTALA TAG essentially concede this fact.

In the EMTALA context, CMS has asked the TAG to consider whether additional or unique rules should be applied to specialty hospitals regarding on-call coverage, and whether specialty hospitals that do not operate emergency departments should be required to accept EMTALA-related transfers due to their specialized capabilities. In

fact, CMS acknowledged receiving legal advice that it may implement a separate policy for specialty hospitals regarding the transfer issue.

CMS' statement to the EMTALA TAG alone reflects the agency's thinking that special requirements may be appropriate for specialty hospitals. While we agree that such issues should be considered closely, the crux of the problem -- the conflict of interest presented by physician-owners who self refer – should be properly dealt with in the context of the regulations implementing the physician self-referral ban and not in a piecemeal fashion through other contexts.

Part VII of The NPRM

B – Critical Access Hospitals

CMS is proposing to limit critical access hospital (CAH) status for those CAHs that cannot meet the mileage requirements, and therefore, must qualify for CAH status by being designated as a "necessary provider." In particular, CMS has proposed that continued CAH status for facilities deemed "necessary providers" that are building replacement facilities at another location will be permitted only for those providers that can demonstrate that their construction plans were under development as of the effective date of Pub. L. 108-173 (December 8, 2003). This date restriction is arbitrary and is not mandated by statute. The statute requires only that no new necessary providers will be certified after December 31, 2005, and grandfathers certain other existing necessary providers. The statute does not specifically address a cut-off date for how existing necessary providers that are building new facilities in the same area, but at a different location, should be handled.

The choice of December 8, 2003 places in jeopardy many bona-fide relocation projects (i.e., replacement facilities in new locations) that have been started during the year and a half since the passage of the MMA. Such providers had no reason to believe until now that they would lose their necessary provider status through relocating an existing necessary provider CAH by virtue of constructing a replacement facility, more than 250 yards away from the original structure, unless construction plans actually began prior to December 8, 2003. In these cases, no new necessary providers are seeking necessary provider status. Rather, an existing facility is simply relocating to a newer and hopefully more efficient facility in the hope of providing better and more effective patient care for the same community.

FAH also notes that CMS's proposed changes afford hospitals no flexibility to rebuild and relocate facilities if and when this becomes necessary in future. FAH believes that the proposed elimination of necessary provider status for existing necessary provider designated facilities that choose to replace an existing facility at another location within the same general community serves no statutory or health policy driven purpose.

FAH requests, therefore, that CMS omit the requirement, or any other like it, that necessary provider status for replacement facilities constructed at new locations be limited to situations where construction plans on the replacement or relocated facility are

deemed to have been under development as of December 8, 2003, or any other specific date. The other criteria for retaining the necessary provider status for such relocated existing CAHs provide more than ample assurance that no new necessary providers will be certified after December 31, 2005.

Part IX of the NPRM

MedPAC Recommendations

Please see the FAH's comments regarding Specialty Hospitals in Section V.L. of this letter, above. Those comments are also responsive to the MedPAC recommendations.

Addendum Part II. A. 4.c.

Outliers

CMS has proposed to establish the fixed-loss cost outlier threshold for FY 2006 as the prospective payment rate for the diagnosis related group ("DRG"), plus any indirect medical education ("IME") and disproportionate share hospital ("DSH") payments, and any add-on payments for new technology, plus **$26,675**. The present threshold, which has been in effect for all of FY 2005, is $25,800. In establishing the proposed FY 2006 threshold, CMS has proposed to continue using the "charge methodology" that it began using for FY 2003, with a slight change in the methodology for projecting an increase in charges. As part of the calculation, CMS is using the 1-year average annualized rate of change in charges per case from the last quarter of FY 2003 in combination with the first quarter of FY 2004 (July 1, 2003 through December 31, 2003) to the last quarter of FY 2004 in combination with the first quarter of FY 2005 (July 1, 2004 through December 31, 2004), in order to update charges from FY 2004 to FY 2006. According to CMS, the average annualized rate of change in charges per case between these periods was 8.65 percent, or 18.04 percent for two years. Also, CMS has proposed, as has been done in the past, to use the hospital cost-to-charge ratio from the most recently-available Provider Specific File, which for FY 2006 is the December 2004 update.

CMS has proposed to establish the FY 2006 threshold using the same model as was used for FY 2005, except for a slight change in how the rate of increase in charges is estimated.[3] The FAH objected strongly in our comments last year that the model being used by CMS would severely underreimburse hospitals for their outlier payments. As with the prior year, this has turned out to be true. For FY 2004, CMS has disclosed in the proposed rule that estimated outlier payments will be 3.5%, an estimate significantly lower than the 4.4% estimate that was given based on available data in last year's

[3] For FY 2005, the estimated rate of increase in charges was determined by comparing the rate of increase in charges from the first half-year of FY 2003 to the first half-year of FY 2004.

proposed IPPS rule. This represents an aggregate underpayment of approximately $1.4 billion to hospitals nationwide. For FY 2005, CMS states:

> "We currently estimate that actual outlier payments for FY 2005 will be approximately 4.4 percent of actual total DRG payments, 0.7 percentage points lower than the 5.1 percent we projected in setting outlier policies for FY 2005."

The estimated payments of 4.4 percent, or 0.7 percentage points lower than the 5.1 percent that was set aside to pay outliers is a significant underpayment. This represents an aggregate underpayment of over $600 million. The currently estimated underpayment amounts to an approximate 16% underpayment, and, is likely to be much greater when more recent estimates are made, as occurred for FY 2004. It is clear from the experience of the past two years that CMS's methodology to project outlier payments and set the outlier thresholds is not working. The FAH urges CMS to recognize this fact and to consider altering its methodology so that more accurate projections can be made.

The FAH believes that the model that CMS has used for FYs 2004 and 2005 and has proposed to continue to use for FY 2006 fails to incorporate one extremely significant variable: the resulting decline in the cost-to-charge ratio ("RCC") that is a by-product of significant projected charge increases. The objective of the outlier model should be to project outlier costs. The present CMS model using the two year average annualized rate of change in charges per case based on two recent six month periods, but with the RCC locked as of December 2004, will fail to reasonably project outlier costs. Outlier costs are equal to charges times RCC. CMS is projecting the charges to increase for FY 2006 by 18.04% over 2 years; yet, the RCCs are locked as of December 2004. Such a model will invariably underpay outliers. The FAH urges CMS to consider alternate models, discussed herein, which should lead to a more accurate projection of outliers.

As was done in support of its comments for FY 2005, the FAH engaged Vaida Health Data Consultants ("VHDC") to model the outlier thresholds for FY 2006 using CMS's proposed 2-year charge increase model, modified to reflect the decline in the RCCs. The FAH has attached as Exhibit C to this letter a copy of the outlier study performed by VHDC for the FAH. Based upon that model, the FAH recommends that the outlier threshold for FY 2006 be set at **$24,050** or lower.

Significantly, the FAH notes that VHDC's projections for both FY 2004 and FY 2005 were considerably closer to the threshold that would have resulted in the 5.1% target being met than were the projections done by CMS for those two fiscal years. In its comments for FYs 2004 and 2005, the FAH modeled the 2-year charge increase model that was used by CMS, but recommended that CMS also model the decline in the RCCs rather than locking the RCCs in at a point in time. Using the projected decline in RCCs, VHDC's model for the outlier threshold resulted in a threshold of $25,375 for FY 2004, which was what the FAH recommended in its comments. This can be contrasted with the threshold of $31,000 that was adopted by CMS (revised downward mid-year to $30,150). As explained by CMS in this year's Proposed Rule, these thresholds resulted in outliers at the 3.5% level, representing a 34%, or $1.4 billion, underpayment. For FY 2005,

VHDC's model resulted in a threshold of $28,445, compared to the $35,085 threshold proposed by CMS (which would have been $32,510 if CMS had used the 3/31/04 HCRIS update that VHDC used). The FAH was pleased that CMS considered its comments and significantly lowered the threshold when the Final Rule was published, ultimately setting the threshold at $25,800.[4] However, as it has turned out, even this significant reduction in the threshold was not large enough. As stated in the Proposed Rule, the threshold set by CMS for FY 2005 has resulted in outlier payments being underpaid by an estimated 0.7% or 16% (and the FAH believes that the outlier underpayment will actually be greater than that).

As part of its engagement for FY 2006, VHDC modeled what the threshold should have been to pay out the 5.1% for FY 2005. VHDC estimates that the threshold should have been $21,925 for FY 2005 using the cost to charge ratios from the CMS impact file. When the model is adjusted to reflect the updates that will occur to the RCCs for the remainder of FY 2005, VHDC estimates the threshold for FY 2005 should have been even lower, or $21,640 (as compared to the $25,800 threshold set by CMS), in order to reach the 5.1% target. For FY 2004, using the latest data available, VHDC estimates the threshold should have been $21,555 (as compared to the $31,000/$30,050 thresholds set by CMS), in order to reach the 5.1% target.

For FY 2006, VHDC, as explained in detail in the attached report (Exhibit C), estimated what the fixed loss amounts should be, using the same "charge methodology" used by CMS in its projections. VHDC ran several projections to demonstrate the impact of factors that should be taken into account but were omitted from CMS's projection methodology. First, VHDC ran a projection using the most recent (3/31/2005) HCRIS update. This resulted in an estimated fixed loss amount of **$25,085** (compared to the $26,675 fixed loss amount projected by CMS). Second, VHDC ran a projection that took into account the decline in RCCs that will occur before outliers are actually calculated during FY 2006. The decline in RCCs was projected from the most recent RCC data in the 3/31/2005 HCRIS update to the fiscal periods expected to be used for the calculation of the RCCs determining outlier payments during FY 2006. The projected decrease in RCCs was calculated using the CMS charge inflation factor of 8.65% and the 2001-2003 aggregate annual rate of increase in cost per discharge, calculated by VHDC to be 6.57%. This second projection, taking into account the key factor of updating RCCs, resulted in an estimated fixed loss amount of **$24,050**. Based upon the analysis performed by

[4] The lower threshold published in the Final Rule for FY 2005 resulted from CMS's modification of how it projected the two year increase in charges, as described above. This also impacted the level of the threshold proposed by the FAH. In developing the recommendation of $28,445, the FAH used the CMS estimated charge increase contained in the Proposed Rule of 14.5083% per year for two years. Then, in the Final Rule, CMS significantly revised the estimated charge increase downward to 8.9772% per year. As the FAH had pointed out in its comments last year, a drop in the estimated charge increase would significantly impact the threshold. The FAH's proposed threshold would have been considerably lower if it was working with the charge increase estimate that CMS used in the Final Rule.

VHDC, the FAH recommends that CMS set the outlier threshold at **$24,050** or lower for FY 2006.

As stated previously, the objective of the outlier model should be to reasonably project outlier costs. Thus, as the FAH did for its FY 2005 comments, it also asked VHDC to estimate the fixed loss threshold using the "cost methodology," rather than the "charge methodology." This method uses the most recent cost data available, and projects costs to FY 2006 using the cost inflation factor of 6.57% derived from HCRIS data for 2001, 2002 and 2003. CMS started utilizing the 2-year charge increase model beginning in FY 2003, largely due to the lack of timely cost report data resulting from the delay in filing of cost reports after the implementation of outpatient PPS. Prior to FY 2003, for FFYs 1994-2002, CMS utilized the cost model to project the outlier threshold. Without the timely cost report data for FY 2003, CMS was unable to continue to utilize the cost model for FY 2003. Now that the backlog in filing and processing of Medicare cost reports caused by the implementation of outpatient PPS has been resolved, this methodology could be considered again.

Using data from the recent 3/31/2005 HCRIS Update, VHDC ran projections using the cost methodology, which resulted in an estimated fixed loss threshold for FY 2006 of **$22,520**. The FAH notes that its projections using the cost methodology resulted in a threshold for FY 2005 that was much closer to the threshold that would have resulted in payment of 5.1% outliers than either CMS's charge methodology or the FAH's charge methodology adjusted for the projected decrease in RCCs. For FY 2005, the FAH's projection using the cost methodology resulted in a threshold of $22,830; based on the most recent data, an accurate threshold for FY 2005 would have been $21,640.

We have also retroactively projected an estimate for FY 2004 using the cost methodology, based on data that was available in mid-2003.[5] VHDC has calculated that a projection using the cost methodology would have resulted in a threshold of $20,900, compared to a threshold of $21,555 that would have resulted in the 5.1% target. The VHDC report explaining how these calculations were done is attached as Exhibit D.

To make this easier to understand, the data for these various projections is arrayed in the following table:

[5] When commenting on the Proposed Rule for FY 2004, the FAH did not project the outlier threshold based on the cost methodology. However, VDHC is able to do so now, based on the data that would have been available in June 2003, at the time that outlier thresholds were being set for FY 2004.

FY	CMS Threshold	CMS Est. Actual Pmt	FAH Recommended Outlier Models: Cost Model	FAH Recommended Outlier Models: RCC Inflation Model	FAH Recommended Outlier Models: Threshold to Pay 5.1%
2004	$31,000	3.5%	$20,900	$25,375	$21,555
2005	$25,800	4.4%	$22,830	$28,445	$21,640

As evidenced by these calculations, the estimates using the cost methodology would have been much more accurate projections than the estimates resulting from the "charge" methodology used by CMS or even than the modified "charge" methodology suggested by the FAH. While the cost methodology would have slightly under-projected the outlier threshold for FY 2004 and slightly over- projected the threshold for FY 2005, some reasonable variation should be expected from the most accurate of outlier payment models. It is unrealistic to expect to precisely hit the 5.1% payout each year. However, it is not appropriate to use a model that will invariably underpay the 5.1%, as the FAH believes the proposed CMS model will do. The cost methodology for FY 2004 and FY 2005 would have produced a more reasonable result.

CMS is to be commended for the changes made to the outlier payment methodology in 2003 to eliminate the use of the statewide average for hospitals with low RCCs, to adopt the use of the most recent settled cost report to adjust the RCC, and to require the more timely update of the RCCs. While in the several years prior to FY 2003 the use of the cost methodology was resulting in outlier payments exceeding the 5.1% target, FAH believes that the corrective actions taken by CMS in 2003 significantly strengthen the predictability of the cost methodology Such excess payments prior to 2003 should not be attributed to the cost methodology, but should more likely be attributed to the untimely update of the RCCs and to the use of the statewide average for hospitals with extremely low cost-to-charge ratios.

Because the cost methodology, as shown herein, has proved to be a more accurate predictor in the past couple of years, the FAH recommends that CMS return to the use of the cost methodology for the projection of outlier payments. The fixed loss outlier threshold should be **$22,520**, using the cost methodology.

