101

Submitter : Mrs. Myra Evans

Organization : Community Hospital Association

Category : Critical Access Hospital

CAH/Reloc

Date: 06/14/2005

Hefter
Hartstein
Collins
Morey
Smith

Issue Areas/Comments

GENERAL

GENERAL

I do not think the decision to restrict new building of CAHs as proposed is wise. Our facility was built in 1949 and is land locked. We may need to build new in the future, but could not under the proposed regulations. We serve a 2 1/3 county area in NW Missouri and are an essential provider of healthcare to our communities. There would be many of our patients that would not be able to access healthcare if we were not here. The regulations as proposed prohibits us from building a new facilty because we are not 35 miles from the nearest hospital. We have another CAH at between 30-35 miles and an acute care hospital the other direction between 30-35 miles away. Please reconsider these proposed regulations, or many CAHs will be forced to discontinue serving their patients. I do not believe that is what the CAH program is all about.

102

Submitter : Earl Sheehy

Organization : Saunders County Health Services

Category : Critical Access Hospital

Date: 06/15/2005

CATH/Reloc

Hefter
Hartstein
Collins
Morey
Smith

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-356-Attach-1.DOC

#356

SCHS

Saunders County Health Services
A NEW ERA IN HEALTH CARE

Care Center
844 W. 9th St.
Wahoo, NE 68066
(402) 443-4685

Clinic
735 W. 10th St.
Wahoo, NE 68066
(402) 443-3434

Hospital
805 W. 10th St.
Wahoo, NE 68066
(402) 443-4191

June 15, 2005

Centers for Medicare &
Medicaid Services

RE: ***Critical Access Hospitals***

Ladies and Gentlemen:

I am writing in response to the proposed rule changes regarding the relocation of critical access hospitals. I believe the proposed changes will have devastating effects on CAHs seeking to rebuild or relocate. If enacted, the affected CAHs would be unable to relocate within their communities, even if the move is in the best interest of the community. Also, the proposed changes leave no flexibility to relocate facilities that will inevitably deteriorate in the future.

Further, this rule would limit a CAH's ability to build a new facility on a site in the same community serving the same population when that is what makes the most sense. In other words, if the community leaders on the hospital board decide the best thing for the facility and the community is to start over on a new site rather than trying to update an aging facility, they will not be able to do so. Their only option will be to try to renovate the existing facility, even if that is not the right decision. A community may wish to relocate its CAH in order to downsize, reposition from a residential neighborhood, solve the problem of being landlocked, or get away from a poorly constructed or poorly laid out facility. However, with the date restrictions in place, these communities will never be able to do anything but renovate their existing hospitals, regardless of the needs of the community.

Prior to December, 2003, Saunders County Health Services (a CAH) had begun the process of determining the feasibility of constructing a new facility at a different location. We had engaged an architect to complete a space programming study and develop drawings of a proposed facility. Since SCHS is county-owned, many meetings with the County Board of Supervisors and others was necessary. Also, Nebraska statutes require that an election be held to allow voters to determine whether or not a bond issue to back construction of the facility would be passed.

Just yesterday a bond issue was passed to fund construction of a new hospital (as well as a long-term care center and clinic) that would be located approximately three miles from the current site. SCHS would continue to serve the same population and provide the same services. SCHS must maintain its CAH status to be financially viable. The proposed changes could have a negative impact on this financial viability.

In closing, I understand the need to carefully scrutinize any proposed relocations, but relocation in the same community serving the same population should not result in loss of CAH status.

Thank you for your consideration.

Sincerely,

Earl N. Sheehy

EARL N. SHEEHY
President/CEO

Q-DATa

103

Date: 06/15/2005

Hefter
Hartstein
C. Bodden
M. Krushat

Submitter :

Organization :

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

I feel this proposed rule is premature at this time. More time is needed so that CMS and JCAHO's processes coincide. Using the data from 3rd and 4th quarters of 2004 is data that was reported prior to the alignment of quality measures between CMS and JCAHO.

CMS-1500-P-282

104

DRG/CC

DRG/GeN

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

Submitter : Ms. Leatrice Ford **Date:** 06/10/2005

Organization : ConsultCare Partners

Category : Health Care Industry

Issue Areas/Comments

Issues

CC List

I support the study of CCs to see if they are still relevant.

Issues

Payment for cardioverter defibrillators should be determined by the level of technology (CRT-D versus non) used rather than the diagnosis and concomittant procedures (EPS or Cardiac cath). It's clear that the CRT-D are more costly than the single 'shock only' or pacing defibrillators and most facilities regardless of geographic (wage index)location can cover the costs of the lower end technology. If CMS would look at the differences in resource use (dollars)for those with procedure code 00.51 as opposed to the non CRT device cases, they might discover the DRG logic can be simplified and the payment would be more aligned with the costs and everyone would be happy. I am concerned that the current proposed logic change will encourage unnecessary cardiac catheterizations.

I also believe the implantations of the CRT-D devices should be closely monitored aside from the study of primary ICD implants. Physicians who implant the CRT-D devices should be tracked to make certain they are competent in the placement of the CRT devices and that they are using the appropriate criteria. If they implant devices that are marginally or not indicated, they shouldn't be paid either. The device companies are encouraging physicians who are not technically competent to implant the CRT devices (both pacer and ICD). The physicians are motivated by the additional payment for the LV lead placement. I have reviewed charts where the CRT device was implanted, but the LV lead couldn't be placed so the patient didn't benefit from the technology, or the LV lead had to be surgically placed by another physician. I've seen physicians spend hours trying to place the lead, using lots of contrast (which is a hazard to the patient).I've seen dissections of the coronary sinus requiring surgical repair.

Currently CMS allows physicians to be paid for procedures that are marginally indicated, or not indicated while the hospital pays the costs. The misalignment of incentives places the hospital between the physician and the patient. It should be a team effort and no one should benefit at the expense of the other.

I recognize the potential impact of the new expanded ICD indications on CMS resources, but I don't agree that the changes proposed for 2006 will be the solution.

DRG Reclassifications

I don't agree that the new classifications for percutaneous coronary interventions for acute MI need to be subdivided into classes with and without CC. In my calculations, most facilities will recieve less payment for acute myocardial infarction patients receiving PCI than they are currently receiving. CMS will save money by splitting the DRGs. It just complicates the DRG logic and CMS's motives for doing it are very clear.

105

DRG | Gen

Date: 06/13/2005

Heffer
Hartstein
Brooks
Fagan
Gruber

Submitter : Dr. Kousik KrishnAN

Organization : Dr. Kousik KrishnAN

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

A change of this magnitude requires further study and analysis. bedside EP testing' (CPT codes 93640-93642 the intraoperative EP study (during the implant before closing) no longer maps to 37.26 (as of 2005) and therefore currently is not mapping to DRG 535/536. The NONINVASIVE ep STUDY procedure should be removed from 37.26 which will prevent mapping to the higher DRG. However, the full comprehensive EP study, 93620 should continue to map to 37.26 remaining in DRG 535/536. The resources and clinical similarity of an EP study and other catheterization procedures as listed above are similar.

Kelly
Hue

106

DR G IGen

Date: 06/13/2005

Submitter : Dr. Felix Sogade

Organization : Medical Center of Central Georgia

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I will propose that the CMS should not go forward with the proposed changes to DRG 535 and 536.
Already, Electrophysiologic srvices especially involving the implantation of defibrillators has been considered a financial drain on hospitals especially in my own geographic area.
Any proposal that further reduces reimbursement is going to be a major strain. At our institution, the medical center of central Georgia where I serve as medical director for electrophysiology services, we offer ICD and CRT-ICD services to patients without ability to pay. The impact of the expanded coverage decision to hospitals still has to be determined and to make this proposed changes midstream is fraught with economic danger to a lot of facilities. I full heartedly support the position of the heart rhythm society

Hefler
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

107

DRG/GEN

Submitter : Ms. Shannon Ruman **Date:** 06/11/2005

Organization : Henry Ford Hospital

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

Lowering the reimbursement for the In-patient devices for Y2006 is going to hurt more than just the health care facilities and their overhead but health care itself. I want to help in any way that I can to assist in fighting this legislation.

Thank you

Heffer
Hartstein
Brooks
Fasan
Gruber
Kelly
Hue

108

Nurs/AH/PhAR

Submitter : Dr. Neil Ernst **Date:** 06/07/2005

Organization : Dr. Neil Ernst

Category : Pharmacist

Hefter
Hartstein
Truong
Hefkowitz
Ruiz

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS:

My name is Neil Ernst, and I am currently enrolled in a pharmacy practice (first year) residency program at the University Hospital in Cincinnati, Ohio. I am writing this letter to protest the recent CMS decision not to restore funding for pharmacy specialty residency programs.

Following successful completion of my first year of residency, I will be pursuing a specialized residency in Critical Care. While specialized residency for pharmacists remains optional, there was no choice to be made in my case. You see, for several years now, I have had the goal of becoming a specialized clinician in critical care pharmacy. As I looked at the requirements for achieving such a position, it was clear to me from the beginning that 2 years of residency (including a specialty residency) would be required.
From a healthcare provider perspective, specialized residency makes perfect sense. Critically ill patients have special needs that require immediate, detailed attention.

A recent White Paper from four major critical care societies in the US - the American Association of Critical Care Nurses (AACN), the American College of Chest Physicians (ACCP), the American Thoracic Society (ATS), and the Society of Critical Care Medicine (SCCM) addressed the manpower shortage of healthcare providers INCLUDING PHARMACISTS who care for the critically ill. They state: 'shortages of qualified health-care professionals have created a major threat to the availability and quality of critical care services for seriously ill patients. If the current trend persists, shortages of these specialists, combined with the current shortages of critical care nurses, pharmacists, and respiratory therapists, will become severe by 2007 and will worsen through 2030.'

I urge you to restore funding for second-year, specialized pharmacy residency programs in the interest of patients with critical illness.

Sincerely,
Neil Ernst, PharmD

CMS-1500-P-172-Attach-1.PDF

The Critical Care Medicine Crisis: A Call for Federal Action*

A White Paper From the Critical Care Professional Societies

Gary W. Ewart, MHS; Lynne Marcus, BS; Michael M. Gaba, JD; Robert H. Bradner, JD; Justine L. Medina, RN, MS; and Eric B. Chandler, PhD

In the United States, shortages of qualified health-care professionals have created a major threat to the availability and quality of critical care services for seriously ill patients. An unprecedented, and largely unrecognized, shortage of physician intensivists in the near future will deny standard critical care services for large populations of patients with serious illnesses. If the current trend persists, shortages of these specialists, combined with the current shortages of critical care nurses, pharmacists, and respiratory therapists, will become severe by 2007 and will worsen through 2030. Numerous studies demonstrate that critical care services directed by physicians who are formally trained in critical care medicine reduce mortality in the ICU and reduce health-care costs. While people of all ages, from low-birth-weight newborns to senior citizens, benefit from treatment in the ICU, older Americans receive a disproportionate share of ICU services. The demand for ICU services, therefore, will continue to grow as the baby boom generation ages. To address the shortage, the critical care professional societies recommend that steps be taken to improve the efficiency of critical care providers, to increase the number of critical care providers, and to address the demand for critical care services.

(CHEST 2004; 125:1518–1521)

Key words: critical care; workforce shortage

Abbreviations: CMS = Centers for Medicare and Medicaid Services; COMPACCS = Committee on Manpower for Pulmonary and Critical Care Societies; FOCCUS = Framing Options for Critical Care in the United States; GME = graduate medical education; HRSA = Health Resources and Services Administration

I. Issue Overview

A. General Background on Critical Care Medicine

Critical care medicine is the direct delivery of medical care by a physician to a critically ill or critically injured patient. A critical illness or injury acutely impairs one or more vital organ systems such that there is a high probability of imminent or life-threatening deterioration in the patient's condition. Care of these patients can take place anywhere in the inpatient hospital setting, although it typically occurs in the ICU. Critical care involves highly complex decision making to assess, manipulate, and support vital system functions, to treat single or multiple vital organ system failure, and/or to prevent further life-threatening deterioration of the patient's condition.[1]

Critical care medicine is provided by physician-directed multidisciplinary teams consisting of nurses, respiratory therapists, pharmacists, and physician assistants. Critical care medicine has evolved into a board-certified medical subspecialty that trains physicians to utilize a unique combination of skills needed to care for critically ill patients. Board-certified critical care specialists come from a variety of specialty backgrounds. Most of the physicians who practice critical care come from the internal medicine subspecialty of pulmonology. Other specialties that also practice critical care include anesthesiology, surgery, and pediatrics.

*From the American Thoracic Society (Mr. Ewart), Washington, DC; the American College of Chest Physicians (Mssrs. Gaba and Bradner, and Ms. Marcus), Northbrook, IL; the American Association of Critical-Care Nurses (Ms. Medina), Aliso Viejo, CA; and the Society of Critical Care Medicine (Dr. Chandler), Des Plaines, IL.

Manuscript received January 26, 2004; revision accepted January 28, 2004.

Correspondence to: Gary W. Ewart, MHS, American Thoracic Society, 1150 Eighteenth St, NW, Suite 900, Washington, DC 20036; e-mail: gewart@thoracic.org

Numerous studies[2] have shown that board-certified critical care-directed teams save lives and reduce costs. The strength of these studies is so compelling that organizations such as the LeapFrog Group, a business consortium that studies ways to reduce health-care costs for employers, have required hospitals in their health networks to provide coverage in the ICU 24 h per day/7 days per week with board-certified critical care specialist staffing during daytime hours, and at other times with the return of ICU pages by a board-certified physician, or an arrangement for a specially trained physician or physician extender to reach an ICU patient within 5 min.[3]

While people of all ages, from low-birth weight newborns to senior citizens, receive treatment for critical care services across the United States, older Americans continue to consume a disproportionate share of critical care resources.

B. Shortage of Critical Care Providers

The United States is currently facing an unprecedented, and largely unrecognized, shortage of physicians trained to provide critical care services. As described in a study by the Committee on Manpower for Pulmonary and Critical Care Societies (COMPACCS),[4] future demand for critical care services in the United States will soon exceed the capabilities of the current delivery system. The most alarming problem is that the anticipated shortage of health-care professionals practicing critical care medicine already has begun.

Today, board-certified critical care physician-directed ICU teams care for only one in three patients in the ICU. The aging population, and the coinciding increased demand for critical care services, will exacerbate the situation. If current trends continue, a severe shortage of critical care specialists will occur by 2007 and will worsen until 2030. This means that in the near future, patients with critical care illnesses will be unable to get medical treatment from physicians trained in providing critical care services.

C. Contributing Factors to the Critical Care Shortage

There are several contributing factors that have created the critical care shortage. The following factors should guide any federal policy decisions: the aging of the US population will lead to a predictable increase in the demand for critical care services; the supply of physicians and allied health professionals trained to provide critical care services will remain constant; the limited number of physician residency/fellowship trainee slots prevents medical schools from quickly increasing the number of physicians trained in critical care medicine; cuts in graduate medical education (GME) payments have reduced the funds available for physician training; the cost of medical school education is significant and continues to rise; medical school debt pressures many physicians to pursue the highest paying specialties; and, finally, the complexity of Medicare reimbursement tends to drive physicians out of the field.

The combination of these factors creates the self-fulfilling prophecy of a depleted workforce. Because there are fewer critical care specialists, those remaining become overwhelmed and exit the system prematurely.

There are many challenges facing critical care providers. Considering the intensity of services, and the time commitment and emotional demands involved, the reimbursement for critical care medicine is low. Further complicating the problem is that many critical care practices are finding it difficult to hire new physicians and critical care nurses from a diminishing pool of qualified applicants. While the need for additional critical services many be growing, critical care physicians are prevented from significantly increasing their critical care time because of other clinical and business commitments.

II. Federal Policy Recommendations

Policy initiatives can be implemented to address the looming shortage of physicians trained in critical care medicine. Some of these initiatives are specific to critical care medicine, and others will affect the entire field of medicine. Federal support is required to implement many of these initiatives.

The following sections outline a series of policy initiatives that have been identified by the COMPACCS as key actions with which to address the coming shortage of critical care providers. These initiatives cover the following three general areas: improving the efficiency of critical care providers; increasing the supply of critical care providers; and addressing patient demand for critical care services.

A. Improving the Efficiency of Critical Care Providers

1. Implement the Framing Options for Critical Care in the United States Recommendations: In response to the COMPACCS study, the professional societies for critical care nurses and physicians organized a task force called Framing Options for Critical Care in the United States (FOCCUS), which assessed the current state of critical care and developed recommendations on how to respond to this workforce crisis.

The implementation of a number of the FOCCUS

task force recommendations could be facilitated by federal government assistance, including the following: standardization of the practice of critical care (recommendation 1); examination of the role of medical informatics (recommendation 2); and research to better identify the optimal roles for critical care professionals in the delivery of services (recommendation 4).

To implement the recommendations of the FOCCUS task force, we recommend the following:

- The Agency for Health Research and Quality and the Health Resources and Services Administration (HRSA) should conduct studies on medical informatics, quality of care, and medical practice in the field of critical care medicine.
- HRSA should conduct studies tracking the supply of and demand for critical care services, and their utilization.
- The Centers for Medicare and Medicaid Services (CMS) should conduct research demonstration projects on the optimization of critical care services for the Medicare and Medicaid populations.
- The Institute of Medicine should conduct a study reviewing how the aging population will impact the supply of trained critical care providers in the United States and what steps must be taken to address the critical care needs of the aging population.

2. Redistribute Current Critical Care Workforce: HRSA should develop a model to estimate the appropriate physician/population ratio for critical care specialists. The resulting analysis should be used to assist in the redistribution of the current critical care workforce. To reach the appropriate distribution of physician and allied critical care provider resources will likely require financial incentives to encourage critical care providers to serve in areas of shortage.

3. Explore Innovative Approaches to Relieve Burden on Current Workforce: It is important to explore innovative approaches, where appropriate, to relieve the burden on critical care providers to be physically present in institutional settings on a 24 h per day/7 days per week basis, including the following:

- Telemedicine initiatives that borrow from Department of Defense learning to allow for remote ICU management in rural or other locations that lack staffing depth.
- Borrowing from the trauma center planning model to organize critical care resources in a "tiered" manner that would channel patients who are in need of more intensive or complex services to higher caseload facilities with a better ability to provide the necessary personnel.

4. Simplify Reimbursement System: The reimbursement system is very cumbersome for critical care services because it is time-based, requiring separate rules and guidelines for documentation and payment. It is important to continue, foster, promote, and accelerate the dialog initiated in 1998 between CMS and several provider groups (including the American College of Chest Physicians, the Society for Critical Care Medicine, and the American Thoracic Society) to facilitate billing and reimbursement policies for critical care services.

B. Increasing Supply of Critical Care Providers

1. Long-term Solutions: The federal government provides support for medical education through a variety of mechanisms, including student loan programs and GME payments channeled through Medicare and Medicaid to institutions that train medical residents/fellows, and through a variety of HRSA-sponsored programs. Clearly, the federal government has taken an active role in addressing workforce supply issues.

In accordance with FOCCUS recommendation 3 (to define and promote incentives to ensure the future workforce in the critical care professions), the federal government should consider the following steps to address the looming shortage of critical care providers:

- Eliminate the cap on the number of residency training positions eligible for GME funding.
- Reverse cuts in GME payments to institutions (eg, the recent reduction in Medicare indirect medical education payments to 5.5%).
- Provide sponsoring institutions full GME support through the completion of critical care specialty training. GME currently provides sponsoring institutions with full support for medical residents and fellows through their initial board certification, with support being reduced to 50% for additional specialty training.
- Create a national health service corps-type program for critical care physicians. HRSA would identify areas that have an unmet demand for critical care services. Physicians who complete training as board-certified critical care specialists then would be eligible to apply to the program, through which they would receive loan forgiveness for making an irrevocable 3-year commitment to provide critical care services in an HRSA-designated shortage area.
- Expand the Veterans Affairs career development award to support research in pulmonary/critical care.

2. Short-term Solutions: The federal government can produce a near-term increase in the supply of critical care providers through specific changes in the immigration laws of our country. J-1 physicians,

also known as *foreign medical graduates* or *international medical graduates*, are physicians from other countries who have sought and received a J-1 (education exchange) visitor visa in order to attend a medical residency or fellowship training program in the United States This J-1 visa requires that, on completion of the training program, the foreign physician must return to his or her home country for at least 2 years before applying for immigrant status to the United States The foreign physician can have this J-1 visa home-residence requirement waived in return for providing primary care or general mental health care in a federally designated health professional shortage area or a medically underserved area if sponsored by an interested US government agency. State government agencies also may sponsor J-1 physician waiver requests through the "Conrad State 30" program.

The J-1 visa waiver program for physicians should be retained and expanded. Specifically, additional slots should be permitted under the Conrad 30 program. Critical care providers who agree to provide services in health professional shortage areas and medically underserved areas should be allowed to participate in the program, and nongovernmental entities should be permitted to serve as sponsors for critical care providers.

C. Addressing Patient Demand for Critical Care Services

While improving efficiency and expanding the number of physicians trained to care for the critically ill patient is essential, attention also must be paid to factors driving patient demand for critical care services. As the US population ages, there will be a predictable increased demand for these services. To address this age-driven increased demand, we recommend the following:

- The National Institutes of Health, including the National Institute of Aging, the National Heart, Lung, and Blood Institute, the National Institute for General Medical Sciences, the National Institute of Nursing Research, and the National Institute of Allergy and Infectious Diseases, should expand research on providing critical care services to the elderly.
- The Agency for Health Research and Quality and the CMS should sponsor research on optimal systems for providing critical care for Medicare beneficiaries. Research topics should include critical care triage, alternative care pathways for conditions of high mortality, and appropriate provider/patient/family communication.
- The critical care community should work with the Department of Health and Human Services to develop an education campaign to educate Americans on the benefits and limitations of critical care medicine.
- The Department of Veterans Affairs should conduct an ICU census, collecting data on the number of ICU beds, the number of patients seen in the ICU, patient disease, and the physician specialty providing care to the ICU patient.
- Federal agencies should support health systems research on the standardization of critical care information platforms and care delivery.
- Federal agencies should support health systems research on the regionalization of critical care resources.

Conclusion

Compelling evidence exists that the demand for critical care services has already begun to exceed the supply of physicians trained in critical care. The increased demand in critical care services is caused by a significant growth in the elderly population. To meet the increased demand, health-care policy makers will need to consider steps to increase the efficiency of the current critical care workforce, increase the supply of physicians trained in critical care medicine, and explore ways to address the patient demand for critical care services that is driven by the aging population. While addressing each area can make incremental gains, the crisis will be averted only if policy action is taken on all three fronts. The critical care societies, American College of Chest Physicians, the American Thoracic Society, the Society of Critical Care Medicine, and the American Association of Critical-Care Nurses, encourage health-care policy makers to begin a public discussion on this growing shortage of critical care team members. While the numbers in nursing, respiratory therapy, and pharmacy are already at crisis levels, a concerted, dedicated, and strong response must be undertaken to ensure that our most vulnerable patients have the team that will provide them the best possible care. We hope that this document will provide a thoughtful starting point for this important policy discussion.

References

1 American Medical Association. Current procedural terminology. 4th ed. Chicago, IL: American Medical Association, 2003; 20

2 Pronovost PJ, Angus DC, Dorman T, et al. Physician staffing patterns and clinical outcomes in critically ill patients. JAMA 2002; 288:2151–2162

3 The Leapfrog Group. Fact Sheet: ICU staff. The Leapfrog Group for patient safety. Available at: http://www.leapfrog-group.org/FactSheets. Accessed March 17, 2004

4 Angus DC, Kelley MA, Schmitz RJ, et al. Current and project workforce requirements for care of the critically ill and patients with pulmonary disease: can we meet the requirements of an aging population? JAMA 2000; 284:2762–2770

109

Submitter : Ms. Joan Murray

Organization : St. James Parish Hospital

Category : Critical Access Hospital

Date: 06/08/2005

CAH/Reloc

Hefter
Hartstein
Collins
Morey
Smith

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-178-Attach-1.DOC

Attachment #178
Critical Access Hospitals
Addendum to public comment of 5/18/05

St. James Parish Hospital has been serving its community for fifty years and offers the community quality health care. The total population of the parish is 21,175, and the parish is divided by the Mississippi river. The hospital, which is located on the East bank of the river, was originally built with Hill Burton funds. Our emergency room provides access to primary care for the indigent and underinsured of our parish community. The parish government provides public transportation to residents of the parish, but there is no means of public transportation outside of the parish. We were designated a "necessary provider" Critical Access Hospital by the state of Louisiana on August 1, 2001. Our plan to build a replacement hospital began in 2002 and we would like to maintain our CAH status under "necessary provider". Our project will not be complete until after the sunset rule of January, 2006.

Because of the age of the building, during a strategic planning retreat in 2002, a decision was made to assess the hospital's infrastructure. This assessment began with an analysis of mechanical, electrical, and plumbing and an inventory of medical equipment to identify obsolescence. After this analysis was presented to the board of commissioners on April 1, 2002, a decision was made to develop a facility master plan. The facility master plan with a conceptual design was presented to the board of commissioners and the medical staff on September 16, 2002, at which time a decision was made to pursue building a replacement hospital since the cost was not much more than renovating the current facility. The property of the current hospital is not large enough for expansion.

On January 28, 2003, St. James Parish Hospital signed an agreement with Merrill Lynch as the mortgage broker and began the application process for the HUD 242 loan. We began the affordability process and the pre-application was submitted to HUD in May of 2003 and the first HUD site visit took place on July 1 & 2, 2003. HUD then invited the hospital to continue pursuing the loan application. Although the HUD application process is complete and HUD has given us very positive feed back, they will not give a final approval of the loan until they are certain that we will maintain our CAH status. The delay has already impacted the cost of the project since the cost of construction has drastically increased in the past eight months.

On August 11, 2003 the project manager was selected and started the process of selecting the architects for the project. The hospital signed a purchase agreement for the land on October 1, 2003, which is located 340 yards from the current site. The hospital was built on land owned by the parish and the land that connects both pieces of property is also owned by the parish. The distance from the original building to the new building is approximately 1000 yards. The final sale of the property took place on December 12, 2003.

The hospital selected the architects for the project and the design and development phase began on January 12, 2004. The final plans were complete on June 21, 2004. The hospital has invested a million dollars of its cash on this project.

The proposed rule change for Critical Access Hospitals seeking to rebuild or relocate will negatively affect our project if St. James Parish Hospital cannot maintain its CAH designation under "necessary provider".

In order to help insure that we will be able to continue building our replacement hospital as planned, please consider the following changes to the proposed rule:
Eliminate the date of December 8th, 2003 to determine if plans were "under development". (*We are concerned that our final land purchase was signed on December 12th, 2003, although we did have a signed purchase agreement in October of 2003).*

Develop specific criteria to determine the meaning of "under development", so that the regional offices will have specific guidelines and could make a more objective decision on a case by case basis.

Change the distance requirement to give CAH's the option of selecting land that is up to five miles from the site as long as it does not change the market served.

Develop performance criteria to determine the quality of health care that the CAH provides its community, such as clinical indicators and patient satisfaction scores.

St. James Parish Hospital would like to assure its community that it will be able to continue to serve the health care needs of the people for the next fifty years. In order to do that, we have to be able to continue with the building of a replacement facility as planned. Please consider helping us and other rural hospitals to remain viable.

Sincerely,

Joan Murray

110 - O
(3)

Submitter : **Dr. Paul Hauptman** **Date: 06/15/2005**

Organization : **Dr. Paul Hauptman**

Category : **Physician**

DRG/Gen

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

Issue Areas/Comments

GENERAL

GENERAL

June 15, 2005

VIA: ELECTRONIC MAIL

Mark B. McClellan, M.D., Ph.D
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Dr. McClellan,

I write to you as both a heart failure cardiologist with a clinical and research focus in end-stage heart failure and as a principal investigator for the CorCap CSD US Randomized Trial. Options for patients with cardiomyopathy who remain symptomatic despite aggressive pharmacological therapy are limited. Several existing options remain limited by numbers and access (e.g. heart transplant and ventricular assist devices). In the trial of the CorCap device, I saw first hand the impact the device had on patient?s quality of life and health status. In the trial as a whole, patients implanted with the CorCap device were less likely to progress to more costly interventions such as LVADs and heart transplants.

The CorCap procedure represents not only a major step forward in the treatment of heart failure but it also a potential opportunity for the Medicare program to take a proactive step in controlling the costs associated with this condition. I urge you to seriously reconsider assignment of the CorCap CSD procedure to 110/111 and reassign it to DRG 108 where the resources required for the procedure more closely approximate those associated with implantation of the CorCap CSD and both surgical and medical management of patients in the peri-operative period. It would be counter productive if a financial disincentive is associated with the device, since hospitals and physicians will be less likely to adopt the technology. If this occurs, neither the patients nor the Medicare benefit will reap the full benefits of this important new technology. I respectfully urge you to reevaluate your proposed assignment for procedure code 37.41 and consider reassignment to DRG 108.

Sincerely,

Paul J. Hauptman MD
Professor of Medicine
Saint Louis University School of Medicine
Director of Heart Failure and Transplantation
Saint Louis University Hospital

111

Hefter
Hartstein
Lefkowitz
TRUONG
Ruiz

Submitter : Dr. Erin Koopman

Date: 06/14/2005

Organization : University of Arizona - University Medical Center

Category : Pharmacist

NURS/AH/PHARM

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-345-Attach-1.DOC

Attachment #345

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

NURS/AH/PHARM – TRUONG
LEFKOWITZ
RUIK
~~EMPACT – KRAEMER & ANALYST~~

June 8, 2005

Re: CMS-1500-P Funding for Pharmacy Residency Programs

Dear CMS:

I am currently a critical care specialty pharmacy resident at University Medical Center of the University of Arizona. I am writing to urge the Centers for Medicare and Medicaid Services to restore funding for second-year, specialized pharmacy residencies.

My residency will conclude at the end of June, and I can therefore speak to the value of specialized pharmacy residencies from a personal perspective. Following this residency, I have a critical care pharmacist position in the Medical ICU at St. Mary's Hospital of Mayo Clinic in Rochester, Minnesota. I have no doubt that without my specialized residency training, I would not have been able to obtain this position. However, the credential of having this residency on my CV is just one benefit. Through specialized training, I have gained the knowledge and skills I would not otherwise have to render me competent and confident to practice in a critical care setting. Patients whose care I am involved in benefit from expertise gained from the concentrated specialized training in evidence-based medicine to ensure optimal provision of medications safely and effectively.

Numerous examples demonstrate how specialized training has allowed me to further patient care in the ICU. I have learned how to manage antibiotic therapy to effectively target suspected pathogens as well as to minimize unnecessary exposure, which can foster antimicrobial resistance. I have learned to select candidates for intensive insulin therapy, which results in reduced infection rates and mortality in ICU patients. Among the many other interventions critical care pharmacists play a key role in are stress ulcer and DVT prophylaxis, specific treatments for septic shock, nutrition support, specifically total parenteral nutrition, and fluid and electrolyte management. These are but a few of the interventions by specialists that can improve patient outcomes, and they most definitely would not be consistently applied without a clinical pharmacy specialist's supervision of medication use.

The benefit of maintaining funding for specialized residencies versus the proposed amount saved by CMS's eliminating funding for these programs must not be ignored. Pharmacy specialists, not only in critical care, but oncology, pediatrics, nutrition support, cardiology, infectious disease, and many others, are continually ensuring optimal medication use to improve patient safety, maximize positive outcomes, and reduce excessive health-care costs related to unnecessary medication use. Without a doubt, I would want my family member treated in an ICU staffed with a critical care-trained pharmacist, and would have hesitations otherwise.

Finally please note that in both 2004 and 2005, the American Society of Health-System Pharmacists has submitted survey data to CMS in a timely manner showing that most hospitals require or prefer to employ clinical pharmacy specialists who have completed second-year specialty residency programs. Specialized pharmacy residencies need CMS funding to continue training future specialists and optimizing patient outcomes. Thank you for your time and consideration.

Sincerely,

Erin M. Koopman, PharmD
Critical Care Specialty Resident
University of Arizona – University Medical Center
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Hefter
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DRG/GEN - BROOKS
FAGAN
GRUBER
KELLY
HUE

June 14, 2005

Mark B. McClellan, M.D., Ph.D
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule. File Code CMS-1500-P, Issue Identifier; DRG Reclassifications.

Dear Administrator McClellan,

DRG/GEN

We are writing to you to express our concern with the proposed DRG assignment for the CorCap Cardiac Support Device implant procedure code 37.41, *Implantation of prosthetic cardiac support device around the heart*. Assignment to DRGs 110 and 111 (Major Cardiovascular Procedures w & w/o CC) will not adequately cover the cost of the device and its implantation. We respectfully request that CMS reconsider this decision and reassign 37.41 to DRG 108 (Other Cardiothoracic Procedures) with other procedures that are more clinically similar and where costs more closely compare with the costs associated with implanting the CorCap device.

