JOHN AND MARY E.
KIRBY HOSPITAL
A Tradition of Caring

1
CAH/Reloc
T2H Herter
Marie Hartstein
Mary Collins
George Mercy
Molley Smith

May 3, 2005

steven.tenhouse@kirbyhospital.org

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

RE: Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Rates
Changes in the Requirements for Critical Access Hospitals

To Whom It May Concern:

I have read the abovementioned proposed rule and wish to make the following comments regarding limitations on rebuilding or relocating a Critical Access Hospital.

If I am reading the proposed rule correctly, Critical Access Hospitals could risk losing their CAH status by relocating to a new location. The theory behind this is that the necessary provider designation is due to sunset. Therefore, a relocation of a Critical Access Hospital would be considered a new provider with no opportunity for a new designation as a Critical Access Hospital.

There are several flaws in this thinking.

- Many small rural hospitals that are currently Critical Access Hospitals are located in residential areas. Kirby Hospital, for example, is located in the middle of a heavy populated residential area. The reason being our original hospital was an old mansion that was converted to a hospital in 1942. That mansion was torn down in 1972 and the existing building was constructed. Over the years, residential areas filled in around us and the access to the hospital is limited because of this. As the residential areas have filled around us, we have become more and more landlocked with no opportunity to expand our services or significantly change the structure of our building to incorporate the new services that we need to develop to serve our community.

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www.kirbyhospital.org

- Forcing a Critical Access Hospital to rebuild onto existing property has a number of issues. The first and foremost being the loss of services while the new hospital is being constructed. If a hospital is to truly rebuild on its existing property and not just remodel or put a fresh face on the old building, the structure would need to be torn down and rebuilt from the ground up. Doing this would terminate services for an indefinite amount of time while the new hospital was being constructed. Few Critical Access Hospitals would have the resources to cover the full construction costs with having no revenue to offset that cost. Taking away that healthcare outreach for our community for an undefined length of time risks our community's health. By allowing the facility to relocate to a different area, the old hospital could continue to function and generate income to help offset the construction costs of the new facility.

Other acute care hospitals have the opportunity to relocate to a better setting. Critical Access Hospitals should also have that opportunity. Many Critical Access Hospitals could build more efficient facilities delivering more efficient healthcare that would save lives and ultimately save money for the Federal Government. I appreciate the opportunity to express my thoughts. If you have any questions, please feel free to contact me at (217) 762-6148. Thanking you in advance, I remain,

Very Truly Yours,

Steven D. Tenhouse, FHFMA
Chief Executive Officer

SDT/pjk

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2-0
(6) CAH/Reloc
Mark Hartsken
Mary Collins
George Mercy
Molle Snack

MEMORIAL COMMUNITY HOSPITAL
313 Stoughton Road, Edgerton, Wisconsin 608-884-3441

MAY 17 2005

May 10, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

Re: Proposed CMS Rule Change Dated 4/25/05 Regarding Replacement of Critical Access Hospital (CAH) Facilities

Please be advised that our entire hospital administration, management and Governing body of Memorial Community Hospital, a critical access hospital in Edgerton, WI, are adamantly opposed to the new rule changes proposed by CMS on April 25, 2005. The new rules as proposed would effectively signal the ultimate demise of our hospital by condemning us to remain on a site, which has been deemed unsuitable for expansion.

We are of the opinion that Congress never intended the Medicare Modernization Act (MMA) to be used as a mechanism to throttle the growth plans and undermine the local control of rural hospitals. As proposed, the new rule would prohibit any CAH operating with a "Necessary Provider Designation" from relocating its hospital unless the move is completed by January 1, 2006. The only exception permitted under the rule would allow a CAH that had construction plans under development as of December 3, 2003. By enacting such a rule with the intent of enforcing it retroactively, you will have succeeded in limiting the replacement of any CAH hospital in the future.

Our present circumstances make it imperative that we challenge these new rules. We occupy a building that varies in age from 35 to 45 years old and does not meet existing Life Safety and ADA standards. Its been estimated that basic repairs and upgrades would cost the hospital over $6 million over the next 4 years, not one dime of which would improve health care. A replacement of the entire facility on-site is estimated to cost more than building a new hospital off-site. At the time the new rules were published, we were active engaged in planning a replacement facility on a site 2 miles from our present location, but still inside the city limits. An option on the land had already been secured and bids had been solicited for a project scope analysis. If allowed to pass, the new rules would stop our relocation plans dead in their tracks forcing the ultimate demise of our facility.

We believe the new rule is an over-reactionary provision to enforce a simple statement in the MMA that would require a replacement CAH "to service the same community and operate essentially the same services with essentially the same staff". This standard if allowed to stand, would set a new precedent treating CAHs differently than other hospitals. We find it totally incredulous that CMS would write a rule that a legitimate plan by a locally controlled board to build a new hospital to address safety and environmental concerns that does not conform with the rule, will be deemed to "constitute a cessation of business and loss of provider number". There is no precedent in law to support such a rule.

If this rule change is allowed to stand, what will the next phase of regulations include? Will CMS later expand the rule to include major renovations to an existing facility, new equipment purchases, and acquisitions of provider-based clinics? We are deeply concerned about the extent of these rule changes and the unbridled expansion of powers of an already powerful bureaucratic organization that may or may not conform with the intent of Congress.

We respectfully request that the proposed rules be rescinded as written and appropriate provisions be allowed for CAHs like Memorial Community Hospital with "Necessary Provider Designation" status to replace their aging facilities. The loss of our hospital in this community will result in a major economic recession and force its residents to drive long distances for essential medical care.

Respectfully submitted,

Administrative Staff of Memorial Community Hospital

Ron Wolff, CEO

Charles H. Roeder, CFO

Char Foat, CNE

Brad Young, HR Director

Marilynn Perry, NHA

Lon Becher, Director HH

cc: Senator Herbert Kohl
Senator Russ Feingold
Representative Tammy Baldwin
Representative Paul Ryan
MCH Board of Trustees
Tim Size, RWHC
Steve Brenton, WHA

3-0 (34)
- CAH/Rural
Levi
Nora
Mary Collins
Olympia Snowe
Molly Smith

Stoughton Hospital
Trusted Care...Close to Home

May 9, 2005

MAY 17 2005

Centers for Medicare & Medicaid Services
Dept. of Health & Human Services
PO Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

For your information and record, we oppose the CMS Construction Ban on Critical Access Hospitals because:

1. This Proposed Regulation transfers to the Federal Government 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 Critical Access Hospitals designated as Necessary Providers be perpetually prohibited from replacing or relocating their facility, facilities that are often 40 to 50 years old.

3. This Ban on all construction developed after December 8, 2003 is an over reaction against potential problems that will be appropriated managed by CMS's proposed rule requiring 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."

4. 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 Critical Access Hospital can be treated differently. There is no basis in law that the relocation within a community of a Critical Access Hospital with Necessary Provider status constitutes a cessation of business and loss of its provider number. It is a longstanding policy that the provider number describes the legal entity and services provided not the physical structure or location.