The FAH also suggests that CMS consider making mid-year adjustments to the outlier thresholds, if it appears that outlier payments are going to be significantly below or above the 5.1% target. As CMS made a mid-year change to the fixed loss threshold in FY 2004, it clearly has the ability to do so. After the fiscal year has begun, more current data on hospitals' cost-to-charge ratios will be available, so it should be possible to more accurately predict the amount of outlier payments that will be made. CMS could set a trigger for this adjustment. For example, if outlier payments appeared to be coming out at less than 95% or more than 105% of the 5.1% target, an adjustment would be made. The large discrepancies between outlier payments made and the 5.1% target, both

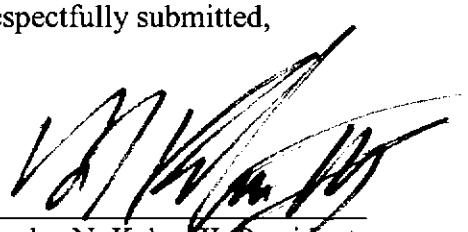
positive and negative, that have occurred over the years could possibly be avoided if CMS tracked the situation mid-year and made an adjustment to the threshold with the goal of hitting the 5.1% target overall for the year. The FAH believes that a mid-year correction process could be an aid to CMS to achieve its goal of making outlier payments at 5.1% irrespective of the payment model that CMS employs. However, we believe there will likely be less need for a mid-year correction process if CMS were to adopt either of the two payment models that we have recommended in these comments, i.e., the cost methodology model or the CMS model modified to reflect the decline in the RCCs.

In summary, the FAH is extremely concerned with the continued use of the present CMS model that has proven to significantly underpay hospitals for outliers for FY 2004 and FY 2005. The CMS model does account for charge increases but fails to account for cost increases. Such a model will invariably continue to significantly under-reimburse hospitals for patient care services rendered to Medicare patients that become outliers. FAH recommends that CMS either adopt the cost methodology that it used prior to FY 2003 or, in the alternative, adopt the model recommended by the FAH that adjusts for both charge and cost increases in computing the RCCs.

* * * *

FAH appreciates CMS's review and careful consideration of the comments in this letter, and would be happy to meet, at your convenience, to discuss them. If you have any questions, please feel free to contact Steve Speil, SVP, CFO at 202-624-1529.

Respectfully submitted,



Charles N. Kahn III, President
Federation of American Hospitals

EXHIBIT A

EXHIBIT B
Concerns Over The Data Utilized To Develop The Occupational Mix Adjustment

Overview – The purpose of this addendum is to support the overall comments related to Occupational Mix data with detailed information and examples. In addition, this addendum includes detailed recommendations that FAH suggests that CMS consider in developing the occupation mix adjustment for fiscal year 2005 and in conducting future Occupational Mix Surveys.

Data Problems:

Errors in the survey dates

The first item reviewed was the date range of the survey. This was selected due to the instructions being very clear on this item and that this was the only item that CMS indicated they had reviewed. The survey instructions indicated the survey should be completed "for a 4-week period beginning on or between December 28, 2003 and January 11, 2004, and ending no later than February 7, 2004, or retrospectively for a 12-month period, that is calendar year 2003."

Our review indicates that over 8% of the providers have errors in the survey date fields. We considered any period ending between 12/12/03 and 1/3/04 and having between 347 and 378 days to fall within calendar year 2003. This expanded date range was utilized since hospital may have input actual pay ending or pay dates that occurred in 2003. In some cases 27 bi-weekly payrolls end or are paid in a calendar year. We also considered any date range with between 25 and 30 days falling within the prescribed 4-week period range to be correct.

The over 8 % of errors are made up of the following issues.

Problem	Number of Facilities	% Of Total Facilities
No Start or End Date	11	0.29%
End Date Prior to Start Date	4	0.11%
Full Year Cost Report Ending on to Prior to 11/30/03 or After 1/31/2004	21	0.56%
Cost Report 1Yr and 9 Months or Longer	3	0.08%
Ending Date prior to 2003 or after 2004	5	0.13%
28 to 335 Day period ending in 2003	18	0.48%
Less Than 23 day period ending in 2004	12	0.32%
Report for 1 Day	1	0.03%
31 to 35 Day Period Ending in 2004	196	5.20%
35 to 43 Day Period Ending in 2004	28	0.74%
4 Weeks in 2004 Ending after the Review Period Ended	16	0.42%
Total	**315**	**8.36%**

Significant variances in hours reported on worksheet S-3 of the cost report and the occupational mix survey

The next item we reviewed was the reasonableness of the total hours included on the Occupational Mix surveys. FAH compared total man-hours from the S-3 PUF to total man-hours on the Occupational Mix PUF to assess the reasonableness of the occupational mix data. The comparison revealed significant variation between the two sets of data. 32% of the hospitals contained in both PUFs had a variance of 20% or greater. 56% had a variation of greater than 10%. The following table shows the breakdown:

Variance	Number	% Of Total
GT 50%	515	14%
30% to 50%	260	7%
20% to 30%	419	11%
10% to 20%	890	24%
0 to 10%	1,606	44%
Total	**3,690**	**100%**

The variation with S-3 data creates significant concern as to the accuracy of the occupational mix data. There are several reasons that can explain a portion of the variation. However, one must note the magnitude of these variations. The following is a list of some of the reasons for the variation:

- The instructions on the occupational mix survey were not consistent with the instructions for Worksheet S-3 of the cost report. For example, the survey indicated: "**Complete this survey for employees that are full-time and part-time, directly hired, and acquired under contract.**" One FAH member followed-up with CMS and was informed this included non-direct patient care hours for the occupational mix survey. The S-3 information from the hospitals cost report excludes non-direct patient care contract man-hours.
- Some variation will occur due to the S-3 data being from a different time period than the occupational mix data.
- The 4-week prospective time period staffing may vary from an annual time period. The timeframe for the sample was set in most hospitals' peak season.
- Hospitals may not have had time to collect all the information needed for the survey (i.e. contract man-hours) and may not have included this in the information. Most hospitals would likely disclose such significant omissions. CMS should query the FIs to see if disclosures were sent with the survey indicating some information was unavailable. All disclosures need to be included in the evaluation of the data, including FI follow-up where necessary.
- Errors will also contribute to these variances. Given the tight timeframe on the hospitals as well as the first time for completing this type of survey it would be very easy to have an error such as failing to eliminate man-hours for excluded

areas. The short timeframe also severely restricted the ability of FIs and CMS to review the accuracy of data, to do proper follow-up, and make corrections.

FAH recommends that CMS revise the survey in the future to facilitate comparison with the S-3 data. This would include breaking out contract and employees data separately by category. In addition, CMS should either make the survey instructions match the S-3 instructions or break out the items that vary between the survey and S-3 into a separate category or categories (i.e. non direct patient care contract man-hours). CMS and or the FIs should compare and investigate significant variances between the S-3 data and the occupational mix survey as part of their review, including any disclosures by hospitals.

Employees appear not to be consistently classified among hospitals

FAH's next major concern is that employees were not classified consistently among hospitals. Inconsistent classification results in incorrect occupational mix adjustments. Hospitals are benefited and or harmed based on where employees are classified when data is not consistently classified.

We feel that this can be seen in the variance in the percentage of employees between the BLS and Occupational Mix Survey results on Charts 4 and 5 in the proposed rule. To demonstrate this concern, we have prepared the chart below. In addition, we have calculated the percent the average hourly rate per category varies from the weighted average hour rate of the 19 specific categories. The higher the variance from the average, the greater the impact hours in the category would have on the occupational mix adjustment.

Comparison of Occupational Mix Survey and BLS survey Information

	Percent of Total Employee Hours				
General Service Categories	**Occupational Mix Survey**	**BLS**	**% Variance**	**Avg. Hr. Rate per BLS**	**%Variance to Overall Avg. Hr. Rate**
Nursing Services and Medical Assistant Services					
Registered Nurses	26.23%	25.88%	1.35%	$ 23.62	18%
Licensed Practical Nurses	2.89%	3.86%	-25.13%	14.65	-27%
Nursing Aides, Orderlies, & Attendants	6.79%	6.96%	-2.44%	10.01	-50%
Medical Assistants	1.36%	0.93%	46.24%	11.79	-41%
Total	**37.27%**	**37.63%**	**-0.96%**		
Physical Therapy Services					

General Service Categories	Percent of Total Employee Hours: Occupational Mix Survey	BLS	% Variance	Avg. Hr. Rate per BLS	%Variance to Overall Avg. Hr. Rate
Physical Therapists	0.83%	0.92%	-9.78%	27.80	39%
Physical Therapist Assistants	0.32%	0.35%	-8.57%	17.11	-14%
Physical Therapist Aides	0.22%	0.24%	-8.33%	10.40	-48%
Total	**1.36%**	**1.50%**	**-9.33%**		
Occupational Therapy Services					
Occupation Therapists	0.35%	0.48%	-27.08%	25.62	28%
Occupation Therapist Assistants	0.08%	0.11%	-27.27%	16.81	-16%
Occupation Therapist Aides	0.03%	0.04%	-25.00%	11.60	-42%
Total	**0.46%**	**0.63%**	**-26.98%**		
Respiratory Therapy Services					
Respiratory Therapists	1.55%	1.36%	13.97%	19.26	-3%
Respiratory Therapy Technicians	0.39%	0.51%	-23.53%	16.96	-15%
Total	**1.94%**	**1.87%**	**3.74%**		
Pharmacy Services					
Pharmacists	1.02%	0.96%	6.25%	34.58	73%
Pharmacy Technicians	1.01%	0.88%	14.77%	12.30	-38%
Pharmacy Assistants/Aides	0.08%	0.13%	-38.46%	11.52	-42%
Total	**2.11%**	**1.97%**	**7.11%**		
Dietary Services					
Dieticians	0.35%	0.33%	6.06%	20.02	0%
Dietetic Technicians	0.48%	0.26%	84.62%	11.64	-42%
Total	**0.84%**	**0.59%**	**42.37%**		
Medical & Clinical Lab Services					
Medical & Clinical Lab Technologists	2.14%	1.73%	23.70%	20.74	4%
Medical & Clinical Lab Technicians	1.97%	1.26%	56.35%	14.90	-25%
Total	**4.10%**	**2.99%**	**37.12%**		

General Service Categories	Percent of Total Employee Hours: Occupational Mix Survey	BLS	% Variance	Avg. Hr. Rate per BLS	%Variance to Overall Avg. Hr. Rate
Total Nursing, Therapy, Pharmacy, Dietary, and Medical & Clinical Occupations	**48.08%**	**47.19%**	**1.89%**		
All Other Occupations	**51.92%**	**52.81%**	**-1.69%**		
Total Hospital Employees	**100.00%**	**100.00%**	**0.00%**		

Occupational mix data can be significantly distorted by relatively small occupational categories. One such category that shows significant variance in comparing the BLS to Occupational Mix survey is Dietary Technicians. This category has a significant impact on the occupational mix adjustment due to it having a very low averagely hourly rate. Per BLS information, this should be a very low volume of employees. BLS information indicates that only .26% of hospital employees fall into this category. The percentage of employees per the occupational mix survey indicates that .48% of hospital employees fall into this categories or approximately 85% greater then the BLS.

FAH has studied the May 2004 Public Use File (PUF) to further understand this variance. This review indicates great variability in the data reported by hospitals for Dietary Technicians. The table below displays the distribution:

Range	Number of Hospitals	% Of Total
>10%	22	0.6%
5 to 10%	152	4.0%
3 to 5%	232	6.2%
2 to 3%	158	4.2%
1 to 2%	199	5.3%
0 to 1%	1418	37.6%
No Hours	1588	42.1%
Total	**3769**	**100.0%**

FAH concludes that the variation in the table is a result of different interpretations of the category on the survey form. A hospital only considering the definitions included on the occupational mix survey could easily conclude that food preparation workers and cooks should be included in this category. This is due to the following section contained within the survey definition "Under the supervision of dietitians, may plan and produce meals". However, hospitals reviewing the full BLS survey should conclude that such employees should not be included, since BLS includes a major group "Food Preparation and Serving Related Occupations" that has 13 specific categories under it. This major group

represents 2.99% of the total hospital workforce. The specific category "Food Preparation Workers" account for .8% of the hospital workforce per the BLS survey. "Cooks, Institution and Cafeteria" account for .65% of the hospitals workforce within this major group.

Based on the overall BLS percentages, it appears that any hospital with greater than 2% of their employees in the Dietary Technician category has likely included food preparation workers in their count. The table above indicates that over 20% of the hospitals completing the survey fall into this category. This inconsistent reporting causes the occupational mix adjustment to be distorted by a relatively small occupational mix category, Dietary Technicians.

FAH recommends that CMS should eliminate the dietary category from the occupational mix adjustment. In addition, CMS should expect variations such as this to have occurred in various areas of the survey. This category is more visible due to its low volume.

FAH also has significant concerns regarding the Medical Assistant category. A hospital considering only the survey definitions could conclude several areas could be included in this category. The description per the occupational mix survey follows: "**Performs administrative and certain clinical duties under the direction of physician. Administrative duties may include scheduling appointments, maintaining medical records, billing, and coding for insurance purposes. Clinical duties may include taking and recording vital signs and medical histories, preparing patients for examination, drawing blood, and administering medications as directed by physician. Exclude "Physician Assistants" (29-1071).**" Based on this definition, some hospitals likely have included various administrative areas including Health Information Management into this category. In addition, phlebotomists likely have been included in the Medical Assistant category for some hospitals, since the category specifically mentions drawing blood. The concern is supported by the fact that the occupational mix survey indicates 1.36% of hospital employees fall into this category verses .93% on the BLS survey. This results in a 41% variance. FAH could not find that the BLS specifically identified the category where phlebotomist should be classified. CMS verbally told a FAH member to report phlebotomists as "all other." However, FAH remains concerned that hospitals did not consistently classify phlebotomist, leading to a distorted occupational mix adjustment.

Another concern about the Medical Assistant category is that it is not a frequent position in a general hospital. This position is normally found in physician offices and in clinics. As seen in the table below, the majority of hospitals submitting the survey do not report any hours for this position on the survey. Over 70% have 1 or less percent reported.

Range	Number of Hospitals	% Of Total Hospitals
>20%	7	0.2%
15 to 20%	13	0.3%
10 to 15%	51	1.4%
5 to 10%	196	5.2%
1 to 5%	740	19.6%
.001 to 1%	812	21.5%
Zero	1,950	51.7%
Total	3,769	100.0%

Thus, inconsistent reporting causes the occupational mix adjustment to be distorted by a relatively small occupational mix category, Medical Assistant.

FAH recommends that CMS exclude the Medical Assistant category from the occupational mix calculation given the concerns on employees being classified into this category and the fact this is not a usual position within a hospital.

Another key area that results in inconsistencies is how employees within categories with administrative functions are categorized. The survey states the following "**As with the BLS survey, workers should be classified in the occupation that requires their highest level of skill. If no measurable difference in skills, workers are to be included in the occupation they spend the most time. For example, if an RN primarily functions in an administrative capacity, the RN's hours should be included on the line for "All Other Occupations" rather than on the line for Registered Nurses."**

Hospitals will draw different conclusions regarding where RNs in management will fall. Hospitals have various levels of RNs within their organizations. Common levels include the Charge Nurses, Head Nurses and House Supervisors. The charge nurse generally carries a patient load, schedules employees for a shift, and supervises the nursing unit for a shift. The Head Nurse normally manages a specific nursing unit and provides patient care from time to time. The House Supervisor provides overall general management for all nursing units for a shift and may provide direct patient care.