The Nebraska Heart Institute (NHI) is a group of 25 cardiologists and six surgeons with offices in Lincoln, Omaha, Papillion, Grand Island, Hastings and North Platte and over 40 satellite clinics throughout the region including Iowa and Kansas. We perform more than 1,100 open-heart procedures, 3,000 interventions, over 7,000 cardiac catheterizations and treat over 1,200 heart failure patients annually.

As a cardiothoracic surgeon and heart failure cardiologist who served as co-principal investigators at NHI during the CorCap pivotal randomized trial, we have significant experience with the CorCap implant procedure. Out of 29 centers in the United States who enrolled patients in this heart failure surgical trial, NHI was one of the top 3 enrolling centers. Because of our experience, we feel we are uniquely qualified to draw clinical and resource comparisons between the CorCap procedure and other cardiothoracic procedures.

The CorCap implant procedure is an invasive cardiothoracic procedure that utilizes a midline sternotomy and pericardiotomy to circumferentially access the heart and attach the device directly to the myocardium. Based

Nebraska Heart Institute

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on our experience, it is clear that assignment of the CorCap implant procedure to DRGs 110/111 is inappropriate. In general, the resources required to both surgically and post-operatively manage patients undergoing the procedures listed under 110/111 do not rise to the level of the resources required to manage a patient undergoing a CorCap procedure. Specifically, the majority of the procedures assigned to DRGs 110/111 do not involve an open sternotomy, an operation directly on the heart, or a permanent device implant. Overall, these procedures are less intense and demanding than the CorCap CSD procedure.

Procedures in DRG 108 are more clinically similar to the CorCap procedure. The procedures in DRG 108 are exclusively performed on the internal or external structures of the heart and generally require access through a sternotomy. Several procedures in 108 also involve permanent device implants.

Based on our clinical and surgical experience, we believe open chest epicardial radiofrequency (RF) ablation for the treatment of atrial fibrillation (ICD-9-CM 37.33) is a specific procedure example that falls under DRG 108 that demonstrates comparable resource utilization with the CorCap implant procedure. This procedure involves placing a grid of electrodes over the surface of the beating heart to identify the source of the arrhythmia. Once located, the arrhythmia-producing tissue is destroyed using radiofrequency (RF) or other method. This procedure is comparable to the CorCap CSD procedure in the following respects:

- Both procedures are performed on the surface of the myocardium.
- Both procedure involves accessing the heart via a sternotomy
- While RF ablation does not involve a device implant, it does employ device technology that similarly increases the cost of the procedure.
- Both RF ablation and CorCap procedures require additional custom tools to assist in the procedure
- The average length of stays for patients undergoing these procedures at our hospital are comparable

While we agree it is important to create incentives for hospitals to operate efficiently it is also important to ensure that they are adequately compensated for valid costs. If the CorCap implant procedure were classified to DRGs 110/111 there would be a financial disincentive for hospitals to adopt this potentially life-saving and cost reducing treatment for Medicare beneficiaries suffering from a problem that may otherwise require a ventricular assist device or heart transplant.

The CorCap technology represents a true advance in heart failure management providing heart failure cardiologists and surgeons with an

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important new option in treating this life-threatening condition. Given the truly novel nature of this therapy, we encourage CMS to make every effort to understand the resources required to deliver this heart failure treatment and we strongly urge CMS to assign the CorCap implant procedure (37.41) to DRG 108 where it appropriately belongs.

If CMS staff would like to discuss these issues in greater detail, please do not hesitate to contact us.

Sincerely,

James Wudel, M.D.
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Hetter
Hartstein
NT – TREITEL
WALZ
Brooks
FASAN
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Kelly
Nule

PO Box 12046
Mill Creek, WA 98082
June 13, 2005

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

Dear Center for Medicare and Medicaid Services,

I am writing to tell you how important it is for CMS to reimburse hospitals (both inpatient and outpatient settings) for rechargeable neurostimulators. Rechargeable neurostimulators are a huge improvement over the previous technology and it is important that this be an option for people with pain. This new technology will cut down on the need for expensive battery replacement and the painful and costly surgery that accompanies it. Additionally, having a rechargeable battery source means that patients can achieve optimal stimulation for pain relief, no longer having to conserve energy and reduce the stimulation power to prolong battery life. People in pain will then be able to personally control their pain relief on a 24-hour basis.

Besides the savings of money to the Medicare and Medicaid Programs, one must look at the improved technology that is now available to those in chronic pain. Unfortunately, those people who are suffering the most are the same people who can't afford neurostimulators. I hope that you have a compassionate heart and implement this vital reimbursement program as soon as possible.

Thank you for your attention to this very important issue for people who have chronic pain. It is vital that everyone, no matter what their insurance or income levels, have equal access to good pain relief treatments.

Sincerely,

Aliese Moran

Columbia HOSPITAL
Your gateway to good health

JUN 17 2005

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BY:

June 15, 2005 Overnight Mail Tracking No: 1Z F4F 249 22 1004 5066

Hefter
Hartstein

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 Avenue, SW
Washington, DC 20201

GEO RECLASS - KENLEY
W/I - MILLER
CBSAs - KENLEY
IMPACT - KRAEMER + ANALYST

RE: Comment on the FY 2006 proposed Inpatient Prospective Payment System regulation regarding "Geographic Reclassifications – Urban Group Hospital Reclassifications".

Dear Sir or Madam:

The purpose of this letter is to comment on the FY 2006 proposed Inpatient Prospective Payment System (IPPS) regulation regarding geographic wage index reclassifications and urban group hospital reclassifications. GEO RECLASS

Our facility is a 250 bed for-profit hospital located in Palm Beach County, Florida. 43.6 percent of our patient population consists of Medicare beneficiaries and adequate Medicare reimbursement is critical to our continuing ability to meet their needs.

Last year when the proposed wage index classification rule was published, we thought we had, for the first time, qualified for the opportunity to reclassify for wage index purposes, because the proposed rule had been broadened to allow more areas to qualify. We joined with all other Palm Beach County hospitals to evaluate this possibility and then applied for re-designation. The final rule, however, changed the proposed criteria and ultimately left us disqualified when the CBSA category was completely dropped. W/I

We request that CMS revise the urban group reclassification eligibility criteria contained in the proposed FY 2006 IPPS regulation as follows (requested revisions are in bold print):

1. "Hospitals must be **in counties that are in the same Core-Based Statistical Area (CBSAs) that comprise metropolitan divisions or** located in counties that are in the same Combined Statistical Area (CSA) as the urban area to which CBSAs

2201 45th Street, West Palm Beach, Florida 33407 • Phone: 561-842-6141 • Fax: 561-844-8955 • www.columbiahospital.com

they seek redesignation to qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation"

2. **"Areas will qualify as a CSA if the OMB designated the area as a CSA or if the area had qualified to elect to be designated a CSA, whether or not the area made that election".**

3. **The FY 2006 proximity criteria will be effective for urban group reclassifications beginning on October 1, 2005 if the urban area:**

   - **Filed an application for urban group reclassification by September 1, 2004 for reclassification beginning on October 1, 2005;**
   - **Met all of the non–proximity urban group reclassification criteria published in the FY 2005 final regulation;**
   - **Had the application denied only because the urban area did not meet the FY 2005 proximity criteria;**
   - **Meets the FY 2006 proximity criteria (described above items 1 and 2); and**
   - **Would have had the application approved had the FY 2006 proximity criterion been published in the FY 2005 final regulation.**

We request that CMS include the revisions, as written above, in the FY 2006 final IPPS regulation.

2. BACKGROUND

A. The Prior Year Federal Fiscal Year End September 30, 2005 (FY 2005) Proposed Inpatient Prospective Payment System (IPPS) Regulation

The FY 2005 proposed inpatient prospective payment system (IPPS) regulation issued on May 18, 2004 supported allowing urban hospital groups located within a Core-Based Statistical Area (CBSA) to seek reclassification to another area within the same CBSA (that is, to another Metropolitan Division) (see Federal Register, May 18, 2004, page 28354). The eleven CBSAs, established by the Office of Management and Budget (OMB) in June 2003, eligible for this reclassification were Boston, Chicago, Dallas, Detroit, Los Angeles, San Francisco, Philadelphia, New York, Seattle, Washington D.C., and Miami. The Miami CBSA consists of the West Palm Beach, Fort Lauderdale, and Miami, Florida Metropolitan Divisions. Therefore, the hospitals within this CBSA could reclassify from one Metropolitan Division to another if they met the remaining application criteria. These new CBSAs, created in 2003 by OMB, had replaced Consolidated Metropolitan Statistical Areas (CMSAs) previously established by OMB in 1990.

CBSAs

B. *The Prior Year FY 2005 Final IPPS Regulation*

In response to public comments regarding the proposed regulation and that the adoption of CBSAs as the criterion for reclassification would disadvantage certain hospital groups, CMS expanded the number of areas eligible for reclassification in the final FY 2005 IPPS regulation (see Federal Register, August 11, 2004, page 49105). The reclassification eligible areas were expanded to include:

- counties located in the same Combined Statistical Area (CSA), a new category created by the OMB; and
- hospitals in counties located in the same CMSA, (a reinstatement of the previous OMB designation).

As a result, the final FY 2005 IPPS regulation expanded the number of reclassification eligible areas from the proposed eleven CBSAs to approximately one-hundred and twenty CSAs and CMSAs.

C. *The Impact the FY 2005 Final IPPS Regulation had on the West Palm Beach Metropolitan division*

IMPACT

Although the hospitals in the West Palm Beach Metropolitan division (West Palm Beach-Boca Raton-Boynton Beach, Florida area) were eligible for reclassification to another metropolitan division within the Miami CBSA under the FY 2005 proposed regulation, those same hospitals became ineligible for reclassification under the final FY 2005 regulation.

The hospitals located in the West Palm Beach Metropolitan division were ineligible for reclassification because:

- the West Palm Beach Metropolitan division is not currently automatically considered a CSA by the OMB;
- the West Palm Beach Metropolitan division was not previously considered a CMSA; and
- the final regulation removed allowing urban hospital groups located within a CBSA to seek reclassification to another area within the same CBSA (that is, to another Metropolitan Division).

The hospitals in the West Palm Beach Metropolitan division, based on the FY 2005 proposed regulation, submitted an application to CMS for a reclassification beginning October 1, 2005. CMS denied the application citing that the hospitals in the West Palm Beach Metropolitan division did not meet the criteria contained in the final regulation. The hospitals have appealed the CMS denial to the Medicare Geographic Classification Review Board (MGCRB).

We understand that the change in criterion between the FY 2005 proposed and final regulation (from the eleven CBSAs that comprise metropolitan divisions to CSAs

and CMSAs) was to be more inclusive regarding what areas qualified. However, the West Palm Beach metropolitan division did not qualify under the final FY 2005 regulation but did under the proposed regulation (not more inclusive for the West Palm Beach metropolitan division). We do not believe CMS intended to exclude the West Palm Beach metropolitan division from eligibility in the final FY 2005 regulation; it was likely an oversight. In fact, it is our understanding that the other ten CBSAs that comprise metropolitan divisions qualified as CSAs or CMSAs and were not harmed by the change from the proposed FY 2005 to the final FY 2005 regulation. Only the West Palm Beach metropolitan division was harmed.

We believe it was the intent of CMS to also include the new CBSAs that comprise metropolitan divisions in the final FY 2005 regulation eligible criterion (along with CSAs and CMSAs). The OMB, in 2003, created the new CBSAs that comprise metropolitan divisions to replace the outdated CMSAs previously established by the OMB in 1990. We feel CMS intended to include both of the new OMB area definitions in the final FY 2005 regulation (CSAs and CBSAs that comprise metropolitan divisions) not the one outdated CMSA area definition. At the very least, CMS should have included all three area definitions (CSAs, the outdated CMSAs, and the new CBSAs that comprise metropolitan divisions) in the final FY 2005 regulation eligible criterion.

Also, the application for urban group reclassification was due to be filed by September 1, 2004. The final FY 2005 regulations were not published until August 11, 2004. The hospitals in the West Palm Beach Metropolitan Division could not have waited until the final regulations were published on August 11, 2004 to organize the entire county knowing that the application was due to be sent only 20 days later, on August 31, 2004. It is a very complex process to organize what are normally competitive organizations to join a common initiative. It takes much longer than 20 days. Therefore, based on the FY 2005 proposed regulations and the fact that the hospitals in the metropolitan division were eligible for an urban group reclassification, tremendous efforts and costs were invested by the hospitals in the West Palm Beach Metropolitan Division to achieve a county-wide reclassification.

3. THE FEDERAL FISCAL YEAR END SEPTEMBER 30, 2006 PROPOSED IPPS REGULATION

A. Urban Group Hospital Reclassifications

The FY 2006 proposed IPPS regulation proposes to delete the reference to the CMSA urban group reclassification criterion. The regulation states in part that "beginning with FY 2006, it is proposed to require that hospitals must be located in the 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 the urban area to which they seek redesignation".

4. REQUESTED REVISIONS TO THE FY 2006 PROPOSED IPPS REGULATION AND ISSUES TO BE CONSIDERED IN THE FY 2006 FINAL IPPS REGULATION

A. *Allow hospitals that are located in counties that are in the same Combined Statistical Area (CSA) OR IN THE SAME CORE- BASED STATISTICAL AREA (CBSA) THAT COMPRISE METROPOLITAN DIVISIONS as the urban area to which they seek redesignation to qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.*

The FY 2006 proposed regulations regarding urban group reclassifications and the removal of CMSAs as urban group reclassification criterion state in part that "based on our experiences now that the new market areas are in effect and since we revised the urban county group regulations, we no longer think it is necessary to retain the use of a 1990-based standard as a criterion for determining whether an urban county group is eligible for reclassification. We believe it is reasonable to use the area definitions that are based on the most recent statistics; in other words, the CSA standards". The proposed regulation goes on to state that "we believe that this proposed change would improve overall consistency of our policies by using a single labor market area definition for all aspects of the wage index and reclassification".

We disagree that the CSA standards alone are the most recent statistics and standards. It is clear throughout the proposed FY 2006 and FY 2005 regulations and the final FY 2005 regulations that the eleven CBSAs that comprise metropolitan divisions are also the most recent standards and statistics, as recent as CSAs. In fact, the eleven CBSAs that comprise metropolitan divisions were intended by the OMB to replace the outdated CMSAs. The same CMSAs that CMS proposes to remove from the criterion as outdated; yet, CMS does not propose to replace the CMSAs in the criterion with the most recent standard and statistic recognized by the OMB for like areas, the eleven CBSAs that comprise metropolitan divisions.

We believe that CMS should include both CSAs and the eleven CBSAs that comprise metropolitan divisions in the qualifying criterion in order to consider all of the most recent and appropriate area designations, statistics and standards as CMS intends in the proposed regulation.

We also disagree that this proposed change to include only CSAs in the criterion provides and improves the overall consistency of the CMS policy by using a single labor market area definition for all aspects of the wage index and reclassification. We believe that the CSA designation and standard is only utilized for purposes of this urban reclassification proximity criterion and not for any aspects of the wage index or other type of reclassification or redesignation. Therefore, including the eleven CBSAs that comprise metropolitan divisions in the qualifying criterion will not have a negative impact on the overall consistency of the CMS policy.

If CMS intends to use the area definitions that are based on the most recent statistics and to improve the overall consistency of their policies to determine the proximity criterion, as the proposed regulation states, then both CSAs and CBSAs that comprise metropolitan divisions must be considered in the proximity criterion.

B. Allow areas to qualify as CSAs if the OMB designates the area as a CSA or if the area has the ability to elect to be designated a CSA, whether or not the area made that election.

We understand, through review of the August 22, 2000 Federal Register and discussions with OMB staff, that the criteria for an area to "automatically" be considered a CSA is when the employment interchange (commuting) measure between adjacent CBSAs is at least 25%. Also, adjacent CBSAs that have an employment interchange measure of at least 15% and less than 25% will combine as a CSA if local opinion, as reported by the congressional delegations in both areas, favors combination. The Federal Register states that the OMB will seek local opinion regarding the CBSA combination (CSA). The Federal Register also states that after a decision has been made regarding the CBSA combination (CSA), the OMB will not request local opinion again on the issue until the next redefinition of CBSAs.

We also understand, through discussions with OMB staff, that although the OMB is to seek local opinion regarding CSA combination, no formal OMB policy for seeking local opinion through congressional delegates is or was in place.

By allowing only adjacent CBSAs that automatically qualify as CSAs to meet the urban group reclassification criterion, CMS has taken the position that adjacent CBSAs that qualify for CSA election were contacted by the OMB (as the Federal Register states) to seek local opinion and the local opinion did not elect CSA combination. We believe the adjacent CBSAs that could elect CSA combination were never informed and local opinion never obtained.

We believe that because their was no formal OMB policy to seek local opinion on CBSA combination to elect CSA designation and the fact that there was opportunity for two adjacent CBSAs to be considered a CSA through an election, CMS should allow areas to qualify as CSAs if the OMB designates the area as a CSA automatically or if the area has the ability to elect to be designated a CSA, whether or not the area made that election.

5. CONCLUSION

Based on the aforementioned information we request that CMS incorporate the revisions, as written in section one of this document, in the FY 2006 final IPPS regulation. The requested revisions are critical to the financial stability of the hospitals located in the West Palm Beach Metropolitan Division and will effect

payments to all hospitals in the West Palm Beach Metropolitan Division beginning October 1, 2005.

We appreciate your consideration of this comment to the FY 2006 proposed IPPS regulation.

Respectfully,

Valerie A. Jackson
CEO
Columbia Hospital

mdg

Rcd by TFM
JUN 15 2005

RECEIVED
JUN 21 2005

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BY:----------

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DRG - BROOKS
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June 14, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
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200 Independence Avenue
Washington, DC 20201

TRANSFERS - WALZ
HART

LABOR S/N - KNIGHT, KRAEMER, SEIFERT, TREITEL

Re: Proposed Changes to the Hospital Inpatient Prospective Payment System, FY2006
Federal Register Dated May 4, 2005

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WALZ

File Code: CMS-1500-P

PYMT RTS/OUTLIER -

University of Michigan Hospitals and Health Centers (UMHHC) appreciates the opportunity to comment on the aforementioned proposed rule. Our comments are set forth in the following pages, and address the following topics:

HEFTER
HARTSTEIN

- DRG Reclassifications
- Post-Acute Care Transfers
- Labor-Related Share
- Outlier Threshold
- New Technology Applications

We appreciate your attention to these comments and recommendations, and would be pleased to provide any clarifications or additional information if you request. Please contact me at 734-647-3321, if you have questions about this letter.

Sincerely,

Thomas Marks, Director
Accounting & Reimbursement Services

DRG RECLASSIFICATIONS

Extracorporeal Membrane Oxygenation (ECMO): CMS proposes to reassign cases involving the ECMO procedure to the tracheostomy DRG (541).

UMHHC fully supports this change, and appreciates CMS' effort to more appropriately reimburse hospitals for this expensive but important technology.

As one of the nation's first and largest providers of ECMO, UMHHC has had to incur significant losses for years from all payers utilizing DRG-based reimbursement. We understand CMS' hesitance to implement DRG changes that may have little impact on services infrequently utilized by Medicare patients. However, as a practical matter, CMS' decisions about DRG structure and classification have an enormous impact on state and local payers, and therefore CMS has a larger responsibility than the operation of the Medicare program. We encourage CMS to continue to work toward making the DRG system more accurate and effective, even when the improvement may have little impact on Medicare.

POST-ACUTE CARE TRANSFERS

Beginning in FY 1999, a post-acute care (PAC) transfer policy was implemented to reduce payments when the length of stay is less than the average length of stay for the given DRG. CMS initially selected 10 DRGs for inclusion in this policy. Since 1999, CMS expanded the list to 30 DRGs. For 2006, CMS is proposing to increase the scope of this policy to cover 223 DRGs.

This change is projected by CMS to produce a 1.1% decrease in hospital inpatient payments (and we project a 1.5% decrease for UMHHC). We cannot recall another PPS change promulgated by CMS, with no legislative mandate, which has an industry-wide impact of this magnitude.

UMHHC is strongly opposed to the PAC transfer policy and believes that it is inconsistent with the DRG payment model. The DRG system is intended to produce fair and reasonable payments on average, even though a hospital may generate large gains on some cases and large losses on others. This concept of averaging the "winners and losers" is fundamental. The PAC transfer policy violates this principle, by eliminating a portion of the gain on cases that are "winners".

We request that CMS provide the rationale for a significant expansion of the PAC transfer policy. In the Proposed Rule, CMS provided no arguments in support of the expansion or explanation of the intended benefit. In past years, CMS cited concerns about cost-shifting from acute care to post-acute care. Data presented by MEDPAC in its March 2005 report shows that since 1999, inpatient costs per case have increased more than the market basket every year, and inpatient Medicare margins have decreased every year – this data contradicts the notion that hospitals are unfairly benefiting from greater use of post-acute care. In past years, CMS has also noted that some hospitals may not have access to a large array of post-acute care options, and that the PAC transfer policy may help level the playing field. Given that every group of hospitals analyzed by CMS in its Impact Analysis will lose significant revenue from the proposed cut, there must be other reasons for the proposal that CMS has failed to explain.

UMHHC also takes exception to the formula for computing the payment reduction. For PAC transfers, CMS has elected to use a similar calculation to that used for transfers to another short-term acute care hospital. However, these transfers are very different from PAC transfers. In a transfer from one short-term acute care hospital to another, the transferring hospital has not

provided the acute care services needed by the patient. In a PAC transfer, the patient has received all of the acute care services required for a safe discharge.

For DRGs with long lengths of stay, such as DRG 541, there is a very high degree of variation in length of stay. Because the variation around the average is so large, the PAC transfer policy has a very significant impact on reimbursement that is *unrelated* to the use of post-acute care services. UMHHC believes that the threshold for a PAC transfer reduction should be a fixed percentage from the mean length of stay, perhaps based on one standard deviation from the mean. For DRGs with shorter lengths of stay, this change would not materially affect the outcome, but for DRGs with long lengths of stay this change would produce a more equitable result.

Lastly, UMHHC believes that any expansion of the PAC transfer policy should be made in a budget neutral manner, consistent with the treatment of outliers. PAC transfer reductions mirror the outlier payment – the former eliminates part of the gain on low cost cases, the latter offsets part of the loss on high cost cases. We believe that the estimated payment reduction for PAC transfer cases should be added back in the calculation of the DRG rate, under the same principle that estimated outlier payments are removed in the calculation of the DRG rate.

UMHHC recommends that CMS reconsider its proposal for expanding the PAC transfer policy. Our belief is the expansion is not warranted and should be eliminated from the Final Rule. However, if CMS insists on implementing the proposal, we believe that the threshold should be modified to one standard deviation variance from the mean length of stay, and the change should be made in a budget neutral manner.

LABOR S/N

LABOR-RELATED SHARE

CMS is proposing a decrease in the labor-related share from 71.1% to 69.7% of the total DRG price. Because hospitals with wage indices lower than 1.0 utilize a 62% labor-related share, this proposal is not budget-neutral and will reduce payments by a significant amount.

UMHHC opposes the proposed decrease in the labor-related share of the PPS rate. In the inpatient PPS rule for FY 2003, CMS examined the methodology used to determine the labor-related share. The CMS calculation of the labor-related share for FY 2003 resulted in an increase from 71.1 percent to 72.5 percent. However, CMS did not implement the increase pending further research to determine whether a different methodology should be adopted for determining the labor-related share. In the FY 2006 proposed rule, CMS discusses continuing research on alternative methodologies for calculating the labor-related share and states that the analysis has not yet produced sound enough evidence to propose a change. It is clearly inequitable to decline to implement in one year a labor-share increase pending an analysis of the methodology, and then propose a labor-share decrease in a subsequent year while that analysis is still not completed.

Further, UMHHC believes that CMS should broaden its view of labor-related categories to include all categories where the cost of goods and services acquired may be influenced by local market wage differences. In the proposed rule, CMS discusses the fact that a portion of professional services are purchased from national sources. However, CMS does not appear to be considering the local market influence on the cost of goods/services that are not considered "labor-intensive". For example, food, energy, and telephone are goods that have an underlying labor component that is impacted by local market differences in wages. Even pharmaceuticals and supplies purchased from national vendors require local distribution networks that may affect cost.

UMHHC recommends that CMS maintain the labor-related share of the PPS rate at the current 71.066 percent for hospitals with a wage index of 1.0 or greater, until further research is completed.

OUTLIER THRESHOLD

CMS proposes an increase in the outlier threshold to $26,675, a 3.4% increase over the 2005 threshold. It appears unreasonable that an increase in the threshold would be required given that CMS is projecting that 2004 and 2005 outlier payments will be well below the target. CMS' projection for 2004 and 2005 is that outlier payments will be 3.5% and 4.4%, respectively, compared to the 5.1% target. In other words, outlier payments will fall short of the target by 31% for 2004 and 14% for 2005.

We believe that CMS' methodology is likely to cause a continued underpayment of outliers. To model the 2006 outlier threshold, CMS is using a projected two-year rate of increase in charges of 18%, and cost-to-charge ratios on file as of December 2004. Based on our understanding of the outlier methodology, CMS is assuming no change in cost-to-charge ratios. We do not believe that this is a reasonable assumption. CMS' Table 8A shows that cost-to-charge ratios consistently decrease over time, including the most recent year which reflects the impact of the June 2003 final outlier rule. We do not believe it is logical or appropriate to assume that average charges will increase by 18% from 2004 to 2006, without some decrease in cost-to-charge ratios.

We recommend that CMS revise its outlier policy to incorporate an assumption about average cost-to-charge ratios, consistent with its assumption about average charges.

NEW TECHNOLOGY APPLICATIONS

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Section 503 of the MMA provided additional funding for add-on payments for new medical services and technologies under the inpatient PPS. Previously, due to budget neutrality requirements, increases in payments for new technologies decreased payments for all other inpatient services. In addition, the MMA reduced the cost threshold for new technologies to qualify for new technology payments to the lesser of:

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

For FY 2006, the CMS is essentially proposing to reject all eight applications (six new and two reevaluations) and only maintain payment for only one currently-approved technology. UMHHC is concerned that the CMS continues to resist approving new technologies for add-on payments. In addition, UMHHC is disappointed that the CMS did not propose to increase the marginal payment rate to 80 percent rather than 50 percent, which the agency has the authority to do without reducing payments to other services. UMHHC urges that the CMS re-evaluate the eight applications that it previously rejected and, upon approval increase the marginal payment rate to 80 percent. This is essential for ensuring that Medicare beneficiaries continue to have access to new medical devices and technologies.

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Baltimore, MD 21244-1850

GEORECLASS - KENLY
LABOR S/N - KNIGHT, KRAEMER, SEIFERT, TREITEL
CBSAS - KENLY
RRC - NAVARRO
DRG/WEIGHTS - KRAEMER, TREITEL, ZEZZA, HUE
WI/BI - MILLER
IMPACT - KRAEMER

Re: Hospital Reclassifications – CMS-1500-P
– South Central Regional Medical Center
– Medicare Provider No. 25-0058

Dear Sir or Madam:

In its proposed rule entitled, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates," published in the May 4, 2005 *Federal Register*, the Centers for Medicare and Medicaid Services ("CMS") solicited public comment on various proposals that would affect the wage index reclassification process for various categories of hospitals. *See* 70 Fed. Reg. 23,306 (May 4, 2005). This comment is submitted on behalf of South Central Regional Medical Center ("South Central"), CMS Provider No. 25-0058. The purpose of this comment is to request relief for hospitals, including South Central, who qualify for reclassification to a core based statistical area ("CBSA") in which all hospitals located in that CBSA have reclassified to another CBSA.

1. Medicare Geographic Reclassification Program.[1]

GEORECLASS

Under the Medicare inpatient prospective payment system, hospitals receive a fixed, predetermined payment per Medicare patient based upon a standardized amount published in the *Federal Register* annually as part of Medicare's Changes to the Hospital Inpatient Prospective Payment System (the "Final Rule"). The standardized amount is adjusted to account for variation in the cost of providing care to specific patients in specific locations and is divided into labor-related payment and non-labor-related payment.

[1] *See* generally, 42 U.S.C. § 1395ww(d)(10); 42 C.F.R. Part 412.

CMS makes a labor cost adjustment that takes into account geographic variation in hospitals' labor costs. CMS makes this adjustment because the wages hospitals pay to employees vary significantly based upon geographic location. For this reason, the portion of the standardized amount that reflects labor-related expenses is multiplied by the area "wage index," or the ratio of the average hourly hospital wage (the "average hourly wage" or "AHW") in the area compared to the national average hourly wage. The Medicare program uses the Office of Management and Budget's classification system to define its geographic areas for wage index purposes. Each CBSA[2] is defined as a metropolitan labor market. The remaining area in the state is defined as a single rural labor market.

The Omnibus Budget Reconciliation Act of 1989 established an administrative process for geographic reclassification in which hospitals that meet certain criteria may qualify to be paid for Medicare inpatient hospital services as if they were located in another geographic area. Once reclassified, the hospital receives the other area's wage index for a three-year period. Hospitals may reclassify to the nearest urban or rural area. To reclassify, the hospital must apply to the Medicare Geographic Classification Review Board (the "MGCRB"), which determines whether the hospital meets the requisite reclassification criteria.

Typically, in order for a hospital to reclassify to another area, the hospital must meet certain criteria. First, the hospital must meet certain proximity requirements. Generally, an urban hospital must be located within 15 miles of the area to which it wishes to reclassify, while a rural hospital must be within 35 miles of the area to which it wishes to reclassify.[3] The distance requirements are waived for RRCs, but the RRC must reclassify to the closest CBSA.[4] Second, the hospital's AHW must be a specified percentage (108% for urban hospitals, 106% for rural hospitals) of the AHW of the area in which the hospital is located and a specified percentage (84% for urban hospitals, 82% for rural hospitals and RRCs) of the AHW of the area to which the hospital wishes to reclassify.[5] For RRCs, CMS waives the upper threshold requirement but not the lower threshold requirement.[6]

2. South Central Regional Medical Center.

South Central Regional Medical Center ("South Central") is a 285-bed Medicare-designated sole community hospital and RRC located in Laurel, Jones County, Mississippi. South Central's nearest competitors offering comparable services are located approximately 30 miles from South Central. South Central provides vital health care services that residents of Jones County and the surrounding areas otherwise would receive from hospitals in larger medical communities many miles distant. These services include emergency services, a

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[2] Due to the Office of Management and Budget's redrawing of urban areas subsequent to the 2000 census, areas referred to as metropolitan statistical areas or "MSAs" prior to the 2004 Final Rule may now be referred to as core-based statistical areas or "CBSAs." For consistency's sake, urban areas will be referred to as "CBSAs" in this paper.

[3] 42 C.F.R. § 412.230.

[4] *Id.*

[5] *Id.*

[6] *Id.*

women's center, rehabilitation services, a wellness center, surgical services, diagnostic and imaging services, cardiac services, outpatient services, a nursing home, home health services and hospice services.

In the past, through the Medicare geographic reclassification program, South Central received Medicare payment in amounts comparable to payment received by competitor urban hospitals located across county lines. Until fiscal year 1995, South Central was periodically reclassified to the Jackson, Mississippi CBSA and received a substantial benefit from reclassification. Reclassification allowed South Central to compete, not only with nearby urban hospitals, but also with nearby rural hospitals that reclassified to the Jackson CBSA and the Gulfport-Biloxi CBSA.[7]

The additional payment from geographic reclassification also allowed South Central to participate in many community activities. For example, South Central initiated a project known as ALIVE Jones County to develop a community health improvement plan focusing on critical issues facing Jones County, including breakdown of the family, teenage pregnancy, health care access and poor nutrition and exercise. South Central also serves as a training site for many area schools, universities and organizations, and provides a variety of community education programs, including a diabetes education and support group. South Central's Women's Life Center offers a health library complete with video tapes, books and pamphlets, as well as classes such as the Prepared Childbirth, Sibling Preparation and Safe Sitter classes. In addition, the Women's Life Center offers a monthly luncheon program called "Speaking of Women" and an annual Women's Life Conference which is Mississippi's premier women's health and wellness event. In addition to these activities, South Central sponsors Health Break, a weekly television program featuring physicians and other health professionals discussing topics of interest to the community relating to health and well-being. Thus, Medicare geographic reclassification benefited not only South Central, but also the residents of Jones County and the surrounding areas.

In fiscal year 1995, the Hattiesburg, Mississippi CBSA was formed, comprised of Forrest and Lamar counties. The Hattiesburg CBSA borders Jones County, where South Central is located. Thus, South Central was no longer able to reclassify to the Jackson CBSA or to the Gulfport-Biloxi CBSA, but could qualify for reclassification only to the Hattiesburg CBSA. The Hattiesburg CBSA received (and continues to receive) a wage index equal to the Mississippi rural wage index.