5. Ironically, CMS proposed to ban a local community's ability to rebuild on an adjacent or nearby location will cost Medicare more, not less – the higher labor costs of operating in a retrofitted building more than offsetting the slightly higher cost of rebuilding versus renovating.

6. CMS is retroactively applying 2000 Life Safety Code to older hospital buildings which in some cases may result in decision to construct new hospital facilities vs. remodel aging, less efficient and obsolete buildings.

Sincerely,

Terry Brenny

Terry Brenny
President/CEO

900 Ridge Street • Stoughton WI 53589 • 608-873-6611 • www.stoughtonhospital.com

4

MAY 17 2005

CAH/Relocation
Trish Heller
Nan - Hartstein
Mary Collins
George Morley
Molley Smith

Barton County Memorial Hospital

Second and Gulf Street, Lamar, MO 64759
417-9/5-9081 – 417-682-2138 (fax)
"Birthplace of President Harry S. Truman"

May 3, 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: **Critical Access Hospitals / CMS-1500-P**

Dear Sirs:

I am writing in regards to the proposed rule changes to the Medicare hospital inpatient prospective payment system for operating and capital-related costs, specifically those proposed rule changes related to Critical Access Hospitals (CAH).

While it is imperative for MedPAC to understand the current status of the CAH program in order to evaluate policy issues, we are concerned that the Commission staff does not truly understand the value of a CAH to the community it serves and the physical condition of most CAHs.

It is true that conversion to CAH status has assisted rural hospitals in making improvements to their facilities, purchase new technology, attract and retain physicians that otherwise would not practice in rural communities, and provide much needed pay increases to hospital staff. Further, CAHs have added services that have been identified as meeting community need, or to improve quality of care, according to the March 2005 report by the Office of Rural Health Policy (ORHP) Medicare Rural Hospital Flexibility Program Monitoring Team Briefing paper number five.

On the other hand, it is extremely important to remember that previous inadequate Medicare reimbursement that was substantially less than costs, has created a situation where many facilities that were constructed 50 or more years ago were not able to properly maintain their plant. Even with the transition to cost-based reimbursement, most rural hospitals have yet to address their building and technology needs because of the need to establish a more favorable cash position prior to taking on new debt. In addition, the

shift from primarily an inpatient facility to an outpatient facility has created a need to address the physical limitation of most rural hospitals. It should also be pointed out that while many rural facilities were originally built at the edge of their community, they are now land-locked as the community has grown and surrounded the community hospitals. Please note that in addition to the above situations that we find our hospital facing, the average age of plant for Barton County Memorial Hospital is 14.12 years while the national average for CAH hospitals is 10.09. Consequently, consideration for a new facility is of high importance for our Board and our community.

The specific proposed rule change that would require a demonstration that construction plans were "under development" prior to December 8, 2003 is extremely impractical and will eliminate all possibilities for the construction of a new hospital that will be more efficient, customer friendly, operationally economical, and that will enable us to continue to provide high quality medical services to the rural community we serve. Without CAH status, our hospital will not be able to survive. In addition to the loss of medical care to an entire county, the economic loss to the community would be tremendous.

I ask that you re-consider the entire proposed rule change for hospitals considering relocating to another location within the same community and offering the same services. The requirement of having specific plans for a specific site prior to December 8, 2003 would eliminate the ability for many hospitals to build new and improved facilities or lose their Critical Access Hospital status. Both scenarios would result in either losing or greatly decreasing the health care for the community.

I thank you for your considerations.

* * * * * * * * *

However beautiful the strategy, you should occasionally look at the results.
Sir Winston Churchill 1874-1965, English statesman

Sincerely,

Rudy Snedigar

Rudy Snedigar, CEO

Cc: Senator Christopher Bond
Senator Jim Talent
Congressman Ike Skelton

YELLOWSTONE NEUROSURGICAL ASSOCIATES, P.C.

5

MAY 17 2005 NT

May 6, 2005

Tx. Heffley
Tx. Hartstein
Mike Trostel
Meredith Walz

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

Issue Identifier: New Technology Applications

Dear Sir or Madam:

On behalf of the Northern Rockies Regional Pain Management Center, Yellowstone Neurosurgical Associates, and my patients, I appreciate the opportunity to submit comments on the proposed rule (CMS-1500-P) for the 2006 Inpatient Prospective Payment System. I am writing specifically to request that CMS grant the new technology add-on payment request for rechargeable implantable neurostimulators.

The FDA recently approved rechargeable implantable neurostimulators by three manufacturers that would qualify as technologies that are substantially similar. Advanced Bionics Corporation received FDA approval in April of 2004 and began commercial distribution in June of 2004 of its Precision™ Rechargeable Spinal Cord Stimulation (SCS) system. This was followed by the Advanced Neuromodulation Systems (ANS) Genesis® unit in December 2004 and the EON™ system from ANS in March 2005. Medtronic received approval for their Restore™ system in April 2005.

These new systems are substantially different than previous SCS systems. This new generation of stimulators has fully implantable generators as opposed to Radiofrequency units which require external transmitting devices. These fully implantable and rechargeable units have lifetimes projected to seven to ten years as opposed to the 18 months to three year cycle for battery powered units. This will result in substantial cost savings to Medicare by avoiding the frequent surgical procedures required to replace a depleted battery. This will also decrease the risk of infection that exists with each battery replacement and is associated with a marked increase in cost to treat and morbidity for the patient. The newer rechargeable units utilize an advanced method of programming both intraoperatively and through the clinic. The patient can now take control of optimizing their therapy without the intervention of nurse or physician. Using current

Yellowstone Medical Center East 2900 12th Avenue North Suite 501 Billings, Montana 59101
FAX 406-238-6660 406-238-6650 1-800-648-6274
www.YellowstoneNeurosurg.com

modulation as opposed to the voltage modulation of older systems the patient obtains a more acceptable feeling of stimulation and less variability through movement.

Given the advances in the technology, a substantial clinical improvement over prior technology has been noticeable. The ability of the patient to enter into their therapy by individually programming the system has been one of the reasons for improved outcomes. This has not been available with prior systems. Medicare beneficiaries often have difficulty with advanced technology. The newer programming systems no longer require any knowledge of how the system works but only the ability to report what relieves pain and what does not. The newer waveform of the current modulated systems has also been described as more tolerable or pleasant, thus making the system more usable especially in an older Medicare age range.

I strongly support approval by CMS of the new technology add-on payment request for rechargeable implantable neurostimulators. Approval of this request will enable my facility to offer this treatment option and thereby provide the substantial benefit of rechargeable technology for my Medicare patients.

I appreciate the Agency's recognition of the importance of access to new technology for Medicare beneficiaries and hope that you will carefully consider the enclosed comments. Please feel free to contact me at 406-238-6650, or joshir @aol.com, should you have any questions or need additional information.