FAH is concerned that hospitals have classified these categories differently.

FAH is also concerned that there are some obvious errors in the RN category that will not be corrected. The table below shows the RN % of total hospital employees:

Range	Number of Hospitals	% Of Total
0 to 5%	38	1.0%
5 to 10%	49	1.3%
10 to 15%	200	5.3%
15 to 20%	521	13.8%
20 to 25%	1,066	28.3%
25 to 30%	1,047	27.8%
30 to 35%	489	13.0%
35 to 40%	192	5.1%
40 to 50%	115	3.1%
> 50%	52	1.4%
Total	3,769	100.0%

Based on the distribution, it appears unreasonable that a hospital would have RNs make up less than 15% or more than 50% of its total employees. FAH recommends that CMS review all hospitals that appear unreasonable and correct the information where necessary. FAH recommends for future surveys that the description for each category with administrative functions be clearly stated, including either instructions to properly prorate the time for individuals that perform two or more occupational mix categories or instructions to classify such individuals to a category where the majority of their time is spent as opposed to being classified to the highest job category (i.e., administrative rather than RN, if RN duties take the majority of time).

We also looked at the hospitals that had less than 4.6 RN FTEs indicated. Hospitals on this list appear to have less than 1 RN around the clock, since 4.6 FTEs are required to staff one person 7 days a week 24 hours a day with 10% non productive time (vacation, holiday and sick).

Range	Number of Hospitals	% Of Total Hospitals
No RN Hours Reported	3	0.1%
Less Than .5 FTE	18	0.5%
.5 to 1.0 FTE	14	0.4%
1 to 2 FTEs	37	1.0%
2 to 4.6 FTE's	65	1.7%
Total	137	3.6%

FAH recommends that CMS review and correct, if necessary, all hospitals with under 4.6 FTEs.

FAH also noticed several hospitals that did not have any hours reflected for some positions that appear to be required for a hospital. The following table summarizes the number of hospitals by issue.

Hospitals with no Hours Reported for Required Positions

Description	Number of Hospitals
No Pharmacists Hours	168
No Dietitian Hours	427
No PT Hours for Hospitals with Hours in PT Services	38
No OT Hours for Hospitals with Hours in OT Services	31

Hospitals on this list are likely the result of the following issues:

- Error in completing the Occupational Mix Form
- They are out of compliance with the Conditions of Participation or other requirements
- They are considering the employees that meet these criteria in the "All Other Category"

Hospitals may have placed employees in "all other" if they have administrative functions such as being a department manager. In cases where the position is filled with 1 person, that person likely spends the majority of their time in direct patient care. However, based on the instructions, they do have a basis for reporting hours as "all other".

FAH recommends that CMS review all hospitals that fall into the categories above to ensure no errors have occurred and that the hospitals are in compliance with regulatory requirements. FAH also recommends that CMS adjust the survey form instructions to capture the clinical hours these positions provide.

FAH believes that there are additional classification problems not covered above. A specific category of concern that we were unable to study due to time was Nursing Assistant. This category seemed to have a wide variation by hospital. FAH encourages CMS to review all the other categories for reasonableness.

Hospitals were allowed to complete the survey for a 4-week period during their peak season

Our last major concern relates to hospitals being allowed to complete the survey for a 4-week period during their peak season. FAH is concerned that this sample period will not be representative of the hospitals' actual staffing mix. A review of the May 2004 PUF reveals that over 25% of the hospitals utilized this very short period.

We recommend for future occupational mix surveys that CMS consider all the issues mentioned above in both the design of the survey as well as in reviewing the process employed.

EXHIBIT C

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June 14, 2005

MODELING FFY 2006 OUTLIER PAYMENTS

DATA SOURCES.

1. The MEDPAR 2004 computer file obtained from CMS. The file contains 13,610,386 records, each corresponding to a Medicare hospital discharge occurring in FFY 2004.

2. CMS FFY 2006 Impact File (Proposed Rule Version). This file produced by CMS shows the estimated level of FFY 2006 outlier payments by hospital (as percentages). It also shows the hospital-specific parameters used for calculating PPS payments, such as DSH and IME adjustment factors, cost to charge ratios (CCRs), wage indexes, etc.

3. The March 31, 2005 update of the HCRIS database. This database consists of Medicare cost reports beginning in Federal Fiscal Years (FFYs) 1996 through 2004.

REPLICATION OF THE CMS ESTIMATED 2006 OUTLIER PAYMENT LEVELS (IPPS PROPOSED RULE OF MAY 4).

The regular and outlier FFY 2006 payments were estimated for each patient in the MEDPAR database. Regular payments were calculated based on the proposed DRG weight, the patient discharge destination (for identifying transfers), the applicable proposed standardized amounts and the other hospital-specific parameters determining PPS payments. The latter are the wage index, the non-labor cost of living adjustment, and the DSH and IME adjustment factors. Each of these parameters has different values applicable to operating and capital payments. The parameters were obtained from the CMS Impact File.

Outlier payments were calculated inflating 2004 charges by 18.04 percent (the inflation factor used by CMS), reducing charges to costs using the cost to charge ratios from the CMS Impact File and comparing costs to the proposed FFY 2006 fixed loss amount of $26,675. The latter was adjusted as appropriate on a hospital-specific basis. It should be noted that the Impact File cost to charge ratios are mostly from fiscal periods beginning in FFY 2003. Also, no allowance was made for the anticipated continued decrease in the CCRs.

With these assumptions, both the FFY 2006 operating and capital outlier payments were estimated at 5.02 percent of the respective total payments, net of DSH and IME amounts. In the case of operating payments the result is slightly lower than the Proposed Rule CMS estimate of 5.10 percent. Interestingly, the published CMS estimates do not agree entirely with the CMS Impact File. Using the Impact File CMS individual hospital outlier percentages and calculating DRG payments from other Impact File data, the operating outlier level is 5.01 percent and the capital level is 5.08 percent. At least in the case of operating payments, the CMS Impact File result is very close to the MEDPAR-based estimate. In any event, these differences are not particularly significant. Most likely, they originate from different estimates being based on different stages of completeness of the MEDPAR file. The dollar amount of FFY 2006 outlier payments was estimated at $4,340B.

ESTIMATE OF THE FFY 2006 FIXED LOSS AMOUNT USING THE MOST RECENT COST TO CHARGE RATIOS.

More recent cost to charge ratios were calculated from the latest cost reports available in the HCRIS database. Medicare inpatient operating costs were obtained from Worksheet D-1, Part II, Medicare inpatient capital costs from Worksheet D, Parts I and II and Medicare inpatient charges from Worksheet D-4. A comparison with the dates of the CCRs in the Impact File, presumably used to establish the proposed FFY 2006 fixed loss threshold, is shown in the table below.

Beginning in FFY	Number of Cost Reports Used for the Impact File CCRs	Percent of Cost Reports Used for the Impact File CCRs	Number of HCRIS Latest Cost Reports for Impact File Hospitals	Percent of HCRIS Latest Cost Reports for Impact File Hospitals
	(a)	(b)	(c)	(d)
2000	12	0.4%	4	0.1%
2001	18	0.6%	3	0.1%
2002	562	19.5%	91	2.5%
2003	2,271	78.7%	3,057	83.0%
2004	23	0.8%	526	14.3%
Unknown/Not Matching	807		12	
Total	3,693		3,693	

Table Notes: Column (a) numbers are based on matching Impact File CCRs with HCRIS CCRs for fiscal periods beginning between 2000 and 2004. If both operating and capital CCRs were within 0.001 of their respective counterparts, the HCRIS cost report was considered to be the source for the Impact File CCR. Percentages in columns (b) and (c) are based on the total of FFYs 2000-2004, i.e., unkown/not matching hospitals were not included.

Using the more recent HCRIS CCRs and the CMS assumptions listed above, the estimate of the fixed loss threshold is **$25,085**, significantly lower than the proposed value.

ESTIMATE OF THE FFY 2006 FIXED LOSS AMOUNT PROJECTING BOTH CHARGE AND COST INFLATION.

Outlier payments are calculated from costs. Costs are determined by applying a cost to charge ratio to actual charges. It follows that accurate outlier estimates require projecting **both** costs and charges. An additional complication is the inevitable lag between CCRs that can only be determined retrospectively at the end of an elapsed cost reporting period and the current charges to which they

are applied. Historically, CMS has projected outlier payments by projecting only costs or only charges and ignored the time lag problem. This approach works well in periods when cost and charges move more or less in tandem. When costs and charges change at significantly different rates, relying on only one measure of inflation can result in either outlier over- or underpayments[1]. An alternative methodology that overcomes these shortcomings is described below.

In order to account for the time lag problem, cost to charge ratios were projected from the most recent fiscal period in the March 31, 2005 HCRIS update to the fiscal period(s) expected to be used for the calculation of the CCR(s) determining FFY 2006 outlier payments. The CMS Program Memorandum A-03-058 dated July 3, 2003 instructs Fiscal Intermediaries to update the CCRs "not later than 45 days after the date of the tentative settlement or final settlement used in calculating the CCRs". Combining this deadline with the maximum of eight months between the end of the cost reporting period and tentative settlement, it is reasonable to expect CCRs to be updated no later than nine months after the end of the cost reporting periods. Assuming a nine-month lag in updating CCRs, FFY 2006 outlier payments will be based partly on 2004 and partly on 2005 ratios, depending on the fiscal period ending date (FPE). Hospitals with a January FPE will have their CCR updated to the FPE January 2005 by October 31, 2005. Their FFY 2006 outlier payments will be based on the FPE January 2004 CCR for one month (October 2005) and on the FPE January 2005 CCR for the remaining eleven months. Similarly, FFY 2006 outlier payments for hospitals with a February FPE will be based on the 2004 CCR for two months and the 2005 CCR for ten months, and so on. Hospitals with a December FPE would have their FFY 2006 outlier payments based entirely on the FPE December 2004 CCR.

The cost inflation factor for projecting CCRs was determined from the costs reports of a cohort of 3,756 matched hospitals for periods beginning in FFYs 2001, 2002 and 2003. All three costs reports were available for each hospital from the recent update of HCRIS. The 2001-2003 aggregate annual rate of increase in the cost per discharge for these hospitals was 6.57 percent[2]. This cost inflation factor and the CMS charge inflation factor of 8.65 percent were used to project cost to charge ratios over the time periods described above. The projected CCRs were applied to projected FFY 2006 charges to simulate the determination of costs for FFY 2006 outlier payments. The estimated fixed loss amount that would result in 5.1 percent outlier payments in this scenario is **$24,050**. It should be noted that this model (as well as all the ones discussed here) does not take into account the potential impact of outlier reconciliation. The model assumes FFY 2006 outlier payments based on costs determined using pre-2006 CCRs. If outlier payments were adjusted retrospectively based on FFY 2006 "true" costs determined using 2006 CCRs, final outlier payments would be lower (assuming a continuing trend of decreasing cost to charge ratios).

1 Of course, regardless of methodology, over- or under estimates of outlier payments may result from cost and/or charge inflation projections -usually based on the assumption that historical values are a reasonable indicator of future trends- that turn out to be inaccurate.

2 An audit adjustment was applied to costs from "as submitted" cost reports. The audit adjustment was determined by comparing 1,881 "as submitted" cost reports from the December 31, 2003 HCRIS database with the settled reports of the same hospitals in the March 31, 2005 HCRIS update.

ESTIMATE OF THE FFY 2006 FIXED LOSS AMOUNT PROJECTING ONLY COST INFLATION.

This is the methodology CMS used for the FFYs 1994-2002. For projecting FFY 2006 outlier payments, it consists of applying historical CCRs to FFY 2004 charges to determine FFY 2004 costs. These costs are projected forward to FFY 2006 using a cost inflation factor. However, the "cost inflation only" approach ignores the time lag problem. This may result in underestimating FFY 2006 costs for outlier payment determination and, therefore, underestimating the FFY 2006 fixed loss threshold. The underestimate results from using historical CCRs generally more recent than the CCRs actually available in 2004[3]. However, as discussed above, this model ignores the potential impact of outlier reconciliation. If FFY 2006 outlier payments were determined retrospectively from "true" FFY 2006 costs, the use of CCRs yielding FFY 2004 costs closer to the "true" costs is likely to result in a more accurate estimate of the FFY 2006 fixed loss amount.

The cost inflation approach using an annual cost inflation factor of 6.57 percent and the Impact File CCRs resulted in a FFY 2006 estimated fixed loss amount of **$23,610**. If the most recent CCRs from the HCRIS database were used instead, the estimated FFY 2006 fixed loss amount was **$22,520**.

ESTIMATE OF THE FFY 2005 OUTLIER PAYMENTS

The May 4 IPPS proposed rule states that FFY 2005 outlier payments are now estimated at 4.4 percent of total DRG payments. Using the "charge inflation only" model and the Impact File cost to charge ratios, the outlier payment level was estimated at 4.3 percent, essentially replicating the CMS finding. Using the same model, the fixed loss amount that would result in a payment level of 5.1 percent was estimated at **$21,925**.

The FFY 2005 fixed loss amount was estimated using all the other models described above. Still using the "charge inflation only" but substituting the most recent HCRIS CCRs for the Impact File ratios, the fixed loss threshold was estimated at **$21,710**. It should be noted that the most recent CCRs used in these model were selected by taking into account their applicability to FFY 2005. For example, assuming a nine-month lag in updating CCRs, hospitals with fiscal periods ending in June 2004 had their first six months of FFY 2005 outlier payments based on the June 2003 FPE cost to charge ratio, and the last six months based on the June 2004 FPE ratio. Even the June 2004 FPE ratio is the most recent ratio available, the CCR used in this model was an average of the 2003 and 2004 ratios weighted by the number of months of usage in FFY 2005.

If both cost and charge inflation are taken into account, and assuming a nine-month lag in updating

3 This discussion assumes charges increasing at a faster pace than costs. In that case, because FFY 2006 "costs for outlier payment determination" are obtained by applying CCRs from earlier periods to FFY 2006 charges, 2004 "costs" should be determined with similarly lagged CCRs.

CCRs, the FFY 2005 fixed loss threshold amount was estimated at **$21,640**.

Using the "cost inflation only" models the fixed loss amounts were estimated at **$20,745** and **$20,535**, based on Impact File and most recent HCRIS cost to charge ratios, respectively. Because of the problems with the "cost inflation only" model noted for the FFY 2006 estimates, i.e. not taking into account the lag in updating CCRs, it is quite likely these amounts are underestimated.

Both FFY 2005 and 2006 results and underlying assumptions are summarized in the tables on the following pages.