On the other hand, all of the hospitals actually located within the Hattiesburg CBSA reclassify for wage index purposes to the next closest urban area, the Gulfport-Biloxi CBSA. This reclassification resulted in significant increased Medicare payments to these reclassified hospitals as evidence by the following chart:

[7] Effective for reclassifications beginning in FY 2005, the area previously referred to as the Biloxi-Gulfport-Pascagoula CBSA has been divided into the Gulfport-Biloxi CBSA and the Pascagoula CBSA. For clarity's sake, this paper will refer to the Gulfport-Biloxi CBSA.

Fiscal Year	Rural Mississippi Wage Index	Hattiesburg CBSA Wage Index for Reclassified Hospitals	Gulfport-Biloxi CBSA Wage Index for Reclassified Hospitals	Jackson CBSA Wage Index for Reclassified Hospitals
2002[8]	0.7528[9]	0.7528[10]	0.8105[11]	0.8491[12]
2003	0.7680[13]	0.7680[14]	0.8368[15]	0.8607[16]
2004	0.7778[17]	0.7778[18]	0.8407[19]	0.8399[20]
2005	0.7649[21]	0.7649[22]	0.8764[23]	0.8285[24]
2006[25]	0.7685[26]	0.7685[27]	0.8612[28]	0.8182[29]

Suddenly, through no action of its own and no shift in the labor market or in patient needs, South Central's ability to compete with other hospitals in the area was drastically reduced. South Central now may apply for reclassification to the Hattiesburg CBSA but, unlike each of its competitors, **receives no benefit from such reclassification.**

[8] The two hospitals located within the Hattiesburg CBSA were both RRCs prior to the formation of the Hattiesburg CBSA. Due to a change in the reclassification regulations, these hospitals have been allowed to regain their RRC status for reclassification purposes and reclassify to the Gulfport-Biloxi CBSA every year since FY 2002.
[9] Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Rates and Costs of Graduate Medical Education; Fiscal Year 2002 Rates, Etc.; Final Rules, 66 Fed. Reg. 39,827, 40,046 (Aug. 1, 2001).
[10] *Id.* at 40,046.
[11] *Id.*
[12] *Id.*
[13] Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2003 Rates; Final Rule, 67 Fed. Reg. 49,981, 50,221 (Aug. 1, 2002).
[14] *Id.* at 50,222.
[15] *Id.* at 50,321.
[16] *Id.* at 50,222.
[17] Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates; Correction of Final Rule, 68 Fed. Reg. 57,732, 57,743 (Oct. 6, 2003).
[18] *Id.* at 57,739.
[19] *Id* at 57,744.
[20] *Id.*
[21] *See* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates; Correcting Amendment; Final Rule, 69 Fed. Reg. 78,526, 78,661 (Dec. 30, 2004).
[22] *Id.* at 78,646.
[23] *Id.* at 78,666.
[24] *Id.*
[25] Based upon proposed rates published in the May 4, 2005 proposed rule; *See* 70 Fed. Reg. 23,306.
[26] *Id.* at 25,573.
[27] *Id.* at 23,559.
[28] *Id.* at 23,575.
[29] *Id.*

3. Why Should CMS Provide Relief to South Central?

a. Congress has indicated its intent to aid rural hospitals and RRCs, but South Central receives no benefit from its RRC status for wage index purposes.

(1) Congress created RRCs in order to provide additional benefits to rural hospitals that face issues similar to urban hospitals.

An RRC is a hospital that is located in a rural area and meets one of the following characteristics:

(a) The hospital has 275 or more beds; or

(b) More than 50% of the hospital's Medicare patients are referred from other hospitals or from physicians not on the hospital's medical staff and 60% of the hospital's Medicare patients live more than 25 miles from the hospital.[30]

RRCs receive special benefits under Medicare laws because they preserve access to care for beneficiaries in rural areas. RRCs typically provide an array of services not typically offered by smaller rural hospitals, and treat patients from a wide geographic area.

Although these hospitals receive certain benefits, as discussed below, Congress and CMS also impose additional responsibilities upon RRCs. As part of the Emergency Medical Treatment and Labor Act ("EMTALA")[31], Congress enacted a non-discrimination provision, stating:

> A participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units, **or (with respect to rural areas) regional referral centers** as identified by the Secretary in regulation) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.[32]

This requirement imposes significant economic burdens upon RRCs, many of which are already struggling economically.

Congress recognized that RRCs, although rural, often meet challenges that are more similar to urban hospitals than their smaller rural counterparts. For this reason, Congress and

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[30] *See* 42 C.F.R. § 412.96. These are the basic criteria for RRC designation. Congress and CMS have developed alternative criteria to enable certain hospitals to qualify for RRC designation that are not relevant to this discussion.
[31] 42 U.S.C. § 1395dd.
[32] *Id.* at § 1395dd(g) (emphasis added).

CMS have attempted to provide additional benefits to RRCs, to assist these hospitals in providing the enhanced services that they provide. The major benefit that Congress has provided to RRCs is assistance in achieving geographic reclassification. As noted below, RRCs are not required to meet the 106% test for geographic reclassification, nor are they required to meet certain proximity requirements.[33] However, a RRC must reclassify, if it reclassifies at all, to the closest CBSA, whether in distance or driving time. In the case of South Central, the closest CBSA is the Hattiesburg CBSA.

(2) Congress has frequently supported measures aimed at helping rural hospitals and RRCs.

In the Balanced Budget Act of 1997 and the Balanced Budget Refinement Act of 1999, Congress took a number of actions to assist rural hospitals and RRCs. The reasons for this assistance was explained by CMS in the preamble to its August 1, 2000 final inpatient PPS rule (the "August 1, 2000 Rule"), where CMS explained:

> Historically, the financial performance of rural hospitals under the prospective payment system has lagged behind that of urban hospitals. Despite an overall increase in recent years of Medicare inpatient operating profit margins, some rural hospitals continue to struggle financially. For example, during FY 1997, while the national average hospital margin was 15.1%, it was 8.9% for rural hospitals. In addition, approximately one-third of rural hospitals continue to experience negative Medicare inpatient margins despite this relatively high average margin.
>
> In response to the lower margins of rural hospitals and the potential for a negative impact on beneficiaries' access to care if these hospitals were to close, we considered potential administrative changes that could help improve payments for rural hospitals. One approach in that regard would be to make it easier for rural hospitals to reclassify for purposes of receiving a higher wage index.[34]

The Balanced Budget Act of 1997 included a substantial section entitled "Subtitle C – Rural Initiatives." The purpose of Subtitle C was to address some of the inequities facing rural hospitals and RRCs. Section 4202 specifically addressed RRCs. The first part of Section 4202 amended 42 U.S.C. § 1395ww(d)(10)(D) to state:

> In the case of a hospital which has ever been classified by the Secretary as a rural referral center, the Board may not reject the

[33] *See* 42 C.F.R. § 412.230.

[34] Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2001 Rates, 65 Fed. Reg. 47,026, 47,090 (August 1, 2000).

> application of the hospital under this paragraph on the basis of any comparison between the average hourly wage of the hospital and the average hourly wage of the hospitals in the area in which it is located.[35]

Thus, RRCs receive special treatment during the reclassification process by receiving an exemption from the upper threshold test comparing the AHW of the hospital to the AHW of all hospitals in the area in which it is located. The second part of Section 4202 states:

> Any hospital classified as a rural referral center by the Secretary of Health and Human Services for fiscal year 1991 shall be classified as a rural referral center for fiscal year 1998 and each subsequent fiscal year.[36]

In the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Congress again passed a number of measures intended to aid rural hospitals and RRCs. Included in these measures was Section 401, which allows RRCs located in urban areas to be treated as rural.

More recently, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA")[37] included a number of provisions aimed at helping rural hospitals and RRCs. Section 401 of the MMA benefits rural hospitals by equalizing the standardized amount received for the labor and non-labor related portion of Medicare payment.[38] Section 402 increased the cap on disproportionate share hospital payments from 5.25% to 12% for rural hospitals and eliminated the cap for RRCs.[39] Section 405 contained improvements for critical access hospitals.[40] Perhaps most importantly, Section 508 directed CMS to create a one-time only process for reclassification for hospitals that failed to meet the proximity requirements for reclassification but that met certain other requirements established by CMS.[41]

Taking its lead from Congress, CMS also created regulatory measures intended to aid rural hospitals and RRCs, particularly those in unique situations not addressed by Section 508 of the MMA. For example, included in the August 1, 2000 Final Rule[42] was a measure designed to aid rural hospitals by lowering the upper and lower thresholds for wage index reclassification. Prior to this rule, both urban and rural hospitals were required to meet an upper threshold of 108% and a lower threshold of 84%. 42 C.F.R. §§ 412.230(e)(1)(iii) and (iv) were amended to

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[35] Pub. Law 105-33, § 4202(a).
[36] *Id.*, § 4202(b)(1).
[37] Pub. Law 108-173.
[38] *Id.* § 401.
[39] *Id.* § 402.
[40] *Id.* § 405.
[41] *Id.* § 508. Unfortunately, the criteria ultimately adopted by CMS for Section 508 reclassification did not address South Central's circumstances. Although South Central applied for reclassification under Section 508, the Medicare Geographic Classification Review Board denied South Central's application.
[42] 65 Fed. Reg. at 47,054.

lower these thresholds for rural hospitals to 106% and 82%, respectively. In 2004, CMS made similar changes to aid RRCs, rural hospitals and sole community hospitals. CMS used its discretion under 42 U.S.C. § 1395ww(d)(5)(I)(i) to make exceptions to the Medicare geographic reclassification rules for certain hospitals which would otherwise be disadvantaged by these rules. For example, CMS assisted urban RRCs that fail to meet the 84% urban threshold for reclassification but would have been able to meet the 82% threshold.[43] CMS also provided relief for sole community hospitals in certain low population density states and dominant hospitals[44] that were not assisted by reclassification under Section 508 of the MMA.[45]

Unfortunately, none of these measures addressed South Central's unique situation. Nevertheless, it is apparent that both Congress and CMS have adopted a public policy of seeking to aid rural hospitals, and particularly, RRCs.

(3) Unlike all other RRCs in Mississippi, South Central does not benefit from its RRC status for wage index purposes.

With the single exception of South Central, all of the RRCs in Mississippi, including South Central's competitors, reclassify to urban areas with a higher wage index as a result of their RRC status. South Central's competitors include RRCs in Meridian, Mississippi (57 miles distant) and in Hattiesburg, Mississippi (30 miles distant).[46] These hospitals have historically reclassified to the Jackson CBSA and the Gulfport-Biloxi CBSA.[47] As a result of the formation of the Hattiesburg CBSA and South Central's inability to reclassify to any other urban area, **South Central receives a lower wage index than any other RRC in Mississippi.**

Hospital Name	Provider Number	Location	Current Reclassification	Proposed FY 2006 Wage Index
North Mississippi Medical Center	25-0004	Tupelo, MS	Memphis, TN-AR-MS	0.9108[48]
Magnolia Hospital	25-0009	Corinth, MS	Jackson, TN	0.8799[49]
Vicksburg Medical Center	25-0031	Vicksburg, MS	Jackson, MS	0.8182[50]
South Central Regional Medical Center	**25-0058**	**Laurel, MS**	**None**	**0.7685**[51]

[43] *See* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates; Final Rule, 69 Fed. Reg. 48,916, 49,105 (Aug. 11, 2004); *see also* 42 C.F.R. §§ 412.230(d)(3) and 412.64(j).
[44] 69 Fed. Reg. at 49,108-09; 42 C.F.R. § 412.230(e)(1)(iii)(B).
[45] 69 Fed. Reg. at 49,107.
[46] Distances were calculated based upon expedia.com's driving directions using the shortest route.
[47] As a result of the redrawing of the CBSAs based upon 2000 census data, it appears that the Meridian hospitals may now qualify for reclassification to the Tuscaloosa, Alabama CBSA, which has a reclassified wage index of 0.8339.
[48] 70 Fed. Reg. at 23,576.
[49] *Id.* 70 Fed. Reg. at 23,575.
[50] *Id.*
[51] *Id.*

Hospital Name	Provider Number	Location	Current Reclassification	Proposed FY 2006 Wage Index
Rush Foundation Hospital	25-0069	Meridian, MS	Tuscaloosa, AL	0.8614[52]
Forrest General Hospital	25-0078	Hattiesburg, MS	Gulfport-Biloxi, MS	0.8612[53]
Riley Medical Center	25-0081	Meridian, MS	Jackson, MS	0.8182[54]
Delta Regional Medical Center	25-0082	Greenville, MS	Pine Bluff, AR	0.8099[55]
Wesley Medical Center	25-0094	Hattiesburg, MS	Gulfport-Biloxi, MS	0.8612[56]
Southwest Mississippi Regional Medical Center	25-0097	McComb, MS	Baton Rouge, LA	0.8470[57]
Greenwood-Leflore Hospital	25-0099	Greenwood, MS	Jackson, MS	0.8182[58]
Jeff Anderson Regional Medical Center	25-0104	Meridian, MS	Jackson, MS	0.8182[59]

This situation places South Central in the position of reclassifying to the Hattiesburg CBSA, which receives the rural floor wage index (0.7685), while its nearest competitors qualify for reclassification to the Gulfport-Biloxi CBSA, the Jackson CBSA or the Tuscaloosa CBSA, each of which receive a much higher reclassified wage index (0.8612, 0.8182 and 0.8614, respectively). Based on fiscal year 2005 PPS rates, South Central will receive an estimated $398.64 less per Medicare discharge in fiscal year 2006 than it would have received had it reclassified to the Gulfport-Biloxi CBSA. South Central's payment from Medicare on a per discharge basis is lower than that of any of its competitor hospitals in Hattiesburg, Meridian, Jackson and the Mississippi Gulf Coast and than any other reclassified RRC in Mississippi.

In fiscal year 2006, South Central will be the only RRC in Mississippi that does not receive a benefit from the Medicare geographic reclassification process. South Central competes with reclassified hospitals for labor from the same labor pool, buys supplies and equipment from the same suppliers and has costs comparable to the competing hospitals. As a RRC, South Central must comply (as must other referral centers) with federal statutes, such as the Emergency Medical Treatment and Labor Act, that restrict activities of RRCs and impose upon South Central expensive administrative and clinical burdens. Yet South Central receives lower Medicare payments per discharge than any of its competitors.

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[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] *Id.*

b. South Central must compete for labor with hospitals in the Hattiesburg CBSA, all of which reclassify to the Gulfport-Biloxi CBSA.

In order to retain its employees, South Central must pay its employees wages comparable to the wages paid by its competitors in Hattiesburg, both of which reclassify to the Gulfport-Biloxi area. If South Central does not offer comparable wages, its best employees will leave South Central and drive the extra 30 minutes to work in a Hattiesburg hospital. Thus, South Central must pay its employees wages comparable to the Gulfport-Biloxi wages.[60] In fiscal year 2006, hospitals located in the Gulport-Biloxi CBSA will receive a wage index of 0.8922. Hospitals reclassifying to the Gulfport-Biloxi CBSA will receive a wage index of 0.8612. South Central will receive a wage index of 0.7685, resulting in significantly lower Medicare reimbursement and thus less income with which to pay competitive salaries. South Central's inability to compete with nearby hospitals for labor threatens its very existence.

c. Although it has a case mix index similar to Mississippi urban hospitals and reclassified RRCs, South Central does not receive the additional Medicare reimbursement these hospitals receive to assist in treating the costliest patients.

In addition to competing with other RRCs for labor and equipment, South Central also treats the same patients that larger urban hospitals and RRCs treat. A hospital's "case mix index" is "a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG weights as a measure of the relative costliness."[61]

Of the 86 Mississippi hospitals listed in Table 2 of the 2005 Proposed Rule[62], South Central's case mix index is among the top 25 highest case mix indices in the state. As demonstrated on the chart attached as Exhibit A, each of the 21 hospitals with a case mix index that is higher than South Central's case mix index is either an urban hospital or a rural hospital that reclassifies to an urban area. Thus, each of these hospitals receive an urban area's wage index or reclassified wage index. These hospitals receive wage indices ranging from 0.8182 to 0.9346. South Central is the only hospital on the list receiving the rural Mississippi wage index of 0.7685. Of note is the fact that South Central has a higher case mix index than Riley Medical Center (an RRC reclassified to an urban area with a wage index of 0.8182), Magnolia Hospital (a rural hospital reclassified to an urban area with a wage index of 0.8799), and Biloxi Regional Medical Center (an urban hospital with a wage index of 0.8922).

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[60] Examination of the relevant hospitals' AHW data will show that South Central has a lower AHW than its competitor hospitals. Unlike some of its competitors, South Central employs its laundry, janitorial and cafeteria personnel in-house, rather than outsourcing these jobs. South Central's AHW is therefore lower than the AHW of hospitals that outsource these traditionally lower-wage jobs. However, South Central pays competitive wages to its health care personnel such as nurses and nurse practitioners, physical, occupational and speech therapists, pharmacists, radiation technologists and respiratory therapists.

[61] 69 Fed. Reg. 28,196, 28,338 (May 18, 2004).

[62] *See* 70 Fed. Reg. at 28,483 (corrected as of June 1, 2005 at http://www.cms.hhs.gov/providers/hipps/ippswage.asp).

Thus, it is clear that South Central treats costly cases similar to those treated by urban hospitals and other RRCs in the state, but is required to treat these cases with significantly lower Medicare reimbursement due to its inability to reclassify to any urban area other than Hattiesburg, Mississippi.

4. What is the Impact of Ineligibility for Geographic Reclassification to South Central? IMPACT

Based upon the rates published in the proposed inpatient prospective payment system rule and subsequent corrections concerning fiscal year 2005 payment rates and wage indices and information provided by TriSpan Health Services concerning South Central's disproportionate share hospital adjustment, South Central estimates that it will receive approximately $398.64 less per Medicare discharge in fiscal year 2006 than it would receive were it reclassified to the Gulfport-Biloxi CBSA. For the fiscal year ending September 30, 2004, South Central had 5,425 Medicare discharges. Assuming that South Central has approximately the same number of Medicare discharges in fiscal year 2006, this means that South Central will lose approximately $2,162,609.58 due to its inability to reclassify to the Gulfport-Biloxi CBSA as its competitors do. Over a three-year period, the total loss to South Central will be approximately $7,581,736.42.

South Central's inability to reclassify has far-reaching impact upon its ability to provide high-quality care to its patients. According to the U. S. Census Bureau, in 2000, 14.2% of the 64,536 residents of Jones County (over 9,000 people) were over the age of 65. Obviously, South Central's ability to provide services to Medicare recipients is vital to the residents of Jones County. The drastic reduction in Medicare payment that South Central experiences as a result of the formation of the Hattiesburg CBSA threatens South Central's ability to provide services to these individuals.

In order to retain employees, South Central must pay its employees wages comparable to the wages paid by its competitors in Hattiesburg, both of which reclassify to the Gulfport-Biloxi area and will receive a fiscal year 2006 wage index for reclassified hospitals of approximately 0.8612. As demonstrated above, South Central receives significantly lower Medicare reimbursement and thus less income with which to pay these competitive salaries. South Central's inability to compete with nearby hospitals for labor threatens its very existence.

South Central's case mix index shows that the costliness and acuity of South Central's patients is comparable to those treated by its competitors, other urban hospitals and RRCs. South Central's inability to benefit from the geographic reclassification process results in lower Medicare reimbursement, which jeopardizes its ability to provide high quality care to its sickest patients.

In addition to providing health care services and as noted above, South Central participates actively in many community activities, including ALIVE Jones County, the diabetes education and support group, Health Break and activities sponsored by the Women's Life Center. The reduction in funds that South Central receives threatens its ability to participate in

such charitable activities. Thus, Jones County is threatened in its ability to obtain not only health care services, but many community services as well.

5. How can CMS Provide Relief to South Central?

There are several possible ways to correct these inequities suffered by South Central and other rural hospitals that may reclassify only to an empty CBSA. South Central suggests the following as possible solutions, but is willing to work with CMS to consider other viable alternatives:

a. Alternative 1.

> If all of the hospitals located within the area to which a rural referral center would otherwise seek reclassification (the "home area") have reclassified to another area (the "reclassified area"), the rural referral center may reclassify to the reclassified area if the rural referral center's average hourly wage is at least 72% of the reclassified area's average hourly wage.

This alternative would allow South Central to reclassify to the Gulfport-Biloxi CBSA based upon the fact that all of the hospitals located in the Hattiesburg CBSA (the area to which South Central would otherwise seek reclassification) have reclassified to the Gulfport-Biloxi CBSA. South Central's AHW is currently 72% of the Gulfport-Biloxi CBSA's AHW as a result of its inability to pay higher wages and a large in-house staff of low wage earners.

b. Alternative 2.

> If all of the hospitals located within the area to which a rural referral center would otherwise seek reclassification (the "home area") have reclassified to another area (the "reclassified area"), the rural referral center may reclassify to the reclassified area if the rural referral center otherwise qualifies for reclassification to the home area without regard to whether the average hourly wage of the hospital's current area is greater than the average hourly wage of the home area.

This alternative would also allow South Central to reclassify to the Gulfport-Biloxi CBSA based upon the fact that all of the hospitals located in the Hattiesburg CBSA (the area to which South Central would otherwise seek reclassification) have reclassified to the Gulfport-Biloxi CBSA. South Central's AHW is currently 91% of the Hattiesburg CBSA's AHW. South Central therefore would qualify to reclassify to the Hattiesburg CBSA were it not for the fact that rural Mississippi's AHW ($20.3970) is greater than the Hattiesburg CBSA's AHW ($19.6542). The language for the second alternative above would allow South Central to qualify for

reclassification to the empty Hattiesburg CBSA and then to, in effect, "jump" to the Gulfport-Biloxi CBSA, the area to which all of the Hattiesburg hospitals have reclassified.

6. Conclusion.

South Central appreciates the opportunity to present to CMS the problems that it faces as a result of its inability to benefit from the Medicare geographic reclassification process. South Central requests consideration of the above alternatives for reclassification, and is willing to discuss any other viable alternatives suggested by policymakers to provide relief for its current situation.

If you have any questions concerning this comment, please call me at (662) 690-8137.

Sincerely,

Jeffrey S. Moore

JSM:mrh
cc: Honorable Senator Thad Cochran
Honorable Senator Trent Lott

TOP 25 CASE MIX INDEX HOSPITALS IN MISSISSIPPI[63]

	Provider Number	Name	Urban, Rural or RRC	Reclassification	Case Mix Index	Wage Index
1.	25-0001	University of Mississippi Medical Center	Urban (Jackson, MS)	N/A	1.8697	0.8313
2.	25-0004	North Mississippi Medical Center	Rural RRC	Memphis, TN-AR-MS	1.8380	0.9108
3.	25-0078	Forrest General Hospital	Urban RRC (Hattiesburg, MS)	Gulfport-Biloxi, MS	1.6134	0.8612
4.	25-0094	Wesley Medical Center	Urban RRC (Hattiesburg, MS)	Gulfport-Biloxi, MS	1.5981	0.8612
5.	25-0048	St. Dominic Medical Center	Urban (Jackson, MS)	N/A	1.5931	0.8313
6.	25-0019	Memorial Hospital at Gulfport	Urban (Gulfport-Biloxi, MS)	N/A	1.5585	0.8922
7.	25-0102	Mississippi Baptist Medical Center	Urban (Jackson, MS)	N/A	1.5552	0.8313
8.	25-0141	Baptist Memorial Hospital – DeSoto County	Urban (Memphis, TN-AR-MS)	N/A	1.5519	0.9346
9.	25-0034	Baptist Memorial Hospital – North Mississippi	Rural	Memphis, TN-AR-MS	1.5396	0.9108
10.	25-0072	Methodist Medical Center	Urban (Jackson, MS)	N/A	1.5198	0.8313

[63] Based upon proposed case mix index and wage index information in Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule, 70 Fed. Reg. 23,306 (May 4, 2005), as corrected at http://cms.hhs.gov/providers/hipps/ippswage.asp.

	Provider Number	Name	Urban, Rural or RRC	Reclassification	Case Mix Index	Wage Index
11.	25-0069	Rush Foundation Hospital	Rural RRC	Tuscaloosa, AL	1.5168	0.8614
12.	25-0040	Singing River Health Systems	Urban (Pascagoula, MS)	Gulfport-Biloxi, MS	1.4780	0.8612
13.	25-0100	Golden Triangle Regional Medical Center	Rural	Tuscaloosa, AL	1.4538	0.8614
14.	25-0104	Jeff Anderson Regional Medical Center	Rural RRC	Jackson, MS	1.4432	0.8182
15.	25-0097	Southwest Mississippi Regional Medical Center	Rural RRC	Baton Rouge, LA	1.4195	0.8470
16.	25-0031	Vicksburg Medical Center	Urban (Jackson, MS)	N/A	1.3128	0.8182
17.	25-0082	Delta Regional Medical Center	Rural RRC	Pine Bluff, AR	1.2893	0.8099
18.	25-0125	Gulf Coast Medical Center	Urban (Gulfport-Biloxi, MS)	N/A	1.2851	0.8922
19.	25-0123	Garden Park Community Hospital	Urban (Gulfport-Biloxi, MS)	N/A	1.2730	0.8922
20.	25-0138	River Oaks Medical Center	Urban (Jackson, MS)	N/A	1.2730	0.8313
21.	25-0099	Greenwood-Leflore Hospital	Rural RRC	Jackson, MS	1.2590	0.8182
22.	25-0058	South Central Regional Medical Center	Rural RRC	N/A	1.2564	0.7685
23.	25-0009	Magnolia Hospital	Rural	Jackson, TN	1.2479	0.8799
24.	25-0081	Riley Medical Center	Rural RRC	Jackson, MS	1.2411	0.8182

	Provider Number	Name	Urban, Rural or RRC	Reclassification	Case Mix Index	Wage Index
25.	25-0007	Biloxi Regional Medical Center	Urban (Gulfport-Biloxi, MS)	N/A	1.2386	0.8922

117

Transfers - Walz
Hart
MEDPAC - TREITEL
WYNN
BROOKS

CAH/RELOC - COLLINS
MOREY
SMITH

DRG/GEN - BROOKS
FAGAN
GRUBER
KELLY
HUE

SCH - NAVARRO
SMITH

DSH - SMITH

HEFTER
HARTSTEIN

Ephraim McDowell Health

June 13, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Greetings:

We appreciate the opportunity to comment on the proposed rule implementing changes to the hospital inpatient prospective payment system, published in the May 4, 2005, **Federal Register**.

Postacute Care Transfers

CMS once again proposes to expand the postacute 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 SCH

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. DSH

Critical Access Hospitals CAH

We are very concerned about the proposed policy change related to replacement or relocation of a critical access hospital (CAH) that has been designated as a necessary provider (NP).

We strongly oppose the proposed December 8, 2003 deadlines related to CAH replacement or relocation in the Inpatient Prospective Payment System (IPPS) final rule. The replacement deadline relates to ownership of contiguous land, while the relocation deadline relates to documenting plans to relocate the CAH. 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. It was clearly not the intent of Congress in the Medicare Modernization Act that a CAH designated as a necessary provider be perpetually prohibited from replacing or relocating their facility, facilities that are often 40 to 50 years old.

2. 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.

3. 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 maintain an aging and declining healthcare infrastructure in rural America. Ironically, the CMS proposal to ban a local community's ability to rebuild at a nearby location will likely cost Medicare more over time, not less. Over time, the higher labor costs of operating in a retrofitted building will likely more than offset the higher initial cost of rebuilding.

4. A ban on major construction projects developed after December 8, 2003 is an unnecessary added burden on CAHs. CMS' concern about a provider using its CAH designation to fund a new facility serving a different market can be appropriately managed by the portion of CMS's proposed rule that would require assurance that, after the construction, the CAH will be serving the same community and will be operating essentially the same services with essentially the same staff.

We would request one clarification on the 75% tests. The tests related to services and staffing should be relatively easy to document. The test related to serving the same service area is generally measured from historical data. Because of this difficulty, we request clarification that the service area test be determined through an attestation process or be certified by the state office of rural health.

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.

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 is perceiving the growth of the CAH program incorrectly. **This growth of the CAH program 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 1500 hospitals nation-wide. Since

more that 1100 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 $3 billion annually) and the additional cost as compared with all these CAHs being PPS hospitals (less than $800 million according to MedPAC figures) compared with the total hospital budget this year for CMS of better than $239 billion. This makes the total CAH expenditure less than 0.4% of the total annual CMS hospital budget. MEDPAC

These are the simple, straightforward facts concerning the CAH program, and the actual impact on the overall Medicare program budget. We strongly encourage CMS to implement regulations for the CAH program based on facts, not on urban-based perceptions of how rural healthcare operates today.

Again, we appreciate this opportunity to submit comments. Please contact me at 859-239-2400 if you have questions or need further information concerning our comments.

Sincerely,

David Stenerson
Chief Financial Officer

118

CATHOLIC HEALTH INITIATIVES

Saint Joseph HealthCare

Hetter.
Hartstein
WI/DC
WI/GEN/UPDATE } MILLER
CBSAs - KENLY

June 8, 2005

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

Re: Comments on **WAGE DATA CORRECTIONS**

Dear Dr. McClellan:

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

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

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

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

The hospitals received a letter dated October 15, 2004 from James Hart, Deputy Director of the Division of Acute Care for CMS, stating that CMS had reviewed this wage data matter and that it agreed that it was necessary to correct the hospitals' wage data. The letter also states,"[t]he corrected wage data will be retroactive to October 1, 2004, and will be published in an upcoming correction notice and/or joint signature letter." Because this letter is dated October 15, 2004, it does not technically meet the third criteria proposed by CMS at page 23382. As a practical matter, we believe that CMS had determined that the wage data for provider nos. 18-0010 and 18-0043 should be corrected prior to October 1, 2004, but did not issue its letter stating so until October 15, 2004. Note that prior to October 1, 2004 there were numerous conversations between CMS, PricewaterhouseCoopers (which was acting as St. Joseph's representative on this matter) and St. Joseph. In these conversations CMS verbally agreed that the fiscal intermediary had incorrectly tabulated St. Joseph's wage index data and the correction should be effective October 1, 2004.

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

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

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

Sincerely,

Eugene A. Woods, FACHE
President & CEO

cc: Scott Raab, Office of Senator Mitch McConnell

119

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June 16, 2005

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VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED

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

Re: Hospital Reclassifications – CMS-1500-P
– Iuka Hospital
– Medicare Provider No. 25-0002

Dear Sir or Madam:

In its proposed rule entitled, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates," published in the May 4, 2005 Federal Register, the Centers for Medicare and Medicaid Services ("CMS") solicited public comments under various proposals that would affect the wage index reclassification process for various hospitals. *See* 70 Fed. Reg. 23,306 (May 4, 2005). This comment is submitted on behalf of Iuka Hospital, CMS Provider No. 25-0002. The purpose of this comment is to request guidance from CMS concerning reclassification of hospitals under Section 508 of the Medicare Modernization Act of 2003.

WI/Bd

HOSP REDES

1. Reclassification Under Section 508 of the Medicare Modernization Act of 2003. Pursuant to Section 508 of Public Law 108-173 (the "Medicare Modernization Act of 2003" or "MMA"), qualifying hospitals were allowed to appeal the wage index classification otherwise applicable to the hospitals and apply for reclassification to other areas in the states in which the hospitals were located. The process for reclassification was implemented through notices published in the Federal Register on January 6, 2004 and February 13, 2004. Pursuant to this process, Iuka Hospital applied for and received wage index reclassification from the rural Mississippi area to the Gulfport-Biloxi, Mississippi CBSA. Reclassification pursuant to Section 508 of the MMA is applicable to discharges occurring between April 1, 2004 and March 31, 2007.

2. Reclassifications Pursuant to 42 C.F.R. § 412.230. Prior to the implementation of Section 508 of the MMA, Iuka Hospital frequently qualified for reclassification pursuant to 42 U.S.C. § 1395ww(d)(10) and its implementing regulation at 42 C.F.R. § 412.230 ("Criteria for an individual hospital seeking redesignation to another rural area or an urban area") to reclassify to the rural Tennessee area. Reclassification pursuant to 42 U.S.C. § 1395ww(d)(10) is effective for a three-year period, beginning October 1. *See* 42 C.F.R. § 412.274(b)(2). Thus, if a hospital qualified for reclassification for fiscal year 2007, the reclassification will be effective for discharges between October 1, 2006 and September 30, 2009.

3. Overlap of Reclassification Periods. Because Iuka Hospital qualified for reclassification under Section 508 of the MMA, its reclassification to the Gulfport-Biloxi, Mississippi CBSA will end on March 31, 2007. Iuka Hospital would otherwise be eligible for reclassification to the rural Tennessee area for fiscal year 2007, which reclassification would cover the period from October 1, 2006 through September 30, 2009. However, Iuka Hospital is concerned that if it applies for reclassification for fiscal year 2007, it will lose the benefit of reclassification to the Gulfport-Biloxi, Mississippi CBSA for the period of October 1, 2006 through March 31, 2007.