Sincerely,

John C. Oakley, MD
Director, Northern Rockies Regional Pain Center
2900 12th N
Billings, Montana 59101

RICHARD P. CAMBRIA, M.D.
Professor of Surgery

Chief, Division of Vascular and
Endovascular Surgery
Massachusetts General Hospital
15 Parkman Street WAC 458
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MAY 17 2005

NT

April 29, 2005

Attention: CMS-1500-P
P. O. Box 8011
Baltimore, MD 21244-1850

T. Heffer
M. Hartstein
Mike Treitel
Meredith Walz

RE: New Tec status for endovascular grafting of thoracic aorta

Dear Sir(s):

I write in follow-up of a presentation I gave before CMS on March 31, 2005, referable to new coding status for stent graft repair of the thoracic aorta. We have extensive experience and parallel academic publication in the field of treating thoracic and thoracoabdominal aneurysm disease. There has been tremendous progress in bringing surgical repair of these extensive and complex aneurysms to a level of sophistication, where most patients afflicted with this life-threatening disease can be brought through surgical repair. However the investment in recovery from major surgery is a constant accompaniment of such surgical treatment. It is logical to use the parallel with the evolution of stent graft repair of abdominal aortic aneurysms. This technology is now well established, and in our current practice at the Massachusetts General Hospital over 50% of abdominal aortic aneurysms are repaired with stent graft technology. Furthermore, there is now level 1 clinical evidence that stent graft repair in the abdominal aorta is accompanied by significantly less morbidity and mortality of treatment compared to open surgery. There is no reason to expect that this eventually well documented advantage for stent graft technology will also hold true for treatment of aneurysms of the thoracic aorta. Furthermore, there is a vast differential in the morbidity and mortality of open surgical repair when one considers the thoracic as opposed to the abdominal aorta. In fact, open surgical repair of aneurysms of the thoracic aorta is always a major surgical undertaking and even in centers of excellence, the risk of either mortality or paraplegia complicating surgery runs up to the 10% range.

Finally, these open operations are so extensive that patients with significant comorbidities or elderly, frail patients cannot be offered treatment even for life-threatening aneurysms.

Over the past 6-8 years multiple clinical series report experience with stent graft repair in the thoracic aorta. We published experience without our initial 30 patients some years ago demonstrating a clear benefit for this technology. There have subsequently appeared multicenter publications from both Europe and initial pivotal trial sponsored by the WL Gore Company and recently presented before the FDA. These cumulative data clearly show the benefit - even advantage - of stent graft repair for thoracic aortic aneurysms. Indeed, in the WL Gore Pivotal Trial, there was a significant reduction in both operative mortality and spinal cord ischemic complications in the stent graft treated patients when compared to open surgical controls.

Speaking from the perspective of extensive experience in central aortic surgery, I can unequivocally state that stent graft repair of the thoracic aorta is the single greatest advance in the treatment of this pathology in our lifetime. The WL Gore Incorporated thoracic aortic stent graft will provide a valuable - if not preferred - treatment option for many patients with thoracic aortic aneurysms. There is no doubt that the technology should receive favorable review from all of our regulatory agencies since it has great promise to save lives and minimize the pain, resource consumption, and risks of conventional open surgery, and ultimately decrease the cost of treatment of aneurysms involving the thoracic aorta.

With every best wish.

Sincerely,

Richard P. Cambria, M.D.

RPC/asi 04-00966235-1.doc

MAY 17 2005

LSU Health Sciences Center
HEALTH CARE SERVICES DIVISION
Medical Center of Louisiana at New Orleans

Dr. Walter O. Moss Regional Medical Center
Earl K. Long Medical Center
Huey P. Long Medical Center
Lallie Kemp Regional Medical Center
Leonard J. Chabert Medical Center
Medical Center of Louisiana at New Orleans
University Medical Center in Lafayette
Washington - St. Tammany Regional Medical Center

Date: May 4, 2005

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

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

Dear CMS:

I am writing in support of restoring funding for second-year specialized pharmacy residency programs. I am a currently a Clinical Coordinator for the Medical center of Louisiana, and an adjunct instructor for University of Louisiana at Monroe, School of Pharmacy, College of Health Sciences, Tulane University School of Medicine, Department of Medicine, and Xavier Univeristy of Louisiana College of Pharmacy. My current position entails supervision of the pharmacy practice residents, faculty, investigational drug services, clinical staff pharmacists and management of the Formulary for a large teaching hospital and indigent care pharmacy. My practice specialty area is critical care and pharmacokinetics at the Medical Center of Louisiana at New Orleans. I also participate in the LSU-HSC Internal Medicine residency program and serve on various committees within the the colleges and institution. I am also a member of numerous standing commitees at Medical Center of Louisiana at New Orleans including: Instutional Review Board, Pharmacy & Therapeutics Committee; and Cancer Care, Pediatrics, Medical Records, Disease Management and Access to Care, Neuroscience, Surgical & Surgical Intensive Care Process Improvement Committees.

The purpose of my letter is to specifically address funding for 2nd year or specialty pharmacy residencies because these residencies are costly and difficult to fund without outside funding. I currently precept residents in our general practice residency and we have met numerous funding barriers when attempting to establish a critical care & emergency residency program. This area and that of anitmicrobial and antifungal drug use, hemopoeitic stimulating factors and cancer chemotherapy need to be addressed. Cost have risen rapidly in these areas, and speciality trained pharmacists are in short supply. There is such a great need and so few qualified practitioners available. I strongly urge CMS to restore funding for these valuable programs. Thank you for allowing me to express my views and please do not hestitate to contact me if I can be of further assistance.

Sincerely yours,

Helen M Calmes, PharmD, MBA
Clinical Pharmacy Manager
MCLNO
1532 Tulane Avenue
New Orleans, Louisiana 70112

NUS/AH/Pharm
CMS/ERP

MAY 17 2005

May 5, 2005

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

T. Hefl
M. Hu
E. Tr
M. Le
E. Lu

THE UNIVERSITY OF
TOLEDO
College of Pharmacy

Mail Stop #608
Toledo, Ohio 43606-3390
419.530.1904 Phone
www.utoledo.edu

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

Dear Sir or Madam:

Thank you for allowing me to write to you regarding the proposed rule for 2006 payment rates for the Hospital Inpatient Prospective Payment Systems (HIPPS). First, please allow me to express my gratitude for CMS' willingness to support post-doctoral training in pharmacy, specifically in the form of post-graduate year 1 (PGY1) pharmacy practice residencies. I applaud the Center's decision nearly 2 years ago to continue providing financial reimbursement for the provision of care to Medicare and Medicaid patients by pharmacy residents. Without this assistance, many programs would not have been able to continue, and many patients would have lost the valuable services of well-trained clinical pharmacists.

I am, however, deeply concerned that funding for specialized residency training remains unsecured. As pharmacists have expanded services beyond dispensing a product (medication) to becoming a health-care provider, post-doctoral training has become a necessity; training that is focused, rigorous, and extensive. CMS has already recognized the importance of medication therapy management, as this is now part of the new Medicare drug benefit. While it is true not all pharmacists currently are required to complete residency training, it would be both errant and short-sighted to infer that residency training is simply an extra rung on the pharmacy career ladder, or to assume that residency training will never be mandated. The fact that residency training is not a requirement of all pharmacy graduates is, to a great extent, a reflection of the relative youth of clinical pharmacy. Although residency accreditation standards and employment standards have not yet been uniformly adopted throughout the profession, that day is on the very near horizon.