FFY 2006 ESTIMATED FIXED LOSS AMOUNTS AND UNDERLYING ASSUMPTIONS

METHODOLOGY	Data Source for Cost to Charge Ratios	Charge Inflation (2003-2004 MEDPAR, From Proposed Rule	Cost Inflation	Change in Cost to Charge Ratios	Assumed Lag Between the Fiscal Period End and Effective Date of the CCRs	ESTIMATED FFY 2006 FIXED LOSS AMOUNT ($)
		(Per Year)	(Per Year)	(Per Year)		
Charges Projected From FFY 2004 to FFY 2006	CMS Impact File-Proposed FY 2006	8.65%	None	None	None	26,675
Charges Projected From FFY 2004 to FFY 2006	HCRIS 03/31/2005 Update	8.65%	None	None	None	25,085
Charges Projected From FFY 2004 to FFY 2006; Cost to Charge Ratios Projected to Simulate Effective CCRs for FFY 2006 Outlier Payments	HCRIS 03/31/2005 Update	8.65%	6.57% (From HCRIS Cost Reports 2001-2003)	-1.91%	Nine Months	24,050
Costs Projected From FFY 2004 to FFY 2006	CMS Impact File-Proposed FY 2006	None	6.57% (From HCRIS Cost Reports 2001-2003)	None	None	23,610
Costs Projected From FFY 2004 to FFY 2006	HCRIS 03/31/2005 Update	None	6.57% (From HCRIS Cost Reports 2001-2003)	None	None	22,520

FFY 2005 ESTIMATED FIXED LOSS AMOUNTS AND UNDERLYING ASSUMPTIONS

METHODOLOGY	Data Source for Cost to Charge Ratios	Charge Inflation (2003-2004 MEDPAR, From Proposed Rule)	Cost Inflation	Change in Cost to Charge Ratios	Assumed Lag Between the Fiscal Period End and Effective Date of the CCRs	ESTIMATED FFY 2005 FIXED LOSS AMOUNT ($)
		(Per Year)	(Per Year)	(Per Year)		
Charges Projected From FFY 2004 to FFY 2005	CMS Impact File-Proposed FY 2006	8.65%	None	None	None	21,925
Charges Projected From FFY 2004 to FFY 2005	HCRIS 03/31/2005 Update	8.65%	None	None	None	21,710
Charges Projected From FFY 2004 to FFY 2005; Cost to Charge Ratios Projected to Simulate Effective CCRs for FFY 2005 Outlier Payments	HCRIS 03/31/2005 Update	8.65%	6.57% (From HCRIS Cost Reports 2001-2003)	-1.91%	Nine Months	21,640
Costs Projected From FFY 2004 to FFY 2005	CMS Impact File-Proposed FY 2006	None	6.57% (From HCRIS Cost Reports 2001-2003)	None	None	20,745
Costs Projected From FFY 2004 to FFY 2005	HCRIS 03/31/2005 Update	None	6.57% (From HCRIS Cost Reports 2001-2003)	None	None	20,535

EXHIBIT D

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June 21, 2005

CALCULATION OF THE FFY 2004 FIXED LOSS AMOUNT THAT WOULD HAVE RESULTED IN OUTLIER PAYMENTS OF 5.1 PERCENT

The level of outlier payments actually made in 2004 can be determined from the 2004 MEDPAR data. The operating outlier payment, if any, is explicitly shown for each Medicare discharge. The regular DRG operating payment can be easily determined from data in the file. Specifically, the operating payment net of indirect medical and disproportionate share adjustments is the DRG PRICE less CAPITAL, DSH and IME payments. The amounts shown in capitals are all fields in the MEDPAR records. The total outlier payments made in 2004 amounted to 2.679B. This represents 3.4 percent of total Medicare IPPS payments net of indirect medical and disproportionate share adjustments. The result is slightly different from the CMS estimate of 3.5 percent. The difference is not significant and may be due to the different degrees of completeness of the MEDPAR file used for the two calculations.

The outlier amounts that should have been paid could be calculated from the MEDPAR data if the cost to charge ratios actually used were available. To my knowledge there is no public data source for them. An alternative would be to estimate the CCRs from other data sources, e.g., HCRIS. However, this would involve assumptions about the rates of cost and charge inflation. In order to avoid dependence on such assumptions the CCRs were estimated from the MEDPAR file itself. The comparison of any two outlier payments *calculated using the same CCRs* allows the determination of the CCR:

$O_1 = 0.8 \times (OPCCR \times C_1 - D_1 - AFL)$

$O_2 = 0.8 \times (OPCCR \times C_2 - D_2 - AFL)$

where O = outlier payment, C = charges, D = DRG payment, AFL = adjusted fixed loss amount and OPCCR = operating cost to charge ratio.

Note that AFL is actually dependent of the cost to charge ratios, but since it cancels out of the final equation, this fact can be ignored

Adding up the two equations and solving for OPCCR:

$$OPCCR = [(O_2 - O_1) / 0.8 + (D_2 - D_1)] / (C_2 - C_1)$$

A similar calculation can be carried out for the capital cost to charge ratio. This method was used to determine the CCRs by arraying all outlier payments made to a hospital during a given quarter in increasing order of the covered charges. The calculation shown above was performed by comparing each outlier payment in the array to the outlier payment with the highest covered charges and, again, to the outlier payment with the lowest charges. The median of the CCRs thus obtained was considered to have been the CCR used to determine outlier payments for the quarter and hospital under consideration. If the actual CCR remained the same during the entire quarter, the method

above should in principle determine it exactly. If the CCR did change during the quarter, the

calculation yields an approximate "effective" CCR. (The date of discharge shown in MEDPAR is limited to the quarter of discharge). The approach outlined above can be applied only when a hospital had at least two outliers in a given quarter. For hospitals with less than two outliers in a quarter, the CCR ratios were taken from the CMS Impact File for FFY 2004 (the Final Rule version).

In order to validate the CCRs obtained as described above, they were used to calculate "simulated" 2004 outlier payments based on the fixed loss amounts effective in FFY 2004 ($31,000 for the first six months and $30,150 for the remainder of the year). The total amount of "simulated" payments was $2,672B compared with the actual amount of $2,679B[1]. The CCRs were then used to calculate the 2004 fixed loss amount that would have resulted in a 5.1 percent outlier payment level. The result was **$21,555**. It should be noted that the shortfall in operating outlier payments in FFY 2004 amounted to $1.4B.

ESTIMATED FFY 2004 FIXED LOSS AMOUNT USING THE COST INFLATION METHODOLOGY

When preparing comments to the FFY 2004 Proposed Rule, FAH did not use the cost inflation approach. The reason may have been the perception that the cost report database (HCRIS) was incomplete at the time due to the implementation of the Outpatient Prospective Payment System. Revisiting the issue now, it turns out there was sufficient cost report data to determine a cost inflation factor. The cost inflation calculation for 2004 was performed now using *only* the data available in June 2003. The historical 1999-2001 cost inflation rate was determined from the cost reports of a cohort of 3,509 matched hospitals for periods beginning in 1999, 2000 and 2001. The cost report data for these hospitals was obtained from the *March 31, 2003* update of the HCRIS database. The resulting annual rate of cost inflation was 5.0 percent[2].

The 1999-2001 cost inflation rate was assumed to apply to the 2002-2004 period. Costs were determined from the *2002* MEDPAR file by applying cost to charge ratios from the most recent cost reports available in the *March 31, 2003* update of HCRIS. With these assumptions the 2004 fixed loss amount resulting in a 5.1 outlier payment level was estimated at **$20,900.**

1 The comparison was limited to cases when outlier payments were actually made. Simulated payments for all cases are slightly higher ($2,746B). This may reflect situations when outlier payments were denied for not being submitted in accordance with Medicare laws and regulations.

2 Because of the limited time available to perform this calculation, no audit adjustment was applied to costs from "as submitted" reports. Had such an adjustment been available, the resulting rate of inflation would have been slightly lower as most "as submitted" reports were for the later years. This would have resulted in a slightly lower 2004 fixed loss amount than the one estimated here.

June 20, 2005

DRG/GeN

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MED EL CORPORATION

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

RECEIVED
JUN 24 2005
BY:.....

Nefler
Norwich
Brooks
Fagan
Gruber
Kelly

RE: CMS-1500-P: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems (IPPS) and FY 2006 Rates

Dear Dr. McClellan:

I am writing to submit public comment on the proposed ruled indicated above on behalf of MED-EL Corporation, one of the world's three cochlear implant manufacturers.

"DRG Reclassifications"

Although payment for cochlear implants in the outpatient setting under Medicare has increased over the past three years (payment still inadequate to cover the cost of device and facility charge, however), payment under the IPPS is considerably well below the cost of providing this service. For years, manufacturer representatives, implant surgeons and hospital representatives have submitted comments in opposition to the established DRG assignment for the cochlear technology (DRG 49) on the basis of clinical incongruity and economical inconsistency of cochlear implants with other procedures in DRG 49. Accordingly, the request was made for creation of a new DRG or re-assignment of cochlear implants to a more appropriate paying DRG. To no avail, cochlear implants still remain under DRG 49, and are poorly reimbursed, despite CMS' acknowledgement of this disparity between payment and cost in the preamble of CMS-1470-P.

As CMS maintains a commitment to further evaluation of re-classification options for cochlear implants, we propose the following:

1. Splitting of DRG 49 into two new DRGs based on procedures utilizing high cost implantable devices and those without
2. Creation of a new DRG for cochlear implants with appropriate weight assignment (1.6375**X2**)
3. Temporary re-assignment of cochlear implants to a more weight appropriate DRG (i.e. DRGs 1 or 482, Craniotomy Age>17 W/CC and Tracheostomy for Face, Mouth and Neck Diagnoses, respectively)

Cochlear implants represent the only procedure in DRG 49 that involve implantation of a high cost medical device and therefore **the most appropriate solution is creation of a**

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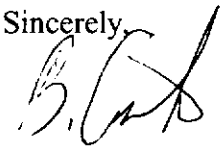
separate DRG. It is believed that the effect on the weight for DRG 49 would be negligible.

In order to allow Medicare beneficiaries continued access to cochlear implants when the patient's health condition require performance of the procedure as inpatient, we implore CMS to strongly consider re-classification of cochlear implants to a more weight appropriate DRG. CMS' previous acknowledgement of the disparity between payment and cost for cochlear implants provides an opportunity for CMS and stakeholder groups to work together to come up with an effective solution to this serious payment issue.

Sincerely,



Barbara Carter
Manager, Reimbursement Services
MED-EL Corporation

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CALIFORNIA HOSPITAL ASSOCIATION
Providing Leadership in Health Policy and Advocacy

June 24, 2005

Mark B. McClellan, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P.O. Box 8010
Baltimore, MD 21244-1850

RE: CMS 1500-P — Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Payment Rates; Proposed Rule (*70 Federal Register 23305*), May 4, 2005.

Dear Administrator McClellan:

The California Hospital Association (CHA), on behalf of its nearly 500 member hospitals, health systems and ancillary providers, respectfully submits comments regarding the proposed changes to the inpatient prospective payment system (IPPS). In addition to these comments, CHA supports the comments and recommendations of the American Hospital Association (AHA).

Hospital Market Basket

In an effort to correct market basket over-estimations, in 1998 the Centers for Medicare & Medicaid Services (CMS) implemented a methodology change — a change that over the last several years appears to have resulted in market basket projections that are lower than the actual increase. For example, the projected increase in fiscal year (FY) 2003 was 3.5 percent; the actual increase was 3.9 percent. In FY 2004, the actual increase was 3.8 percent compared to CMS' projected increase of 3.4 percent.

Based on the most recent data, CMS reports that the FY 2005 market basket increase is now estimated to be 4.1 percent compared to the projected 3.3 percent increase that was used to determine the update factor. Given a 4.1 percent cost increase for FY 2005, a projected FY 2006 increase of 3.2 percent does not seem reasonable. CHA is concerned that the methodology used to project the market basket increase is flawed and fails to provide a reliable estimate of hospital cost increases. CHA requests that CMS review and revise the methodology that was used to determine the projected FY 2005 market basket and make details of the calculation available to the public.

Labor-Related Share

Due to the use of more recent data and the removal of postage from the labor share, CMS proposes to reduce the labor-related share from 71.1 percent to 69.7 percent for FY 2006. This proposed change, if adopted, would adversely affect hospitals with an average wage index (AWI) greater than 1.0. Hospitals with AWIs less than 1.0 are not impacted by this change, as the Medicare Prescription Dug, Improvement, and Modernization Act (MMA) of 2003 set the

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labor share of the standardized amount of such hospitals at 62 percent. In 2003, CMS acknowledged that it was unable to discover an alternative methodology that is reliable, accurate and easy to apply. Given that CMS has not offered an alternative methodology for consideration since that time, CHA is concerned about CMS proposing any changes to the calculation of the labor-related share.

In particular, CHA is concerned about the removal of postage from the labor-related categories. CMS' assertion in 2003 that additional analyses are needed still stands today. CHA believes that CMS should continue to consider this category labor-related until a broader look at the calculation of the labor-related share is taken. Arbitrarily pulling out one item, postage, will unfairly penalize California hospitals, particularly those in high wage areas.

CHA is also concerned about the large drop in the other labor-intensive services category (landscaping, protective services, laundry, etc.). CHA urges CMS to investigate this drop and whether it is a result of a flaw in the methodology. For instance, an inappropriately low growth factor could cause an improper category weight and the underestimation of the market basket.

CHA believes that CMS should continue to investigate alternative methodologies for computing the labor-related share and in the interim should leave the labor-related share at 71.1 percent for FY 2006.

Blood and Blood Products Category

In the proposed rule, CMS proposes to remove the blood and blood products category from the market basket and instead include those costs in the miscellaneous products category. CMS believes that the Bureau of Labor Statistics (BLS) Producer Price Index (PPI) for blood and derivatives "may not be consistent with the trends in blood costs faced by hospitals," and that "the PPI for finished goods minus food and energy moves most like the recent blood cost and price trends." We urge CMS to publish the data upon which this judgment is based.

CHA appreciates CMS' recognition that the current BLS PPI for blood and derivatives is not capturing the increasing price trends for the blood products most commonly used by hospitals. While we support CMS' proposal to include blood and blood product costs in the miscellaneous products category, we support it only as a temporary measure until a more appropriate blood and blood products PPI can be developed by BLS. We strongly encourage CMS to work with BLS as it proceeds in its stated intention to add the Blood and Organ Banks, North American Industry Classification System industry code 621991 to the BLS PPI program. We further urge CMS to work with BLS to ensure that: 1) the key, high-volume blood products used in transfusion medicine be included in the PPI survey — especially red blood cells (with or without leukoreduction), single donor platelets, whole blood derived platelets (random donor, with or without leukoreduction), and fresh frozen plasma and plasma; and 2) the costs associated with ongoing blood testing and processing should be included as price changes in the new PPI, since these procedures are required either by federal regulation, voluntary accrediting agencies or as standard of care to protect the public's health and safety and to ensure that the all blood collected in the country meets the same safety standards. The goal should be supporting the development of a PPI index that tracks the price of a safe unit of blood over time.