4. Requested Relief. Iuka Hospital requests that CMS clarify in its fiscal year 2006 final rule, to be published on or around August 1, 2005, that hospitals reclassified pursuant to Section 508 of the MMA may apply for reclassification for fiscal year 2007 without losing the benefit of Section 508 reclassification for the period beginning October 1, 2006 and ending March 31, 2007. In other words, a hospital could apply for reclassification for fiscal year 2007 with the understanding that the hospital would retain its Section 508 reclassification for the period of October 1, 2006 through March 31, 2007. The fiscal year 2007 classification would not take effect until April 1, 2007 and would extend through September 30, 2009.

If you have any questions, please call me at (662) 690-8137.

Sincerely,

Jeffrey S. Moore

JSM:mrh
cc: Bruce J. Toppin, Esq.
Ms. Marjorie E. McNeil

120

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JUN 21 2005
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STROKE SCIENCES GROUP

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

DRG/GEN

Hcfac r
Hartstein
Brooks
Gruber
Kelly
Hue

June 13, 2005

RE: CMS Stroke Reimbursement

To Whom It May Concern:

My name is S. Claiborne Johnston, and I currently practice as Director of the Stroke Service and Associate Professor of Neurology and Epidemiology at the University of California, San Francisco. I spend 25% of my time caring for patients with stroke. My remaining time is spent performing research in the causes and care of all forms of stroke. I have received a number of grants to study stroke from the National Institutes of Health, the Centers for Disease Control, the American Heart Association, and from industry. In addition, I have published more than 100 manuscripts in scientific journals.

I am writing to ask Centers for Medicare and Medicaid Services to support proposed changes to Medicare hospital inpatient reimbursement for advanced stroke treatment in FY 2006. I believe it is crucial that CMS modify the current reimbursement structure for hospitals and remove barriers to care for stroke patients. Specifically, I would ask your support of the creation of new DRG code for cases involving tPA (tissue plasminogen activator) administration.

DRG

Stroke remains the No. 1 cause of disability and the third cause of death in the United States. More than 700,000 people have a stroke each year, causing about 160,000 deaths. Clinical studies have shown that the clot-buster tPA can reduce the debilitating and crippling effects of stroke. The only proven and FDA-approved medication for the treatment of acute stroke is tPA. The introduction of tPA has revolutionized the management of acute ischemic stroke, with a greater emphasis on efficient, structured care. tPA dramatically improves outcomes for patients with ischemic stroke who can receive it, and results in major savings to society due to reductions in cost of long-term care. Although a corkscrew device has also been approved recently by the FDA for treatment of patients with acute ischemic stroke, neuro-interventional equipment and practitioners are required, and its use is expected to be quite limited; thus, tPA is the primary treatment at this time.

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As it stands now, 2-4% of patients with ischemic stroke receive tPA. There are many barriers to its use, which we have carefully studied as part of the California Acute Stroke Pilot Registry (CASPR), a Coverdell Prototype registry. Even a modest 1% absolute increase in utilization of tPA for patients with ischemic stroke could result in an additional 3,350 quality-adjusted life years and a savings of $27 million in the US each year. Thus, improving rates of utilization of tPA is clearly justified from a public health perspective. We recommend the creation of a new DRG to allow specific tracking of this important public health intervention. For this reason, I would ask CMS to support changes to stroke reimbursement.

UCSF Medical Center recently underwent the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) stroke center credentialing process, becoming San Francisco's first primary stroke center. At present, our Neurovascular Service admits over 500 cerebrovascular disease patients each year and has primary responsibility for care of Neuro-Intensive Care patients. Currently, costs of care for patients treated with tPA far exceed those of stroke patients not treated aggressively. Appropriate reimbursement for tPA, a cost-saving intervention, is essential to motivate our hospital administration and others to use tPA and improve patient outcomes.

I hope that you will support this change and would be happy to provide additional information.

Sincerely,

S. Claiborne Johnston, MD, PhD
Director, Stroke Service
Associate Professor, Neurology and Epidemiology

121

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BY:.....

June 13, 2005

DRG/GEN - BROCK
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HARTSTEIN

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

Dear Sir or Madam,

I am the President and CEO of Atritech, Inc., an emerging medical device company which has developed an implantable device called the WATCHMAN® Left Atrial Appendage System. The WATCHMAN device is designed to prevent ischemic strokes in patients with non-valvular atrial fibrillation. This technology was granted a new ICD-9-CM procedure code, 37.90 which became effective last October. We did offer comments on the DRG assignment for this code last year (CMS-1428-P) and are asking CMS to reconsider the DRG classification for this year.

Since commenting last year the WATCHMAN Left Atrial Appendage System has received IDE approval from the FDA and was granted a Category B coverage status. The test arm of the trial will enroll up to 500 patients, with approximately seventy percent of these being Medicare beneficiaries. We understood that the Category B designation was designed to allow Medicare Beneficiaries access to new technologies and to ensure clinical trials include Medicare aged patients. At this time, ICD-9-CM code 37.90 is grouped into DRG 518, "percutaneous cardiovascular procedures, without acute myocardial infarction and without coronary artery stent implant." This DRG does not include any procedures that have an implantable device and therefore does not allow for the device cost to be covered. DRG

As you know, IDE clinical trials follow strict clinical protocols to ensure consistency throughout the clinical trial. We have collected UB-92 charge data on the first three patients from two different clinical sites (see Figure I) and the total charges for the procedure are estimated to be $41,000. The current procedure to eliminate the left atrial appendage is an open procedure that falls into DRG 108. Figure II shows the 2003 MedPar charge data for DRGs 108, 111 and 518. As you can see the charges for the WATHCMAN procedures fits within the twenty five percentile of charges for DRG 108 and close to the seventy five percentile for DRG 111 but lies well outside the seventy fifth percentile for DRG 518 (see Figure II.).

Last year CMS commented that the length of stay for DRG 108 was longer than the estimated length of stay for this new procedure and that most of the procedures grouped into DRG 108 were open procedures, not percutaneous. Many new technologies that have been developed are "minimally invasive" with shorter length of stays. These procedures decrease patient morbidity and decrease recovery time, however the cost of these procedures are similar due to the cost of the device. There are a limited number of DRGs that are available and by using rational developed for these older technologies; Medicare Beneficiaries will have limited access to these clinical trials.

763/258/0250 • Fax: 763/258/0253 • 3750 Annapolis Lane, Suite 105 • Plymouth, MN 55447

Figure I: UB-92 Charge Data for ICD-9-CM 37.90
Not Including the Device

		302-001	302-002	308-001
120	Semiprivate general	$1,680.00	$1,120.00	
210	CCU/CPU			$1,240.00
230	Incremental nursing care	$4,738.50	$3,786.75	
250	Pharmacy	$238.20	$317.90	$468.07
258	Pharmacy IV Solutions	$269.80	$236.25	$142.27
270	Medical/surgical supplies	$76.00	$136.25	$14.52
272	Sterile supply	$6,875.00	$4,617.25	$2,655.04
300	Laboratory	$1,221.25	$809.25	$16.74
301	Lab/chemistry			$276.05
305	Lab/hematology			$287.59
320	Radiology diagnostic	$834.25	$1,244.25	
324	DX X-ray/chest			$170.00
350	CT Scan		$3,238.50	
360	OR Services	$782.50	$253.75	
361	OR/Minor			$1,169.56
370	Anesthesia			$426.42
390	Blood storage & processing	$600.00	$600.00	
480	Cardiology	$9,518.25	$7,559.50	$3,435.00
620	Medical surgical supplies	$5.00	$3.00	
624	Research patient			
624	Research patient			
636	Drugs requiring detailed codes	$729.30	$593.62	
637	Drugs self administered	$152.60	$228.65	
730	EKG/ECG	$1,411.75	$821.50	$125.00
	Total Charges	$29,132.40	$25,566.42	$10,426.26

Average Charge: **$21,705.03**
Device Charge: **$18,394**
Total Charge: **$40,099.03**

Figure II Charge Data for DRGs 108, 111 and 518

	75th Percentile	50th Percentile	25th Percentile
DRG 108, other cardiothoracic procedures	$103,048	$60,599	$37,521
DRG 111, major cardiovascular procedures w/o complications	$50,008	$32,605	$21,024
DRG 518, Percutaneous cardiovascular procedures w/o AMI w/o coronary artery stent	$36,480	$26,846	$20,305

*Source Solucient 2003 MEDPAR data

We urge you to reconsider the DRG placement for this clinical trial and consider placement of ICD-9-CM code 37.90 into DRG 108 or DRG 111 with similar charges/costs. Clinical trials which meet the Category B criteria should have the ability to have both the procedure and device reimbursed and allow Medicare Beneficiaries access to the new technology. Thank you for the opportunity to comment on the DRG placement for ICD-9-CM 37.90. We look forward to continuing to work with CMS to ensure Medicare Beneficiaries will benefit from this new technology.

Sincerely,

Thomas E. Borillo
President and CEO
Atritech, Inc.

American Stroke Association.
A Division of American Heart Association

American Heart Association.
Learn and Live.

Advocacy Department
Office of Legislative and Regulatory Affairs
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americanheart.org

DRG/GEN - BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN

June 16, 2005

VIA E-MAIL

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

Re: The American Heart Association's Response to CMS' Request for Comment on CMS-1500-P Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates.

To whom it may concern:

On behalf of the American Stroke Association (ASA), a division of the American Heart Association (AHA), and over 22.5 million ASA and AHA volunteers and supporters, we submit the following comments in response to the Federal Register (FR) notice CMS-1500-P entitled "Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates.[1]"

The American Stroke Association is dedicated to improving stroke prevention, treatment, and rehabilitation through research, education, advocacy and development. Last fiscal year alone, ASA invested more than $162 million on these efforts in activities such as:

- Working with hospitals and hospital systems with treatment of stroke patients, which includes increasing adoption of the ASA's Get with the Guidelines (GWTGs) stroke program[2] — a computerized system designed to improve adherence with our evidence based ischemic stroke treatment and secondary prevention guidelines;

- Collaborating with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to develop and implement a voluntary Primary Stroke Center Certification Program[3] to help the general public, Emergency Medical Services (EMS), and health care professionals easily recognize which hospitals are optimally equipped and organized to treat

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1 70 Fed. Reg at 23306 (May 4, 2005).
2 To learn more about GWTG go to: http://www.strokeassociation.org/presenter.jhtml?identifier=3002728
3 To learn more about the Primary Stroke Center Certification program go to: http://www.strokeassociation.org/presenter.jhtml?identifier=3016808

patients with acute ischemic stroke. The Primary Stroke Center Certification Program evaluates several nationally recognized performance measures;

- Training EMS professionals on the warning signs of stroke and appropriate response, which includes working at a state level to mandate stroke training and protocol development; and

- Collaborating with the Ad Council in a stroke awareness campaign. The key message for this campaign is to "learn to recognize a stroke and act quickly, because time lost is brain lost." To date, our public service announcement campaign has raised stroke awareness from 6% to 11%. As a part of this campaign, we are attempting to drive the public to call 911 at the onset of symptoms in order to activate the healthcare system for early intervention and treatment.

ASA efforts extend to the development of clinical practice guidelines and scientific statements designed to advise physicians and other providers on the prevention, treatment and chronic management of stroke,[4] such as "Guidelines for the Early Management of Patients with Ischemic Stroke.[5]" Most recently, the American Stroke Association released its "Recommendations for the Establishment of Stroke Systems Care," which addresses the entire continuum of care from primordial prevention to rehabilitation.[6]

As a leading voluntary health organization focused on stroke, the ASA is uniquely qualified to provide the agency with comments on the proposed rule, and limits its comments to the discussion that appeared in the preamble relating to whether CMS should change the current stroke DRG system.

I. Background

Earlier this year, the Centers for Medicare and Medicaid Services (CMS) published a notice delineating the agency's proposed changes to hospital inpatient prospective payment systems (IPPS) and payment rates for the fiscal year (FY) 2006. Last year, the agency met with a number of hospital stroke center representatives, which recommended modifying the existing stroke DRG 14 and DRG 15 by using the administration of tissue plasminogen activator (tPA) as a proxy to identify patients who had a severe stroke.[7] The representatives indicated that using tPA as a proxy

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[4] To see a complete listing of AHA guidelines, including joint ACC/AHA guidelines go to: http://www.americanheart.org/presenter.jhtml?identifier=3004546

[5] Harold Adams, Robert Adams, Gregory Del Zoppo, and Larry B. Goldstein Guidelines for the Early Management of Patients With Ischemic Stroke: 2005 Guidelines Update A Scientific Statement From the Stroke Council of the American Heart Association/American Stroke Association; Stroke 36: 916-923.

[6] Schwamm LH, Pancioli A, Acker JE 3rd, Goldstein LB, Zorowitz RD, Shephard TJ, Moyer P, Gorman M, Johnston SC, Duncan PW, Gorelick P, Frank J, Stranne SK, Smith R, Federspiel W, Horton KB, Magnis E, Adams RJ; American Stroke Association's Task Force on the Development of Stroke Systems.
Recommendations for the establishment of stroke systems of care: recommendations from the American Stroke Association's Task Force on the Development of Stroke Systems. Stroke 36(3):690-703.

[7] 70 Fed. Reg. at 23315.

for severely ill stroke patients would recognize the higher costs associated with treating these patients.[8]

In the preamble to this rule, CMS wrote that the agency would not change the current stroke DRG system to reflect costs associated with administering the reperfusion drug tissue plasminogen activator (tPA) to stroke patients who may qualify for this treatment. This decision was based on a review of data from Medicare Provider Analysis and Review (MedPAR). Although the agency noted "patients treated with a reperfusion agent are more expensive than all other stroke patients,"[9] the data revealed that only a small number of DRG 14 & DRG 15 cases included code 99.10. CMS acknowledged that the number of cases of patients treated with a reperfusion agent might be underreported. Therefore, CMS asked for comments on two issues that relate to the administration of reperfusion agents to stroke patients:

DRG

(1) The agency requested comments on the changes to DRG 14 & 15 that were suggested by hospital representatives to CMS; and

(2) The agency requested comment on the number of patients currently being treated with a reperfusion agent and the potential costs of these patients relative to others with stroke included in DRGs 14 & 15.

In responding to these requests for comments, the ASA strongly urges CMS to reconsider its decision not to change the current stroke DRGs in the proposed rule. We recommend that CMS create a new DRG code (entitled "*Ischemic Stroke, Treatment with a Reperfusion Agent*"), which would more accurately reflect the costs associated with this therapy. In our opinion, creating a new code will help promote patient access to a therapy that can improve his or her outcomes. Our recommendation is based on the reasons delineated below.

II. Evidence Based Research Has Shown the Overall Benefits of tPA Use in Ischemic Stroke Patients When Properly Administered

Stroke continues to be a significant cause of morbidity and mortality in the United States. Approximately 700,000 Americans have a new or recurrent stroke each year and it remains a leading cause of long-term disability in the United States.[10] Between 15 to 30 percent of stroke patients are permanently disabled and 20% will require some form of institutional care three months after onset.[11]

Nearly 88% of all stroke patients have ischemic strokes—which means that these patients have strokes caused when blood clots block the blood flow to an area of the brain. Currently, the only FDA-approved drug for treating ischemic stroke is the administration of tPA. When tPA is administered within the first three hours after the start of symptoms, the patient is at least thirty-percent more likely to have minimal or no disability in three months compared with those patients who go untreated.

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[8] Id.
[9] 70 Fed. Reg. at 23316.
[10] American Heart Association, *Heart Disease and Stroke Statistics—2005 Update. Dallas Tex: American Heart Association: 2005.*
[11] Id at 13.

Symptomatic hemorrhagic transformation continues to be a primary concern with the administration of tPA in the treatment of ischemic stroke.[12] However, numerous studies have shown that this risk is minimized in community settings when recommended guidelines for selection and treatment of patients are followed. The decision to administer tPA, the only FDA approved reperfusion agent, is based upon a physician's review of the patient's history, a physical examination consistent with a significant stroke, a brain scan to exclude bleeding, and several other laboratory tests. Without conducting these exams a physician would not be able to assess whether the patient was an appropriate candidate for tPA.

The ASA evidence-based guideline statement on acute stroke treatment indicates that reperfusion with tPA is supported by Level 1A evidence.[13] This is the highest endorsement for an acute stroke therapy.

III. Current CMS Reimbursement is Inadequate for Patients Treated with Reperfusion Agents

The Inpatient Prospective Payment System creates a financial disincentive for hospitals by failing to provide adequate reimbursement for those costs incurred by facilities that treat ischemic stroke by administering tPA. Hospitals administering tPA in accordance with the Level 1A guideline incur substantial costs not reflected in the current payment methodology. These costs reflect services rendered during care, include increased personnel requirements to rapidly evaluate and follow acute stroke patients, intensive care unit services, as well as the cost of the drug itself.

The current reimbursement system does not account for the societal cost savings generated by the use of tPA in ischemic stroke patients, nor for the quality of care rendered by these hospitals. Proper use of this drug can reduce the patients' long-term care and nursing home service need, resulting in savings for the Medicare system. In 1998, an analysis revealed that the average cost savings when administering tPA was $4,255.00 per treated patient.[14] The savings reflected in this study were a result of decreased length of stay in the hospital, decreased need for skilled nursing facilities and decreased utilization of rehabilitation by the patient who received tPA, and improved patient outcomes. It is reasonable to infer that the generated costs savings would be greater today.

According to the New Mexico Stroke Task Force review conducted last year, only 0.4% of eligible stroke patients in New Mexico receive this clot-busting drug to reduce the neurological impairments of stroke.[15] Without providing adequate financial reimbursement, the ability of states

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[12] Wardlaw JM, Zoppo G, Yamagushi T, Berge E. Thrombolysis for acute ischemic stroke. Cochrane Database Syst. Rev. 2003; CDC000213.

[13] Level 1A means:

- that the evidence has been established as useful/predictive for the given condition in a specified population; and
- the evidence has been provided by a prospective study in a board spectrum of person with the suspected condition, using a "gold standard" for case definition, where test is applied in a blinded evaluation and enabled the assessment of the appropriate tests of diagnostic accuracy.

[14] Fagan, SC, Morgenstern LB, Ettitta A. et al. Cost-effectiveness of tissue plasminogen activiator for acute ischemic stroke. NINDS rt-PA Stroke Study Group. *Neurology*, Vol 50, Issue 4 883-890, 1998.

[15] To see the New Mexico report go to: http://www.health.state.nm.us/pdf/Report-Stroke_The-Challenge-09-2004.pdf

like New Mexico to increase the number of eligible stroke patients treated with reperfusion agents will be significantly impaired.

IV. Establishment and Maintenance of Primary Stroke Centers

Improving the organization of stroke-related care is expected to translate into improved outcomes. Both JCAHO and some state departments of health have begun certifying primary stroke centers. A common cited reason for why a physician may not use thrombolytic therapy is the lack of adequate support, including readily available consultative resources.[16] Providing reperfusion therapy requires the establishment of hospital infrastructures that support its safe and effective administration.

The ASA in its "Recommendations for Stroke Systems Care" states that hospitals providing primary stroke care should provide such care under the direction of a stroke director, and include stroke teams, written care protocols, education, interface with EMS, have a stroke unit or its equivalent, and appropriate neuroimaging, and laboratory services.[17] The hospital should also use protocols assist the stroke team to rapidly evaluate and treat acute patients, resulting in improved patient outcomes. Organizational features required as part of these certifications have been associated with increased use of tPA.[18] This infrastructure may be associated with improvements in care of stroke patients, regardless of whether they receive a reperfusion therapy.

Unless proper reimbursement is provided for both administering tPA and the necessary staffing and infrastructure, facilities will not have the adequate support to maintain or achieve stroke center certification. This may affect hospital readiness to treat acute stroke patients and the general quality of care these facilities can provide to stroke patients. Having protocols in place at hospitals for treating stroke patients will not only maximize the potential for improved patient outcomes, but also may reduce overall Medicare spending on outpatient services. For those hospitals that do not have stroke center status, our recommendations suggest that they should have at a minimum a predetermined plan to collaborate with other facilities, such as telemedicine or transport protocols.

IV. Inadequate Reporting of the Utilization of Reperfusion Therapy with Code 99.10

We agree with CMS that the use of reperfusion therapy with tPA is likely to be under-reported by the code 99.10. Recently, Dr. Lawrence Brass, Dr. Walter Koroshetz, and the American Academy of Neurology and Brain Attack Coalition (BAC) shared with us a review of the Premier data for FY 2001-2004, which found that many hospitals used the ICD-9 code 99.10 only 50% of the time for patients receiving thrombolytic agents in DRGs 14 and 15. During FY 03' and 04', nearly 2% of stroke patients in DRGs 14 and 15 received a thrombolytic agent. However, the same hospitals used the ICD-9 code 99.10 for half of the patients. Based on this information it appears that if CMS were to apply the same utilization to MedPAR, nearly 6,000 stroke patients would have

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[16] Schuwamm LH et al. at 695.
[17] Schuwamm LH et al.
[18] Arora S, Broderick JP, Frankel M, Heinrich JP, Hickenbottom S, Karp H, LaBresh KA, Malarcher A, Moomaw CJ, Reeves MJ, Schwamm L, Weiss P; Paul Coverdell Prototype Registries Writing Group.Acute Stroke Care in the US: Results from 4 Pilot Prototypes of the Paul Coverdell. *Stroke*.2005; 36: 1232-1240.

received a thrombolytic in DRGs 14 &15, a number that would further support the need for a new code.

In addition to these data, the results published earlier this year from the four Coverdell Pilot Stroke Registries in the states of Georgia, Massachusetts, Michigan and Ohio of the, concluded that:

> "Across the 4 prototypes, a total of 177 subjects were treated with rtPA (IV, IA, or IV/IA) among 4280 eligible subjects (defined as those with a final diagnosis of IS or ISUD) (Table 3). Site-specific overall rtPA treatment rates varied from 3.0% in Ga to 8.5% in Mass. A total of 118 subjects had IV-only rtPA treatment that was initiated in a Coverdell registry hospital; site-specific IV-only rtPA treatment rates varied from 2.0% in Ohio to 6.3% in Mass. A total of 27 subjects (from Mass, Mich, and Ohio) received IV treatment that was initiated outside a Coverdell registry hospital, whereas 32 cases (from all 4 sites) received either IA or IV/IA combined treatment.[19]"

The number of stroke cases treated with rtPA has been increasing and is greater in areas where stroke care is better organized.[20] In Cleveland, Ohio quality improvement programs have led to increased appropriate administration of tPA.[21] Therefore, the establishment of a new code for ischemic stroke patients given a reperfusion agent will not only help ensure the treatment of stroke patients with tPA, but will provide the agency with a better mechanism to track the number of instances for which the reperfusion agent is administered, and will become critical as the baby boomer generation becomes eligible for Medicare.

V. Conclusions & Recommendations

The ASA strongly recommends that CMS adopt the second recommendation made by the hospital stroke center representatives and create a new DRG code entitled "Ischemic Stroke, Treatment with a Reperfusion Agent." This new code would only include strokes cause by clots, not by hemorrhages, and would include the administration of tPA with the procedure code 99.10. The creation of a new code would ensure that providers receive adequate reimbursement for the costs associated with providing quality care to severe stroke patients, improve the overall quality of

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[19] Arora S, Broderick JP et al at 1235.

[20] Ernst R, Pancioli A, Tomsick T, Kissela B, Woo D, Kanter D, Jauch E, Carrozzella J, Spilker J, Broderick J. Combined intravenous and intra-arterial recombinant tissue plasminogen activator in acute ischemic stroke. Stroke. 2000; 31: 2552–2557.

Tanne D, Bates VE, Verro P, Kasner SE, Binder JR, Patel SC, Mansbach HH, Daley S, Schultz LR, Karanjia PN, Scott P, Dayno JM, Vereczkey-Porter K, Benesch C, Book D, Coplin WM, Dulli D, Levine SR. Initial clinical experience with IV tissue plasminogen activator for acute ischemic stroke: a multicenter survey. The t-PA Stroke Survey Group. Neurology. 1999; 53: 424–427.

Chiu D, Krieger D, Villar-Cordova C, Kasner SE, Morgenstern LB, Bratina PL, Yatsu FM, Grotta JC. Intravenous tissue plasminogen activator for acute ischemic stroke: feasibility, safety, and efficacy in the first year of clinical practice. Stroke. 1998; 29: 18–22.

[21] Katzan IL, Hammer MD, Furlan AJ, Hixson ED, Nadzam DM; Cleveland Clinic Health System Stroke Quality Improvement Team. Quality improvement and tissue-type plasminogen activator for acute ischemic stroke: a Cleveland update. Stroke. 2003; 34: 799–800.

stroke care, increase the number of hospitals seeking primary stroke center certification, and provide a more accurate accounting of the number of patients receiving the reperfusion therapy.

As an advocate for stroke education, research, prevention and treatment, ASA believes that proper reimbursement for treatment of patients with a reperfusion agent is critical to ensure patient access to quality care. The lack of proper reimbursement represents an important barrier for hospitals to provide and maintain the highest possible level of stroke-related care.

If you need any additional information, please do not hesitate to contact Penelope Solis, our Regulatory Relations Manager, at 202.785.7905 or by email at penelope.solis@heart.org. We look forward to continuing our work with you on improving the quality of care provided to stroke patients in the inpatient and outpatient setting.

Sincerely,

Ellen Magnis
Vice-President

Marc Mayberg, MD
Chairman
Stroke Council Leadership Committee

Larry B. Goldstein, MD
Vice Chair
Stroke Council Leadership Committee

Ralph Sacco, MD
Incoming Chairman
ASA Advisory Committee

cc:
Ms. Elizabeth Richter, Director of the Division of Acute Care
Mr. Marc Hartstein, Deputy Director of the Division of Acute Care

122

McDermott
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GEO RECLASS - KENLY
WI/Bd - MILLER
CBSAs - KENLY HEFTER
HOSP REDES - KENLY HARTSTEIN

June 13, 2005

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

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; CMS-1500-P; Proposed Rule; 70 *Fed. Reg.* 23,306 *et seq.* (May 4, 2005).

Dear Sir or Madam:

Please accept these comments regarding Geographic Reclassifications. Hospitals with active wage index reclassifications under Section 508 of the *Medicare Modernization Act* ("MMA") need guidance from CMS concerning when they should next apply for reclassification in light of a rule barring the Medicare Geographic Classification Review Board ("MGCRB") from approving requests for reclassification to the same area for which a hospital has a pending reclassification.

A. Description of the Problem

Under the MMA, hospitals that qualified for wage index reclassification are reclassified for the period April 1, 2004 through March 31, 2007. Most of the hospitals that qualified for reclassification under Section 508 cannot otherwise qualify for wage index reclassification, and their pending reclassifications will expire March 31, 2007, unless Congress takes action to extend their reclassifications. However, some hospitals that qualified for reclassification under Section 508 can qualify for wage index geographic reclassification under one of the opportunities available through 42 C.F.R. Part 412, Subpart L. Because of various changes to the reclassification rules and metropolitan area configurations implemented on October 1, 2004, some of these hospitals can even qualify for reclassification to the same area to which they are reclassified under Section 508. For example, certain hospitals in Fairfield County, Connecticut qualified for reclassification under Section 508 to the New York-Wayne-White Plains, NY-NJ (35644) Core-based Statistical Area ("CBSA") for the period April 1, 2004 through March 31, 2007. Likewise, and certain hospitals in New Haven County, Connecticut qualified for reclassification under Section 508 to the Nassau-Suffolk, NY (35004) CBSA for the same period. Because of changes to certain reclassification rules that CMS made effective October 1,

2004, the hospitals in these two counties can now also qualify for reclassification to these same areas under § 412.234.

These hospitals need to know when to apply for reclassification under one of the Subpart L opportunities. (Note, this issue is related to, but distinguishable from the timing question confronted by hospitals that can qualify for reclassification under Subpart L to a different area than the area to which they are reclassified by Section 508.) Specifically, should they apply in September 2005 for the period beginning October 1, 2006, or September 2006 for the period beginning October 1, 2007? If the answer is the former, their applications could be affected by a current regulation that bars the Board from approving a request for reclassification to the same area for which the hospital has a pending reclassification. Specifically, § 412.230(a)(5)(iv) provides, "if a hospital is already reclassified to a given geographic area for wage index purposes for a 3-year period, and submits an application for reclassification to the same area for either the second or third year of the 3-year period, that application will not be approved." (emphasis added).

The Fairfield and New Haven hospitals have pending reclassifications through March 31, 2007. If they apply September 1, 2005 for reclassification to the same CBSAs, they would be applying to the same area for which they have an approved reclassification. The overlapping period of reclassification would be the six-month period October 1, 2006 through March 31, 2007. In light of this regulation, the Board may be forced to reject the hospitals' requests.

However, if these hospitals wait until September 1, 2006 to apply, they will experience a gap in reclassifications for the six months between March 31, 2007, when their Section 508 reclassifications expire, and October 1, 2007, when their new Subpart L reclassifications activate. These and other similarly situated hospitals cannot afford a reclassification gap.

B. Possible Solutions

Following are some suggested ways that CMS could resolve this matter for these hospitals.

1. **Clarify that the limitation under § 412.230(a)(5)(iv) does not apply to hospital groups seeking reclassification under § 412.234.** The hospitals in Fairfield and New Haven counties that have approved Section 508 reclassifications may qualify for reclassification to the same area for which they are reclassified under Section 508 only if they apply as groups under § 412.234. These hospitals will NOT be applying individually to the same areas. CMS could clarify that the rules specified under § 412.230, including the limitation imposed under § 412.230(a)(5)(iv), apply only to hospitals applying individually, and do not apply to hospitals applying as groups under § 412.234. A clarification of this nature would be necessary, because MGCRB has interpreted § 412.230(a)(5)(iv) as applying to hospitals seeking reclassification as groups under § 412.234 (*See* MGCRB's instructions for group applications). This approach would resolve the matter for the hospitals in Fairfield and New Haven counties, and all

other hospitals seeking reclassification as a group; it would not resolve the matter for hospitals that might choose to seek reclassification as individuals.

2. **Clarify that the limitation under § 412.230(a)(5)(iv) applies only when the applicant has a full twelve months of direct overlap.** The Section 508 hospitals will have only six months of overlapping reclassifications. CMS could resolve this matter for hospitals applying individually and as part of a group by clarifying that the limitation does not apply when there would be overlapping reclassifications for only part of a year.

3. **Make an exception to § 412.230(a)(5)(iv) for hospitals reclassified under section 508.** CMS could resolve the matter for hospitals applying individually and as part of a group by permitting hospitals with Section 508 reclassifications to apply for an overlapping reclassification under a Subpart L opportunity notwithstanding the limitation imposed by § 412.230(a)(5)(iv). CMS could justify this exception on the basis that the Section 508 opportunity was extraordinary in that it established a non-renewable off-cycle reclassification period, and CMS did not contemplate the implications of the limitation imposed under § 412.230(a)(5)(iv) on off-cycle reclassifications when the limitation was initially established. Hosp Assocs

4. **Allow Section 508 hospitals to simultaneously apply for reclassification for federal fiscal year (FFY) 2007 and waive their Section 508 reclassification.** CMS could resolve the matter for hospitals applying individually and as part of a group by permitting hospitals with Section 508 reclassifications to apply for reclassification for FFY 2007, and concurrently waive their Section 508 reclassification for the overlapping six-month period. CMS should permit these hospitals to make the waiver contingent on approval of the Subpart L reclassification request. To pursue this approach, CMS would have to establish a new opportunity to waive Section 508 reclassification, because, under existing rules, a hospital may waive its Section 508 reclassification for the relevant portion of FFY 2007 only during the 45-day period following publication of the proposed inpatient PPS update for FFY 2007. CMS could not force hospitals to wait until then to waive their Section 508 reclassifications, because the MGCRB will have made decisions on applications for FFY 2007 before the proposed update rule for that year is published, and before the 45-day period begins. In the interim, MGCRB may be forced to reject some applications because of the limitation imposed by § 412.230(a)(5)(iv).

5. **Allow Section 508 hospitals to apply September 1, 2005 for a reclassification to be effective for 2.5 years beginning April 1, 2007.** CMS could permit hospitals with Section 508 reclassifications to apply September 1, 2005 to the same area under a Subpart L opportunity by providing that the hospitals' approved reclassification would be effective for 2.5 years beginning April 1, 2007. Under this approach, the hospitals seeking reclassification September 1, 2005 would not be seeking reclassification to the same area for an overlapping period, and therefore would not need any kind of exception

to the § 412.230(a)(5)(iv) limitation. This approach would resolve the matter for hospitals applying individually and as part of a group.

6. **Allow Section 508 hospitals to apply September 1, 2006 for a reclassification to be effective for 3.5 years beginning April 1, 2007.** Similarly, CMS could permit hospitals with Section 508 reclassifications to apply September 1, 2006 under a Subpart L opportunity, but provide that the approved reclassifications would be effective for 3.5 years beginning April 1, 2007. Under this approach, the hospitals seeking reclassification September 1, 2005 would not be seeking reclassification to the same area for an overlapping period, and therefore would not need any kind of exception to the § 412.230(a)(5)(iv) limitation. This approach also would resolve the matter for hospitals applying individually and as part of a group.