As an individual who completed a specialized residency in critical care and emergency medicine at Detroit Receiving Hospital, one of the premier critical care/trauma medical centers in the country, I can testify to the value of a specialized residency program. Not only was this training essential for my first career position, working with the Trauma and Critical Care Service at a Level I Trauma Center, but it was also invaluable in my preparation for a career in academia. Residency training provided me with specialized skills in patient care, teaching, and research, and instilled in me qualities and values unmatched by any other learning experience; among others, professionalism, dedication to patient advocacy, a strong work ethic, and an appreciation for role of pharmacy, health-care education, and research in our society. These attributes can *not* be acquired through routine academic programs. These attributes can *not* be acquired through "on-the-job-training". Finally, these attributes necessary for specialized settings can *not* be acquired through one year of general post-graduate training.

Imagine the following scenario: You are involved in a horrible motor vehicle collision and are admitted to the nearest trauma center with multiple life-threatening injuries.

Over the course of the next few days, you are placed on a dozen or more medications – medications used only in critically ill patients; medication therapy which becomes extremely complex in such a complicated patient. On rounds, the trauma surgeon asks the pharmacist's assistance regarding your antibiotic therapy and cardiac medications, as you (the patient) are now going into septic shock. Would you want that pharmacist, who is about to make a crucial decision regarding your care, to be someone with only one year of general training who may have never even seen a trauma ICU patient? Or would you want that pharmacist to be someone who has completed an entire year of training in critical care pharmacy, and knows how to make difficult decisions under intense pressure?

The above "pretend" story is not at all "pretend" for the patients my specialty resident and I see every day in intensive care units. Although we have a small and relatively new program, we have been able to demonstrate a significant impact on patient outcomes, cost-effectiveness of drug utilization, education of physicians, residents and other healthcare professionals, and many other important areas within healthcare. A substantial proportion of the patients our residents care for every day are Medicare or Medicaid patients. Without support from sources such as CMS, our program will not be able to continue in its current capacity, and may disappear completely.

It is with the best interest in mind of our patients, as well as our students, residents, and future practitioners, all practitioners who benefit from the contributions of pharmacy residency programs, I most respectfully request that CMS restore funding for specialized residency programs.

Thank you again for your consideration on this very important matter. I very much appreciate your time.

My best,

Martin J. Ohlinger, PharmD
Assistant Professor of Pharmacy Practice
Residency Program Director, Critical Care
University of Toledo College of Pharmacy
Wolfe Hall Suite 1246
2801 W. Bancroft St.
Toledo, OH 43606

9-0
(6)

GMHFKP
Nurs/AH/Pharm
T. Hefter
M. Hartstein
E. Trulis
M. Lefkowitz
- E. Ruiz

Memorial Hospital

May 4, 2005

MAY 17 2005

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

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

Dear CMS:

I am the Pharmacy Clinical Coordinator and Residency Program Director at Memorial Hospital in Colorado Springs, a 477-bed community hospital, and I am writing about my concern for the recent decision that the Centers for Medicare & Medicaid Services (CMS) has made to NOT support second-year, specialized pharmacy residency programs. It was recently announced that you would no longer support payment rates for the Hospital Inpatient Prospective Payment System (HIPPS).

As a Residency Director I oversee the post-graduate education of our one-year residents. This experience provides the individual with invaluable experience that would otherwise be accomplished with three to five years of on the job experience. The second year training is to further train our pharmacists in specialty areas such as pediatrics, oncology, critical care, or primary care. Here at Memorial Hospital we request that our new hires have this level of expertise to better serve our patients.

This expertise is particularly important when the pharmacy community is preparing to implement medication therapy management programs as part of the Medicare drug benefit. Failure to restore funding will limit Medicare beneficiaries' access to the expertise of clinical pharmacy specialist and will lead to increased Medicare spending for health care.

This cutback will effect many programs here in the state of Colorado. The University of Colorado Health Sciences Center has three second-year, specialized residency programs in the area of Primary Care, Critical Care and Oncology that will directly effected by this cutback.

The 32,000 member American Society of Healthsystem Pharmacists (ASHP) has worked tirelessly for two years to restore this funding, and CMS blatantly disregarded ASHP's request. I hope that CMS will reconsider this decision.

CMS spends over $8 Billion in educational programs. This program costs less less than $8 Million. In the big picture, this is a very small cost for a very large benefit.

Thank you for your consideration,

Paula Moyers, PharmD, BCPS
Pharmacy Clinical Coordinator and Residency Program Director
719-365-1109
paula.moyers@memhospcs.org

ID-O (3)

MAY 17 2005

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

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

Dear CMS:

My name is Orly Anconina. I am a 4th – year pharmacy student at Nova Southeastern University's College of Pharmacy, who has worked in both hospital and community pharmacy practice settings. I intend to enhance my ability to help my patients with a residency after graduation, in less than a year.

As a student pharmacist, under the supervision of pharmacists, I have already been able to help innumerable Medicare patients with their medication questions and concerns, and in this capacity have even averted potential medication mishaps, that may have resulted in costly hospitalizations and ER admissions. As an intern at a state psychiatric hospital, where I was supervised by clinical pharmacists, I have had the chance to review patient charts and make suggestions to physicians on how to improve the patients' medication regimens, many of whom are Medicare beneficiaries. I believe these experiences, as well as the rotations I will be participating in this year, will give me the opportunity to prepare for my residency, so that I can help patients like this for my career. Cutting funding to residencies will impair my ability to become a clinical pharmacist, and in turn to help so many more of these patients in the future.

As you are aware, pharmacists are preparing to implement medication therapy management programs as part of the new Medicare drug benefit. If funding is not restored to these residency programs, beneficiaries will lose access to the valuable services of a clinical pharmacist, who needs residency training first. Many studies have shown, and continue to show, that patients who work with clinical pharmacists have better outcomes, and as a result, cost less money to the healthcare system. This funding for residencies is an investment that has the potential to save a lot of money for the healthcare system.

In the community pharmacy setting, I have helped Medicare beneficiaries with things like showing them how to use their albuterol inhalers correctly, making them aware of drug and food interactions that can affect the efficacy of their therapy, and making sure that they (or their caretakers) understand how and when to take their medication(s) properly. One common thing that I educate all of my patients about, including Medicare beneficiaries over 65, is the impact of minerals on the absorption of fluoroquinolones. It is known that taking any type of mineral, including calcium and iron, at the same time as a fluoroquinolone drug, will significantly decrease the absorption (and thus efficacy) of this class of antibiotics. Without this type of counseling, many of these patients would take their fluoroquinolone medication incorrectly, and could potentially end up in the hospital, with much more serious infections. In addition, these patients would then risk

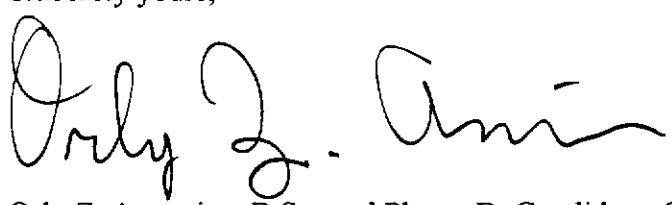
exposure to nosocomial pathogens, which are harder to treat and could result in an increased duration of hospitalization.