Quality Reporting

While many of the requirements for receiving a full update in FY 2006 remain unchanged from those established in FY 2005, CMS proffers the following two proposed requirements.

For FY 2006, CMS proposes that hospitals must submit data on the required 10 measures for each of four quarters for discharges through the fourth quarter of the calendar year 2004 (October to December 2004). According to the proposed rule, hospitals had until May 15, 2005, to comply with this requirement and to ensure that the submitted data are error free.

In addition, CMS proposes to require that hospitals must have passed the validation requirement of a minimum of 80 percent reliability, based upon their chart-audit validation process, for the third-quarter data of calendar year 2004 in order to receive the full market basket update in FY 2006. If a hospital disagrees with any of the results, the hospital has 10 days to appeal these results to its Quality Improvement Organization, which will make the final determination.

CHA opposes this proposed validation requirement for payment purposes. CHA strongly supports auditing and validating the data submitted by hospitals; however, hospitals' experience with CMS' validation process to date shows that the process itself is unreliable and needs improvement before it can or should be used to determine which hospitals receive full updates. No hospital's payment should be held hostage to an unreliable validation process.

Expanding the Post-Acute-Care Transfer Payment Policy

CMS proposes to expand from 29 to 231 the number of diagnosis-related groups (DRGs) for which hospital discharges to a post-acute-care provider will be treated as transfer cases and paid according to Medicare's post-acute-care transfer policy.

CMS indicates that the findings resulting from its analysis call into question the requirements that a DRG have at least 14,000 transfer cases and that a DRG experience a decline in the geometric mean length of stay over the most recent five-year period. It is on the basis of this analysis and the findings that CMS is proposing to expand the application of the post-acute-care transfer policy to any DRG that meets the following criteria:

- The DRG has at least 2,000 post-acute-care transfer cases.
- At least 20 percent of the cases in the DRG are discharged to post-acute care.
- Out of the cases discharged to post-acute care, at least 10 percent occur before the geometric mean length of stay for the DRG.
- The DRG has a geometric mean length of stay of at least 3.0 days.
- If the DRG is one of a paired set of DRGs based on the presence or absence of a comorbidity or complication, both paired DRGs are included if either one meets the first three criteria above.

The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare PPS. The Medicare IPPS is based on a system of averages. Cases with higher-than-average lengths of stay tend to be paid less than costs, while cases with shorter-than-average stays tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals "lose" if a patient is dis-

charged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay.

In the July 31, 1998, publication of the FY 1999 final rule implementing the policy for the current 10 DRGs, CMS included an analysis showing that across almost all lengths of stay for each of the 10 DRGs, hospitals would, on average, be paid in excess of their costs even after the implementation of the provision. We have not seen any such data for the new proposed 231 DRGs, and CHA believes expansion of the provision is just a backdoor budget cut to hospitals — especially given that Health Economics Research, Inc. in its report of July 31, 2000, showed that short-stay post-acute-care transfer cases are 7.4 percent more costly than short-stay non-post acute-care transfer cases. While the length of stay may be shorter, the level of services provided during the stay is more intense and costly.

The post-acute-care transfer policy is not necessary, as the perceived "gaming" hypothesis does not exist. When Congress first called for expansion of the transfer policy in the Balanced Budget Act of 1997, data showed that Medicare inpatient lengths of stay were dropping, and that both use and cost of post-acute care by Medicare beneficiaries was growing. Since that time, however, inpatient length of stay has stabilized. Medicare spending on post-acute care has slowed as post-acute payment systems have moved from cost-based reimbursement to prospective payment. Additionally, studies by AHA and others show that the majority of patients who use post-acute care have <u>longer</u> — not shorter — hospital stays than patients who do not use post-acute care, demonstrating that these patients are truly "sicker" and in need of additional care. In FY 2004, for instance, patients who were not transferred to post-acute care had an average length of stay of 4.93 days, while those who did receive post-acute care had an average length or stay of 7.51 days. If the agency is concerned about premature discharges, then CHA recommends it focus on improving the quality review process rather than further expand the transfer provision.

Section 1886(d)(4)(J) of the Social Security Act directs CMS to focus on DRGs that have a high volume of discharges to post-acute care and a disproportionate use of post-discharge services. It is inherently impossible for all DRGs, or even 231, to have *disproportionate* use of post-discharge services. The 231 DRGs selected by CMS represent 88 percent of all DRGs with patients discharged to post-acute care in FY 2004. Clearly, 88 percent of DRGs with *any* post-acute care use cannot have *disproportionate* use. Furthermore, CMS is also capturing DRGs that are not at all *high-volume*. For example, DRG 473 (acute leukemia without major operating room procedure age > 17) has 2,070 discharges to post-acute care, as compared to DRG 544 (major joint replacement or reattachment of lower extremity) which has 349,085 discharges to post-acute care. It cannot be argued that while DRG 473 does not have a *high-volume* of discharges to post-acute care, it still has *disproportionate* use. Only 22.7 percent of the cases in DRG 473 were discharged to post-acute care versus 83 percent for DRG 544. CMS' current criteria cast far too wide of a net and capture far more DRGs than appropriate.

CMS has argued that the post-acute-care transfer policy levels the playing field for rural hospitals that do not have comparable access to post-acute care. CHA challenges this assertion. CHA compared the rates of discharge to post-acute care for the DRGs to which the post-acute care transfer policy would apply using the 2004 MedPAR data and found that urban hospitals discharged patients before the average length of stay 10.6 percent of the time, while rural hospitals

discharged patients 9.2 percent of the time. This demonstrates that the transfer policy will have fundamentally the same negative affect on rural hospitals as urban. Moreover, 4.5 percent of discharges from rural hospitals are to other acute-care facilities, while only 1.6 percent of discharges at urban hospitals are to other acute-care facilities. It is likely that that some of the patients discharged from rural hospitals are then admitted at urban hospitals that then in turn discharge patients to post-acute care. Thus, rural patients have essentially the same access to post-acute care as their urban counterparts. The policy does not create equity; rather it harms all hospitals and the patients they serve.

Furthermore, it is unclear whether this policy will end up costing the Medicare program as a whole more money. Patients who are kept in the inpatient setting longer may not be discharged to skilled-nursing care or rehabilitation care, but may receive home health and additional physician services in both the inpatient and outpatient settings that increase the costs of care. CHA encourages CMS to take a broader look at the total cost of care across a full patient episode, rather than focusing on the distinct portions of the care captured under individual payment systems.

CHA is extremely disappointed that CMS has proffered another proposal to expand the post-acute-care transfer provision. This proposal has the effect of not only penalizing hospitals for helping to ensure that patients receive the highest quality care in the most appropriate setting, but for making good medical decisions in discharge planning. Additionally, if implemented, the proposal would effectively reduce DRG payments for any hospital discharge that has less than the average length of stay and when the patient receives post-acute care after discharge, thus costing California hospitals $80 million for FY 2006 alone, the equivalent of a .86 percent cut in hospital payments.

CHA strongly opposes any expansion of the post-acute-care transfer policy, and we urge CMS to remove this provision from the final rule.

Operating Payment Rates

Outliers

The rule proposes to establish a fixed-loss cost outlier threshold equal to the IPPS rate for the DRG, including IME, DSH and new technology payments, plus $26,675. While this is not a particularly sizable increase from the FY 2005 payment threshold of $25,800, we remain very concerned that the threshold is too high. CMS states in the proposed rule that actual outlier payments for 2005 are estimated to be 0.7 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments, and that the payments in 2004 were 1.6 percentage points lower than the funds withheld.

In the rule, CMS proposes to use a one-year average annual rate-of-change in charges per case from the last quarter of 2003 in combination with the first quarter of 2004 to the last quarter of 2004 in combination with the first quarter of 2005 to establish an average rate of increase. This results in an 8.65 percent rate-of-change over one year or 18.04 percent over two years.

CHA appreciates that CMS is proposing this methodology in an effort to avoid using data prior to the major changes in the outlier policy. However, using the proposed charge inflation methodology will only result in an inappropriately high threshold and a real payment cut to hospitals. CHA strongly opposes using this methodology to estimate the outlier threshold. Thus, AHA conducted a series of analyses to identify a more appropriate methodology. Below, in support of AHA's analysis, we put forth for CMS' consideration a methodology that incorporates both *cost* inflation and *charge* inflation. The use of more than one indicator may make the threshold calculation more accurate and reliable.

First, AHA inflated 2004 charges by 18.04 percent (the inflation factor used by CMS in the proposed rule) and then reduced the charges to costs. Instead of using the cost-to-charge ratios (CCRs) from the CMS Impact File, we used the CCRs from the March 31, 2005, HCRIS release. In addition, AHA accounted for the nine-month lag from the end of a cost reporting period until the fiscal intermediary is able to update the CCR. AHA accomplished this by projecting forward from the most recent fiscal period in the March 31 HCRIS update to the fiscal period(s) expected to be used for the calculation of the CCR(s) determining federal FY 2006 outlier payments.

The cost inflation factor for projecting CCRs was determined from the cost reports of a cohort of 3,756 matched hospitals for periods beginning in federal FYs 2001, 2002 and 2003. All three costs reports were available for each hospital from the recent update of HCRIS. The 2001-2003 aggregate annual rate of increase in the cost per discharge for these hospitals was 6.57 percent[1]. This cost inflation factor and the CMS charge inflation factor of 8.65 percent were used to project CCRs over the time periods described above. The projected CCRs were applied to projected federal FY 2006 charges to simulate the determination of costs for federal FY 2006 outlier payments. The estimated fixed-loss amount that would result in 5.1 percent outlier payments under this methodology is $24,050.

CHA strongly urges CMS to adopt this methodology. We estimate that the fixed-loss threshold to achieve 5.1 percent in FY 2005 should have been set at $21,640, as compared to the $25,800 actually utilized. CMS underspent the funds set aside for outliers by an estimated $610 million in FY 2005 and $1.3 billion in FY 2004. If CMS leaves the threshold at $26,675, rather than dropping it to $24,050, we believe that CMS will again underspend by at least $510 million. We urge CMS to adopt this methodology to lower the outlier threshold.

Occupational Mix Adjustment to Proposed FY 2006 Index

As required by the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000, CMS implemented an occupational mix adjustment to the AWI beginning FY 2005. For FY 2006, CMS does not propose any changes to the methodology used in FY 2005, which consisted of determining an adjustment for each of the seven general occupational categories and applying each adjustment separately to the wage index. CMS notes that nearly one-third of rural areas and more than one-half of urban areas would see a decrease in their wage index as a result of the adjustment. According to CMS, these decreases would be minimal; the largest negative impact for a rural area would be 0.19 percent and for an urban area 0.42 percent.

1 An audit adjustment was applied to costs from "as submitted" cost reports. The audit adjustment was determined by comparing 1,881 "as submitted" cost reports from the December 31, 2003, HCRIS database with the settled reports of the same hospitals in the March 31, 2005, HCRIS update.

Given the potential financial impact on hospitals, CMS proposes to base the FY 2006 wage index on a blend of 10 percent of an average hourly wage, adjusted for occupational mix, and 90 percent of an average hourly wage, unadjusted for occupational mix.

Due to concerns expressed by CMS in the proposed rule, CHA supports CMS' decision to limit implementation of the occupational mix adjustment and for again proceeding cautiously in this regard.

Future Data Collection

CHA urges CMS to release a proposed survey for comment as soon as possible. The sooner the survey is out in the field, the more likely the data will be accurate and reliable. We urge CMS to allow for an appropriate amount of time to develop the survey, provide clear instructions, adapt the systems, collect the data, prepare the survey responses, audit the data, correct the data and calculate the adjustment. Given that CMS must have the adjustment ready for the FY 2008 adjustment (or the April 2007 proposed rule), CHA recommends that CMS release the proposed survey this summer to meet this timeframe and allow hospitals adequate time to prepare for the data collection and reporting.

Hospital Wage Index

Area Wage Index

The FY 2006 proposed rule bases the hospital wage index on cost reporting periods for October 1, 2001, through September 30, 2002 (the FY 2002 cost report). In CHA's review of the proposed wage index changes, we became aware that the rule contains a change in the wage index calculation that does not include corresponding discussion. This change was made in step 4 of the Computation of the Proposed FY 2006 Unadjusted Wage Index on page 23373 in the *Federal Register*.

The change is in the calculation for Overhead Wage-Related Cost Allocation to Excluded Areas. This calculation is made up of three steps:

1. Determine the ratio of overhead hours to revised hours.
2. Compute overhead wage-related costs by multiplying the overhead hour's ratio from step 1 by wage-related costs.
3. Multiply the overhead wage-related costs by the excluded hour's ratio.

The change in the calculation occurred in step 1. For 2006, the calculation for revised hours was changed to subtract excluded areas (Lines 8 and 8.01). This change results in a higher ratio for step 1, which results in an increase in the overhead cost allocated to excluded areas. This change ultimately lowers the hospital's average hourly rate.

The CHA is concerned that CMS would make such a change to the calculation of the wage index with out any discussion. We request that CMS explain the basis for the change and how a proper allocation can be achieved using the formula set forth in the proposed rule. Providers should be given an opportunity to comment on this revision to the methodology before it is implemented. The CHA believes that this methodological revision will have a significant impact on the wage

indexes for some hospitals. Accordingly, we believe that CMS should return to the established methodology, go through the full notice, and comment process before making such a change. We further recommend that hospitals be given an opportunity to withdraw or reinstate their requests for geographic reclassification within 30 days of the publication of the Final Rule.

New Hospital Labor Market Areas

Beginning with FY 2005, CMS has defined hospital labor market areas based on Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget in December 2003. During FY 2005, CMS provided a blend of wage indexes to hospitals that would experience a drop in their wage indexes because of the adoption of the new labor market areas. During FY 2005, such hospitals received 50 percent of the wage index using the new labor market index definition and 50 percent of the wage index that the provider would have received under the old Metropolitan Statistical Area standards. Consistent with the FY 2005 final rule, hospitals will receive 100 percent of their AWI based on the new CBSA configurations beginning in FY 2006. CHA supports CMS' proposal to end the one-year, 50/50 transition blend.

Hospital Geographic Reclassification

Urban Group Hospital Reclassification

Beginning in FY 2006, CMS proposes to require that hospitals must be located in counties that are in the same Combined Statistical Area (CSA) as the urban area to which they seek redesignation to qualify as meeting the proximity requirement for reclassification to that area.

CHA believes that this is appropriate public policy and acknowledges the realities of areas such as Ventura County, which are just outside major areas such as Los Angeles and must meet the competitive salary scales in order to attract and retain competent professionals, to provide needed hospital services in areas just outside major metropolitan areas throughout the United States.