All of the options above would affect Medicare expenditures. To the extent that CMS converts hospital reclassifications from Section 508 to Subpart L reclassifications for the six-month period October 1, 2006 through March 31, 2007, Medicare expenditures likely would decrease, since reclassifications made under Subpart L are subject to budget neutrality rules, whereas reclassifications made under Section 508 are not.

Please contact me at 202.756.8148 or ezimmerman@mwe.com if you have any questions.

Sincerely,

Eric Zimmerman

WDC99 1094482-1.064553.0011

123

CENTRAL BAPTIST HOSPITAL

RECEIVED
JUN 21 2005
BY:.....

William G. Sisson
President

1740 Nicholasville Road
Lexington, KY 40503

859-260-6100
www.centralbap.com

June 10, 2005

WI/DC - MILLER
CBSAs - KENLY
HEFTER
HARTSTEIN

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

Re: Comments on **WAGE DATA CORRECTIONS**

Dear Dr. McClellan:

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

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

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

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

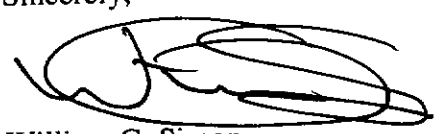
The hospitals received a letter dated October 15, 2004 from James Hart, Deputy Director of the Division of Acute Care for CMS, stating that CMS had reviewed this wage data matter and that it agreed that it was necessary to correct the hospitals' wage data. The letter also states,"[t]he corrected wage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

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

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

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

Sincerely,



William G. Sisson
President

cc: Scott Raab, Office of Senator Mitch McConnell

184

Rural Wisconsin
Health Cooperative

Serving rural communities for 25 Years 1979-2004

Hefter
Hartstein
Collins
Morey
Smith

CMH/Relcd

June 10, 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

To Whom It May Concern:

I am writing on behalf of the Rural Wisconsin Health Cooperative to oppose the proposed construction ban on the vast majority of Critical Access Hospitals in our state and across America.

In particular, 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.")

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 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 forever 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.

4. Ironically, the CMS proposal to ban a local community's ability to rebuild on an adjacent or nearby location will cost Medicare over time, more, not less—the higher labor costs of operating in a retrofitted building more than offset the slightly higher cost of rebuilding.

880 Independence Lane • P.O. Box 490 • Sauk City, Wisconsin 53583 • (608) 643-2343 • FAX (608) 643-4936 • www.rwhc.com

5. Many rural hospitals are in 40-50 year old 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 outdated facilities 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 thoroughly 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 for 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 fundamental 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.

We would be pleased to be part of any discussion to assist in the immediate resolution of this issue.

Respectfully submitted,

Tim Size

Tim Size
Executive Director

Original mailed with two copies

ATTACHMENT C

UNITED STATES DEPARTMENT OF COMMERCE
Economics and Statistics Administration
U.S. Census Bureau
Washington, DC 20233-0001

February 4, 2005

WI - MILLER
HEFTER
HARTSTEIN

Dale Baker
Baker Healthcare Consulting, Inc
Suite 2000, Box 82058
One American Square
Indianapolis, IN 46282

Dear Mr. Baker,

I am writing in response to your inquiry regarding whether Bristol County, MA meets the 1990 Metropolitan Area Standards for inclusion in the Boston-Worcester-Lawrence-Lowell-Brockton, MA-NH New England County Metropolitan Area (NECMA). Bristol County, MA did qualify for inclusion in that NECMA based on the 1990 standards applied with 1990 decennial census data, and is reflected as a component of the Boston NECMA in lists of areas announced by the Office of Management and Budget.

As you know, NECMAs are county-based representations of the city- and town-based metropolitan areas defined under the 1990 standards. If the 1990 standards had been applied at the county-level in New England, Bristol County, MA would have met the criteria (see section 3A(4)a and b) for inclusion in a county-based Boston metropolitan area. The relevant data for meeting these criteria are:

- Percentage of workers residing in Bristol County who work in the central counties of the Boston area: 21.5%
- 1990 population density of Bristol County: 910 ppsm
- 1990 percent urban population, Bristol County: 83.8%

In addition, based on 1990 commuting data (provided to you by my colleague, Darryl Cohen, in an e-mail message dated 5 June 2002), if the criteria for combining adjacent MAs to form larger Metropolitan Statistical Areas (MSAs) or Consolidated Metropolitan Statistical Areas (CMSAs) had been applied to NECMAs, the Providence-Warwick-Pawtucket, RI NECMA would have qualified to combine with the Boston-Worcester-Lawrence-Lowell-Brockton, MA-NH NECMA.

I might also mention that under the 2000 Metropolitan and Micropolitan Statistical Area Standards, the Providence-New Bedford-Fall River, RI-MA Metropolitan Statistical Area (which includes Bristol County, MA) qualified to form an optional combination with the Boston-Cambridge-Quincy, MA-NH Metropolitan Statistical Area. The employment interchange rate (EIR) between the two areas was 16.8 (a minimum EIR of 15 was necessary to qualify for an optional combination). Local officials, however, chose not to exercise that option, and as a result a combined statistical area encompassing the two metropolitan statistical areas was not defined.

If you have any questions about the information provided in this letter, please feel free to contact me by telephone at 301-763-8977 or by e-mail at michael.r.ratcliffe@census.gov.

Sincerely,

Michael R. Ratcliffe
Chief, Geographic Standards and Criteria Branch
Geography Division
U.S. Census Bureau

HOSPITAL GROUP WAGE INDEX COMPARISON
42 CFR 412.23(c) OR 412.234(b)

Group Name: Bristol (MA) Hospital Group

Hospital	Provider #	Inflated Wages (Per CMS)	Hours (Per CMS)
STURDY MEMORIAL HOSPITAL	220008	$129,768,465	5,038,356
ST ANNES HOSPITAL CORPORATION	220020	$106,458,287	4,534,245
MORTON HOSPITAL & MEDICAL CENTER	220073	$129,245,038	4,579,146
Totals for Group:		$365,471,790	14,151,747

Average Hourly Wage for Group: $25.8252

Average Hourly Wage for Requested Area: (Boston-Quincy, MA) $29.1519

Test for 85% criteria (GROUP AHW / REQUESTED AREA AHW)

25.8252 / 29.1519 x 100 = 88.5883%

Meets the Wage Criteria [42 CFR 412.234(b)]: Yes

HOSPITAL GROUP WAGE INDEX COMPARISON
42 CFR 412.23(c) OR 412.234(b)

Group Name: Bristol (MA) Hospital Group

Hospital	Provider #	Inflated Wages (Per CMS)	Hours (Per CMS)
STURDY MEMORIAL HOSPITAL	220008	$129,768,465	5,038,356
ST ANNES HOSPITAL CORPORATION	220020	$106,458,287	4,534,245
MORTON HOSPITAL & MEDICAL CENTER	220073	$129,245,038	4,579,146
SOUTHCOAST HOSPITAL GROUP INC	220074	$552,578,441	21,044,307
Totals for Group:		$918,050,231	35,196,054

Average Hourly Wage for Group: $26.0839

Average Hourly Wage for Requested Area: $29.1519
(Boston-Quincy, MA)

Test for 85% criteria (GROUP AHW / REQUESTED AREA AHW)

26.0839 / 29.1519 x 100 = 89.4758%

Meets the Wage Criteria [42 CFR 412.234(b)]: Yes

126

Submitter : Mr. Steven Anderson

Organization : Acorn Cardiovascular, Inc.

Category : Device Industry

Date: 06/10/2005

DRG/Gen

Hefter
Hartstein
Brooks
FASAN
Gruber
Kelly
Hue

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-264-Attach-1.DOC

Attachment to #264

June 10, 2005

VIA: ELECTRONIC MAIL

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule. File Code CMS-1500-P, Issue Identifier: DRG Reclassifications.

Dear Administrator McClellan:

On behalf of Acorn Cardiovascular, Inc. (Acorn), we appreciate the opportunity to comment on the proposed rule published by the Centers for Medicare & Medicaid Services (CMS) on May 4, 2005, which proposes changes to the hospital inpatient prospective payment systems and fiscal year 2006 Rates.[1]

Acorn is a small medical device company that was incorporated in 1996 and is located in St. Paul, Minnesota. This comment letter concerns Acorn's introductory product, the CorCap™ Cardiac Support Device (CSD), which prevents and reverses heart failure by improving the heart's structure and function, leading to significant quality of life improvements. Heart failure affects more than 5.5 million people in the United States, with an estimated 550,000 new cases diagnosed each year. Drug therapy (e.g., beta blockers, ACE inhibitors, diuretics) has been very helpful in the management of heart failure. However, as heart failure continues to progress despite drug therapy, even multi-drug regimens may not prevent disease progress, suggesting the need for alternative approaches. The CorCap CSD was developed to provide a new treatment option for patients with heart failure for whom drug therapy is inadequate, many of whom would otherwise need to consider a heart transplant. We are concerned that the Proposed Rule, by assigning the CorCap CSD implantation procedure to inappropriate DRGs, would restrict access to this new technology for Medicare beneficiaries suffering from heart failure.

Under the Proposed Rule, new procedure code 37.41 (Implantation of prosthetic cardiac support device around the heart), the code for implantation of the CorCap device,

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[1] See Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule, 70 Fed. Reg. 23306 (May 4, 2005) (Proposed Rule).

would be classified to DRGs 110/111.[2] Such a classification would be inconsistent with CMS's established methodology of classifying new procedure codes to DRGs according to clinical coherence with other procedures that map to the same DRG.[3] Furthermore, this DRG assignment is also inconsistent with the statutory criteria for DRG assignment of new technology in section 503(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA), which directs CMS to "identify one or more diagnosis-related groups associated with such [new] technology, based on similar clinical or anatomical characteristics and the cost of the technology." SSA § 1886(d)(5)(K)(ix), 42 U.S.C. 1395ww(d)(5)(K)(ix) (emphasis added). Similarly, 42 CFR § 412.10(b) provides that all changes to the DRG classification system "are made using the principles established for the DRG system," which means that cases are classified so that each DRG is: "(1) Clinically coherent; and (2) Embraces an acceptable range of resource consumption." CMS classified 37.41 to DRGs 110/111, but based on the DRG classification criterion of clinical similarity to existing inpatient procedures, new procedure code 37.41 is most appropriately classified to DRG 108.

We set forth greater details below.

I. PROCEDURES THAT MAP TO DRGs 110/111 ARE NOT CLINICALLY SIMILAR TO 37.41 ((IMPLANTATION OF PROSTHETIC CARDIAC SUPPORT DEVICE AROUND THE HEART)

The Proposed Rule lists the DRG classifications of new procedure codes in Table 6B.[4] The Proposed Rule does not explicitly describe CMS's methodology for determining the DRG assignments for these procedure codes listed in Table 6B, or discuss the rationale for any of the specific classifications proposed. However, the criteria for DRG assignment that are repeatedly discussed in the DRG Reclassifications sections of the Proposed Rule are: (1) clinical coherence and (2) similar resource consumption as compared to other procedures assigned to the same DRG.[5] These criteria are the same as the criteria mandated by MMA § 503(c) and 42 CFR 412.10(b), which are noted above. Therefore, a new procedure should be assigned to the DRG with procedures that have the greatest similarity to the new procedure both in terms of the clinical surgical steps that comprise the procedure and the resources necessary to perform the procedure.

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2 70 Fed. Reg. at 23594.

3 The other commonly used factor for DRG assignment, cost similarity, cannot be used for new procedure codes such as 37.41 for which cost data are not yet available.

4 See 70 Fed. Reg. 23594.

5 See e.g., 70 Fed. Reg. 23325.

Resource cost data is typically unavailable for new procedures, and therefore the DRG assignment can only be based on clinical similarity to other procedures. In particular, there are no claims data available for the CorCap CSD implant procedure because the CorCap is a breakthrough medical technology for heart failure that was designated a Category A device; the device and implantation procedure were thus ineligible for coverage during the clinical trial.[6] Because the clinical trial on the CorCap device was funded by Acorn due to the noncovered status of Category A devices and their routine costs, charge data was not readily available during the clinical trial and, if available, would not reflect total charges since device charges were excluded.

The new procedure code 37.41 describes Acorn's CorCap CSD procedure, which is an invasive cardiothoracic procedure that utilizes a full median sternotomy (a large incision through the sternum exposing the entire heart) and pericardiotomy (incision of the sac surrounding the heart) to circumferentially access the heart to suture the prosthetic cardiac support device implant directly to the myocardium. The steps involved in this procedure are listed in Exhibit A. It is apparent after examining the listed steps of the CorCap CSD procedure that assignment to DRGs 110/111 (Major Cardiovascular Procedures w & w/o CC) is inappropriate. Procedures in the 110/111 DRGs are predominately endovascular procedures (i.e., catheter-based procedures). Specifically, only 14 of 51 procedure codes in DRGs 110/111 involve operations on the heart. Only 5 of the 14 procedures involving operations on the heart utilize a full sternotomy to access the heart, and none of the procedures in DRGs 110/111 involves the permanent placement of a prosthetic device. Quite simply, unlike 37.41, the overwhelming majority of the procedures assigned to DRGs 110/111 do not involve an open sternotomy, an operation directly on the heart, or a prosthetic device implant therefore, they are less intense and demanding than the CorCap CSD procedure.

While the pericardial procedures (37.12, 37.24, and 37.31) that map to DRGs 110/111 may appear to be similar to the CorCap CSD procedure, they are in fact significantly different. Unlike the CorCap CSD procedure, these pericardial operations under DRGs 110/111 do not include surgery on the actual surface of the heart. Instead, in almost 50% of the cases, these procedures involve accessing the pericardium via a thoracotomy, which is a much more limited incision into the chest wall than a full sternotomy,[7] and once inside the chest the operation is limited to the pericardial sac. The extent of the surgical intervention performed with 37.12, 37.24, and 37.31 differs significantly from the CorCap procedure in that the pericardiotomy performed during the

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[6] The CorCap trial was completed prior to the January 1, 2005, effective date for the MMA provision providing coverage of routine costs in certain Category A device trials.

[7] CMS 2003 PSPSF data files detailing frequency of claims for CPT codes that crosswalk to the referenced ICD-9 procedure codes for pericardial procedures in DRG 110/111.

CorCap CSD procedure is done only to gain circumferential access to the myocardium where the actual work of sizing, fitting, and suturing the prosthetic device to the anterior and posterior myocardium is performed. In other words, in the CorCap CSD procedure, the pericardiotomy is another step to gain access to the myocardium where the primary surgery takes place, whereas with 37.12, 37.24, and 37.31 the pericardiotomy is the primary surgery.

Further analysis of Medicare claims data shows that the two most commonly reported procedures under 37.12, 37.24, and 37.31 were pericardiocentesis and creation of a pericardial window[8]. The skin to skin time for these procedures was 27 minutes and 81 minutes, respectively[9]. By contrast, the skin to skin time for the CorCap CSD procedure is 133 minutes,[10] reflecting the fact that the procedure is much more extensive (and thus more resource intensive) than the most similar procedures under 110/111. Additional clinical differences that impact resource utilization are as follows:

- With the exception of 37.61 (implant of pulsation balloon (IABP)) and 37.67 (implantation of cardiomyostimulation system), the 51 procedures in DRGs 110/111 do not involve device implantation.

- Neither 37.61 nor 37.67 involve implantation of a permanent prosthetic device as is the case with the CorCap.

- Approximately 20% of CorCap CSD implants utilize an IABP during the implantation procedure[11]. IABP placement alone triggers payment under DRGs 110/111. Therefore, if the CorCap procedure mapped to DRGs 110/111, a payment anomaly could result in that a CorCap implant procedure requiring IABP placement would be paid no differently than IABP placement alone, resulting in no additional payment for the CorCap placement.

II. PROCEDURES CLINICALLY SIMILAR TO 37.41 ((IMPLANTATION OF PROSTHETIC CARDIAC SUPPORT DEVICE AROUND THE HEART) MAP TO DRG 108 – OTHER CARDIOTHORACIC PROCEDURES

[8] CMS 2003 PSPSF data file.

[9] 2005 Medicare Physician Fee Schedule, Relative Value Unit Input files for Physician Work.

[10] CorCap CSD US Randomized Clinical Trial.

[11] Id.

surface of the beating heart to identify the source of the arrhythmia. Once located, the arrhythmia-producing tissue is destroyed using radiofrequency (RF) or other method. While RF ablation does not involve a device implant, it does employ device technology that similarly increases the cost of the procedure. Both RF ablation and CorCap procedures also require single-use custom tools to assist in the procedure.

[12] 2005 Medicare Physician Fee Schedule, Relative Value Unit Input files for Physician Work.

[13] CorCap CSD US Randomized Clinical Trial

By contrast to procedures grouping to DRGs 110/111, procedures grouping to DRG 108 (Other Cardiothoracic Procedures) are clinically similar to the CorCap procedure. The procedures in DRG 108 are exclusively performed on the internal or external structures of the heart and generally require a sternotomy. Unlike DRGs 110/111, where no procedures involve prosthetic implants, there are four procedures in DRG 108 that specifically involve implantation of prosthetic devices (i.e., 35.50, 35.51, 35.53, and 35.54), all of which treat septal defects. The steps involved in performing procedures that map to DRG 108 more closely match the steps of the CorCap CSD implant procedure than do the procedures within DRGs 110/111.

For example, open transmyocardial revascularization (36.31-TMR) is comparable to the CorCap CSD procedure because it is also performed on the surface of the myocardium. Open TMR involves the use of a laser to create channels in the myocardium in order to promote angiogenesis and revascularization in patients with refractory angina who are not candidates for coronary bypass or percutaneous catheter procedures designed to increase blood flow to the heart. In open TMR, access to the myocardium is less invasive than with the CorCap procedure because it is performed via a thoracotomy with a limited pericardiotomy as opposed to the full sternotomy and full pericardiotomy required with the CorCap CSD implant; otherwise, however, open TMR is similar in many respects to the CorCap procedure. While TMR does not involve a device implant, it does employ device technology (laser) that similarly increases the cost of the procedure, and like the CorCap procedure, TMR also requires a single-use custom tool to perform the procedure. Open TMR and the CorCap implant procedure have similar skin-to-skin surgical times (120 minutes[12] vs. 133 minutes[13] respectively) which is another indicator of similar resource utilization. A complete summary of the clinical similarities between the CorCap CSD and TMR is attached in Exhibit B.

Another example is open chest epicardial ablation for the treatment of atrial fibrillation (AF) (coded with ICD-9-CM 37.33 (Excision or destruction of other lesion or tissue of the heart, open approach)), which also groups to DRG 108. This procedure also could be compared to the CorCap CSD procedure because it is performed on the surface of the myocardium. Like the CorCap CSD implant, this procedure involves accessing the heart via a sternotomy where the surgeon then attaches a grid of electrodes over the surface of the beating heart to identify the source of the arrhythmia. Once located, the arrhythmia-producing tissue is destroyed using radiofrequency (RF) or other method. While RF ablation does not involve a device implant, it does employ device technology that similarly increases the cost of the procedure. Both RF ablation and CorCap procedures also require single-use custom tools to assist in the procedure.

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[12] 2005 Medicare Physician Fee Schedule, Relative Value Unit Input files for Physician Work.

[13] CorCap CSD US Randomized Clinical Trial

Another useful comparison that demonstrates similar resource utilization between the CorCap implantation procedure and at least two other clinically similar procedures that group to DRG 108 is the mean length of stay (See Table 1). The mean length of stay for the CorCap procedure is somewhat greater than for both open TMR and open chest ablation procedures, the comparability of mean length of stay provide further evidence of clinical and resource homogeneity with procedures in DRG 108.

Table 1

Procedure	Mean Length of Stay
37.41 – CorCap Cardiac Support Device	**9.33 days**[14]
36.31 – Open TMR	**8.3 days**[15]
37.33 – Open Chest Ablation Procedures	**8.6 days**[16]

III. CONCLUSION

As stated in the Proposed Rule, the "primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs." See 70 Fed. Reg. 23654. If the CorCap Implant Procedure were classified to DRGs 110/111, with dissimilar and less intense procedures, then this stated goal of the IPPS would be frustrated, and there would be a financial disincentive for hospitals to adopt this potentially life-saving and cost reducing treatment for Medicare beneficiaries suffering from a problem that could otherwise require a ventricular assist device or heart transplant. To ensure Medicare beneficiaries' access to the CorCap implantation procedure, we strongly urge CMS to assign new procedure code 37.41 to DRG 108 where it appropriately belongs.

Acorn Cardiovascular appreciates the opportunity to comment on the Proposed Rule, and we are eager to provide CMS with any additional information that would enable the

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[14] CorCap CSD US Randomized Clinical Trial.

[15] Healthcare Cost and Utilization Project (HCUP) Weighted National Estimates, Nationwide Inpatient Sample, Agency for Healthcare Policy and Research (AHRQ), 2002.

[16] Id.

agency to evaluate the DRG assignment of 37.41. If CMS staff would like to discuss these issues in greater detail, or if we may be of any further assistance, please do not hesitate to contact me at (651) 286-4802 or Lisa Wipperman Heine, Director, Regulatory & Reimbursement, at (651) 286-4828.

Sincerely,

Steve Anderson
Vice-President, Corporate Assurance

Cc: Mark Hartstein, Acting Deputy Director, Division of Acute Care, CMS
Herb Kuhn, Director, Center for Medicare Management
Lisa W. Heine, Director, Regulatory & Reimbursement, Acorn Cardiovascular

Exhibit A

CorCap Cardiac Support Device (CSD) Implant Procedure Steps

CorCap Cardiac Support Device (CSD) Implant Procedure Steps

- To optimize cardiac function of failing heart, surgeon may elect to insert inter-aortic balloon pump in ICU or, if hemodynamically unstable, in the OR during surgery
- Pre-operative Swan-Ganz catheter is placed
- Standard midline sternotomy performed
- Pericardiotomy performed to expose the heart
- Baseline measures of the left ventricle diameter conducted using transesophageal echocardiography (TEE)
- Cardiopulmonary bypass (CPB) may be used to avoid precipitating hemodynamic alterations and arrhythmias during placement of posterior sutures
- Outside circumference and base-to-apex dimension of the heart also measured using specially designed tools provided by the manufacturer
- From these measurements, one of 6 sizes of the device is selected for implant
- The CSD is then positioned around the ventricles with the hemline placed near the atrioventricular (AV) groove
- Interrupted tacking sutures are placed every 2-4 centimeters along the posterior, lateral and anterior aspects of the base of the heart to secure the device near the AV groove
- The device is custom fit by gathering excess fabric toward the anterior seam using a specially designed custom clamp provided by the manufacturer
- The tension on the CSD is evaluated for even distribution over its entire circumference to avoid shortening or excess tension on the tacking sutures
- The left ventricular end diastolic dimension (LVEDD) via TEE is measured at this time to ensure that there is no excess reduction in LVEDD. If necessary, the

amount of gathered fabric within the clamp is adjusted. The excess fabric is then trimmed with the clamp in place.

- A running mattress stitch between the clamp and the myocardium make a new initial anterior seam.
- The custom fitting clamp is removed and the new anterior seam is reinforced with a second running interrupted suture.
- The remaining anterior portion of the hem line of the CSD is then completed using interrupted tacking sutures spaced 2 to 4 centimeters apart.
- The device is visually inspected to ensure that it conforms properly, with no excess loading of base sutures, no fore-shortening of the heart.
- After visual inspection is completed, the patient is decannulated if CPB has been used, the mediastinum is thoroughly irrigated, and the sternotomy is closed after placement of the standard drainage catheters
- The mean procedure length (skin to skin time) is 133 minutes.
- Patient care following the CSD implant requires intensive post-operative management.
- On average, patients are followed in the ICU for 3.84 days with a total length of stay averaging 9.33 days.
- The CSD is a prosthetic implant that is not intended to be explanted

Exhibit B

Summary of Clinical Similarities between the CorCap CSD Procedure and TMR Procedure

CorCap CSD Implant Procedure	% of Cases	Transmyocaridal Laser Revascularization (TMR) Procedure	% of Cases
1. Insert IABP to optimize cardiac function of failing heart	20%[17]	1. Insert IABP for unstable patient or patient with low EF	8.7%[18]
2. Pre-operative Swan-Ganz Catheter is placed	100%[17]	2. Pre-operative Swan-Ganz Catheter is placed	*
3. Standard midline sternotomy performed	100%[17]	3. Limited anterior or anterior-lateral thoracotomy	100%[19]
4. Pericardiotomy performed to expose entire heart	100%	4. Pericardiotomy performed to access the heart but access required is more limited than what is required for CSD implant (TMR focused on 1-2 areas of LV)	100%
5. Transesophageal echocardiography (TEE) conducted to obtain baseline measure of left ventricular diameter	100%[17]	5. Does not require TEE for measurement or for verification of transmural penetration	--
6. Cardiopulmonary bypass (CPB) may be used to avoid arrhythmias and hemodynamic changes during placement of posterior heart sutures	40-60%[17,20]	6. CPB rarely used during isolated TMR except for urgent or emergent cases (access most likely via femoral cannulation, if needed)	**
7. Outside circumference and base-to-apex dimension of the heart also measured using specially designed, single use tool and 1 of 6 sizes of device selected for implant	100%	7. No measuring or device selection involved in TMR	--
8. Interrupted tacking sutures are placed every 2-4 centimeters along the posterior, lateral and anterior aspects of the base of the heart to secure the device near the AV groove. Manipulation of the heart is required to secure the CSD around the entire cardiac circumference.	100%	8. There are generally no sutures placed in the heart and little, if any, manipulation of the heart is required	--
9. Specially designed surgical clamp is used to custom fit the CSD. A running mattress stitch between the clamp and myocardium is used to make initial anterior seam followed by second running interrupted suture to reinforce final seam	100%	9. Single use, custom hand-piece used to deliver TMR laser to myocardium. Laser bursts create channels into the heart chamber that are about as thick as a standard sewing needle. During a typical procedure, approximately 20 - 45 channels are made in the heart muscle.	100%
10. Mean procedure length (skin to skin time) is 133 minutes[17]		10. Mean procedure length (skin to skin time) is 120 minutes[21]	
11. Average length of stay is 9.33 days[17]		11. Average length of stay is 8.6 days[22]	
12. Average ICU length of stay is 3.84 days[17]		12. Average ICU length of stay is 3.94[18]	

*There were no cases reported in the HCUP State Independent Databases where right heart catheter use (37.21) was reported concomitant to 36.31 (TMR), however, discussions with Cardiothoracic Surgeon indicated that Swan-Ganz Catheter may occur in some cases, although less often than with CorCap procedures.

**Unable to quantify specific percentage related to rare urgent or emergent CPB utilization for isolated TMR due to lack of specificity in claims data

17 CorCap CSD US randomized trial

18 Healthcare Cost and Utilization Project (HCUP) State Independent Databases for WA, NY, MD. Agency for Healthcare Policy and Research (AHRQ). 2002

19 Ingenix Encoder Pro, CPT/ICD-9 Procedure Cross Code, 2005.

20 CorCap™ Cardiac Support Device, Instructions for Use, PMA P040049, Amendment 3

21 2005 Medicare Physician Fee Schedule, Practice Expense Inputs for Intra-Services Times (skin to skin time)

22 Healthcare Cost and Utilization Project (HCUP) Weighted National Estimates, Nationwide Inpatient Sample, Agency for Healthcare Policy and Research (AHRQ). 2002.

127-0
(2)

Submitter : Damon Benson

Date: 06/10/2005

Organization : Kingfisher Regional Hospital

Category : Critical Access Hospital

CAH/Reloc

Hefter
Hartstein
Collins
Morey
Smith

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1500-P-279-Attach-1.DOC

Same as E comment

KINGFISHER REGIONAL HOSPITAL

June 10, 2005

CAH/Reloc — Collins
Morey
Smith

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

Reference: CMS-1500-P

Via e-mail: **cms.hhs.gov/regulations/ecomments**
"Critical Access Hospitals"

To Whom It May Concern:

Comment on 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).

A recent proposed rule (Inpatient PPS) from the Centers for Medicare and Medicaid Services (CMS) 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.

Kingfisher Regional Hospital (KRH) is a Critical Access Hospital since the State of Oklahoma has designated it a "necessary provider." We are the only hospital in the county of Kingfisher.

KRH was built through citizen support in 1950. The last renovations to the building were made in 1979. Medicine, especially hospital care, has changed dramatically in the last 25 to 50 years.

KRH has patients from a wide area of central Oklahoma and has a varied socioeconomic clientele.

KRH is fortunate to still provide obstetric and surgical services to the community.

The community we serve deserves the best quality and efficient care available.

For these many reasons and others, KRH needs to renovate and possibly relocate. While renovation is a possibility, relocation maybe the best opportunity for the hospital to meet its patients' needs and provide that care in the most efficient way possible. Any renovation is difficult. When a building is 25-50 years old and has been added on several times, renovation becomes extremely difficult and the result is often more inefficient.

When considering a new building or relocation, it is impossible for KRH to build within 250 yards of its current location. We were built in a residential area and thus have very limited property.

Under the proposed rule, we would not be able to relocate without losing our Critical Access Designation. While we completely agree that it is unreasonable for a Critical Access Hospital to relocate into a totally new market and maintain its Critical Access Designation, we do believe that the rule needs to be more reasonable. Perhaps a simple analysis of the current versus proposed location to ensure that roughly the same population is going to be served. If so established, the relocation should be approved; and the hospital should be able to maintain its Critical Access Designation.

We urge CMS to issue a final rule that is both reasonable and prudent that will allow Critical Access Hospitals the right to relocate within the same market without fear of the risk of losing its Critical Access Designation.

Sincerely,

Damon Benson, CEO
Kingfisher Regional Hospital
Kingfisher, OK
405/375-7950

128

Submitter : Ms. Naomi Farris
Organization : Atoka Memorial Hospital
Category : Critical Access Hospital

CAH/Reloc

Date: 06/10/2005

Hefter
Hartstein
Collins
Morey
Smith

Issue Areas/Comments

GENERAL

GENERAL

"Critical Access Hospital - Proposed Rule Comments"

CMS-1500-P-284-Attach-1.DOC

Attachmcnt to #284

June 10, 2005

To Whom It May Concern:

Comment on 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).

Our community hospital is a 25 bed Critical Access hospital located in rural south eastern Oklahoma. Atoka Memorial Hospital (AMH) was the first hospital in Oklahoma to be certified as a Critical Access Hospital and was certified as a "necessary provider".

A recent proposed rule (Inpatient PPS) from the Centers for Medicare and Medicaid Services (CMS) 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 are 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".

AMH was built in 1959 (prior to major life safety codes enacted in the late 1960's) and is in need of a new facility. Our 46 year old facility is outdated, inefficient to operate, lacks space for needed services, and hinders our ability to provided quality services. In addition land space is not available at our existing location. AMH had an Architect conduct a feasibility study on whether it was more economical to renovate and expand our existing facility or to build a new facility and it was determined that a new facility was more cost effective.

If it is more cost effective isn't it logical to build a new facility rather than embark on a more expensive renovation? If you are land locked isn't it reasonable to relocate a few miles to a feasible site within the community?

The proposed rule would prevent AMH from addressing our facility needs and the quality medical care needs of our community.

Why if AMH was certified as a "necessary provider" would AMH not be a necessary provider if AMH relocated 2 miles to another site? AMH would still be servicing the same community.

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.

The proposed rule will force CAH's 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 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

Based on the information presented above, my 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. I 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. I 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, I 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."

I would also propose that if a facility relocates 3 miles or less from its current location, that the CAH status be maintained.

Att #284 P. 3

Respectfully,

Naomi Farris
Administrative Assistant

129

CAH Reloc

Heftey
Hartstein
Collins
Money
Smith

Mary Robinson

From: Collins, Mary E. (CMS) [Mary.Collins@cms.hhs.gov]
Sent: Thursday, June 23, 2005 4:49 PM
To: Mary Robinson
Subject: FW: Galena Stauss Hospital

Please log this comment in as an official comment. Thanks

From: Collins, Mary E. (CMS)
Sent: Thursday, June 23, 2005 2:46 PM
To: Hayes, Yolanda K. (CMS)
Cc: Miller, Jeannie J. (CMS)
Subject: FW: Galena Stauss Hospital

Please log in the attached comment received on CMS-1500-P from Galena-Stauss Hospital. Thanks Yolanda.

From: Miller, Jeannie J. (CMS)
Sent: Thursday, June 23, 2005 12:02 PM
To: Collins, Mary E. (CMS)
Subject: FW: Galena Stauss Hospital

fyi--please make sure this gets logged in.