However, in the community setting, my time is limited; as a clinical pharmacist, I will be able to dedicate these skills to helping patients full-time. But I cannot do it without the help of funding for the residency programs that will teach me even more about how to help them.

I recently learned that ASHP submitted survey data to CMS in 2004 and 2005 to show that most hospitals require or prefer to employ clinical pharmacy specialists who have completed second-year specialty residency programs. If I cannot get into a residency program due to insufficient funding, this will hurt my chances of becoming a clinical pharmacist, and will decrease the time I will have to review patients' medication regimens and counsel them. Medicare patients over 65 tend to take a wide variety of medications today, and regular medication reviews by a clinical pharmacist are critical to their continued health and well-being.

I urge you to restore funding to residency programs, and to make an investment in tomorrow's clinical pharmacists, who will benefit Medicare recipients even as residents. I thank you for taking the time to read this letter.

Sincerely yours,



Orly Z. Anconina, B.S., and Pharm.D. Candidate, Class of 2006

MAY 24 2005 (9) 11-0

Cooper
University Hospital

Structural Heart Disease Program

Zoltan Turi, M.D.
Professor of Medicine
Director, Cooper Structural Heart Disease Program

Administrative Office:
One Cooper Plaza
Camden, NJ 08103-1489
phone: (856) 342-3488
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turi-zoltan@cooperhealth.edu

UMDNJ ROBERT WOOD JOHNSON MEDICAL SCHOOL

A core affiliate and principal hospital of University of Medicine & Dentistry of New Jersey/Robert Wood Johnson Medical School

JRafan.

Mady Hue

May 12, 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

Gentlemen:

I would like to offer my comments on the current DRG classification for an ICD-9-CM code that was listed in the CMS-1500-P (Inpatient Proposed Rule). The ICD-9-CM procedure code is: 37.90, "Insertion of Left Atrial Appendage Device" and the DRG classification is 518, "Percutaneous Cardiovascular Procedures without Acute Myocardial Infarction without Coronary Artery Stent Implant." As one of the investigators for the IDE clinical trial for the Left Atrial Appendage System I believe the proposed DRG classification is not appropriate because it does not cover the costs for the procedure and the device.

In 1995, CMS expanded the Medicare coverage policy to include certain investigational devices (Category B Devices) undergoing IDE approved clinical trials. The Left Atrial Appendage System has been granted a Category B designation by the FDA. It is my understanding that CMS may reimburse for both the procedure and the device under a Category B designation. The Left Atrial Appendage Device is designed to prevent the migration of clot that may form in the appendage of patients with non-valvular atrial fibrillation to prevent the occurrence of ischemic stroke and systemic thromboembolism. This procedure is a less invasive approach to surgically ligating the left atrial appendage via an open heart procedure which is the only option we have to eliminate the left atrial appendage as a source of clot causing ischemic strokes in these patients.

From the facility in which I practice, the consumption of resources between these two procedures is similar because of the cost of the device. Since this new procedure is minimally invasive, my patients should have shorter recovery time with the potential of fewer, more costly complications.

My practice includes a number of Medicare aged patients that are at an increased risk of atrial fibrillation related stroke and may benefit from having this technology. I would like to have this technology available to my Medicare patient population during the clinical trial. I respectively request you reconsider the DRG placement for ICD-9-CM code 37.90 into a DRG that includes similar procedures like the surgical ligation that more adequately reflects the consumption of resources.

Sincerely,

Zoltan G. Turi, M.D.
Professor of Medicine
Director, Cooper Vascular Center

12

May 16, 2005

MAY 2 4 2005
CAH/ReLoc
Tzvi Hefter
Mark Hartstein
Mary Collins
George Morey
Molley Smith

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

To Whom It May Concern:

I am writing to express my concern about the proposed ruling that would not allow Critical Access Hospitals (CAH) to build new facilities that are with in the 35-mile rule and still maintain their CAH status.

I am Chairman of the East Phillips County Hospital District in Holyoke, CO. We have a facility that is over 40 years old and suffers from a sever lack of space for specialty doctors, laboratory services, and clinic space for our providers. The last 16 months we have spent considerable money to look into the most feasible way to expand our facility to give us the room that we need to provide quality services for our patients.

Realistically the best option we have is to build a new facility with in our city limits (a community of 2200), but due to the uncertainty of this ruling we are on hold at the point. Our existing facility in addition to being old and having an antiquated heating and cooling systems is poorly designed for today's healthcare delivery style. If we were to remodel our existing facility we would still not gain the efficiencies that we could with a new facility. We would still have problems with a remodeled facility in that our current facility has been developed on all sides of and we have no room to expand and do not have even close to adequate parking for our employees and patients.

The problems that I have mentioned relate to our community, but I am sure that they are not unique to only Holyoke, CO. This is a proposal that will eventually drive up the cost of health care in Holyoke as well as many other rural areas across the United States. We are hoping that you will be able to allow rural hospitals to be able to replace outdated facilities and give us the opportunity to provided reasonable priced, easily accessible healthcare to our communities.

Thank you for your consideration,

Steve D Young
Chairman of Board
East Phillips County Hospital District

MAY 2 4 2005

13

CAH/Reloc

Tzvi Hefter
Mark Hartstein
Mary Collins
George Mosley

Murray County Hospital & Clinic

~ Health Care Close To Home ~

Equal Opportunity Employer

May 16, 2005

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

Gentlemen:

As the Administrator/CEO of a Critical Access Hospital I want to inform you that your proposed rule of a Construction Ban on Critical Access Hospitals is bad for our hospital and for rural health in our community because:

1) Loss of local control would be detrimental to the future of our community, to our medical care delivery and to the hospital as a whole;
2) I cannot believe that it was anyone's intent to perpetually prohibit a hospital that's been designated as a Necessary Provider from replacing or relocating our facility which is 50+ years old; it's not cost effective to retrofit an old outdated building and try to bring it up to current standards, it's cheaper and more efficient to build a new facility and find another use for the old building.

If we were to build a new facility we would still be servicing the same community, the same consumers; and we would still be operating with essentially the same services and the same staff. We would, in effect, be better able to serve our consumers in a more timely and efficient manner because we would have the necessary equipment where it needs to be, instead of having to make do. Building a new facility would not constitute a cessation of business nor should it require us to lose our provider agreement and number as we would still be the same facility, just in a new building. It's always been my understanding that the Medicare provider agreement describes the legal entity and services provided; not the physical structure or location.

I would ask, no demand, that you delete the arbitrary deadline on Critical Access Hospital replacement or relocation in the Inpatient Prospective Payment System (IPPS) final rule.

Thank you for your attention.

Very truly yours,

RICK NORDAHL, Administrator/CEO

Murray County Hospital ~ 2042 Juniper Avenue ~ Slayton, MN 56172 ~ (507) 836-6111 ~ Fax (507) 836-6700
Murray County Clinic ~ 2040 Juniper Avenue ~ Slayton, MN 56172 ~ (507) 836-6153 ~ Fax (507) 836-8787

University of Michigan
Health System

MAY 2 4 2005

14

DEPARTMENT OF
EMERGENCY MEDICINE
1500 E. Medical Center Drive
Ann Arbor, Michigan 48109-0303
(734) 936-6020
FAX (734) 763-7228

DRG/Gen.