Presently, hospitals in Ventura County are potentially eligible for urban county group reclassification. Under current regulations, for all hospitals in an urban county to be reclassified as a group, all hospitals in the county are required to apply for reclassification. One hospital in this county is currently reclassified under Section 508 and is receiving its own wage index, a wage index higher than that available under group reclassification criteria. In order for the group to be considered for reclassification, the Medicare Geographic Classification Review Board (MGCRB) requires the Section 508 hospital to terminate its existing reclassification in order for the group to reclassify. Under Section 508, qualifying hospitals are reclassified for the three-year period beginning April 1, 2004, and ending March 31, 2007.

It is unfair to require the Section 508 hospital to terminate the existing reclassification. Section 508 is not budget neutral, and there is a statutory additional $900 million budget. If hospitals withdraw, it could reduce payments to less than what Congress intended. CHA recommends that CMS implement an exception to the existing regulations that would allow hospitals that file an urban county group reclassification request and are determined to meet all applicable reclassification requirements to be reclassified, even if one or more hospitals in the group are reclassified under Section 508. The exception would allow the group to be reclassified and would allow the Section 508 hospitals to retain their reclassification until it expires (presently March 31,

2007). Effective upon expiration, the former Section 508 hospital would then become a part of the existing group reclassification. The exception would be applicable in the limited circumstances involving an urban county group with one or more Section 508 hospitals in the county. CHA believes Congress did not intend to prevent group reclassifications simply because one or more hospitals in the county were granted a Section 508 reclassification.

Hold Harmless Protection for Certain Urban Hospitals Redesignated as Rural
Section 401 of the Balanced Budget Refinement Act of 1999 provided a mechanism that permits an urban hospital to be treated, for all purposes of Medicare IPPS payment, as being located in the rural area of the state in which the hospital is located. Under current CMS policy, approved redesignation results in the exclusion of the hospital's wage index data from the wage index calculation for the urban area where the hospital is geographically located.

To address instances where the approved redesignation of an urban hospital as rural results in the hospital's data having an adverse impact on the rural wage index, CMS proposes for FY 2006 to apply its hold harmless rule that currently applies when rural hospitals are reclassified as urban to situations where hospitals are reclassified into the rural area. In other words, the wage data of the urban hospital reclassifying into the rural area are included in the rural area's wage index, only if including the urban hospital's data increases the wage index of the rural area. CMS also proposes to apply the current hold harmless rule that is applicable when urban hospitals are reclassified. In doing so, CMS proposes that the wage data for an urban hospital be included in the wage index of the urban area where the hospital is located, and also included in the wage index of the rural area to which it is reclassifying (if doing so increases the wage index of the rural area).

CHA supports CMS' efforts to promote consistency and predictability in the wage index.

Proposed FY 2006 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees
MMA provided hospitals located in lower wage areas a wage index out-migration adjustment if a significant number of hospital employees residing in the area commuted from the lower wage area to a higher wage area for work. Beginning in FY 2005, CMS set the wage index adjustment threshold at 10 percent.

While CHA continues to support CMS' decision to maintain the 10 percent adjustment threshold, and to not require a minimum difference between the county wage index and the higher wage index areas, it is still unclear how CMS will measure the commuter patterns and determine the applicability of the wage index adjustment. As we did in response to the FY 2005 proposed rule, CHA requests that CMS make the data used to compute the out-migration adjustment available in a public-use file.

Multi-Campus Hospital Reclassification
Current CMS policy dictates that multi-campus hospitals with campuses in the same MSA receive a single wage index. However, if campuses are located in more than one MSA (or metropolitan division, where applicable), payment for each discharge is determined using the wage

index value for the MSA (or metropolitan division, where applicable) in which the campus is located.

For FY 2007 and subsequent year reclassifications, CMS proposes to allow a campus of a multi-campus hospital system that wishes to seek geographic reclassification to another labor market area to report campus-specific wage data using a supplemental Form S-3 (CMS' manual version of Worksheet S-3) for purposes of the wage data comparison. These data would then constitute the appropriate wage data as required in regulation for purposes of comparing the hospital's wages to the wages of hospitals in the area to which it seeks reclassification, as well as the area in which it is located. The hospital's fiscal intermediary would have to review the allocation of the entire hospital's wage data among the individual campuses before the data could be used in a reclassification application.

For FY 2006 reclassification applications, CMS proposes to allow a campus of a multi-campus hospital system to use the average hourly wage data submitted for the entire multi-campus hospital system as its appropriate wage data under current regulation. Because the deadline for submitting an application to MGCRB, which was September 1, 2004, has passed and there no longer is an opportunity to provide a supplemental Form S-3 that allocates the wage data by individual hospital campus, CMS is also proposing to establish a special rule applicable to FY 2006 reclassifications. This special rule would be applied only to an individual campus of a multi-campus hospital system that made an application for reclassification for FY 2006 and that otherwise meets all of the reclassification criteria.

In many cases, multi-campus hospital systems form because there is a benefit to doing so, for example billing system integration may lead to efficiency in billing as well as cost savings throughout the system. While the CHA recognizes that this proposal is intended to mitigate an unintended negative impact to multi-campus hospital systems resulting from the FY 2005 implementation of the new labor areas, CHA is concerned that this proposal may encourage an individual hospital that is part of such a system to seek reclassification to different labor market areas. CHA believes that the use of the manual S-3 would be appropriate to collect the necessary data. However, CHA believes that this option should only be available in cases where an individual campus is requesting reclassification for purposes of reclassifying to an area where another one of the campuses in located.

Rural-Urban Area Commuting Codes

CMS proposes to update Medicare regulations to incorporate the use of Rural-Urban Area Commuting Codes (RUCAs) in the identification of rural census tracts.

While we recognize that RUCA is an improvement from the county-based definitions used by other federal agencies, the RUCA classification scheme falls short of meeting California's diverse rural health care access needs.

The RUCA system uses urbanization, population density and daily commuting data from the 1990 decennial census to classify census tracts, on a scale of 1 to 10, as initially metropolitan, large town, small town or rural commuting areas, based on the size and direction of the tract's largest commuting flows. Applied to California, RUCA results in the inaccurate classification of

more than 20 percent of California's current rural communities as urban. At present, 10 hospitals currently defined as a rural would be excluded under RUCA.

CHA urges CMS to work with Office of Rural Health Policy to address problems in the methodology and to ensure that rural areas are not inadvertently classified as urban.

Critical Access Hospitals

Necessary Provider Status Relocation

MMA terminated a state's authority to waive the location requirements for Critical Access Hospitals (CAHs) by designating the CAHs as necessary providers, effective January 1, 2006. CAHs that were designated by a state as necessary providers prior to January 1, 2006, would be grandfathered. However, the regulations are limited to CAHs that were necessary providers as of January 1, 2006, and does not address the situation where a CAH is no longer the same facility due to relocation, cessation of business or a substitute facility.

CMS maintains that it is crucial to define whether the necessary provider designation remains pertinent in the event a certified CAH builds in a different location; and, accordingly, to determine whether building a new CAH in a different location is a replacement of an existing facility in essentially the same location, a relocation of the facility in a new location, or a cessation of business at one location and establishment of a new business at another location.

Beginning with FY 2006, CMS proposes extremely restrictive guidelines that are tantamount to barring CAHs with necessary provider status from relocating. Specifically, the rule would allow hospitals to rebuild within 250 yards of their existing site or relocate onto a contiguous piece of property if it was purchased by December 8, 2003. For a hospital that moves any further, the hospital will have to show that it:

- Submitted an application to the state agency for relocation prior to January 1, 2006;
- Meets the same criteria for necessary provider status that it did when it originally qualified (e.g., in a health professional shortage area [HPSA] and remains in a HPSA);
- Serves the same community (75 percent of same population, 75 percent of same services, 75 percent of the same staff);
- Complies with the same conditions of participation; and
- Was "under development" as of December 8, 2003, using similar criteria as the specialty hospitals' guidelines (architectural plans, financing, zoning, construction bids, etc).

CHA opposes this proposal for several reasons:

- In 1994, California enacted SB 1953 (Chapter 740), which requires that by 2008 hospitals meet building code standards that prevent hospital buildings from collapsing during significant seismic activity. By 2030, SB 1953 requires hospitals to remain operational following such seismic activity. SB 1953 benefits the federal government by reducing the financial burden on the Federal Emergency Management Agency (FEMA) after future California earthquakes.

- In the 1994 Northridge Earthquake, California hospitals suffered approximately $3 billion in damage. In many cases the most prudent way for a hospital to comply with SB 1953 is to relocate a hospital facility and build new. Retrofitting a hospital in California can be undesirable and expensive due to the building, geotechnical and environmental codes. Also, a seismically retrofitted hospital does not necessarily meet the needs of 21st century medicine. Under the CMS proposal, CHA hospitals complying with SB 1953 would be penalized for choosing a new site that is safer and results in construction that may be less costly due to efficiencies.
- CMS' proposal, if implemented, would prevent any CAH with necessary provider status from relocating its facility unless the construction of the facility was under development prior to December 8, 2003, when MMA was signed into law. There are legitimate reasons for a CAH to rebuild. In many cases, CAHs are relocating to not only improve the quality of care, but also to improve site safety. For example, in California, due to the age and conditions of existing facilities and the state's hospital seismic-safety compliance requirements by 2030, many of our hospitals will be forced to replace their facilities in order to comply with state law by 2030. Such improvements will undoubtedly result in higher quality care, better patient outcomes and more efficient service. In assessing its ability to meet this mandate, implementation of this shortsighted proposal may mean that a CAH in California may not be able to rebuild in its current area. Facilities that must relocate to make critical safety improvements, such as those in California, should not be barred from relocating and penalized for circumstances beyond their control. If enacted, the rule will significantly affect the decisions made by hospitals and could result in significant additional costs as they struggle to meet state law and these onerous federal requirements. For the most severely fragile CAHs, the rule could result in closure and jeopardize access to emergency and acute care in critically underserved rural areas of California.
- The proposed date restrictions are unreasonable and unrealistic. CHA fails to see how CMS determined that December 8, 2003, the date MMA was signed into law, should also serve as the date for the CAH relocation deadline. The deadline has no basis in law, thus CHA recommends that CMS remove the arbitrary relocation date restrictions.

If a CAH moves further than five miles, and CMS is concerned about whether the same population is being served, then CHA recommends an approach similar to the 75 percent test described earlier. However, given that these criteria would have to withstand the changing health care landscape for the indefinite future, we believe some modifications to the test of whether the newly relocated provider is serving 75 percent of the same population, with 75 percent of the same staff, and providing 75 percent of the same services are warranted.

For instance, natural changes in demographics and the practice of medicine will occur over time that may necessitate a change in services when a hospital is rebuilt. Or, a greater reliance on new technology may limit the number or type of staff needed at a newly built facility. Some flexibility in the measures is needed to allow for such expected changes in the needs of the community.

Therefore, CHA recommends that CMS alter its criteria to allow three out of five to be satisfied. In addition to the staff, services and population measures, CMS should consider adding a needs assessment and cost comparison. For example, if a CAH can show through a needs assessment

that a change in services provided would be appropriate, then the test of 75 percent of the services would not need to be met. If a CAH has undertaken a cost comparison that shows a new facility on another site would be less expensive than rebuilding on the current location, then only two other measures would need to be satisfied. A combination of suggested criteria would offer CAHs some flexibility and allow for the natural development and maturation of CAHs and their communities.

CAHs need clear expectations and advanced warning of the standards to which they will be held, and these should be clearly delineated in advance. For example, when counting the staff, should contractors be included or just employed staff? How would a CAH compare the population it serves to a hospital that has yet to be built? Would the services be considered based on departments or actual individual services? For instance, the CAH provides lab services at the old location and expects to do so at the new location, but plans to purchase new machines that are capable of a wider variety of tests. Is the fact that the CAH plans to provide lab services in general sufficient? Moreover, the comparison between the old facility and the soon-to-be built facility should be a one-time comparison based on the facts at the time of the application.

While CHA agrees there may be a need for criteria to assess the situation for allowing CAHs to rebuild elsewhere, before finalizing a proposal that will most certainly have a detrimental impact on CAHs, we recommend that CMS rescind this proposal and expand and use the criteria recommended above to ensure that appropriate and necessary CAH relocation is permitted in the future.

Pending Necessary Provider Status Applications

CHA is concerned about hospitals that are currently in the process of converting to CAH status under the necessary provider program. We have heard reports from some states that the queue to be surveyed is growing and, despite a hospital's best efforts and advanced planning, the survey to obtain the new provider number may not occur by January 1. It is also possible that the survey will occur, but the plan of correction will not be accepted by the deadline if one is needed. States have an enormous survey workload that is further exacerbated by EMTALA surveys that take priority. Providers that have gotten to the stage of requesting a survey in advance of the January 1 deadline, but are unable to get the state to complete the survey, have clearly demonstrated a good-faith effort and should be considered as meeting the deadline.

Provider-Based Determinations

Provider-Based Location Requirement for Off-Campus Facilities; Application to Certain Neonatal Intensive-Care Units

In this proposed rule, CMS includes a detailed discussion of the current location requirements of off-campus facilities and its concerns that these requirements may inadvertently impede the delivery of intensive-care services to newborn infants in areas where there is no nearby children's hospital with a Neonatal Intensive-Care Unit (NICU). To enhance its understanding of this issue, CMS requested specific comment on whether the problem is actually occurring and on the most effective way to resolve the problem.

In California, CHA is aware of only one children's hospital that is providing the services as described. Children's Hospital Central California (Children's) participates in the Medicare program under Section 1886(d)(1)(B)(iii) of the Social Security Act, serving patients who are predominantly under 18 years of age. For many years, Children's has operated an offsite NICU in each of three community hospitals, two of which are more than 35 miles from the main campus. The space is leased from the host hospital, but these units are operated under Children's license; they are under Children's ownership and control; they are subject to the same frequency, intensity and level of accountability as any department on Children's main campus; they are staffed by Children's employees, are subject to Children's quality-assurance and performance-improvement standards and meet all the rule's criteria for integration of clinical services; the financial operations are fully integrated; and the units are held out to be and are widely recognized as part of Children's.

These units provide high-quality, essential intensive care to newborns without requiring their families to travel to the main campus to support these fragile infants. The operation of these units also promotes higher standards in the host hospitals, improves efficiency by using excess capacity at lower cost than building additional beds at the main campus, and significantly increases access to care in a region that is severely medically underserved.

With the implementation of the Provider-Based Status Rule on October 10, 2000, which implemented the "vicinity" requirement, Children's has worked diligently to preserve these important services without jeopardizing their compliance with the Medicare regulations. CHA appreciates the time, attention and consideration that we have been given by CMS administrators and staff members.

The problem described in the proposed rule accurately describes the circumstances, conditions and dilemma of the experience at Children's. Children's is located near a major city, but provides service to a large, economically impoverished and medically underserved area that is primarily rural. CHA is not aware of any other children's hospital that is currently providing satellite NICU services in host hospitals more than 35 miles from the main campus. As set forth above in the statistical description of the services Children's provides, the number of newborns born prematurely or with serious complications requiring the specialty and sub-specialty care that is only available through Children's would be significantly reduced if Children's were required to discontinue the services provided in Hanford and Merced. Access to the level of care provided in the main campus NICU is limited by both the number of beds available and the significant distances for families to travel.