From: Jeff Hill [mailto:jhill@galenahealth.org]
Sent: Thursday, June 23, 2005 11:36 AM
To: Miller, Jeannie J. (CMS)
Subject: Galena Stauss Hospital

Dear Jeannie,

Thank you for taking time out of your busy schedule to listen to the Galena Stauss Hospital "story" on June 20th. I certainly appreciated the opportunity to share with you and others some of the challenges we face with rural health care delivery and our community's opposition to the proposed critical access hospital rule changes. As the sole emergency and acute care provider in our county, relocation to a site that is visible and accessible is essential to the long term survival of the Galena Stauss Hospital. Attached is our comment letter to CMS for your perusal.

I would also like to reiterate the invitation to visit us here in Galena, Illinois. We would consider it an honor to share with you some of our unique approaches to rural health care delivery such as our partnership with the University of Illinois School of Medicine www.galenahealth.org/uic, our affiliation with Planetree www.planetree.org and our affiliation with the Illinois Critical Access Hospital Network. www.icahn.org

Sincerely,

Jeff Hill
CEO
Galena Stauss Hospital
215 Summit Street
Galena, Illinois 61036

815-776-7266
www.galenahealth.org

130

Edwin Gast, Administrator
712-263-5021
Fax: 712-263-1600

CRAWFORD COUNTY
MEMORIAL HOSPITAL
2020 First Avenue South
Denison, Iowa 51442

CAH Reloc

Hefter
Hartstein
Collins
Morey
Smith

June 17, 2005

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

Inpatient Prospective Payment Rules – Critical Access Proposed Policy Changes Relating to Designation of CAHs as Necessary Providers – Hospital Replacement and Relocation

The proposed policy change embodied in the inpatient prospective payment regulations will have the affect of not allowing us and many other CAHs to replace our facility within or adjacent to the city limits of the community/population that we serve.

Many rural hospitals continue to operate in facilities that were built with Hill-Burton funds over 50 years ago and have become inefficient in a number of ways. What you are effectively saying is that a hospital that achieved CAH status by means of the necessary provider provisions but did not have the need or means to begin planning a replacement facility prior to December 8, 2003, is forever doomed to operate out of its current facility, no matter how outdated and inefficient it becomes. Furthermore, you are willing to reimburse the additional cost of operating in these inefficient facilities rather than promote the construction of new cost effective facilities that would be more efficient to operate and better serve their communities.

I would urge you to strongly consider removing the provisions of the proposed regulations regarding "cut off" dates and distances (i.e. 250 yds.). The sole test for retaining the CAH designation should be that essentially the same services will continue to be provided to essentially the same community/population as in the previous location. Please give us the ability to serve our rural communities in the most efficient and cost effective manner possible.

The Iowa Hospital Association is also submitting more detailed comments on these provisions of the proposed regulations. I have had an opportunity to review these comments and fully support the position they have taken.

Thank you for the opportunity to provide comments on the proposed CAH policy change regarding replacement and relocation.

Sincerely,

Edwin A. Gast

Edwin A. Gast

C: Senator Charles Grassley
Senator Thomas Harkin
Representative Steve King
Representative James Nussle

131

UNC HEALTH CARE

RECEIVED
JUN 23 2005
BY: CAH Reloc

Heffer
Hartstein
Collins
Morey
Smith

William L. Roper, MD, MPH
Chief Executive Officer
Phone (919) 966-4161
Fax (919) 966-8623
roper@med.unc.edu

June 20, 2005

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

Dear Sir:

In its recently released Inpatient Prospective Payment System (IPPS) proposed rule regarding the relocation of critical access hospitals (CAH), the Centers for Medicare and Medicaid Services (CMS) only provides continued CAH status for necessary providers that are building replacement facilities at another location and can demonstrate that their construction plans began before December 8, 2003. This arbitrary date restriction puts in jeopardy CAH relocation projects that were started in the year and a half since the passage of the MMA. This rule change also leaves no flexibility to rebuild or relocate CAHs in the future.

The relocation language in the proposed IPPS rule is harmful for CAHs in North Carolina. Nineteen of the twenty-one CAH hospitals in North Carolina achieved the CAH designation as necessary providers. Many of these facilities were built during the Hill-Burton era. Hospitals built at that time were designed primarily to care for inpatients; were built with materials that are laden with asbestos and other hazardous materials; and were located in or near the downtown intersections of small towns, which represented the transportation corridors in America over a half century ago.

The University of North Carolina Health Care System is working closely with one CAH that is in the process of upgrading its facilities. This hospital has determined that renovation of its current building is not financially feasible or appropriate. The old building would require significant redesign to support the outpatient orientation of the CAH concept, as well as a complete overhaul to upgrade the facility to meet the latest life safety and patient safety standards. As a result, this hospital reached the conclusion that building a new hospital was its only option. In addition to the hospital campus being landlocked, the transportation route has changed with the construction of a four-lane road that bypasses the downtown area. Therefore, the Hospital Board of Trustees made the only decision possible which was to rebuild its new, modern CAH on the accessible transportation corridor on the outside of town, 3.5 miles from its current location.

The University of North Carolina
Health Care System
125 MacNider Building
Campus Box 7000
Chapel Hill, NC 27599-7000

This is only one example. We know there are other CAHs in the same situation. This proposed change has the potential to penalize and handicap the small hospitals and communities whose residents the CAH program was designed to save and help.

I support the North Carolina Hospital Association in their suggestion that CMS regional offices review reconstruction and relocation plans on a case-by-case basis. If the CAH falls into the relocation criteria, then CMS should determine if the CAH is serving the same population with the same staff and services (the 75% rule that is proposed) in generally the same area. Perhaps a mileage criterion could be developed. If the CAH meets the criteria, then the CAH should be able to receive an expedited favorable decision from CMS approving the CAH's reconstruction or relocation plan, with continued approval to operate as a CAH.

Simply determining whether or not a CAH is "under construction" prior to December 2003 is not adequate to preserve Congress' intent in establishing the CAH program. I urge you to reconsider your proposed rule.

Sincerely,

William L. Roper

WLR:mm

132

CAH Reloc

Hefter
Hartstein
Collins
Morey
Smith

Farmers State Bank FSB

JOSEPH G. PIERCE
President
Chief Executive Officer

June 20, 2005

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

RE: Proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

"Critical Access Hospitals"

Gentlemen:

LaGrange County, Indiana was recently blessed by the acquisition of our current hospital facility by Parkview Health of Fort Wayne, Indiana. This blessing includes a commitment to replace our current, outdated facility. Such a replacement would have a very positive effect on local economic development as well as the health of our 38,000 local citizens.

The proposed regulatory deadline date of December 8, 2003 for ownership of land or plans for a new hospital may limit Parkview's ability to optimally improve access to care, quality of care and services to local residents by inhibiting or limiting the improvement of our local, healthcare facility.

I urge you to reconsider the timeline requirements proposed and to allow our community to enjoy the benefits of quality healthcare in a location that best suits the needs of our citizens.

Sincerely,

Joseph G. Pierce
President and CEO

220 S. Detroit Street
LaGrange, Indiana 46761
Phone 1.260.463.7111
Fax 1.260.463.2209

www.FarmersStateBank.com

133.

CAH Reloc Hefter.
Hartstein
Collins
Morey
Smith

Jac Price, Pres.
Price's Laundry, Inc.
112 East Central Ave.
LaGrange, In 46761
June 20, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
PO Box 8011
Baltimore, Md 21244-1855

RE: Proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

"Critical Access Hospital"

To Whom It May Concern:

Thank you for allowing comment on the proposed changes to the above referred Medicare/Medicaid program.

Our local hospital was recently sold, with the purchaser knowing it is a Critical Access Hospital and with plan to build a new facility. The new facility would replace an aging 60 year old facility which presently serves a community of 38,000 people.

As a local business leader in central LaGrange County, Indiana I am concerned that the proposed changes to the regulations and the deadline of December 8, 2003 for "Under Construction" may inhibit the improvement of this healthcare delivery system to the residents of LaGrange County. In small rural communities such as ours the 250 yard restriction may limit any plans to improve access to care, quality of care and services to more of our citizens.

I urge you to reconsider the time line requirement (December 8, 2003) proposed in these changes and allow the new owner to improve the health care delivery system to the benefit of the local citizens.

Jac Price

Jac Price, Pres
Price's Laundry, Inc.

134

ICAHN

ILLINOIS CRITICAL ACCESS HOSPITAL NETWORK

10 PARK AVENUE WEST ■ PRINCETON, ILLINOIS 61356
815.875.2999 PHONE ■ 815.875.2990 FAX

CAH Reloc

Hefter
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Morey
Smith

June 13, 2005

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

Subject: Proposed Rules for Critical Access Hospital – Determination of the Relocation of a CAH

Illinois currently has 47 critical access hospitals (CAH) and will soon add five additional hospitals pending survey approval. Each one of these hospitals has been determined to be a necessary provider of health services and qualified for the CAH program under the State Rural Health Plan. Each one of the Illinois CAHs will be affected by the proposed Centers for Medicare & Medicaid Services (CMS) rule [CMS-1500-P] RIN 0938-AN57. Section B: Critical Access Hospital, Proposed Policy Change Relating to Designation of CAHs as Necessary Providers Section 405(h) of Pub. L. 108-173…Determination of the Relocation of a CAH: Part (3) Cessation of business at one location.

The Illinois Critical Access Hospital Network is a not for profit membership based organization established in 2003 for the purpose of sharing resources, providing educational opportunities and improving small hospitals operations. ICAHN has 45 critical access hospital members located across Illinois which provide primary and emergency health care services to communities in over 50 rural counties. The Illinois Critical Access Hospital wishes to provide comment on the above proposed CMS regulation. Network members are very concerned that this proposed regulation will eliminate their ability to rebuild at a new site and remain a critical access hospital if that is the best option when facing the need to rebuild a new facility.

Regulation Comments – Reasons for a CAH to Rebuild at a New Site

The proposed regulation transfers CMS control over the basic structure of local rural health care limiting options for our critical access hospital communities. For instance, many of the Illinois CAHs are "land-locked" and do not have the land space on campus to rebuild a new facility. Residential areas have grown around the CAHs making it difficult to accommodate for parking and traffic control for the hospital. Often, building a new facility across town is a better business decision and ensures the longevity of the hospital. Such a new site may provide easier access for the community and emergency services as well as provide opportunity for the CAH to expand various services in the future than the CAH's current site location. A second argument for allowing the rebuilding of a CAH at a new site is the only option in case of a fire or natural disaster where a tornado or fire has destroyed the hospital structure. Why should a small rural

hospital lose its CAH status because it has to rebuild at a new location because of destruction of the building due to fire or disaster?

A third argument to allow a CAH to rebuild at a new site is that three-fourth of the Illinois critical access hospitals are older facilities and have multiple inefficiencies due to change in hospital delivery system from inpatient to outpatient and/or the need for utility energy upgrades. It may be that the current site does not allow the hospital to build its services horizontally or to take advantage of new energy saving and information technologies. Should small rural hospitals be relegated to stay in their inefficient facilities in order to maintain CAH status? What about the cost of rebuilding on site when a hospital has to build in phases to remain operational when building off site would be less costly? Would not tax payer dollars for those rural communities be better spent on more efficient health care services if rebuilding was necessary? Would not the cost of rebuilding a hospital at a new site offset the higher cost of operating an outdated building? Do not rural residents/communities deserve the option of building a new hospital, if needed, in the best location for that community? In fact, one of the intentions of the critical access hospital program has been to modernize health care facilities for rural communities.

Why should necessary provider/critical access hospitals not have the opportunity to rebuild at a different site?

As a necessary provider state, Illinois CAHs, under the CMS proposed regulation for determining CAH relocation, will not have the opportunity to rebuild as a CAH in a new location regardless of the circumstance. Our Illinois critical access hospitals, soon to be 52, provide primary and emergency services to over half of Illinois' rural counties. A loss of one critical access hospital would dramatically impact the viability of the rural community and eliminate access to primary care services in that rural county. The critical access hospital program has made a tremendous difference to Illinois small rural hospitals. The CAH program has strengthened our small rural hospitals financially and prevented almost half from closing their doors. These small rural/critical access hospitals are financially fragile and the conversion back to the prospective payment system would endanger their existence and their rural communities.

The proposed CMS regulation is unfair rule for necessary provider/ critical access hospitals that would be potentially locked to their location due to the "sunset of the necessary provider provision". Critical access hospitals should be treated equally across the country regardless, whether approved through the necessary provider provision or because the hospital is located 35 miles or greater from another hospital. The CMS regulation will immediately prohibit at least one Illinois CAH from building a new facility at a new location which already has community support but missed the actual December 2003 deadline for blue print plans. This particularly CAH has a very old building, "land locked" and desperately needs to build a new facility. In addition, Illinois has two CAHs in a larger county area that are considering building a new CAH facility between the two hospitals. Both CAHs have old buildings, are "land locked" and believe the two hospitals merging into one CAH will save health care dollars in the future and conserve rural health professional resources. The two hospitals can not do this

without the critical access hospital program because those hospitals serve a poor rural area and need the improved financial support through the CAH program.

In Summary
On behalf of the current 47 Illinois critical access hospitals and the additional five hospitals pending certification prior to December 31, 2005, the Illinois Critical Access Hospital Network asks that CMS not enact its proposed regulation for determining rebuilding and relocation options for necessary provider/ CAHs. The Network asks that CMS establish guidelines equally for all critical access hospitals, regardless whether the CAH was certified through necessary provider eligibility or certified because it is located 35 miles or greater from another hospital. All CAHs should be allowed to rebuild at a new location as long as the hospital can demonstrate community support and that the hospital will continue to provide (75 percent) the same services to the same service area with essentially the same staff.

Thank you for your consideration. If you have any questions or would like additional information about the Illinois critical access hospital program, please feel free to contact me at the Illinois Critical Access Hospital Network, 815-875-2999.

Sincerely,

Pat Schou
Executive Director
Illinois Critical Access Hospital Network
www.icahn.org

135.

John A. Price, Pres.
LaGrange County Chamber of Commerce
901 South Detroit Street
LaGrange, In 46761
June 20, 2005

RECEIVED
JUN 23 2005
BY: CAH

Reloc Hefter. Hartstein Collins Morey Smith

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
P. O. Box 8011
Baltimore, Md 21244-1855

RE: Proposed changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Rates

"Critical Access Hospital"

To Whom It May Concern:

Thank you for allowing comment on the proposed changes to the Hospital Inpatient Prospective Payment System. I will direct my comments to "Critical Access Hospitals".

As the president of the LaGrange County Chamber of Commerce, which represents 175 member businesses in LaGrange County. I want to express our concern with the restrictive deadline of December 8, 2003 in the proposed changes. Our local hospital was recently sold, with the purchaser knowing it is a critical Access Hospital. There plan is to build a new facility to replace the aging 60 year old facility that now serves our community of 38,000 local residents.

In a small rural community, such as ours, the 250 yard restriction may adversely limit any plans to build a new facility and improve the access to and quality of care and deliver services to our residents. We are concerned that the proposed changes to the regulations and the deadline of December 8, 2003 for "Under Construction" may severely affect future health care delivery systems to us.

We urge you to reconsider the time line requirement (December 8, 2003) proposed in these changes and allow facility owners to improve the health care delivery systems to the benefit of the local citizens.

John A. Price

John A. Price, Pres.
LaGrange County Chamber of Commerce

1736-0 (4)

EISENHOWER MEDICAL CENTER

June 17, 2005

DRG/Gen

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

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

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

My association is with Eisenhower Medical Center in Rancho Mirage, CA.

As Chief Nursing Officer and VP of Patient Care Services of a large acute care, not-for-profit hospital with robust electrophysiology services, I am writing to express my concern with the proposed rule, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates", published by the Centers for Medicare and Medicaid Services (CMS) on April 25, 2005. My concern is on page 50 of the proposed rule where CMS proposes to modify the DRGs for ICD implants.

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

The payment change CMS proposes would have a severe financial impact on my hospital – without data to justify the change. This is particularly true for CRT-D devices which are ICDs that addresses both Sudden Cardiac Death and heart failure and cost more than single purpose ICDs. CMS says its not appropriate to have all three procedures in code 37.26 drive to higher paying DRGs. Its equally inappropriate to have all three drive to lower paying DRGs.

I respectfully request that CMS withdraw the proposed ICD DRG revision and address this coding problem, with a coding solution, before attempting to make detrimental changes to the current defibrillator DRG structure that would hurt my hospital. I know if the situation were reversed and I came to CMS and said "I don't have any data, but want you to raise the ICD DRGs to help my hospital", no action would be taken.

Thank you for your consideration.

Sincerely,

Louise White
CNO, VP Patient Care Services

39000 Bob Hope Drive / Rancho Mirage, California 92270 / 760-340-3911

137

BELOIT MEMORIAL HOSPITAL

WI/Bd

Hefter
Hartstein
v. Miller
Kraemer

June 16, 2005

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

Physical Address:
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Sir or Madam:

RE: Wage Index

In regards to the IPPS Proposed Rule dated May 4, 2005, we have been informed of a change in Computation of the Proposed FY 2006 Unadjusted Wage Index that we oppose. On page 23372 and 23373 is a description of the computation of the unadjusted wage index. Section F., Step 4 describes the formulas for allocating overhead salaries and wage related costs to excluded areas for removal from the wage index. This formula has been used for several years. However, there is a change in the formula in the Proposed Rule FY2006 that is not explained in the text:

> FRVol.70, No. 85 page 23373
> "Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, **8, and 8.01**);"

The change in the formula reflects the addition of lines 8 and 8.01 to the denominator of the formula, thus lowering the denominator of the equation by the embedded subtraction from line 1, and increasing the ratio of overhead to revised hours. The higher ratio increases the amount of wage related costs removed from the wage index for excluded

areas. The formula reported in the IPPS Final Rule dated August 11, 2004 reads as follows:

> FRVol.69, No. 154 page 49050
> "Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, and 7)"

Thus, lines 8 and 8.01 do not appear in the denominator of the equation in the IPPS Final Rule for FY2005.

This change is not explained in the text of the IPPS Proposed Rule for FY2006. No impact study has been performed for the proposed change, which will particularly affect CBSA's with hospitals that have a large component of excluded area salaries.

Beloit Memorial Hospital's wage index would be reduced 1.57%, this represents a significant amount of Medicare reimbursement. We oppose the change in the Computation of the Proposed FY2006 Unadjusted Wage Index. There is no explanation of why it was done and it causes a significant shift in reimbursement.

Sincerely,

M. C. Bua

Michael Bua
Beloit Memorial Hospital, Inc.

Memorial
HEALTH

138

Pymt/Rates/Outliers/Transfers

Hefler
Hartstein
Treitel
Walz
Hart

June 13, 2005

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

Re: CMS-1500-P – Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; Proposed Rule (42 *Federal Register* 23307-23673).

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule concerning the Hospital Inpatient Prospective Payment System. Memorial Health University Medical Center (MHUMC) is a 530 bed teaching hospital with Level I Trauma Center status located in Savannah, Georgia.

This letter will focus on the proposed changes to the Outlier Payment Threshold (pages 23,469-23,470), and the Post-Acute Care Transfer Payment Policy (pages 23,411-23,424).

I. Outliers (pages 23,469-23,470)

"Outliers Background"

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments, for "outlier" cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs above a fixed –loss cost threshold amount. Under section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year must be projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments.

"Outliers Comment"

The proposal is to establish a fixed-loss cost outlier threshold equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $26,675. CMS is also proposing to maintain the marginal cost factor for cost outliers at 80 percent. Increasing the threshold would result in lower outlier payments for all hospitals, not just those that have been aggressively maximizing their outlier payments.

According to law, outlier payments must be between 5 and 6 percent of total estimated operating DRG payments plus outlier payments. MHUMC has only received through May 31, 2005, outlier payments totaling less than 2 percent. CMS's current estimates for 2006, per the proposed rule, is that outlier payments will be 5.1 percent of actual total DRG payments. MHUMC's outlier payments to date are more than 3 percent below the mandated minimum. It appears that if the average is predicted to end up at 5.1 percent, many providers are still getting paid significantly more, although less than the mandated minimum, at our expense.

In addition to serving a disproportionate share of low-income patients in our community, MHUMC also has a significant number of cases involving extraordinarily high costs due to our Level I trauma status and the fact that we are a teaching hospital. MHUMC is the kind of hospital that the outlier payment was established for and we are not getting our just share, more than likely due to those providers that have manipulated the current outlier system. It is MHUMC's hope that the provisions of the final rule will better target outlier payments to the most costly cases because it is obvious that just raising the threshold is not having the desired effect.

MHUMC appreciates CMS's effort to address the flaws in the outlier methodology and we believe that the use of more current cost-to-charge ratios and the ability to reconcile outlier payments at audit will thwart the efforts of those attempting to game the system at the expense of those providers that rightfully deserve those payments. We believe that if the threshold is increased along with the above provisions, outlier payments will fall below the statutorily mandated levels and will all but disappear for the hospitals that are not gaming the system. If the new provisions do not work toward better targeting outlier payments, more analysis should be done to come up with a better solution that will be able to target payment more appropriately. Another option that CMS could consider is the elimination of outlier payments entirely and increasing standardize payments to providers by the 5 to 6 percent range that that outliers must fall within. This would at least provide MHUMC and other deserving providers with a much deserved 5 percent increase in its standardize payments. This methodology would remove the ability to game the current system and although still lacking, would be more desirable to deserving providers that do not abuse the system.

In addition, to achieve a more appropriate update factor for the outlier threshold, all providers should not be included in the calculation because to do so would skew the results because of those providers that have gamed the system. Only providers between a

certain range should be included so that the providers that do not game the system will not be adversely affected.

II. Post-Acute Care Transfers (pages 23,411-23,424)

"Post-Acute Care Transfers Background"

Medicare Patients who are sent from one acute care hospital to another are viewed as "transfers." The transferring hospital is paid a per diem rate based on the DRG payment and the number of days spent at the transferring hospital; the receiving hospital receives the full DRG payment. In FFY 1999, in accordance with the BBA, CMS expanded its transfer policy such that hospitals that discharge patients associated with one of 10 specified DRGs to a post-acute care facility – such as rehabilitation hospitals and units, psychiatric hospitals and units, cancer, long-term care and children's hospitals, skilled nursing facilities, or are discharged home and receive home health services within three days after the date of discharge – would receive payments under the "post-acute care (PAC) transfer" policy, and as a result, a total of 30 DRGs were subject to the PAC transfer policy in FFY 2005.

"Post-Acute Care Transfers Comment"

The proposal for FFY 2006 is to expand the post-acute care transfer policy from 30 to 223, resulting in an $880 million reduction in Medicare program payments to hospitals. Included in the proposal, are DRGs that meet the following criteria:

- The DRG has at least 2,000 discharges to post-acute care;
- It has at least 20 percent of its cases discharged to post-acute care;
- Out of the cases discharges to post-acute care, at least 10 percent occurs before the geometric length of stay for the DRG;
- The DRG has a geometric mean length of stay of at least 3 days; and
- 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.

Memorial Health University Medical Center believes that this proposed change penalizes hospitals (in excess of $500,000 reduction in reimbursement for our institution) that ensure that Medicare patients receive care in the most appropriate setting, and therefore should not be implemented. Moreover, it undercuts the fundamental principle of the PPS, which is that some cases will cost more than the DRG payment, while other will cost less, but on average, the overall payments should be adequate. It is also important to recognize that to the extent there still are cost reductions associated with discharging patients to post-acute care facilities (a debatable presumption given the current low average lengths of stay), such reductions will be reflected in lower DRG case weights during the DRG recalibration process. In addition, any changes in the transfer policy should include any observation days for cases ultimately resulting in a full inpatient admission in the calculation of the total length of stay being compared to the geometrical length of stay.

Thank you for considering our remarks on the proposed rule. If you have any questions about our comments, please feel free to contact me.

Sincerely,

Bob Colvin
President and CEO

cc: Amy Hughes, MHUMC

Suzanne Heck, CFO, MHUMC

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DRG/Gen

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

Abbott
A Promise for Life

June 15, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington DC 20201

Re: Comments on May 4, 2005 Proposed FY 2006 Medicare Hospital Inpatient Payment Rule (CMS-1500-P)

Dear Dr. McClellan:

Abbott Laboratories appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services ("CMS") proposed rule for FY 2006 hospital inpatient payment, as published in the Federal Register on May 4, 2005. Our comments will focus on the issue of payment for carotid artery stent procedures (Federal Register page 23323).

Abbott Laboratories is a global, broad-based health care company devoted to the discovery, development, manufacture, and marketing of pharmaceuticals and medical products. The company employs more than 70,000 people and markets its products in more than 130 countries.

Payment for Carotid Artery Stent Procedures

In the proposed rule, CMS indicates that it is premature to restructure current payment for carotid stent procedures under DRGs 533 (Extracranial Procedures with C/C) and 534 (Extracranial procedures w/o C/C), citing a paucity of data, low procedure volumes and an insufficient differential in average charges for carotid stenting compared with average charges for DRGs 533 and 534. Furthermore, the agency indicates that it does not have data utilizing the new ICD-9-CM procedure codes for carotid stenting established October 1, 2004. CMS bases its conclusions on an analysis of the MedPar database. While not stated in the proposed rule, we assume that CMS analysis is of the FY 2004 database. Lastly, as part of the proposed rule discussion, CMS states that carotid stenting is only covered in Category B IDE trials.

Abbott appreciates that CMS is continuing to monitor and examine the adequacy of payment for carotid stenting. However, we do not agree that it is premature to restructure payment for the procedure in FY 2006, at least on a temporary basis until additional MedPar and other data can be analyzed.

We would like to point out that Medicare coverage is no longer limited to procedures performed in Category B IDE clinical trials. On October 12, 2004, CMS issued a national coverage decision extending coverage to procedures performed in FDA post approval trials.

Subsequently, on March 17, 2005 CMS issued a national coverage decision further extending coverage to beneficiaries at high risk for surgery with symptomatic carotid artery stenosis equal to or greater than 70%. One FDA approved carotid stent is already on the market and Abbott expects to obtain FDA marketing approval for its carotid stent later this year. It is likely that other manufacturers will obtain marketing approval for additional stents during FY 2006. We estimate that approximately 50,000 carotid stent procedures will be performed in 2006. Broader Medicare coverage and the increased procedure volumes associated with the market approval of multiple stents increases the importance of providing adequate payment for the procedure. Adequate payment is essential to assure that patients at high risk for endarterectomy have access to this therapy.

We question the CMS conclusion that average charges for carotid stenting procedures are not high enough to warrant a payment restructuring. The CMS analysis shows that the average charges for carotid stenting cases paid under DRG 533 are $5,273 higher than the average charges for all cases in DRG 533. In the case of DRG 534, CMS analysis shows that average charges for carotid stenting cases are $6,129 higher than average charges for all cases in the DRG. However, the carotid stenting charges contained in the FY 2004 MedPar database represent clinical trial procedures, the majority of which did not include a device charge. If device charges had been included, the differential in charges would have been significantly higher. We believe that an analysis of the initial 6 months of data in the FY 2005 MedPar database would provide a more accurate assessment of the charge differential for carotid stenting procedures. This database would more accurately reflect the charges associated with carotid stenting as the database should include a significant number of procedures utilizing market-approved devices with associated device charges.

Abbott Recommendation

Abbott urges CMS to analyze the initial 6 months of data in the FY 2005 MedPar database in order to further assess the charge differential for carotid stenting procedures and the need for payment restructuring. In order to assure patient access to this therapy in the short-term, we recommend that CMS assign all carotid stenting cases paid under the DRG 533/534 pair to DRG 533 on an interim basis for FY 2006, pending the analysis of additional MedPar and other data.

We look forward to continuing to work closely with CMS to support an inpatient payment system that ensures quality patient care and fosters medical technology innovation.

Sincerely,

Barbara Calvert/OT

Barbara J. Calvert
Director, Medical Products Reimbursement

140-O

RECEIVED (12)
JUN 2 [illegible] 2005
BY:----------

John L. Walker
620 West Green Street
Hastings, Michigan 49058

Geo. Reclas
Hosp. Redes.

Hefter
Hartstein
Kenly
V. Miller

June 15, 2005

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

Dear Sirs:

I ask you to consider Geographic Reclassification for Pennock Hospital from the Grand Rapids MSA to the Kalamazoo-Battle Creek MSA.

All Grand Rapids-Muskegon-Holland MSA hospitals - all farther from Kalamazoo - were reclassified under Section 508 to Kalamazoo. The reclassified hospitals were Metropolitan Hospital, Saint Mary's Mercy Medical Center, Spectrum Health, Gerber Memorial Hospital, Holland Community Hospital, Hackley Hospital, Zeeland Community Hospital, Munson Medical Center, Mercy General Health Partners and North Ottawa Community Hospital.

Pennock is the closest of those hospitals to Kalamazoo and had been a reclassified "Lugar Hospital" to Kalamazoo for many years. We compete directly for scarce professional labor and other costs with the Kalamazoo MSA. However, we were reclassified to the Grand Rapids MSA for 2006.

Pennock Hospital is the only hospital in Barry County and furnishes quality health care services to our nearly 70,000 residents. Outpatient services exceed 170,000 visits annually, including 28,000 emergency room visits. We also average approximately 3,300 inpatient annual admissions. Pennock Hospital is the Hastings community's largest employer. The Grand Rapids wage index is 11.9% less than the Kalamazoo wage index and will put Pennock Hospital at a severe disadvantage in competing for health care workers. It will also cause a loss of nearly $1,000,000 in Medicare reimbursement for fiscal year 2006.

Pennock Hospital is a full service healthcare provider with diverse physician specialities in Obstetrics, General Surgery, Orthopedics, Urology, Opthalmology, Internal Medicine, Radiology, Pathology, Podiatry, Cardiology, Oncology, Neurology and Family Practice. Pennock Hospital must incur the same significantly large equipment expenses as surrounding healthcare providers to maintain technologically up to date patient services. Some recent large expenditures have been a "PACS" system in our Radiology department costing $1.2 million dollars, an Emergency Department renovation and expansion costing $3.4 million dollars, and

fetal heart monitoring systems, cardiac heart monitors, telemetry and anesthesia monitoring systems costing $485 thousand dollars. The capital budget for technology equipment expenditures approximates $2-3 million dollars annually.

Pennock Hospital's wage and benefit expense is 59% of total operating expenses. A 3% wage increase will cost approximately $801,000 annually. We must offer equally competitive wage scales for scarce healthcare professionals in the areas of Pharmacy, Physical Therapy, Registered Nursing, Language Pathology, Radiology and Laboratory Technicians. Pennock Hospital will be unable to attract these necessary professionals and provide continued, highest quality patient services, expected by our patients, in consideration of $1,000,000 lower Medicare reimbursement due to the inequitable classification into the Grand Rapids MSA and resultant lower wage index.

For these reasons, I ask that the Department of Health and Human Services administratively reclassify Pennock Hospital to the Kalamazoo-Battle Creek MSA so that we will be reimbursed on the same equal basis as all other surrounding Grand Rapids-Battle Creek MSA hospitals.

Sincerely,

John L Walker, C.P.A.

John L. Walker, C.P.A.
Pennock Hospital Board Treasurer
Chairman – Pennock Hospital Finance Committee

cc. Representative Vernon Ehlers
Senator Carl Levin
Senator Debbie Stabenow

142

GUYAN
VALLEY
HOSPITAL

An Affiliate of Logan Regional Medical Center

CAH Reloc

Hefter
Hartstein
Collins
Morey
Smith

June 15, 2005

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

Reference: Medicare Program Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates. (CMS-1500-P)

Subject: Proposed Policy Change Related to Designation of Critical Access Hospitals as Necessary Providers.

Dear CMS Rulemakers:

I am writing this letter to voice my opposition to proposed rule regarding critical access hospital rebuilding projects.

The CMS proposed rule will prevent replacement projects of current CAH's through fear of loss of facility critical access designation. Passage of this ruling could result in hospital closures. This possibility is contrary to the fact the Rural Hospital Flexibility Program and the Critical Access Hospital Program were originally established to prevent the closure of small rural hospitals.

Guyan Valley Hospital, located in Logan, West Virginia is one such facility. Guyan Valley Hospital, an original participant in the Essential Access Community Hospital Program since 1994, was grandfathered into the Critical Access Hospital Program. Guyan Valley Hospital is located in Logan County, an MUA with 24.1 % of the families living at or below the 100% poverty level.

In recent years, Guyan Valley Hospital has faced many hardships in the attempt to keep its doors open. In December of 2002, Guyan Valley Hospital was purchased by LifePoint Hospitals, Inc. The twelve months after the purchase was a time of transition for employees and our community. The date restriction for construction plans of December 8, 2003 proposed by CMS was impossible for us to meet because of our circumstances at the time. This proposed rule offers no consideration of circumstances.

Due to this recent proposed rule, we now face a dilemma. The current site of Guyan Valley Hospital is not large enough to build a new facility and renovation to an eighty

year- old building is not feasible. During our last survey for certification from OHFLAC, our patient rooms were not up to current specifications for semi-private occupancy; and as a result, our bed count dropped from 15 beds to 8 beds. We now have a waiting list for admission to our hospital. If we are to continue to provide quality healthcare in Logan County, relocation is the only answer.