May 16, 2005

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

Heffel
Hartstein
Brown
Fagan
Gruber
Kelly
Mady Hue

To Whom It May Concern:

I am an Assistant Professor in the Department of Emergency Medicine at the University of Michigan and Director of the emergency stroke team. I have been actively involved in acute treatment of stroke patients for over a decade and am writing to ask you to contact CMS in support of the proposed changes to Medicare hospital inpatient reimbursement for advanced stroke treatment in FY 2006.

In Ann Arbor area alone approximately 2,000 patients will suffer an acute ischemic stroke this year. Since 1996, we have partnered with hospitals around Ann Arbor to provide state-of-the-art stroke care in addition to promoting public education on the recognition of the signs and symptoms of acute stroke.

Currently, only treatment with thrombolytic therapy within three hours of symptom onset can reverse the effects of an acute stroke. Treatment of patients results in a greater than 50% increase in the number of patients who return to the community normal. Cost analysis data clearly indicates increasing appropriate treatment results in savings to the health care system by reducing subsequent nursing home and medical costs.

Unfortunately, current reimbursement strategies under CMS act as a disincentive to increasing stroke treatment. Hospitals that administer thrombolytic therapies to their patients incur higher costs than those who do not. We have been working with CMS for the past year in support of modest changes to the hospital inpatient reimbursement for advance stroke treatment and believe your assistance is critical to its success. We propose the development of a new DRG for the treatment of stroke patients with thrombolytic therapy.

Hurley Medical Center Division
One Hurley Plaza
Flint, Michigan 48503
(810) 257-9824
Fax (810) 760-0853

Foote Hospital Division
205 N. East Avenue
Jackson, Michigan 49201
(517) 780-9628
Fax (517) 796-6410

Again, in support of our efforts I would ask that you write CMS requesting their support of these proposed changes to hospital inpatient reimbursement for advanced stroke treatment in FY 2006.

On behalf of Medicare patients throughout our area I appreciate the special attention you have given their needs. If I can provide additional information please feel free to contact me at 734-936-6284 or via e-mail at phillip.scott@umich.edu.

Sincerely,

Phillip A. Scott, MD
Director, Emergency Stroke Team
Assistant Professor
Department of Emergency Medicine

15

MAY 2 4 2005

McGuireWoods LLP
77 West Wacker Drive
Suite 4100
Chicago, IL 60601-1815
Phone: 312.849.8100
Fax: 312.849.3690
www.mcguirewoods.com

Scott Becker
Direct: 312.750.6016

McGUIREWOODS

sbecker@mcguirewoods.com
Direct Fax: 312.920.6135

SPH

Hefter
Hartstein
Dr. Romano

May 20, 2005

VIA U.S. PRIORITY EXPRESS MAIL

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

Re: Specialty Hospitals

Dear Martha:

Upon review of the comments relating to specialty hospitals on page 23447 in the Federal Register, Volume 70, published May 4, 2005, we are compelled to address what we believe are problematic aspects of the commentary. The comments indicate that CMS intends to be more proactive in denying or revoking provider agreements due to the fact that the hospital is not primarily engaged in furnishing services to inpatients. These comments emphasize a very aggressive approach to a problem which the Centers for Medicare and Medicaid Services ("CMS") can and has dealt with effectively. The commentary raises concern with the situation in which a hospital is treated as a hospital for Medicare or reimbursement purposes but serves very few inpatients. CMS has dealt with this situation in practice by terminating the Medicare provider agreements of hospitals that that are certified as hospitals but treat essentially no inpatients. For example, in Arizona, Arizona Surgical Hospital, LLC, a Medicare-certified hospital, treated eleven inpatients out of nearly 4,000 to 5,000 patients over a three year period. There, CMS terminated its Medicare provider agreement on the basis that it did not meet the definition of a hospital. Thus, CMS has already shown that where the grant of a provider agreement is not warranted, it has the ability to handle such a problem.

Moreover, the commentary is problematic for several reasons: (1) it essentially encourages outlawing physician ownership of surgical hospitals and is inconsistent with the Medicare Modernization Act of 2003 ("MMA") and the physician self-referral law (the "Stark Act"); (2) it fails to recognize the shift in the provision of services at substantially all hospitals from primarily inpatient services to primarily outpatient services; (3) it is overly broad and not needed by CMS to achieve its legitimate objectives; (4) it encourages the usurpation of the power of the states; and (5) it advocates an approach that is incompatible with the authority and purpose of CMS.

First, the effect of the commentary will be to essentially outlaw physician ownership of surgical hospitals. This is because of the focus on the phrase "primarily engaged in providing... inpatient services" and the fact that very few hospitals today, physician-owned or otherwise,

provide primarily inpatient services.[1] The emphasis on defining specialty hospitals in this manner would be an aggressive and far-reaching reaction to the issue of physician ownership, an issue which has been and is continuing to be addressed by Congress through direct Congressional action. As you are aware, as part of the MMA, Congress amended the Stark Act and ordered an eighteen month ban on physician billing of Medicare or Medicaid for patients treated at any new specialty hospital in which the doctor has a financial interest. As part of the MMA, Congress asked CMS, along with MedPac, to study the issue and make recommendations to Congress. Instead, the commentary indicates that CMS is apparently attempting to take action on its own instead of following the MMA, i.e., report back to Congress so that Congress can determine how and whether to act. Prior to the amendment, referring physicians were excepted from the Stark Act prohibition on referrals if they had an ownership interest in a "whole hospital." Despite the temporary moratorium on the development of specialty and surgical hospitals and the exclusion of specialty hospitals from the whole hospital exception during that time, Congress specifically chose not to eliminate the whole hospital exception to the Stark Act for physician ownership. In comparison, the commentary intimates that a hospital cannot be licensed as a hospital if it provides more outpatient services than inpatient services, citing to Section 1861(e) of the Social Security Act and 42 C.F.R. 489.53 of the regulations. Under this approach, the commentary, on its face, essentially outlaws ownership by physicians of specialty hospitals because most hospitals (surgical or full service) perform a greater number of outpatient services than inpatient services. This action is in direct contrast to Congressional action taken to this point and overrides clear Congressional intent.

Moreover, the commentary is not consistent with the Stark Act. As mentioned above, the commentary intimates that if a hospital does not engage primarily in the provision of inpatient services, it will not satisfy the Medicare conditions for coverage and will not be eligible for a provider agreement. However, refusing to provide a provider agreement to a hospital that provides more outpatient services than inpatient services is inconsistent with the Stark Act which recognizes that hospitals provide outpatient services and in fact, most hospitals provide more outpatient services than inpatient services. Further, the Stark Act prohibitions apply to referrals by owners. For example, a hospital could still readily comply with the Stark Act as long as it billed the Medicare/Medicaid program solely for referrals made by non-owner physicians.