In an effort to address this issue, CMS requested comments on several options. To increase the mileage limitation as suggested in option 1 would not accommodate the NICUs currently operating in Central California, the furthest of which is 90 miles from the main campus. The city of Bakersfield is relatively large, but has no regional NICU and must transport patients to either Children's or to Los Angeles, which is even further. To meet the needs in Bakersfield, for example, the distance would need to be increased to 130 miles.

CHA encourages CMS to adopt option 2, CMS' proposal to change the national Medicaid regulations to exempt a hospital participating in the Medicare program under Section

1886(d)(1)(B)(iii) of the Social Security Act from the location provisions of where all other provisions of § 413.65 have been met is the best approach to address this need. This narrow and limited exemption would allow inpatient hospital services to be provided under the Medicaid program to a needy population in a cost-efficient method without jeopardizing the hospital's participation in Medicare.

While option 3 may provide a workable solution in states other than California, it is not a viable option for Children's. Over the years, CHA and representatives from Children's have met with officials from the California Department of Health Services and have been repeatedly advised that there is no possibility of modifying the state's Medicaid Plan or developing a financial incentive plan separate from the disproportionate-share program that would provide sufficient support to community hospitals so that provision of the level of NICU service Children's provides would be economically possible. For similar reasons, a "hospital-within-a-hospital," as suggested in option 4 would not satisfy the requirements for the California disproportionate-share funding formulas and, therefore, would not be economically feasible.

Rural Health Clinics

In the proposed rule, CMS proposes to add rural health clinics with 50 or more beds to the list of specific types of facilities and organizations for which determinations of provider-based status would not be made. CHA supports this change as there is no reason to require such determination when there is no payment differential.

Specialty Hospitals

In the proposed rule, CMS notes that it recently became aware that many surgical and orthopedic specialty hospitals provide primarily outpatient services and look more like ambulatory surgical centers than hospitals. To address this situation, CMS clarifies that specialty hospitals do not qualify under the Medicare statutory definition of a "hospital" if they are not engaged primarily in furnishing services to hospital inpatients. Even if they met the MMA test for grandfathering under the 18-month moratorium on physician self-referrals to specialty hospitals, those tests were applied only after meeting the basic statutory definition of a hospital.

In clarifying that there is a need for increased scrutiny, CMS does not identify exactly how the agency will judge whether limited-service facilities meet the definition of a hospital. CHA recommends that, in the final rule, CMS provide a detailed explanation of how CMS will determine whether limited-service facilities meet the definition of a hospital. Additionally, CHA requests that CMS provide clarification regarding whether the specialty hospital moratorium would apply in instances where an existing hospital is purchased, prior to November 18, 2003, and its service line is materially changed. We also look forward to further clarification on our issues of concern.

CHA commends CMS not only for taking a proactive stance, but for its decision to place these facilities under increased scrutiny. CHA also applauds the additional steps CMS' has taken to address this issue. In its May 12 *Report to Congress*, CMS outlined four essential steps it plans to take to correct system problems that may unfairly advantage physician-owned specialty hospitals. CMS considered a complimentary report from the Medicare Payment Advisory Commission (MedPAC) in developing the recommendations. Further, CMS indicated that its fiscal intermediaries have been instructed to refrain from processing further Medicare participation ap-

plications from specialty hospitals until a comprehensive review of its enrollment process is completed. CMS expects this process to take at least six months. While CHA was disappointed that the six-month suspension would not apply to specialty hospitals that had submitted an enrollment application or requested an advisory opinion regarding grandfathering under the moratorium prior to June 9, 2005, we believe this interim is a positive step forward in the effort to ensure fair competition and the provision of high-quality care to all patients.

As CMS undertakes its review, CHA recommends that CMS focus on what the public expects of any entity labeled a "hospital," whether it is a full-service or limited-service hospital. All Medicare-certified hospitals should have to meet all relevant Medicare conditions of participation (COPs), but the core requirement that we believe CMS should stress for specialty hospitals (some existing and some suggested new requirements) are:

- An adequately staffed inpatient capacity, including a full-functioning quality monitoring and improvement system. The Medicare COPs already require this.
- The ability to deal with complications that may arise during or after a surgical procedure in a way that protects the patient's wellbeing. That means internal teams capable of handling those complications typical to the procedures normally performed in that hospital and, when transfers are needed to access other specialties or services at another hospital, EMTALA-like provisions should apply with respect to how the transfer is executed and communication with the receiving hospital. Other comments related to the application of EMTALA to specialty hospitals will be addressed separately in comments to the EMTALA Technical Advisory Group. In the case of specialty hospitals, CHA also believes that specialty hospitals should disclose to their patients upfront that if complications occur outside their limited capability patients will be transferred to another hospital.
- The ability to deal with emergencies. Current COP requirements related to emergency services should be strictly enforced. Hospitals that do not offer emergency services are required nonetheless to ensure that they have the ability to appraise emergencies, initially treat, and refer when appropriate. This requires more than simply dialing 911 and waiting for an ambulance to arrive. Hospitals that do offer emergency services (whether by choice or by state requirement) should be required to fully meet the provisions of 42 CFR 482.55. As was identified by MedPAC in its March 2005 report, some specialty hospitals have what they call an emergency department in order to meet state licensure requirements, but, given MedPAC's description of what it found, some of those hospitals cannot possibly be in compliance with the provisions of Section 482.55. If a hospital holds itself out as having emergency services, that proffer must be real or the public's health and safety will be endangered.
- A fully functioning discharge planning process and relationships with post-acute providers in the community. CHA believes this is especially important for Medicare beneficiaries given CMS' finding that limited-service hospitals have shorter lengths of stay and higher readmission rates. While discharge planning is required of all hospitals, those findings suggest that some limited-service hospitals may have inadequate discharge planning processes and, as a result, Medicare patients are being sent home too quickly or without adequate post-discharge support.

CHA would urge caution, however, with respect to how CMS judges whether a hospital is primarily engaged in providing services to inpatients. The delivery of health care has changed significantly in the 40 years since Medicare was enacted. Many hospitals are now health care systems that provide a wide range of inpatient and outpatient care. CHA recommends that CMS look at a hospital's operation comprehensively to ascertain whether the facility is *significantly* (or *seriously*, if you will) engaged in providing inpatient hospital care and avoid adopting any rigid standard for the proportion of inpatient versus outpatient care. There is a significant difference between a hospital with 278 hospital beds that has 14,400 inpatient discharges and 94,500 hospital inpatient days a year that provides almost 80 percent of its care to outpatients because of the scope of services, and a limited-service hospital with eight beds, only 537 discharges and 1,200 hospital inpatient days a year that also provides almost 80 percent of its care to outpatients. The fact that most surgical and orthopedic hospitals' performances could not be measured due to insufficient numbers of inpatient discharges is telling.

CMS also should consider whether the inpatient component of the hospital, even if small, represents a vital health care resource, as in the case of a small rural hospital or a highly specialized center of excellence.

Treatment of Specialty Hospitals During the Review Process: As we mentioned above, CHA was surprised to see in the June 9 notice that CMS would not be applying the suspension of the enrollment process for specialty hospitals across the board. Despite the fact that many specialty hospitals have had their applications pending during review of whether they were eligible for grandfathering under the moratorium, it is difficult to understand how CMS plans to act on those applications when it has not yet completed its review of standards and the enrollment process. Consequently, CHA recommends that CMS apply the suspension of processing enrollment applications for all specialty hospitals until its review is completed and appropriate revisions adopted.

Provider-Based Determinations
In the proposed rule, CMS proposes to add rural health clinics with 50 or more beds to the list of specific types of facilities and organizations for which determinations of provider-based status would not be made. CHA supports this change as there is no reason to require such determination when there is no payment differential.

Medicare Disproportionate-Share Hospital Payments
MMA Section 951 requires the Health and Human Services (HHS) secretary to arrange to furnish data necessary for hospitals to compute the number of patient days used in calculating the disproportionate patient percentages.

CMS proposes to make this information available for either the federal FY or, if the hospital's FY differs from the federal FY, for the months included in the two federal FYs that encompass the hospital's cost reporting period. Under the proposal, the hospital could use these data to calculate and verify its Medicare fraction, and to decide whether it prefers to have the fraction determined on the basis of its FY rather than a federal FY. The data set made available to hospitals would be the same data set CMS uses to calculate the Medicare fractions for the federal FY. CMS also proposes to make available a MedPAR limited data set for both Supplemental Security

Income (SSI) and Medicare at the hospital's request, but advised that hospitals would need to rely on states for the Medicaid information.

CHA supports CMS' proposal to allow hospitals the opportunity to decide whether to use the data based on their own FY or on the federal FY. With respect to CMS' decision to maintain the status quo in regards to requiring that state plans verify Medicaid eligibility, we recommend that, with increased interest in the Medicaid program, expansion of Medicaid managed care programs and general concern regarding the DSH calculation, CMS not only continue to monitor this process but consider involving hospitals in any future decision-making discussions.

Payment Adjustments for Low-Volume Hospitals
MMA provided for low-volume payment adjustment for hospitals located more than 25 road miles from another hospital that has fewer than 800 total inpatient discharges during the FY.

For FY 2006, CMS proposes to extend the current low-volume adjustment for qualifying hospitals with less than 200 discharges. CMS proposes that hospitals with greater than 200 but less than 800 discharges for the year receive no adjustments.

CHA is concerned that CMS chooses to ignore congressional intent by continuing to deny hospitals with greater than 200 but less than 800 discharges access to this necessary payment adjustment. In California, hospitals that have between 200 and 800 discharges continue to operate with negative operating margins, thus this adjustment is crucial to their financial health. The law gives CMS the authority to provide a low-volume adjustment for hospitals with fewer than 800 discharges. CHA urges CMS to take advantage of this authority and, to the full extent of the law and its authority, to extend the adjustment up to 800 discharges.

Graduate Medical Education

Initial Residency Period
CMS proposes to revise current regulations to state that when a hospital can document that a resident matched in an advanced residency training program beginning in the second residency year prior to commencement of any residency training, the resident's initial residency period (IRP) will be determined based on the period of board eligibility for the specialty associated with the advanced training program, without regard to the fact that the resident had not matched for a clinical base year program. CHA supports this change.

GME Affiliation Agreements
Previously, rural hospitals that began residency-training programs on or after January 1, 2005, were able to establish affiliation agreements with hospitals that had existing residency programs. CMS proposes to revise current regulations to provide that a hospital that qualifies for an adjustment to its full-time equivalent (FTE) residents' cap under the regulation would not be permitted to enter into an affiliation agreement that would result in a negative adjustment to its FTE residents' cap. This would prevent hospitals from creating new residency programs and then moving most or all of its residents over to an existing program. CHA supports this proposal.

Indirect Medical Education

IME Adjustment

CMS proposes to incorporate into the regulations its existing policy in such situations that provide for the establishment of an IME FTE cap for a hospital that was excluded from the IPPS during its base year and that subsequently became subject to the IPPS. In this rule, CMS is clarifying and proposing that, in such a situation, the fiscal intermediary would determine an IME FTE cap for the hospital, applicable beginning with the hospital's payments under the IPPS, based on the FTE count of residents during the cost reporting period(s) used to determine the hospital's direct GME FTE cap in accordance with existing regulations. The new IPPS hospital's IME FTE cap would be subject to the same rules and adjustments as any IPPS hospital's IME FTE cap.

No IME FTE count was calculated for hospitals that were exempt from the IPPS for cost-reporting periods ending on or before December 31, 1996. Thus, for IPPS-exempt hospitals that wish to covert to the IPPS, CMS proposes to base the IME FTE count on the GME FTE count established on the cost reports ending on or before December 31, 1996. CHA supports the establishment of an IME cap for PPS-excluded facilities that convert to inpatient PPS entities and further suggests that CMS clarify that the policy would apply to both freestanding hospitals and hospital-based distinct part units. We believe, however, that the cap should be based on data that are more recent than 1996.

Teaching Hospitals That Withdraw Rural Reclassification

Medicare policy allows an urban hospital to become rural under a reclassification request. An urban teaching hospital that reclassifies as rural may receive the 130 percent adjustment to its IME FTE residents' cap. An urban hospital treated as a rural hospital may subsequently withdraw its election and return to its urban status. Effective with discharges occurring on or after October 1, 2005, CMS is proposing that a teaching hospital that rescinds its rural reclassification and returns to being urban would not be eligible for permanent increases in its IME cap. Rather, any adjustments the hospital received to its IME cap due to its rural status would be forfeited upon returning to urban status. CHA supports implementation of this provision.

New Technology Payments

Section 503 of MMA provided new funding for add-on payments for new medical services and technologies, and relaxed the approval criteria under the IPPS. This important provision was enacted to ensure that the IPPS would better account for expensive new drugs, devices and services. Despite this, CMS is essentially proposing to reject all eight applications (six new and two re-evaluations) and only maintain payment for one currently approved technology. CHA is concerned that CMS continues to resist approving new technologies for add-on payments. We are also disappointed that CMS did not propose to increase the marginal payment rate to 80 percent rather than 50 percent, consistent with the outlier payment methodology, which it has the authority to do without reducing payments to other services.

Moreover, CHA is concerned about CMS' ability to implement add-on payments for new services and technologies in the near future. Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. The

ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading.

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

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in the committee language for MMA, recommended that the HHS secretary undertake the regulatory process to upgrade ICD-9-CM to ICD-10. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology as required under BIPA.

To date, in spite of these recommendations, as well as the recommendations of several federal health care agencies and offices, and health care trade and professional associations, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. CHA believes that without a change to ICD-10 soon, there will be a significant data crisis in the U.S. This coding crisis will affect the efficiency of the current coding process, adding significant operational costs. Additionally, failure to recognize this looming problem will only impede the efforts to achieve the president's goal for an electronic health record by 2014.

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

We have now reached the point where category 00 is full and the C&M Committee is entertaining proposals for codes in category 17. At the April 2005 C&M Committee meeting, a proposal was presented that would in effect leave only 80 codes available in this category. Many of the specific body system chapters are already filled (like cardiac and orthopedic procedures). In recent years, as many as 50 new procedure codes have been created in a single year. This means that it is possible for ICD-9-CM to completely run out of space in one and a half years. CHA concurs with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10. We also would support an implementation period of at least two years following issuance of a final rule. Without the publication of even a proposed rule, the prospect of not being able to recognize new major surgical procedures and entirely new medical technology is a certain grim reality.

CHA strongly recommends that the HHS secretary undertake the regulatory process to replace ICD-9-CM with ICD-10 expeditiously. HHS should take the necessary steps to avert this crisis and avoid the situation of not being able to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than re-

spond to a crisis that will likely result in unreasonable implementation timeframes. It is imperative that the rulemaking process start immediately.