Sincerely,

Sharon Chambers

Sharon Chambers
Director of Operations
Guyan Valley Hospital
396 Dingess Street
Logan, WV 25601

Cc: K. Fowler, CEO
M. Meadows, COO
CMS File

143

CAH Reloc

Hefter
Hartstein
Collins
Money
Smith

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

Subject: Critical Access Hospitals

The newly proposed Federal Regulation (File Code 1500-P) is a serious contradiction to the Medicare created category of Critical Access Hospital Status (CAH). With this category, Medicare recognized the essential services that CAHs would provide. In addition, Medicare predicted the present and future needs that a CAH would have for their facility in order to meet the requirements of up-to-date equipment and services.

Contrary to the original CAH purpose, the Center for Medicare & Medicaid Services (CMS) is proposing to adopt the arbitrary regulation for hospitals with this status that any renovation/reconstruction must be on the existing property and within 250 yards of the current facility.

Placing this type of limitation on Selby General Hospital, which was built over 40 years ago and is completely landlocked, leaves our hospital with no possibility to progressively renovate/reconstruct or relocate. Selby's facility is aging and has a greatly limited land mass. The cost of working under the proposed constraints would potentially eliminate any possibility of renovation/reconstruction for our hospital.

If Selby General Hospital was recognized as meeting the needs of an underserved rural community, then why is an artificial distance limitation that would severely limit our ability to keep the facility current being adopted? We do not understand why CMS wants to discourage us from providing a facility that would allow us to keep current with the ever changing and advancing standards of medicine, but rather artificially force us to maintain the standards of 40 years ago.

We, at Selby General Hospital, located in Marietta, OH, urge the CMS to have far more understanding and support for CHA facilities. This support would allow CHAs to do more with today's -- and tomorrow's -- rapidly changing medical care standards and practices.

Sincerely,

Mike Laderosa
Secretary of Selby General Hospital Board of Trustees
1939 Masonic Park Road
Marietta, OH 45750

cc: U.S. Representative Ted Strickland

143

CAH Relocation

Hefter
Hartstein
Collins
Money
Smith

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

Subject: Critical Access Hospitals

The newly proposed Federal Regulation (File Code 1500-P) is a serious contradiction to the Medicare created category of Critical Access Hospital Status (CAH). With this category, Medicare recognized the essential services that CAHs would provide. In addition, Medicare predicted the present and future needs that a CAH would have for their facility in order to meet the requirements of up-to-date equipment and services.

Contrary to the original CAH purpose, the Center for Medicare & Medicaid Services (CMS) is proposing to adopt the arbitrary regulation for hospitals with this status that any renovation/reconstruction must be on the existing property and within 250 yards of the current facility.

Placing this type of limitation on Selby General Hospital, which was built over 40 years ago and is completely landlocked, leaves our hospital with no possibility to progressively renovate/reconstruct or relocate. Selby's facility is aging and has a greatly limited land mass. The cost of working under the proposed constraints would potentially eliminate any possibility of renovation/reconstruction for our hospital.

If Selby General Hospital was recognized as meeting the needs of an underserved rural community, then why is an artificial distance limitation that would severely limit our ability to keep the facility current being adopted? We do not understand why CMS wants to discourage us from providing a facility that would allow us to keep current with the ever changing and advancing standards of medicine, but rather artificially force us to maintain the standards of 40 years ago.

We, at Selby General Hospital, located in Marietta, OH, urge the CMS to have far more understanding and support for CHA facilities. This support would allow CHAs to do more with today's -- and tomorrow's -- rapidly changing medical care standards and practices.

Sincerely,

Mike Laderosa
Secretary of Selby General Hospital Board of Trustees
1939 Masonic Park Road
Marietta, OH 45750

cc: U.S. Representative Ted Strickland

144
(new)

Date: 06/22/2005

BROOKS
GRUBER
KELLY
HUE
FAGAN
HEFTER
HARTSTEIN
TREITEL
WALZ
WYNN

Submitter : Ms. Sarah Wells
Organization : Boston Scientific Corporation
Category : Device Industry
Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-578-Attach-1.PDF

DRG/GEN
DRG/weights
NT
MEDPAC
CC List

Boston Scientific Attachment 578

Randel E. Richner
Vice President
Government Affairs and
Reimbursement & Outcomes Planning

1331 Pennsylvania Avenue, NW
Suite 550 South
Washington, DC 20004

June 22, 2005

BY ELECTRONIC SUBMISSION

Mark McClellan, M.D., Ph.D
Administrator
Centers for Medicare and Medicaid Services
Humbert Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Dr. McClellan:

Boston Scientific Corporation appreciates the opportunity to provide comments in response to the Medicare Program's Proposed Changes to the Hospital Inpatient Prospective Payment System (IPPS) and Fiscal Year (FY) 2006 Rates (CMS-1500-P).

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

- Electrophysiology;
- Endoscopy;
- Gastroenterology;
- Gynecology;
- Interventional Cardiology;
- Neuromodulation;
- Neurovascular;
- Oncology;
- Peripheral Interventions;
- Urology; and
- Vascular Surgery.

Our comments focus on four main policy areas addressed in the proposed rule. Major recommendations for specific issues within each of those areas are as follows:

I. Proposed Changes to DRG Classifications and Relative Weights – Page 3

A. Coronary Artery Stents:

- Implement proposed modifications to split coronary stent DRGs (516 and 526) based on the presence or absence of a secondary diagnosis on the "CC" list.

- Revisit ICD-9-CM Coordination & Maintenance Committee decision not to adopt a discrete ICD-9-CM procedure code for reporting/tracking stenosis at the bifurcation of a vessel for FY 2006; add code 00.44 "Procedure on bifurcated vessels" to Table 6B in the FY 2006 final rule and the ICD-9-CM Volume 3, Procedures Final Addenda.
- Review future data to examine resource use associated with new ICD-9-CM multi-vessel procedure codes (00.41-00.43) and multi-stent codes (00.45-00.48) to evaluate appropriate permanent DRG assignment for these new codes. Based on these findings, consider code reassignments for future updates.
- Retain separate DRGs for coronary drug-eluting stent (DES) discharges that are distinct from coronary bare metal artery stent (BMS) discharges until such a time that BMS represent an insignificant proportion of the total coronary stent discharges.

B. Carotid Artery Stents:

- Assign CAS cases to two new DRGs split on the presence or absence of complications and co-morbidities for FY 2006 so that DRG payments are better aligned with CAS case average resource use.

C. Strokes:

- Create a third DRG for acute stroke for FY 2006 that contain cases from DRGs 14 and 15 in which a reperfusion agent is used to treat an ischemic clot.

D. Coronary Intravascular Ultrasound:

- Perform a FY 2005 MedPAR analysis of coronary IVUS cases and consider reassigning ICD-9-CM procedure code 00.24 in FY 2007 to a clinically similar DRG where the average resource use most closely approximates the resource use of coronary IVUS technology.

II. Refinement of the Complications and Comorbidities (CC) List, Comprehensive Review – Page 7

- Evaluate the potential impact of secondary diagnosis on hospital length of stay and charges; compare existing CC list with those used with other DRG systems;
- Conduct any review of the CC list in a transparent manner with stakeholder input; make methodology, standards, and CC list subject to public comment with sufficient time for changes before final implementation.

III. Proposed Add-On Payments for New Services and Technologies – Page 8

A. Eligibility Criteria and Other Requirements

1. "Newness" Determination Period:

- Begin two to three-year period of "newness" with the date of FDA approval ***or*** ICD-9-CM code issuance, ***whichever comes later*** to ensure the maximum period of eligibility is achieved and the most appropriate period of time is dedicated to evaluating the new service within the Medicare data.

2. "Significant Clinical Improvement" Criterion:

- Indicate whether a technology applicant satisfied the clinical improvement criterion in the proposed rule so the public can respond in a meaningful way.
- Provide preliminary assessments for not just some but all technology applicants.

3. **Use of "Substantial Similarity":**
   - Do not use "substantial similarity" as "threshold" criteria to determine whether a new technology or service is eligible for add-on payment status.
   - Assess the clinical similarity of a new technology applicant when making a determination about significant clinical improvement (after "newness" and "cost threshold" criteria have been met).

4. **Marginal Cost Factor:**
   - Raise add-on payment level from 50 percent to 80 percent to conform to outlier marginal rate.

5. **Requirement to Consider DRG Assignment Before Approving Add-on Payments:**
   - Follow statutory requirement to first seek an appropriate, clinically similar DRG on a temporary basis into which the eligible technology applicant could fit, prior to considering the technology for an add-on payment.

B. FY 2006 Applicants for New Technology Add-on Payments

1. **Restore Rechargeable Implantable Neurostimulator:**
   - Approve manufacturer's request for new technology add-on payments for all rechargeable, implantable stimulators.

2. **Wingspan™ Stent System with Gateway™ PMA PTA Balloon Catheter:**
   - Upon FDA approval, continue to work with Boston Scientific to determine the most appropriate payment pathway for this breakthrough technology.

IV. MedPAC Recommendations – see Page 12
   - Take a measured and fully transparent approach to evaluating MedPAC recommendations pertaining to DRG rate-setting methodology refinements.
   - Recognize the potential for disruption and unintended consequences that may result from making fundamental changes to the entire IPPS based on irregularities purportedly occurring in a small percentage of hospitals nationwide. Consider solutions that would more specifically target elements of concern.
   - Complete comprehensive review of CC list and selective review of specific DRGs prior to implementing systematic DRG refinements.

We address each of these issues in more detail below.

I. Proposed Changes to DRG Classifications and Relative Weights

A. Coronary Artery Stents

Boston Scientific commends CMS for proposing to split 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 shown by CMS's FY 2004 MedPAR analysis presented in the proposed rule, there is a clear differential in the average hospital charges for AMI patients with CCs versus without CCs. Creating new DRGs to distinguish that differential will better align AMI case resource use with appropriate hospital payment levels. We want to thank CMS for its thoughtful consideration of Boston Scientific's proposal that prompted the Agency's analysis and review of coronary stent DRG restructuring for FY 2006.

We also commend CMS for creating four new ICD-9-CM codes for identifying multiple stent insertion (codes 00.45, 00.46, 00.47, and 00.48) and four new codes identifying multiple vessel stent treatment (codes 00.40, .0041, 00.42, and 00.43). We were disappointed, however, that the Agency did not adopt distinct codes for the treatment of stenosis at the bifurcation of two vessels and urge CMS revisit this decision for FY 2006. Specifically, we request that CMS add code 00.44, "Procedure on bifurcated vessels to Table 6B in the final rule and ICD-9-CM Volume 3, Procedures Final Addenda. We look forward to our continued interactions with CMS to discuss the need and importance of facilitating discrete tracking for bifurcation procedures that represent up to 30 percent of all percutaneous coronary interventions and require significantly higher resource use relative to single and multiple vessel cases.

We noted on page 23320 of the proposed rule that CMS believes it is premature to reassign multiple vessel procedure code 36.05 (Multiple vessel percutaneous transluminal coronary angioplasty (PTCA) or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent) for FY 2006. We ask that CMS continue to evaluate this issue and consider code reassignment for future updates as applicable using the 00.4x series of code combinations. Boston Scientific is confident cases involving procedures of more than one vessel and/or multiple stents within one vessel will demonstrate a clear charge differential that merits their reassignment to "with CC" DRGs. We will continue to evaluate available data, along with CMS, so that this issue can be considered for future DRG reassignment changes.

Finally, Boston Scientific supports the Agency's decision to retain separate DRGs for drug-eluting coronary stent cases that are distinct from cases involving bare metal stents (BMS). While hospital utilization of BMS is on the decline, CMS should not eliminate the temporary DES DRGs that allow hospitals to obtain some incremental payment for the more costly DES cases until such a time that BMS represent an insignificant portion of total coronary stent discharges.

Recommendations and CMS Action Requested:

- Implement proposed modifications to split coronary stent DRGs (516 and 526) based on the presence or absence of a secondary diagnosis on the "CC" list.
- Revisit ICD-9-CM Coordination and Maintenance Committee decision not to adopt a discrete ICD-9-CM procedure code for reporting/tracking stenosis at the bifurcation of a vessel for FY 2006; add code 00.44 "Procedure on bifurcated vessels" to Table 6B in the FY 2006 final rule and the ICD-9-CM Volume 3, Procedures Final Addenda.
- Review future data to examine resource use associated with new ICD-9-CM multi-vessel procedure codes (00.41-00.43) and multi-stent codes (00.45-00.48) to evaluate appropriate permanent DRG assignment for these new codes. Based on these findings, consider code reassignments for future updates.
- Retain separate DRGs for coronary drug-eluting stent (DES) discharges that are distinct from coronary bare metal artery stent (BMS) discharges until such a time that BMS represent an insignificant proportion of the total coronary stent discharges.

B. Carotid Artery Stents

We appreciate CMS's recognition of the importance of establishing appropriate DRG payments for carotid artery stent (CAS) cases and welcome this opportunity to comment on CMS's FY 2004 MedPAR analysis in the proposed rule as well as present two additional analyses that corroborate CMS findings. CMS's analysis showed that CAS cases have average charges of $29,737 and $22,002 for DRG 533 and DRG 534, respectively, compared to average charges of $24,464 and $15,873 for all cases within DRG 533 and DRG 534, respectively, resulting in charge differentials of $5,273 (22%) and $6,129 (39%).

In another analysis of FY 2004 MedPAR data, an even greater charge differential between CAS cases and all cases within the DRG was found. In that analysis, the difference in average charges between CAS cases and DRG 533 and DRG 534 is $8,617 (40%) and $6,899 (45%), respectfully, reflecting the significant underpayment for these cases (see Table 1 below).

Table 1: External MedPAR FY 2004 Analysis of Carotid Artery Stent Discharges

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

In a third analysis, Boston Scientific examined resource use associated with the patients who were treated as part of our BEACH IDE clinical trial. The BEACH trial was a multi-center IDE trial evaluating the effectiveness of stenting with embolic protection for patients who are at high-risk for carotid endarterectomy. The data emanating from BEACH trial will serve as the basis for our request for FDA approval of the Carotid Wallstent™ and FilterWire EZ™ embolic protection system. This trial studied 747 patients who were at high risk for surgery and 71.4% (533) were 65 or older and the mean age was 70 years.

As can be seen from Table 2 below, average charges for the high risk patient population are $36,689. This figure is $12,225 higher than the Agency's reported mean charges for all cases within DRG 533 and $20,816 higher than the Agency's reported mean charge for all cases within DRG 534. One major factor that contributes to a lower estimate of resource use using FY 2004 MedPAR data is that FY 2004 MedPAR data captures IDE clinical trial discharges only, and thus does not account for device costs that may not have been charged to the hospital. In addition, length of stay associated with these cases (3.039 days) is significantly longer than what the Agency found in its analysis. Given these results, we believe CAS cases warrant reclassification to DRGs that better reflect their average resource use.

Table 2: Summary of Resources Associated with Treating BEACH Clinical Trial Patients

Number of patients	747
Cath lab costs[1]	$3,836
Device costs –stents, embolic protection, balloons, guidewires, sheaths, catheters, and retrieval devices[2]	$5,632
Length of stay (3.039 days)	$7,042
Total average costs	$16,510
Total average charges	$36,689

The significant charge differential between CAS cases and all cases within DRG 533 and DRG 534 as shown by the three separate analyses summarized above demonstrates the need for improving the

[1] Cost data was calculated using MedPAR 2003 data for cath lab charges.
[2] Device costs were calculated using BEACH data determining number of devices averaged per patient for stents, embolic protection, guidewires, catheters, balloons and retrieval devices.

accuracy of inpatient payments for CAS cases. While the volume of CAS cases from these analyses may appear small, the volume of Medicare CAS discharges will continue to increase steadily given recent and soon to be available FDA-approved devices, new and ongoing clinical trials, post-market registries, and expanded Medicare coverage. We therefore urge CMS to give thoughtful consideration to the creation of a new pair of DRGs for CAS cases, split on the presence or absence of complications and co-morbidities, for FY 2006.

Recommendation and CMS Requested Action:

- Assign CAS cases to two new DRGs split on the presence or absence of complications and co-morbidities for FY 2006 so that DRG payments are better aligned with CAS case average resource use.

C. Strokes

Boston Scientific commends CMS for its consideration of the payment inadequacies associated with the current DRG structure for complex acute stroke cases. Cases that involve reperfusion agents such as thrombolytic therapy are quite resource intensive as shown in CMS's analysis. Hospitals have experienced longstanding financial difficulties in being able to offer the best treatments to these very sick patients, and it is critical that CMS proactively make changes in this fiscal year to help alleviate hospitals' struggles with providing patient access to the latest approved therapies.

Boston Scientific recommends that CMS create a third DRG for acute stroke, Ischemic Stroke with Reperfusion Agent, for FY 2006 which will contain cases from DRGs 14 and DRG 15 in which a reperfusion agent is used to treat an ischemic clot. CMS's timely attention towards DRG restructuring will dramatically improve the barriers faced by hospitals today in providing these treatments, thereby, improving patient outcomes for this urgent disease state. Treatment of ischemic stroke is a rapidly evolving field. We request that CMS act expeditiously to address the current economic efficiencies and continue to review the resource data as the therapy regimen evolves so that the Agency continues to foster vital clinical advances for stroke patients.

Recommendation and CMS Action Requested:

- Create a third DRG for acute stroke for FY 2006 that contain cases from DRGs 14 and 15 in which a reperfusion agent is used to treat an ischemic clot.

D. Coronary Intravascular Ultrasound

Boston Scientific is pleased CMS made data resource tracking possible for intravascular ultrasound (IVUS) with the creation of ICD-9-CM procedure codes 00.21-00.29 effective October 1, 2004. Knowing that IVUS is an added cost to hospitals, Boston Scientific conducted an analysis of coronary IVUS resource use in CY 2004 Premier hospital data to determine possible impact. Since Premier data tracks IVUS as a device distinct from ICD-9-CM procedure codes, a full year was available for review. Table 3 on the following page includes 117 (60%) IVUS users out of 195 geographically dispersed hospitals.

Table 3: Resource Use Comparison of Coronary Stent Cases With and Without Coronary IVUS

	DRG 516 Percutaneous cardiovascular procedures with non-drug-eluting stent with AMI			DRG 517 Percutaneous cardiovascular procedures with non-drug-eluting stent without AMI		
		WITHOUT IVUS	P VALUE*		WITHOUT IVUS	P VALUE *
N		6,541			7,587	
TOTAL CHARGE, $ (+SD)		41,860 (+25097)	*0.02*		33,906 (+20732)	0.25
TOTAL COST, $ (+SD)		13,099 (+7112)	*<.0001*		9,745 (+5527)	*<.0001*
NUMBER OF MEDICARE BENEFICIARIES, N (%)		2,989 (45.7%)	0.19		59.7	0.23
	DRG 526 Percutaneous cardiovascular procedures with drug-eluting stent with AMI			**DRG 527** Percutaneous cardiovascular procedures with drug-eluting stent without AMI		
		WITHOUT IVUS	P VALUE *		WITHOUT IVUS	P VALUE *
N		17,806			44,445	
TOTAL CHARGE, $ (+SD)		50,308 (+28132)	*0.03*		41,481 (+23700)	*<.0001*
TOTAL COST, $ (+SD)		15,185 (+7351)	*0.0007*		11,821 (+6035)	0.08
NUMBER OF MEDICARE BENEFICIARIES, N (%)		7,498 (42.1%)	0.89		23,464 (52.8%)	0.04

*TEST OF SIGNIFICANCE, TTEST & CHI-SQUARE (HIGHLIGHTED IN RED MEANS SIGNIFICANT)

The analysis shows that charges\costs for IVUS cases in coronary stent DRGs are higher than non-IVUS cases. We request CMS to consider these Premier data results and conduct a MedPAR data review of code 00.24 (intravascular vessel imaging of coronary vessels) to evaluate the appropriateness of this code's DRG assignment for FY 2007.

Recommendation and CMS Requested Action:

- Perform a FY 2005 MedPAR analysis of coronary IVUS cases and consider reassigning ICD-9-CM procedure code 00.24 in FY 2007 to a clinically similar DRG where the average resource use most closely approximate the resource use of using coronary IVUS cases.

II. Refinement of the Complications and Cormorbidities (CC) List, Comprehensive Review of the CC List

Boston Scientific reviewed with interest the proposed rule provisions pertaining to refinements of the CC list. We understand the Agency's concerns that changes in inpatient hospital care particularly decreases in length of stay may be marginalizing the impact the CC list is having on differentiating hospital costs compared to years past. We also agree that it may be valuable to conduct a substantive and comprehensive review of the CC list for the future.

We urge CMS to conduct any review of the CC list 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. The agency may find during the course of this complex review that attempting to revise the CC list under this ambitious timeframe is an unrealistic goal and that engaging stakeholder involvement throughout the process would be beneficial.

CMS listed criteria where a CC split appears most justified in the August 1, 2003 FY 2004 Final Rule. On page 45352, the Agency states, "Our analysis identified existing DRGs that meet the following criteria: a reduction in variance in charges within the DRG of at least 4 percent; fewer that 75 percent of all patients in the current DRG would be assigned to the with-CC DRG; and the overall payment impact (higher payments for cases in the with-CC DRG offset by lower payments for cases in the without-CC DRG) is at least $40 million." Current criteria may not represent today's drivers of higher resource intensive cases and thus should be examined as part of CMS's comprehensive review of the CC list.

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 examine several approaches and solicit public input on both the methodologies and the results. We think the proposed methodology, standards and CC list also should be subject to public comment with sufficient time to allow for significant changes if needed before final implementation.

Finally, we encourage CMS to evaluate 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 is likely to have a major 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.

Recommendations and CMS Action Requested:

- Evaluate the potential impact of secondary diagnosis on hospital length of stay and charges; compare existing CC list with those used with other DRG systems;
- Conduct review of the CC list in a transparent manner with stakeholder input; make any changes to methodology, standards, and CC list subject to public comment with sufficient time for changes before final implementation.

III. Proposed Add-On Payments for New Services and Technologies

DRG add-on payments provide an important policy mechanism for hospitals to obtain incremental Medicare payment for new technologies whose costs have not yet been recognized in the claims data and therefore have not been accounted for in DRG relative weight calibrations. Since MMA's enactment, Boston Scientific has been actively monitoring CMS's implementation of the new technology add-on payment program and offers the following comments in response to the agency's interpretations, positions, and proposed decisions as articulated in the FY 2006 proposed rule.

A. Eligibility Criteria and Other Requirements

1. "Newness" Determination Period:

Per the criteria specified at 42 C.F.R. § 412.87(b)(2), a medical service or technology may not be considered new within 2 to 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned. After CMS has recalibrated the DRGs based on available data, the medical service or technology will no longer be considered "new" under the criterion.

Alternatively, in the FY 2006 proposed rule, CMS maintains the position taken in the FY 2005 proposed and final rules that the two to three year period of newness for a technology or medical service would ordinarily begin with the date of FDA approval, unless there is documented delay in bringing the product onto the market after that approval.

Boston Scientific believes there needs to be flexibility in CMS's standard for determining the two to three year period that a technology is considered "new" and therefore eligible for add-on payment status. We feel that ***both*** FDA approval and ICD-9-CM code issuance are key determinants in defining "newness". However, because issuance of codes can pre-date FDA approval and vice versa, FDA approval (or code issuance) alone should not dictate how CMS defines "newness" in every circumstance, otherwise the period of eligibility could be compromised.

Recommendation and CMS Action Requested:

- Begin two to three-year period of "newness" with the date of FDA approval ***or*** ICD-9-CM code issuance, ***whichever comes later*** so to ensure that both a maximum period of eligibility is achieved and the most appropriate period of time is dedicated to evaluating the new service within the Medicare data.

2. "Significant Clinical Improvement" Criterion:

We commend the agency for conducting public meetings giving applicants the opportunity to present information showing that a new technology represents a substantial clinical improvement. Our hope for future meetings, however, is that they will become more interactive, fostering increased dialogue between CMS staff and presenters who are the clinical subject matter experts on the technologies seeking add-on payment eligibility. Also, we urge the agency to provide in the proposed rule its preliminary assessment of whether the significant clinical improvement criterion was satisfied for a given technology. Such an assessment is critical for the public to respond to the proposed rule in a meaningful way.

Finally, we note that in the FY 2006 proposed rule, CMS is inconsistent in providing information concerning whether it views a technology applicant to be a significant clinical improvement even when the other criteria may not be satisfied. The proposed rule provides information for some technology applicants but not others. Specifically, the proposed rule does not discuss whether the new technology would be considered a significant clinical improvement for two technologies that received FDA approval only recently (March 23, 2005) or such approval is pending (Wingspan). This omission deprives the public an opportunity to comment on the agency's views about this critical issue.

Recommendation and CMS Requested Action:

- Indicate whether a technology applicant satisfied the clinical improvement criterion in the proposed rule so the public can respond in a meaningful way.
- Provide preliminary assessments for not just some but all technology applicants.

3. Use of "Substantial Similarity":

Under CMS regulations, a new technology applicant must meet three criteria to be eligible for add-on payment: 1) it must be "new"; 2) have significant additional cost as evidenced by exceeding a cost threshold, and 3) represent a significant clinical improvement. The first two "threshold" criteria must be met before CMS will make determinations about substantial clinical improvement.

In the proposed rule, the Agency signals that several new technology applicants are "substantially similar" to existing technology. We are concerned that CMS is using the determination of "substantial

similarity" as a basis to support a preliminary determination that these technologies are not "new" and therefore not eligible for add-on payment, when no such requirement exists under the "threshold" criteria.

Recommendation and CMS Requested Action:

- Do not use "substantial similarity" as "threshold" criteria to determine whether a new technology or service is eligible for add-on payment status.
- Assess the clinical similarity of a new technology applicant when making a determination about significant clinical improvement (after "newness" and "cost threshold" criteria have been met).

4. Marginal Cost Factor:

The MMA's report language urged CMS to consider raising the add-on payment level from 50 percent to 80 percent of the difference between the standard DRG payment level and the cost of the procedure with the new technology. We were disappointed that CMS did not address this issue in the FY06 proposed rule, but urge CMS to revisit this issue in the future so that add-on payments conform to the marginal rate used for the inpatient outlier payment level.

Recommendation and CMS Requested Action:

- Raise add-on payment level from 50 to 80 percent to conform to outlier marginal rate.

5. Requirement to Consider DRG Assignment Before Approving Add-on Payments:

In the proposed rule, CMS acknowledges the MMA amended section 1886(d)(5)(K) of the Act requiring that the HHS Secretary seek to identify one or more DRGs associated with the new technology, based on similar clinical or anatomical characteristics and the costs of the technology, and to assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology.

Despite this acknowledgement, CMS seems to favor add-on payments over DRG assignment. In the case of one technology applicant for FY 2006, CMS appears to reject DRG assignment, but says that it will continue to study the issue and invites public comments.

Recommendation and CMS Requested Action:

- Follow statutory requirement to first seek an appropriate, clinically similar DRG on a temporary basis into which the eligible applicant technology could fit, prior to considering the technology for an add-on payment.

B. FY 2006 Applicants for New Technology Add-on Payments

1. Restore Rechargeable Implantable Neurostimulator:

Boston Scientific Corporation and Advanced Bionics (a Boston Scientific Company) support the establishment of a new technology add-on payment for rechargeable implantable neurostimulators. The FDA recently approved the first rechargeable implantable neurostimulators. These systems differ substantially from predecessor devices and represent a major new medical technology advancement that will substantially improve the care of patients requiring spinal cord stimulation. Advanced Bionics received the first FDA approval for the Precision™ Rechargeable Spinal Cord Stimulation (SCS) system

in April 2004. Medtronic and ANS have also received FDA approval for rechargeable implantable neurostimulators since that time. Given CMS's policy that approval of a new technology for special payment extends to all technologies that are substantially similar, each of these rechargeable implantable neurostimulators should qualify under this criterion.

Newly developed rechargeable implantable pulse generator (IPG) systems represent substantially different technology than predecessor radiofrequency (RF) systems and non-rechargeable IPG systems, as described below. Table 4 clarifies and summarizes some of the major differences between these different categories of neurostimulator technologies that have been developed over the past 40 years.

Table 4: Major Categories of Neurostimulator Technology

Category	External RF Transmitter with Implanted Receiver	Non-Rechargeable Implantable Pulse Generator	Rechargeable Implantable Pulse Generator
Fully Implantable Generator?	No	Yes	Yes
Sealed Implanted Battery?	No	Yes	Yes
Rechargeable Implanted Battery?	No	No	Yes
Battery Technology	External battery with off-the-shelf specifications that may be rechargeable	Non-rechargeable, primary cell implanted battery	Rechargeable, Lithium-ion, custom chemistry specifications
Patient Inconvenience	High	Low	Low
Power for Clinical Use	High Only	Low to Medium Only	Low to High
Product Examples	Renew (ANS) X-trel, Mattrix (Medtronic)	Genesis, Genesis XP (ANS) Synergy (Medtronic)	Precision (AB/BSC) Genesis RC, Eon (ANS) Restore (Medtronic)

Initially, SCS systems utilized an external RF transmitter with an antenna that was worn outside the body and provided both signal and power to an implanted receiver. An RF system can only deliver stimulation when the patient wears the external transmitter and power source, typically on a large, heavy and bulky belt. The external RF transmitter may utilize non-rechargeable or rechargeable batteries. Despite the substantial patient inconvenience and other drawbacks of these RF systems, they have continued to be used for some patients requiring high power stimulation.

The second major category of SCS technology to be developed was fully implanted pulse generator systems containing a non-rechargeable sealed battery. These fully implantable systems were greatly preferred by patients, and they have now largely replaced RF systems in clinical practice for those patients whose pain could be effectively and feasibly treated with these systems. However, a major limitation associated with second generation implantable neurostimulators was the need for frequent replacement surgeries due to limited generator battery life. This has been identified as a major driver of healthcare costs.[3,4,5] Another major limitation is that physicians in clinical practice have been forced to

[3] Bell, G., Kidd, D., North, R. "Cost-effectiveness of Spinal Cord Stimulation in Treatment of Failed-Back Surgery Syndrome." J Pain Symptom Manage, 13:286-295, 1997.
[4] Kumar, K., Malik, S., Demeria, D. "Treatment of Chronic Pain with Spinal Cord Stimulation Versus Alternative Therapies: Cost-effective Analysis." Neurosurgery, 51:106-116, 2002.

routinely use stimulation settings designed to extend battery life and delay the need for replacement surgeries. Unfortunately, this has compromised their ability to obtain optimal pain relief for patients.

Physicians have long identified that "the definitive solution to battery replacement is an implant which accepts external power...intermittently to recharge an internal battery...."[6] The introduction of rechargeable implantable SCS systems represents a major new medical technology advancement that will revolutionize the field of neurostimulation. These systems feature a fully implantable generator that receives power from a rechargeable, high-technology Lithium-ion battery sealed within the IPG. Rechargeable IPGs offer the benefits of RF generators and conventional IPGs without major drawbacks of earlier generation technologies.

Rechargeable implantable neurostimulator technology represents a substantial clinical improvement over predecessor technologies. First, these systems enable physicians to improve patient outcomes by utilizing settings that optimize pain relief without the need to compromise settings in order to extend generator battery life. These long-lasting systems also will significantly reduce the number of battery replacement surgeries, thereby avoiding many patient hospitalizations for replacement surgeries and the associated surgical complications and healthcare costs.

Recommendation and CMS Action Requested:

- Approve manufacturer's request for new technology add-on payments for all rechargeable, implantable neurostimulators.

2. Wingspan™ Stent System with Gateway™ PTA Balloon Catheter:

Boston Scientific appreciates CMS's review of the new technology add-payment application for the Wingspan™ Stent System as well as the Agency's careful attention to the payment challenges facing intracranial stenting with angioplasty within the current DRG structure. We believe that intracranial stenting represents a substantial clinical improvement over what is currently available to treat patients with intracranial atherosclerotic disease, and who suffer from recurrent stroke.

Recommendation and CMS Action Requested:

- Upon FDA approval, determine the most appropriate payment pathway for this promising new therapy.

IV. MedPAC Recommendations

Boston Scientific is closely evaluating MedPAC recommendations addressing specialty hospitals, particularly those that call for significant refinements to the entire IPPS. MedPAC's proposed changes – 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 – have the potential to cause material and unpredictable effects on Medicare payment to hospitals for inpatient care.

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[5] ECRI. Spinal Cord (Dorsal Column) Stimulation for Chronic Intractable Pain. Health Technology Assessment. Information Service. Plymouth Meeting, PA.

[6] North, R., Brigham, D., Khalessi, A., Calkins, S., Piantodosi, S., Campbell, D., Daly, M., Dey, P., Barolat, G., Taylor, R. "Spinal Cord Stimulator Adjustment to Maximize Implanted Battery Longevity: A Randomized, Controlled Trial Using a Computerized, Patient-Interactive Programmer." Neuromodulation, 7(1):13-25, 2004.