Second, the use of and focus on the term "primarily" is problematic. Almost all hospitals now provide more outpatient services then ever before and as you are aware, there has been a substantive shift in the venue for treatment in hospitals. Inpatient hospital stays have declined as the development of innovative treatments and therapies has decreased dependence on more invasive procedures. In 1990, less than twenty percent of surgical procedures were performed in the outpatient department of a hospital. By 2001, more than sixty percent were performed in this setting.[2] Today, outpatient services account for the vast majority of the services most hospitals provide, with inpatient services accounting for a smaller percent. In comparison, the Arizona Surgical Hospital, LLC treated only eleven inpatients compared to over 4,000

[1] The decline in occupancy in many hospitals is primarily attributable to the increasing prevalence of outpatient surgical procedures and reductions in length of stays. Admissions for inpatient treatment in community hospitals declined from 36.1 million in 1980 to 31.8 million in 1998. During this same period, outpatient surgery grew from 16.3 to 61.6% of all surgeries. Blackstone, Edwin, JOURNAL OF HEALTH LAW, Spring 2003.

[2] Blue Cross/Blue Shield, "Hospital Services and the Cost of Rising Healthcare," *available at* www.fepblue.org/toyourhealth/tyhhwhospitalcost.html

outpatients over a three year period and thus, demonstrates an egregious violation of the definition of hospital warranting termination of the Medicare provider agreement. However, the commentary does not take into account the changing nature of healthcare services. Rather, the commentary emphasizes that in order to be a Medicare-certified participating hospital, the Medicare rules and regulations require that an institution must be "primarily engaged in furnishing services to inpatients." We assume that this test would be applied to all hospitals, not merely to physician-owned hospitals only. If such test were applied to all hospitals equally most acute care hospitals would be denied a provider agreement on that basis because, as noted above, most hospitals today provide more outpatient services than inpatient services. Denying a provider agreement to hospitals which fail such test would result in a large percentage of the nation's hospitals losing the ability to participate in Medicare. This would adversely affect access to health care as well as the quality of care that most Americans currently receive. Accordingly, emphasizing the strength of CMS' ability to terminate a provider agreement based upon whether a hospital "primarily engages" in providing inpatient services is inconsistent with the delivery of care by most hospitals.

Third, if CMS desires to deal with the legitimate and problematic situation in which a party has a hospital provider agreement and essentially provides few or no services to inpatients, CMS has shown, for example in the Arizona Surgical case, that it has the means to do so. There, the party provided essentially no inpatient services but presumably was billing for outpatient services at the higher hospital rate. CMS was successful in revoking the provider agreement. In contrast, the concern with the commentary is that it would empower CMS to revoke provider agreements of most hospitals in that most only perform ten to twenty percent of their services on inpatients.

Fourth, the emphasis of the commentary on the power of CMS to define a hospital as one that primarily engages in inpatient services will allow the federal government to usurp the power of the states. The commentary essentially encourages taking the power to license hospitals out of the hands of state governments and putting that power primarily into the hands of the federal government. As you are aware, states and payors often require that hospitals obtain Medicare certification or be Medicare-eligible in order to be licensed under state law. However, pursuant to the commentary, if a hospital provides more outpatient services than inpatient services it is not Medicare-eligible. Thus, if it is not Medicare-eligible the hospital will be in a difficult situation as it will qualify as one type of provider under state law and a fully different provider under the Medicare program.

A few states, like Arizona, have amended their hospital licensure acts and are in fact modifying the definition of hospital or providing multiple licensure categories for hospitals. However, if the commentary were to impact the approach of CMS in defining specialty hospitals, even hospitals licensed pursuant to state definition would be in an ambiguous position with respect to federal reimbursement. Would these entities bill separately as an ambulatory surgery center or as an imaging facility? By narrowing the definition of hospital from a federal perspective, there will be continual questions with respect to whether entities qualify as hospitals under state and federal law.

Fifth, the commentary clarifies an approach that is incompatible with the authority and purpose of CMS. The regulations promulgated pursuant to Section 1861(e) of the Social Security Act provide that CMS has the authority to promulgate regulations to improve the safety and effectiveness of hospitals. However, the commentary has not been promulgated with the safety

and effectiveness of hospitals in mind. Rather, the commentary is solely aimed at using regulatory power to attack physician-owned hospitals. This approach to regulation is inconsistent with the authority given to CMS.

Should you have any questions with the concerns raised in this letter, please contact myself at (312) 750-6016.

Very truly yours,

Scott Becker

SB/dlk

cc: Elissa Koch

MAY 2 4 2005
16-0 (4)

KENTUCKY RIVER
MEDICAL CENTER

May 16, 2005

WI/DC

Hefter
Hartstein
V. Miller

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 or the intermediary 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. (Although, 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.)

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,

O. David Bevins
Chief Executive Officer

cc: Scott Raab, Office of Senator Mitch McConnell

17-0 (25)
MAY 2 4 2005

MOUNTAIN STATES HEALTH ALLIANCE

Office of Community and Government Relations
32 6th Street • Bristol, Tennessee 37620
Telephone: 423.764.1113
Facsimile: 423.764.1172

Transfers

May 18, 2005

Hefler
Hartstein
Jim Hart
Wall 2

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

Re: Post-acute Care Transfers; Proposed changes to the hospital inpatient prospective payment systems and FY '06 rates; proposed rule

Dear Administrator McClellan:

On behalf of Mountain States Health Alliance (MSHA) we appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Medicare Hospital Inpatient Prospective Payment System, as published in the May 4, 2005 *Federal Register*. We are particularly concerned about CMS' reported proposal to expand the number of DRGs subject to the post-acute transfer policy from the current 30 to 223.

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

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

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

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

Sincerely,

Elliott Moore

Elliott Moore
Director, Community & Government Relations

18

MAY 2 4 2005

Tom D. Parks, DVM, PC
Tom D. Parks, DVM

5056 Old Post Rd
Yuma, CO 80759
970-848-3801
970-848-0563
E Mail cowcare@plains.net

125 W 5th St.
Wray, CO 80758
970-332-4542

CAH/Reloc

Tzvi Hefter
Mark Hartstein
Mary Collins
George Morey

12 May 2005

Secretary Mike Leavitt
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 Secretary Leavitt:

Yuma District Hospital is a critical access hospital located in northeast Colorado. Yuma District Hospital needs to build a replacement hospital within one mile of its existing hospital, but does not want to lose its critical access status. The purpose of this letter is to request your support for an immediate waiver so that Yuma District Hospital may proceed with construction of a replacement hospital. Time is of the essence as construction costs increase and interest rates rise.

Yuma District Hospital became a Critical Access Hospital (CAH) in July 2002, under the "Necessary Provider Criteria." According to the federal regulations, in order to be certified as a CAH, a hospital cannot be located within 35 miles of another hospital, 15 miles if mountainous terrain, or if designated as a "Necessary Provider" by the state. Since Yuma is within 35 miles of the hospital in Wray, it became certified as a CAH under the Necessary Provider provision.