DRG Reclassifications
In general, CHA supports CMS' proposed changes to the DRG system, as the revisions appear rational given the data and information provided. However, we do have concerns about some of the proposals as detailed below.

MDC 1 (Diseases and Disorders of the Nervous System)

Strokes
CMS reviewed the possibility of creating a new DRG with a recommended title "Ischemic Stroke Treatment with a Reperfusion Agent." The data reviewed by CMS suggested that the average standardized charges for cases treated with a reperfusion agent are more than $16,000, or $10,000 higher than all other cases in DRGs 14 and 15, respectively. Although the data suggested that these patients are more expensive than all other stroke patients, CMS proposed not to make a change to the stroke DRGs because the conclusion was based on a small number of cases. CMS believed that the administration of tissue plasminogen activator (tPA) identified by ICD-9-CM procedure code 99.10 may be under-reported because it currently does not affect DRG assignment.

CHA requests that CMS create a new DRG to recognize the additional resources associated with strokes and tPA administration, even if the data analyzed did not have a large number of cases.

While it may be true that code 99.10 is under-reported because it currently does not affect DRG assignment, the number of patients meeting the clinical indications for receiving tPA administration is low. Published clinical data show that only 2 percent of patients with stroke receive intravenous (IV) tPA nationally (*Archives Neurology*, 2004, March; 61) and the rate among community hospitals may be slightly less at 1.6 percent (*Stroke*, 2001 August; 32). These statistics are only slightly higher than the 1.16 percent rate found in CMS data for patients in DRG 14 without intracranial hemorrhage with code 99.10.

The effective administration of tPA requires that treatment be administered within three hours of onset of stroke, and only after ruling out hemorrhagic stroke by computed tomography. IV thrombolytic agents are not recommended when the time of stroke onset cannot be ascertained reliably, including strokes recognized on awakening. These indications significantly limit the number of patients eligible for tPA administration.

According to published clinical studies, using IV tPA in clinical practice has proved very difficult. The biggest challenge is the ability to determine that symptom onset occurred less than 3 hours prior to the time of the tPA infusion. Patients need to be educated to recognize the symptoms of a stroke and to seek early treatment. Administration of tPA in stroke patients requires that the patient recognize that something is wrong; is transported to a hospital equipped to provide this therapy; undergoes a history and physical examination and CT scan; and has this scan read by a qualified radiologist — all within the three hours of initial onset of symptoms.

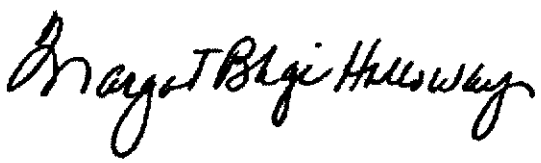
For all the clinical reasons noted above, it is unlikely that the number of stroke cases reported with code 99.10 will increase significantly in the near future. Regardless, the additional resources required to treat these patients should be recognized with a new DRG.

MedPAC Recommendations

The MedPAC recommendations discussed in the proposed rule grew out of concern that limited-service providers were at an unfair advantage under the IPPS. However, it is unclear how such changes will affect the remaining PPS hospitals. While CHA supports refining the PPS, care should be taken in such an endeavor given that the majority of hospitals are losing money under the Medicare IPPS. Therefore, CHA urges CMS to proceed slowly and deliberately with extensive research as a foundation for any proposed changes.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions, please contact me at (202) 488-4688 or mholloway@calhealth.org.

Sincerely,



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Organization : Baker & McKenzie LLP

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachments.

CMS-1500-P-570-Attach-1.PDF

CMS-1500-P-570-Attach-2.PDF

CMS-1500-P-570-Attach-3.PDF

CMS-1500-P-570-Attach-4.PDF

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Attachment 5 to D

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June 22, 2005

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VIA ELECTRONIC & HAND DELIVERY
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
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Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS – 1500 – P; Retroactive Wage Index Data Corrections for October 1, 2004 – December 31, 2004

INTRODUCTION

Baker & McKenzie LLP, on behalf of the following hospitals listed below and located in Palm Beach County, Florida, is pleased to submit these comments on the above referenced proposed regulation for the Medicare hospital Inpatient Prospective Payment System ("IPPS") governing the fiscal period October 1, 2005-September 30, 2006 ("FY 2006"):

- JFK Medical Center
- Palms West Hospital
- Columbia Hospital
- St. Mary's Medical Center
- Delray Medical Center
- Good Samaritan Medical Center
- West Boca Medical Center
- Bethesda Medical Center
- Glades General Hospital
- Boca Raton Community Hospital
- Jupiter Medical Center
- Wellington Regional Medical Center (collectively, the "Palm Beach Hospitals").

On May 4, 2005, the Centers for Medicare and Medicaid Services ("CMS") published the proposed regulation governing IPPS for FY 2006. As part of these proposed rules, CMS proposes, in the preamble, to allow for a retroactive correction to an error in the wage index data affecting certain hospitals for the period covering October 1, 2004 through December 31, 2004.[1] The proposed, one time, retroactive correction does not, however, address the

[1] 70 Fed. Reg. 23306, 23384 (May 4, 2005). The correction is proposed to affect four hospitals.

circumstances of the Palm Beach Hospitals listed above. The Palm Beach Hospitals should be included in the proposed retroactive adjustment because, as described, below, the circumstances of the Palm Beach Hospitals is similar in all material respects to that of the hospitals to which the retroactive correction is being made.

Briefly, CMS made an error in tabulating the wage index data for Palm Beach County when it incorrectly categorized St. Mary's Medical Center ("St. Mary's"), one of the Palm Beach Hospitals listed, above, as a hospital in the Miami-Dade County core based statistical area ("CBSA") in the IPPS final rule for the period October 1, 2004 – September 30, 2005 ("FY 2005") (the "Error").[2] St. Mary's (Medicare Provider Number 100288) is actually located in Palm Beach County and in the West Palm Beach CBSA.

The Error had the effect of improperly and incorrectly lowering the wage index for Palm Beach County, in which St. Mary's is physically located, and inflating the wage index for Miami-Dade County, in which it is not. In December 2004, CMS corrected the Error prospectively for the period beginning January 1, 2005.

The Error clearly was the result of a clerical mistake by CMS. Additionally, the Palm Beach Hospitals could not have known of the Error prior to the release of the IPPS rules for 2005. The Palm Beach Hospitals informed CMS upon learning of the Error before October 1, 2004, and prior to that date, CMS clearly recognized that St. Mary's is a hospital located in Palm Beach County. Therefore, as with the hospitals for which CMS proposes to correct a mistake in the FY 2005 wage index retroactive to October 1, 2004, CMS should also correct the wage index for the Palm Beach Hospitals listed above, retroactive to that same period.

DISCUSSION

A. Proposed Regulation

In the proposed IPPS rule, CMS proposes to revise its current regulation located at 42 C.F.R. § 412.64(k)(2) which allows for a midyear, prospective correction to a hospital's wage index data under certain circumstances.[3] The proposed regulation would allow for a retroactive adjustment to the wage index to the beginning of the Federal fiscal year under the following circumstances:

(1) the fiscal intermediary ("FI") or CMS made an error in tabulating a hospital's wage index data;

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[2] *See* 69 Fed. Reg. 48916 (Aug. 11, 2004).

[3] CMS's rules currently provide that CMS makes a midyear correction to the wage index for an area "only if a hospital can show that (1) the intermediary or CMS made an error in tabulating its data; and (2) the hospital could not have known about the error, or did not have the opportunity to correct the error, before the beginning of the federal fiscal year." 42 C.F.R. § 412.64(k)(1).

(2) the hospital informed the FI or CMS, or both, about the error following the established schedule (which is at least before the beginning of the Federal fiscal year to which the rule applies) and process for requesting corrections to its wage index data; and

(3) CMS agreed before October 1 that the FI or CMS made an error in tabulating the hospital's wage data and the wage index should be corrected.[4]

Most importantly, the preamble to the proposed rules states that CMS proposes to apply these same criteria to make a retroactive correction to the wage index data of certain hospitals for FY 2005.[5] According to the preamble, CMS previously corrected the error that affected those hospitals in the corrections to the IPPS rule for FY 2005 that it published on December 30, 2004 for the period January 1, 2005 – September 30, 2005. 70 Fed. Reg. 23306, 23384 (May 4, 2005). CMS now proposes to correct that error retroactive to October 1, 2004.[6]

B. The Error by CMS

St. Mary's is a hospital that is physically located in Palm Beach County. The wage index public use file ("PUF") posted on CMS's website on May 13, 2004, correctly identifies St. Mary's as a hospital included in Palm Beach County. Thus, the data in the PUF that were available to the Palm Beach Hospitals during the period in which they would be expected to bring errors to the attention of CMS and/or the FI showed St. Mary's as being located in the correct county. *See* Exhibit A. The Error was made in the final rule, which erroneously included St. Mary's wage data in the Miami-Dade County CBSA. Consequently, the first opportunity that St. Mary's and the other Palm Beach Hospitals had to bring the error to the attention of either CMS or the FI occurred after the publication of the FY 2005 IPPS final rule.

Because it was correctly listed in the May 11, 2004 PUF as being located in Palm Beach County, St. Mary's did not have a reason to follow any established procedure for correcting mistakes and errors. The process for resolving substantive wage index data corrections is

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[4] Proposed 42 C.F.R. §412.64 (k)(2), 70 Fed. Reg. at 23461.

[5] 70 Fed. Reg. at 23384.

[6] CMS proposes to do so under what it describes as its discretionary authority under the Section 903(a) of the Medicare Modernization Act, stating that the failure to apply such a correction would be contrary to the public interest. Similarly, the failure to correct the Error retroactively for the Palm Beach Hospitals would be both unlawful and contrary to the public interest.

primarily intended for errors that are identified before the publication of the IPPS final rule in August of each year. Here, the Error was made in the final rule, itself.

Upon discovering the error, the Palm Beach Hospitals, through their representative, Ernst & Young ("E&Y), notified CMS of the Error in a letter dated September 20, 2004. *See* Exhibit B. On the same date, representatives of E&Y also spoke with CMS by telephone, to verbally communicate the Error and to request an immediate correction.[7] In response, CMS by telephone, indicated that it was unable to correct the Error by October 1, 2004, the effective date of the FY 2005 IPPS final rule.

CMS clearly was aware, prior to October 1, 2004, of the fact that St. Mary's is located in Palm Beach County. In a letter, dated August 30, 2004, from CMS to E&Y responding to E&Y's request for a list of hospitals located in Palm Beach County, CMS correctly identified St. Mary's as such a hospital.[8] *See* Exhibit C; *see also* the May PUF data at Exhibit A. Thus, it is clear that CMS was aware of the Error by September 20, 2004.

CMS did not correct the Error by October 1. Rather, CMS corrected the Error in the publication of the December 30 corrections to the IPPS rule for 2005, and did so prospectively only, beginning January 1, 2005.

C. Resolution of CMS's Error

The Palm Beach Hospitals believe that the circumstance involving the St. Mary's Error, described above, clearly is one of those limited situations that warrants a retroactive correction. While we do not know the precise facts involved in the circumstance that CMS proposes to correct retroactive to October 1, 2004 for the four hospitals, it appears that the situation of the Palm Beach Hospitals is similar in all material respects.

Apparently, like the situation for which CMS proposes to make corrections, St. Mary's was not at fault for causing the Error. Rather, the Error was made by either CMS or the FI. In fact, the Error involved not information for which CMS was dependant upon the Palm Beach Hospitals, but rather a demographic fact that was part of public information and totally within the domain of CMS.

The Palm Beach Hospitals could not have known about the Error during the established schedule for bringing errors to the attention of the FI or CMS, because it appears that the

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[7] Richard Kolaska of E&Y spoke with Valerie Miller of CMS in this telephone call. Ms. Miller, in turn, referred Mr. Kolaska to, Margo Blige Holloway, who informed Mr. Kolaska that day that CMS would be unable to make any corrections before October 1.

[8] E&Y made that request for reasons unrelated to the Error. However, it was through that letter and subsequent review that the Hospitals and E&Y discovered the Error.

Error was not made until ***after*** that period had ended. However, the Palm Beach Hospitals notified CMS regarding the Error as soon as reasonably feasible, and prior to October 1, 2004. Finally, CMS clearly was aware, prior to October 1, 2004, that St. Mary's was located in Palm Beach and the West Palm Beach CBSA, and therefore, that an error was made. Thus, under any reasonable and fair application of the criteria proposed by CMS to correct errors in wage index data retroactive to the beginning of the period, the Error that affects the Palm Beach Hospitals should also be corrected retroactive to October 1, 2004. This is especially so given that CMS is proposing what appears to be a similar correction for four other hospitals.

CONCLUSION

In short, the Palm Beach Hospitals submit that it is unfair and unlawful to penalize them for a mistake made by CMS or the FI over a ministerial fact easily within CMS's domain, especially when CMS was given notice of the Error, and CMS, itself, had been in possession of the correct information since at least May 2004. We, therefore, request that CMS correct the Error to the FY 2004 wage index for the Palm Beach Hospitals retroactive to October 1, 2004, as it proposes to do for the other hospitals described in the proposed rule.

Respectfully submitted on behalf of the hospitals listed, above,

Michael H. Cook

MHC/tlo

Enclosures

Q DATA 285
SCH
IMPACT

BODDEN
KRUSHAT
HEFTER
HARSTEIN
NAVARRO
SMITH
KRAEMER

Submitter : Ms. Meylan Lowe-Watler **Date:** 06/22/2005
Organization : Lower Keys Medical Center
Category : Nurse
Issue Areas/Comments

GENERAL

GENERAL
"See Attachment"

CMS-1500-P-572-Attach-1.DOC

Attachment 572

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).

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.

It seems unjust that for the delinquency of 5 charts, a hospital that served 6,554 patient days to 1,200 Medicare patients in 2004 would have to see a decrease of any kind in its reimbursement. We incurred $17,000 in expenses in 2004 to have an outside audit agency review 100% of the inpatient charts that were sent to Medicare for reimbursement. This agency ensured that there were no coding errors on our submission. Our charges are also run through a third party editor to ensure that charges not allowed by Medicare are not included in our bills. We provided nearly $13 Million in care to the indigent in this community. We maintain a licensed Laboratory and Psych department, along with our participation in the JCAHO program. The delinquency of 5 charts is in no way an indicator of the level of service provided to patients in this community.

The long term impact to facilities, particularly Sole Community Providers, can be devastating. To base such a severe ramification on the review of 5 charts seems unfair. The CMS proposal places a tremendous burden on Sole Community Providers and we request that CMS delay until FY 2007, implementation of their proposal tying the market basket update to the validation assessment to allow rural hospitals adequate notice.

Thank you in advance for your consideration of our comments in making decisions relative to the CMS proposed rules.

Sincerely,

Meylan Lowe-Watler
Assistant Administrator