We appreciate CMS responding to these recommendations in the proposed rule and making the public aware of the various policy options the Agency is contemplating to improve accuracy of IPPS rates. We support CMS's view that these options and their impacts on hospitals must be thoroughly analyzed before the Agency makes any concrete proposal on these matters, and we encourage CMS to take a fully transparent approach in examining them. As part of that process, we think that CMS should complete its comprehensive review of the CC list and selective review of specific DRGs prior to moving forward with any adoption of MedPAC's recommendations, or some variants of them.

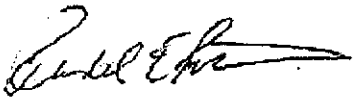
Recommendations and CMS Action Requested:

- Take a measured and fully transparent approach to evaluating MedPAC recommendations pertaining to DRG rate-setting methodology refinements.
- Recognize the potential for disruption and unintended consequences that may result from making fundamental changes to the entire IPPS based on irregularities purportedly occurring in a small percentage of hospitals nationwide. Consider solutions that would more specifically target elements of concern.
- Complete comprehensive review of CC list and selective review of specific DRGs prior to implementing systematic DRG refinements.

* * * *

Boston Scientific appreciates the opportunity to comment on Medicare payment policies that significantly affect the healthcare services beneficiaries receive. Sarah Wells in our Washington office will follow-up with Marc Hartstein within the next few days to confirm receipt of these comments and answer any questions you have. In the interim, please do not hesitate to contact me (508-652-7410; richnerr@bsci.com) or Sarah Wells (202-637-8021; wellss1@bsci.com) if we can be of further assistance.

Sincerely,



Randel E. Richner, BSN, MPH
Vice President, Government Affairs and Reimbursement and Outcomes Planning

cc: Herb Kuhn, Director, Center for Medicare Management
Tom Gustafson, Deputy Director, Center for Medicare Management
Liz Richter, Director, Hospital Ambulatory Payment Group
Tzvi Hefter, Director, Division of Acute Care Services
Marc Harstein, Deputy Director, Division of Acute Care Service
Parashar Patel, Vice President, Reimbursement & Outcomes Planning, Boston Scientific
Sarah Wells, Director, Health Policy & Payment, Boston Scientific

"Whatever you do, do it well"

Upland Hills Health

June 14, 2005

RECEIVED
JUN 23 2005
BY:

CAH Reloc
Hefler
Hartstein
Collins
Morey
Smith

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

To Whom It May Concern:

I am writing on behalf of Upland Hills Health, Inc. to oppose the proposed construction ban on the vast majority of Critical Access Hospitals in our state and across America.

In particular, 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."

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.

4. Ironically, the CMS proposal to ban a local community's ability to rebuild on an adjacent or nearby location will cost Medicare over time, more, not less—the higher labor costs of operating in a retrofitted building more than offset the slightly higher cost of rebuilding.

5. A ban on major construction projects developed after December 8, 2003 is an over reaction against a potential problem that can be appropriated 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.

6. 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 for 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.

7. A CAH's Necessary Provider designation is associated with its current Medicare provider agreement that remains intact unless the CAH fundamental 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.

We would be pleased to be part of any discussion to assist in the immediate resolution of this issue.

Respectfully submitted,

Phyllis A. Fritsch

Phyllis Fritsch, Interim Administrator
Upland Hills Health

Original mailed with two copies.

NATIONAL ASSOCIATION OF URBAN HOSPITALS

Private Safety-Net Hospitals Caring for Needy Communities

146

E Comment
1500 P-425

LABOR S/N — KNIGHT
KRAEMER
SEIFERT
TREITEL
HEFTER
HARTSTEIN
Payment Hts/Outliers
WI/Bd - MILLER
RRC - NAVARRO

June 20, 2005

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

Subject: Labor-Related Share

To Whom it May Concern:

I am writing on behalf of the National Association of Urban Hospitals to express our opposition to the changes that the Centers for Medicare & Medicaid Services (CMS) has proposed in the FY 2006 Medicare inpatient PPS regulation governing the labor-related share of Medicare payments to hospitals.

The proposed regulation calls for reducing the labor-related share from the current 71.1 percent to 69.7 percent for hospitals located in Medicare wage index areas with a wage index greater than 1.0; hospitals located in wage index areas with a wage index of 1.0 or less would not be affected because Congress, not CMS, determines their labor-related share. The National Association of Urban Hospitals believes this proposal is based on a flawed methodology; that it is redistributive without a rationale for being so; that it lacks a public policy basis; and that it proposes harming urban hospitals, and only urban hospitals, without any expressed rationale or policy basis for doing so.

WI/Bd

The Proposed Change is Based on a Flawed Methodology

Three years ago, CMS proposed increasing the labor-related share of Medicare inpatient PPS payments from 71.1 percent to 72.5 percent – for all hospitals. In announcing this proposal, CMS shared its own reservations, writing that

> We are concerned that the result of this methodology could have negative impacts that would fall predominantly on rural hospitals and are interested in public comment on alternative methodologies. While we are not proposing to change the methodology for calculating the labor-related share in this proposed rule, we have begun the research necessary to reevaluate the current assumptions used in determining this share. This reevaluation is consistent with the MedPAC recommendation in MedPAC's June 2001 report. (*Federal Register*, Vol.67, No. 90, May 9, 2002, p. 31447)

MEDPAC

The hospital industry clearly shared CMS's concern over this methodology – so much so that CMS chose not to implement the change in labor-related share that it had proposed, writing three months later that

LABOR S/N

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www.nauh.org

> We have decided not to proceed with reestimating the labor-related share at this time. We will conduct further analysis to determine the most appropriate methodology before proceeding. (*Federal Register*, Vol. 67, No. 148, August 1, 2002, p. 50042)

While CMS was performing this analysis, however, Congress intervened and put part of this issue to rest, enacting legislation that set the labor-related share at 62 percent – but just for hospitals with a wage index of 1.0 or less. This new policy amounted to protection for most rural hospitals from future CMS policy-making efforts.

In proposing to reduce the labor-related share for FY 2006 – but significantly, only for hospitals with a Medicare wage index greater than 1.0 – CMS has chosen to employ the same methodology that the agency itself rejected just three years earlier. Since that time, there has been no public explanation about why a methodology rejected three years ago is now considered valid. It also is unclear why CMS rejected its own methodology three years ago because it did not like the projected outcome for one group of hospitals yet embraces that same methodology today even though the expected outcomes are just as potentially damaging for another group of hospitals.

The Proposed Policy is Redistributive, Without a Rationale, and Premature

By reducing the labor-related share for hospitals with a wage index greater than 1.0, CMS would reduce its anticipated overall Medicare inpatient PPS expenditures. Then, to make this policy revenue-neutral, it proposes redistributing this money by increasing the standardized amount for all hospitals – both those with wage indexes of 1.0 or less and those with wage indexes greater than 1.0. Hospitals with wage indexes greater than 1.0 therefore would lose some revenue on one hand and then regain some on the other. While a few hospitals with wage indexes fairly close to 1.0 might theoretically benefit, on balance, from these two changes, the vast majority of hospitals with a wage index greater than 1.0 – that is, urban hospitals – will end up losing money if this proposal is implemented.

The same policy, on the other hand, will result in a financial windfall for *all* hospitals with a wage index of 1.0 or less – including most rural hospitals. They will be the beneficiaries of a redistributive policy that takes money away from some hospitals and gives it to others. To date, however, there has been no explanation regarding what wrong is being righted by redistributing this Medicare money and no rationale offered for why this redistribution must come at the expense of the particular hospitals – that is, urban hospitals – from which it would be taken.

With rural hospitals already receiving more generous reimbursement through a labor-related share of 62 percent, the National Association of Urban Hospitals also wonders why, if CMS believes 69.7 percent is the correct figure for labor-related share, the agency would propose a policy that would give rural hospitals even more than the overly generous labor-related share CMS believes they already receive. Why, we wonder, has CMS chosen to increase reimbursement to hospitals that the agency's own methodology suggests are already overpaid?

Even if needed – and it should be noted that no such need has ever been articulated or established – any attempt to redistribute Medicare funds for the benefit of rural hospitals, especially at the expense of urban hospitals, is clearly without justification and premature. Rural hospitals are just starting to reap the considerable benefits of additional Medicare payments directed their way through the Medicare Modernization Act of 2003. These enhanced revenues are so new that there has been no time to analyze their financial impact or to determine if they are having the effect that Congress envisioned when it bestowed these new benefits on rural hospitals. Consequently, it is highly premature to direct still more resources to these same rural hospitals before even determining if the benefits from the Medicare Modernization Act have

fulfilled their objectives. Taking money away from urban hospitals by reducing their labor-related share at this time would do precisely that. Absent such analysis, this redistributive policy is, at the least, premature, and at the most, punitive against a group of hospitals – urban hospitals – for which no policy basis has been articulated for a need for such punitive policies.

The Timing of the Proposed Policy is Ill-Advised

The National Association of Urban Hospitals believes that the timing of CMS's attempt to adjust the labor-related share is ill-advised. The agency is under no mandate to make such a change: neither Congress nor MedPAC has indicated any concern about the labor-related share of the hospitals whose labor-related share remains under CMS jurisdiction. In addition, no studies have indicated a pressing need to address this issue.

On the other hand, CMS itself announced just three years ago that it lacked confidence in the efficacy of its own methodology for calculating labor-related share. CMS's continued research into this issue and its continued solicitation of additional data for this purpose suggests that this research is as yet incomplete, and until it is, the National Association of Urban Hospitals believes that the agency should not attempt to adjust the labor-related share of the hospitals over which it retains such authority. If, on the other hand, CMS insists that it now had confidence in this methodology, we believe it also must acknowledge that its decision of three years ago not to raise the labor-related share for urban hospitals resulted in those hospitals being underpaid by Medicare.

The Proposed Policy Reflects a Continued Trend Toward Hurting Urban Hospitals

In general – and there are exceptions – rural hospitals have wage indexes of 1.0 and less and hospitals with wage indexes greater than 1.0 are urban hospitals. The National Association of Urban Hospitals believes that the proposed reduction in the labor-related share for hospitals with wage indexes of greater than 1.0 represents yet another policy that specifically hurts urban hospitals. In recent years, a number of federal policies, some originating with the administration and some with Congress, have been adopted or rejected based primarily on their damaging impact on urban hospitals. Among them are:

1. the aforementioned rejection of an increase in the labor-related share in 2002 that would have helped urban hospitals – a rejection inspired by concern over potential damage to rural hospitals;
2. billions of dollars worth of additional funds lavished, without a policy rationale, on rural hospitals as part of the Medicare Modernization Act of 2003 – and virtually nothing specifically for urban hospitals;
3. a change in federal regulations for FY 2005 governing the reallocation of medical residency slots that clearly was written to steer vacant residency slots away from urban hospitals and toward rural hospitals; and
4. the continued failure of Medicare to meet the statutory threshold of expending at least five percent of Medicare DRG payments on outlier payments – a failure that typically hurts large urban hospitals because those hospitals generally have a greater capacity to deal with critically ill and injured patients than their rural counterparts.

These and other actions all have been taken, moreover, despite clear evidence that urban hospitals – and urban safety-net hospitals, in particular – are in far worse financial condition than rural hospitals. The cumulative effects of years of caring for uninsured, under-insured, and Medicaid patients are taking their toll on urban hospitals: more and more of them are losing money – often, significant amounts of money. In an industry in which a positive operating margin of four percent is considered necessary to operate effectively, a 2003 study

by the National Association of Urban Hospitals found that among hospitals that qualify for Medicare disproportionate share payments – a distinction conferred only on hospitals that care for especially large numbers of low-income patients – the collective financial performance of urban hospitals nation-wide is 25 times worse than that of rural hospitals. Collectively, the operating margins of urban Medicare disproportionate share hospitals in the U.S. is *minus* 5.7 percent – a figure that suggests that without intervention, many of those urban safety-net hospitals may soon be forced to close their doors. That same study found that large urban hospitals that provide at least 15 percent of their services to Medicaid patients have an average operating margin of *negative* 8.52 percent. Organizations with operating margins of negative 8.52 percent – that consistently spend significantly more money than they take in – seldom remain in operation for very long.

At the same time, there have been no credible studies that suggest that rural hospitals are being underpaid by Medicare. Most, in fact, conclude that rural hospitals are adequately reimbursed for the services they provide to Medicare beneficiaries.

The National Association of Urban Hospitals believes that while this proposed policy change would benefit primarily rural hospitals, and would do so primarily at the expense of urban hospitals, there is no possible rationale in the current environment for pursuing such a course of action. If anything, more should be done to benefit urban hospitals, especially urban safety-net hospitals, and not to hurt them as this proposed regulation change clearly would.

Our Recommendation

The National Association of Urban Hospitals urges CMS not to reduce the labor-related share of the Medicare wage index. As currently constituted, this proposal is based on a flawed methodology – and a methodology that CMS itself rejected just three years ago; it is redistributive without a policy basis for the redistribution of Medicare funds; and it targets urban hospitals, and urban hospitals alone, for reimbursement cuts even though there is no conceivable rationale for targeting urban hospitals in this manner.

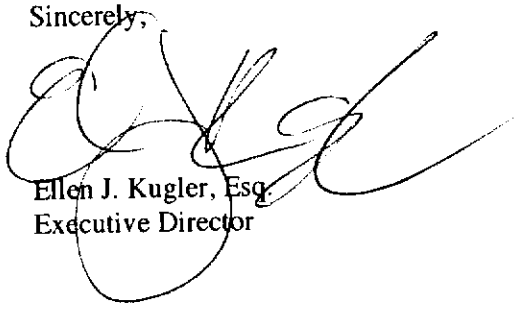
About the National Association of Urban Hospitals

The National Association of Urban Hospitals (NAUH) advocates for adequate recognition and financing of private, non-profit, urban safety-net hospitals that serve America's needy urban communities. These private, urban safety-net hospitals differ from other hospitals in a number of key ways: they serve communities whose residents are much older and poorer; they are far more reliant on Medicare and Medicaid for revenue; they provide far more uncompensated care; and unlike public safety-net hospitals, they have no statutory entitlement to local or state funds to underwrite their costs. NAUH's role is to ensure that when federal officials make policy decisions, they understand the implications of those decisions for these distinctive private, urban safety-net hospitals. NAUH pursues its mission through a combination of vigorous, informed advocacy, data-driven positions, and an energetic membership with a clear stake in the outcome of public policy debates.

* * *

We appreciate your attention to the concerns we have expressed about the proposed change in the Medicare inpatient PPS regulation governing the labor-related share of Medicare wage index payments and welcome any questions you have about our organization, this issue, or our rationale for the position we have stated in this letter.

Sincerely,



Ellen J. Kugler, Esq.
Executive Director

DSH – SMITH
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GEO RECLASS – KENLY
CBSAs
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IMPACT – KRAEMER
+
ANALYST

LABOR S/N – KNIGHT
SEIFERT
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GME/RHRC – TRUONG
LEFKOWITZ
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American Legion Hospital
1305 CROWLEY RAYNE HIGHWAY
CROWLEY, LOUISIANA 70526-9986

(337) 783-3222

June 20, 2005

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

RE: CMS-1500-P: MEDICARE PROGRAM; PROPOSED CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FISCAL YEAR 2006 RATES

COMMENTS RELATE TO FOLLOWING "ISSUE IDENTIFIERS":
- **"REVISED MSAs" (Section III.B.)**
- **"HOSPITAL REDESIGNATIONS" (Section III.H.)**

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services's (CMS's) proposed rule with changes to the hospital inpatient prospective payment system (PPS) and fiscal year 2006 rate published May 4, 2005 in the *Federal Register*. 70 Fed. Reg. 23305 (May 4, 2005). As referenced in Section III.B., FY 2006 will be the second year of the transition period provided in the FY 2005 IPPS final rule (69 Fed. Reg. 48916, August 11, 2004) for the hospitals that were previously classified as urban are now in rural areas, based on the new MSA designations.

I am the Chief Executive Officer of American Legion Hospital in Crowley, Louisiana. American Legion Hospital is a 178-bed hospital, including a 38-bed psychiatric unit, located in Acadia Parish, Louisiana. The Hospital service area includes approximately 65,000 people, and the main campus is located in Crowley, Louisiana. American Legion Hospital relies heavily on Medicare and Medicaid funds. Approximately 83% of the Hospital's inpatients are covered by Medicare or Medicaid. Over 35% of the Hospital's inpatient days are attributable to Medicaid. In 2004, American Legion Hospital treated 17,615 Emergency Room patients, performed 3,493 surgeries, delivered 561 babies, and provided care for 4,156 patients. A $7 million construction project was planned for 2006, which would provide a new, larger Emergency Room and increase the

number of current Operating Rooms from three to five. The project also includes equipment upgrades and new equipment purchases. The Emergency Room expansion is particularly important because the local charity hospital is often on diversion. American Legion Hospital contributes a significant amount to the economic stability of the area. The Hospital employs approximately 470 people with an annual payroll of $12 million, offering wages and related benefits comparable with the Lafayette labor market. Additionally, sales and use taxes of $400,000 dollars are paid to state, parish and local governments each year.

American Legion Hospital is extremely concerned about various aspects of CMS's 2005 and 2006 payment rules relating to the adoption of new geographic classifications regarding Metropolitan Statistical Areas (MSAs). As referenced in Section III.B., FY 2006 will be the second year of the transition period provided in the FY 2005 IPPS final rule for some hospitals that were previously classified as urban are now in rural areas based on new MSA designations. American Legion Hospital is dramatically harmed by the use of these new classifications because Acadia Parish (and thus American Legion Hospital) has been reclassified from urban to rural, causing a reduction in annual Medicare reimbursement of over $2.2 million (representing 7% of our annual revenues and 18% of our Medicare revenues). This reduction in revenues has threatened planned capital projects and may necessitate layoffs and reevaluation of the Hospital's current scope of services is necessary. These cuts could impact both the psychiatric unit and the emergency room, both of which are extremely important to the local community. These reductions may occur despite the fact that Acadia Parish is not any less urban than it was in recent years, and in fact, if anything, has become more urban than in prior years.

The majority of the reduction in revenues is attributable to reductions in the Medicare disproportionate share hospital (DSH) adjustment, which is limited for rural hospitals. One option for American Legion Hospital would normally be to apply for geographic reclassification, and we believe that American Legion Hospital may possibly meet those requirements. However, the proposed rule would prohibit geographic reclassifications that would impact the DSH adjustment, i.e. "standardized amount" reclassifications.

The DSH adjustment provides an incentive for hospitals to provide healthcare services to Medicaid recipients. American Legion Hospital's DSH adjustment percentage is 34.12%, derived from a disproportionate patient percentage combining the percentage of the Hospital's total inpatient days attributable to Medicaid eligible days (39.62%) plus the percentage Medicare Part A inpatient days attributable to SSI recipients (14.81%). As the Hospital has been reclassified as a rural hospital, the DSH adjustment will be limited to a cap of 12%. This reduction from 34.12% to 12% will reduce the Hospital's reimbursement by $1.6 million. (The reduction in the wage index from the Lafayette MSA to the rural statewide average accounts for the remaining portion of the reduction or $600,000.)

In order to address these concerns, which are described in further detail below, we respectfully suggest CMS consider the following to ameliorate the impact that the proposed adoption of the new definitions will have on hospitals such as American Legion Hospital:

Allow Grandfathering from the Old MSA Definitions or Exceptions to the New MSA Definitions

Acadia Parish is adjacent to Lafayette Parish and, until the most recent revision of Geographical Statistical Areas by the Office of Management and Budget (OMB), was included in the Lafayette MSA. Acadia Parish was included in OMB's definition of the Lafayette MSA based on 1990 data. The main reason that Acadia Parish is not included in the Lafayette MSA under the new OMB definitions has to do with commuting levels. In 1990, the lowest acceptable level of commuting to the MSA for qualification was 15% of the potential outlying parish's workers. In 2000, OMB raised the qualifying percentage from 15% to 25%. In 1990, Acadia Parish met the 15% criteria in 1990 with a commuting percentage of 16.3%. However, in 2000, even though Acadia Parish's commuting percentage increased to 23.78%, it does not qualify under the new commuting threshold.

American Legion Hospital is located only 12.2 miles from Lafayette Parish and what OMB now defines as the "new" Lafayette MSA. American Legion Hospital is in direct competition with hospitals in the "new" Lafayette MSA for the healthcare labor market as well as for physicians and patients. Thus, even though Acadia Parish is even more tied to the Lafayette MSA than it was a decade ago, CMS's proposed rule would result in treating the parish (and its hospitals) as if it were more rural.

OMB, in its new standards, established two categories of Core Based Statistical Areas (CBSAs): (1) Metropolitan Statistical Areas and (2) Micropolitan Statistical Areas. According to OMB, Crowley, Louisiana, is a Micropolitan CBSA. However, CMS' rule does not adopt the OMB definition of Micropolitan Statistical Areas for use in the payment system. Rather, Micropolitan Statistical Areas remained part of the statewide rural area for purposes of inpatient prospective payment system payments. Thus, American Legion Hospital in Crowley, Louisiana, was reclassified from part of the Lafayette MSA to the statewide rural area.

It is our opinion that the reclassification of Acadia Parish from urban to rural is unfair, unwarranted and based on insufficient data. During the 2000 census process, OMB included questions regarding commuting patterns only on the "long form" provided to only approximately 1 in every 6 households, per the U. S. Census Bureau. The only reason why Acadia Parish does not qualify as part of the Lafayette MSA is the increase in the required commuting percentage from 15% to 25%. With a commuting percentage of 23.78% (as computed using U.S. Census Bureau, Census 2000 data), Acadia Parish is only 1.22% short of qualifying. OMB notes that the Metropolitan and Micropolitan Statistical Areas are solely for statistical purposes, stating that "***Metropolitan and Micropolitan Statistical Areas are not designated as a general geographic framework for nonstatistical activities or for use in program funding formulas. The CBSA classification does not equate to urban-rural classification ....***" 65 Fed. Reg. 82228, 82236 (Dec. 27, 2000). As such, we believe that CMS should be much more cautious in its use of OMB's standards for payment purposes, particularly when certain hospitals, patients and

communities, such as American Legion Hospital and Crowley, Louisiana, are adversely impacted.

CMS estimated that only nine hospitals are adversely affected by this ruling as a result of capping their DSH payment. Most of the impact on American Legion Hospital is rooted in the impact on our DSH payment adjustment due to our significant Medicaid population, as previously addressed, and we suspect that most other hospitals are as significantly impacted as we are. At the same time, we do not believe that CMS intended for the adoption of the new MSAs to severely harm hospitals such as American Legion Hospital. Therefore, we suggest that CMS consider the following options to ameliorate the harm that adoption of the new MSA definitions would cause:

(a) Allow the nine hospitals that are adversely affected and were moved from an urban to rural area to be grandfathered in to their previously urban MSA; or

(b) Allow an exception for adversely impacted hospitals by CMS's interpretation of OMB's data.

These exceptions should apply to urban classification for both wage index and DSH adjustment purposes. Other policy options are possible. For example, CMS could adopt, as an alternative, OMB's new definitions but allow a 20% commuting threshold instead of a 25% threshold. However, we feel strongly that CMS should adopt a policy interpretation that would not harm hospitals, which would otherwise be adversely affected by the CMS proposed rule. This would result in a fair and equitable recognition of the proper classifications of hospitals.

CMS has already noted elsewhere in the proposed rule that it has **sufficient authority to provide exceptions**. As Section 1886(d)(5)(I)(i) of the Social Security Act notes, the "Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate." *See* 79 Fed. Reg. at 23433.

Thank you for your review and consideration of these comments. If you have any questions, please feel free to contact my office at 337/788-6400.

Sincerely,

AMERICAN LEGION HOSPITAL

Terry W. Osborne
Chief Executive Officer

C The Honorable Mary L. Landrieu, United States Senate
The Honorable David Vitter, United States Senate
The Honorable Charles W. Boustany, Jr., M.D., United States House of Representatives

148

Colorado Rural Health Center

"Enhancing healthcare services in Colorado by providing information, education, linkages, tools & energy toward addressing rural healthcare issues."

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Heflin
Halstein
Collins
Moreau
Smith

June 10, 2005

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

RE: 42 CFR Parts 405,412, 413, 415, 419, 422, and 485
[CMS-1500-P]
RIN 0938-AN57

TO WHOM IT MAY CONCERN:

This letter is in response to the Centers for Medicare & Medicaid Services (CMS)' proposed changes to the Hospital Inpatient Prospective Payment System (IPPS) published in the Federal Register on May 4, 2005.

As Colorado's not-for-profit State Office of Rural Health, the Colorado Rural Health Center ("the Center") provides information, education, linkages, tools and energy toward addressing rural healthcare issues throughout the State. The Center is the recipient of the Medicare Rural Hospital Flexibility (Flex) grant, which has provided funding for the past five years to help implement and sustain Colorado's Critical Access Hospital (CAH) Program. Twenty-five rural facilities in Colorado are currently licensed as CAHs. Nine of those facilities were certified under the State's Necessary Provider criteria. As are all of Colorado's CAHs, these nine facilities are considered necessary providers of healthcare for the communities in which they are located, as well as the surrounding service areas.

Through the Flex and CAH programs, we have been able to develop collaborative systems of care, improve the quality of care provided to rural residents, and expand access to healthcare services in rural communities. Flex program activities involve not only the provision of technical assistance to CAHs, but also involve activities such as outreach, education, and community development that help to strengthen the rural health infrastructure statewide. All CAHs participate equally in these activities, including those that were converted under the Necessary Provider provision.

Prior to converting to CAH licensure, on the average, CAH-eligible hospitals in Colorado were operating with a -13% operating margin. Studies conducted at two years post conversion have revealed an average operating margin of

-8.71%. Although this increase in revenue due to cost based Medicare reimbursement has helped to stabilize rural facilities that might have otherwise closed their doors, it has been gradual, and still does not demonstrate a healthy, positive, operating margin for most facilities. Many of our CAHs continue to struggle with financial challenges, and continue to have difficulty covering expenses, due in part, to the high percentage of Medicare, Medicaid, and uninsured patients in our rural communities.

Prior to CAH licensure, these hospitals had no hope of accessing the capital funding required to build replacement facilities. Many of our CAHs were built prior to 1950 and were funded by the Hill-Burton program. The oldest hospital in Colorado, Heart of the Rockies Regional Medical Center, was built in 1899. These facilities need to be replaced, and the residents in these communities deserve access to the highest quality patient care, and the latest, state of the art technology, in buildings that are comfortable, secure, and meet fire and safety codes.

We believe that the CMS proposed rule, which would prevent Necessary Provider CAHs from building replacement facilities greater than 250 yards away from the current facilitues, unless construction was implemented prior to December 8, 2003, is unreasonable. Even the CAHs in Colorado that converted as early as 1997 are only beginning to experience a gradual turnaround in their financial situations. Very few facilities were in a position to begin construction projects in December 2003.

Two of our Necessary Provider CAHs, Yuma District Hospital and Melissa Memorial Hospital, have conducted needs assessment and financial feasibility studies, and have retained architectural services to design replacement facilities. However, these steps were not taken prior to December 8, 2003. Both hospitals have secured land that is greater than 250 yards from their existing facilities. Once relocated, each hospital will continue to serve the same service area, utiiizing the same staff, and providing the same services. If the proposed CMS rule goes into effect, these hospitals will be unable to complete these projects to replace antiquated, landlocked facilities and provide better care to their communities.

We urge CMS not to place such unreasonable restrictions on major construction projects for Critical Access Hospitals. These facilities are necessary to the survival of our rural communities, and for the health and well-being of the citizens who reside in those communities.

Sincerely,

Denise Denton
Executive Director

Lou Ann Wilroy, Director
Critical Access Hospital Program

149

DRG/GEN — BROOKS
FAGAN
GRUBER
KELLY
HUE
HEFTER
HARTSTEIN

Andrew Ku, M.D.
9531 Parkedge Drive
Allison Park, PA 15101
June 13, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attn: CMS-1500-P
DRG Reclassification: Stroke

Dear Dr. McClellan:

I have reviewed the Center for Medicare and Medicaid Services Proposed Rule for the Hospital Inpatient Prospective Payment Systems and Fiscal-Year 2006 Rates (CMS-1500-P). I applaud the CMS for evaluating the inadequacy of current reimbursement rates to hospitals for the care they provide to ischemic stroke patients

Every year in the United States, about 700,000 individuals suffer a stroke of which 88 percent are ischemic in nature, I believe that the Medicare population may be under treated with reperfusion techniques and may number greater than 2,448 cases that CMS identified in the MedPAR database using ICD-9-CM procedure code 99.10 as the search criteria.

I recommend that CMS take this proposed first step in recognizing the increased hospital costs associated with acute stroke stays by creating a new medical DRG for ischemic stroke patients treated with drug-based therapies, reflecting the real costs to treat these patients. At the same time, CMS should also create a surgical DRG for ischemic stroke patients who are treated with surgical-based interventions, such as mechanical embolectomy and intra-arterial thrombolysis.

As an Interventional Neuroradiologist I appreciate the opportunity to comment on issues related to neurointerventional surgery procedures and practice. I am directly involved in the interventional treatment of stroke and routinely see the effects of stroke when patients arrive too late for treatment. We have an active stroke center, treating patients by all means, including IV thrombolysis, and surgical, catheter-based revascularization.) Our stroke team includes: neurology, neuroradiology, interventional neuroradiology, technologists and nurses. These resources are necessary to adequately treat acutely ill patients and should be reimbursed accordingly. Inadequate reimbursement rates may in

the future limit the availability of reperfusion and IV drug therapy, and of surgical interventions such as mechanical embolectomy or thrombus fragmentation due to financial losses by physicians and hospitals from current reimbursement rates. Some of these therapies reduce the severity of stroke and reduce the economic costs with treatment of stroke in the long term. The reduced social costs of successfully treated stroke are incalculable to the patients and their families.

If I can be of any assistance please do not hesitate to contact me. Thank you for your attention to theis matter of great importance to Medicare patients and for your continuing work.

Sincerely,

Andrew Ku MD

Andrew Ku, M.D.

150

Mary Robinson

DRG/Gen

From: Braxton, Shawn L. (CMS) [Shawn.Braxton@cms.hhs.gov]
Sent: Thursday, June 23, 2005 7:08 AM
To: Mary Robinson
Subject: FW: Medicare coverage for Artificial Disc Prosthesis -Charite

HEFTER
HARTSTEIN
BROOKS
FASAN
Gruber
Kelly
Hud

From: Hartstein, Marc (CMS)
Sent: Friday, June 17, 2005 6:28 PM
To: Braxton, Shawn L. (CMS)
Subject: FW: Medicare coverage for Artificial Disc Prosthesis -Charite

I will consider this as a comment. It should be logged in as a comment unless you have an objection.

From: peresspine peress [mailto:peresspine@msn.com]
Sent: Thursday, June 16, 2005 12:13 AM
To: Hartstein, Marc (CMS)
Subject: Medicare coverage for Artificial Disc Prosthesis -Charite

Mr. Marc Hartstein
Deputy Director of the Division of Acute Care
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Room C4-25-11
Mail Stop C4-03-06
Baltimore, MD 21244-1850
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There are additional factors besides age which must be considered in the decision to provide or deny Medicare coverage for surgery to implant an artificial disc.

1- There are a significant number of young, under 65 patients who are on Medicare as a result of Social Security Disability. This is their only insurance coverage, and by Medicare not covering disc replacement, they would be deprived of a treatment which their working, insured counterparts have access to as a treatment option with great potential of reversing their disability. This inequality is not medically justifiable.

2- Not all patients over 60+ are FEMALE !! Male patients into their 70's unless on steroids, or alcoholics, are generally are not afflicted by osteoporosis. The male Medicare population should not suffer denial simply because they are the same age as their osteoporotic female counterparts.-Again, there is no medical justification for a policy of discrimination resulting in denial equal access which younger male patients with the same indications have.

I have over my 18 years of practice as a spine surgeon on numerous occasions, performed spine surgical procedures on males over 65 years, who lead very active, athletic lives, as well as male and female patients under 65, trapped by their spine condition in a disabled state. Both

of these groups would have, in my opinion, reaped far greater benefits if they had had access to the motion preserving process of lumbar artificial disc replacement.

This disabled, younger group often undergoes more than 2 procedures secondary to the elevated adjacent level stresses associated even with single level fusions. This phenomenon is well documented in the literature in terms of consuming excess healthcare resources.

It is time for spine fusion for disc related pain to take it's rightful place in surgical history alongside knee and hip fusions, and offer the option of an artificial disc replacement to all individuals meeting anatomic criteria, regardless of their age.

It is my hope, and the hope of my Medicare insured patients, who have-patiently awaited the release of the disc prosthesis in the US, enduring pain and disability and emotional and financial hardships, that you will approve coverage, and not discriminate against them further.

I look forward to your reply, and news of a decision to end their suffering and hopefully their disability, as well as the burden to society of the cost of their benefits.

Sincerely,

Richard Peress MD

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701 North Broadway
Sleepy Hollow, NY 10591

914-762-9300