The Medicare Prescription Drug, Improvement and Modernization Act passed into law in December 2003, eliminated the Necessary Provider provision of the Critical Access Hospital regulations, effective January 1, 2006. If a hospital licensed as a CAH under the Necessary Provider provision builds a replacement facility in a different location other than the exact location where it was located when certified, and the construction is completed after January 1, 2006, the hospital may lose its CAH designation.

Yuma District Hospital needs to build a replacement hospital. They are land locked on their existing property. The hospital board identified a site 800 yards from the existing hospital for the replacement facility. However, like the existing site, the new site is within 35 miles of the hospital in Wray.

We understand that there is discussion on a national level about this issue. The Centers for Medicare and Medicaid Services, Department of Health and Human Services proposed changes [CMS-1500-P RIN 0938-AN57], that are a step in the right direction , but do not resolve Yuma District Hospital's immediate need. (The proposed rule allows relocation within 250 yards and Yuma District Hospital needs to relocate about 8 blocks from the existing campus.)

Therefore, we are requesting your support for a waiver so that Yuma District Hospital may proceed with construction of a replacement hospital, without losing its critical access status. In addition to this letter, please find enclosed specific information supporting a waiver for Yuma District Hospital.

Respectfully,

Tom D. Parks

The proposed rules "recognize that the Necessary Provider designation may need to be applied to certain relocated CAHs." The qualifiers for Necessary Provider designation are:

1. The CAH should submit an application for relocation. Yuma District Hospital has submitted a request for waiver.

2. The CAH must meet the same criteria as when the first waiver was issued. Yuma District Hospital continues to operate in the same manner as when the Necessary Provider designation was granted in 2002.

3. The relocated CAH will continue to service the same community in the new location. There will be no change in the service community.

4. The CAH will remain in compliance with all Conditions of Participation in the new location. Yuma District Hospital will continue to be in compliance with all Conditions of Participation.

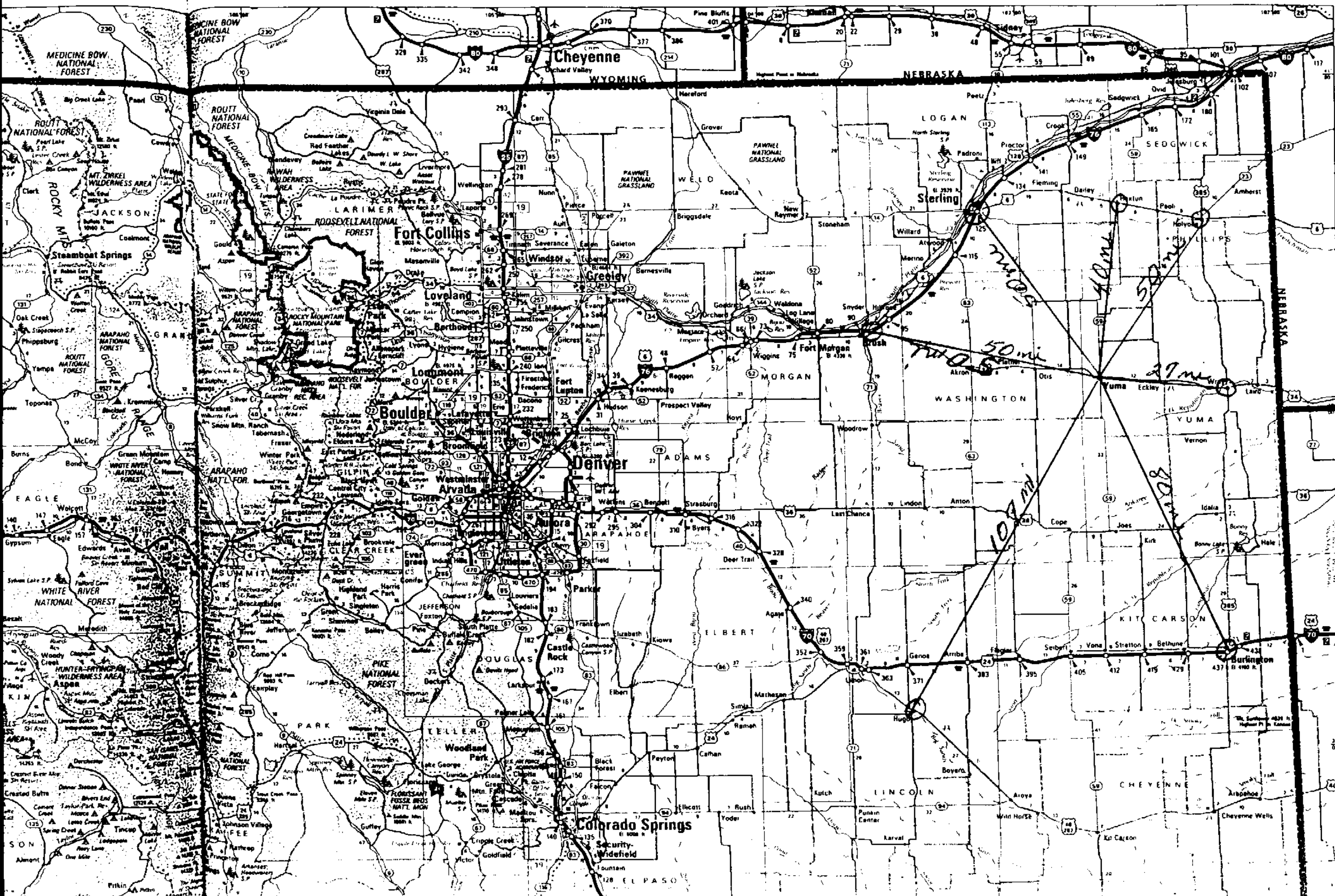
5. The CAH's construction plans were under development as of 12/8/03. Yuma District Hospital began to work on a new hospital in March, 2003 with a fact-finding trip to Spokane, Washington. Yuma District Hospital met with Alan Richmond, a bond underwriter, in May of 2003. Yuma District Hospital received a proforma report on financial feasibility on 10/06/03 from Eide Bailey.

6. The CAH will provide 75% of the same service with 75% of the same staff at the new location. Yuma District Hospital will perform 100% of the same services with 85% of the same staff in the new location (reflects 15% of normal staff turnover rate).

7. Please refer to the enclosed map to see Yuma District Hospital's geographic relationship to other hospitals.

Wayside, Roadside Park — Rest Area (No Toilets) — Highway — symbols, see page 1.

Index page 129.



19

CMS-1500-P-1 **Changes to the Hospital Inpatient Prospective Payment Systems and FY 2006 Rates**

Transfers

Hefter, Harstein Walz J. Hart

Submitter : Mr. John Gallenstein **Date & Time:** 04/28/2005

Organization : Health Alliance of Greater Cincinnati

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

A. Postacute Care Transfer Payment Policy (412.4)
I have read through much of the just listed proposed Medicare IP PPS rule for '06, and have found a reference to 88 DRGs (including 210, 211) that would qualify to receive the special payment consideration under the post acute care transfer rule. but I can not find an actual listing in the rule of the 88 DRGs.(Table 5, and Table 7 of the Addendum are mentioned)

Did I miss it, or can you help with this, as I am trying to analyze the effect of this change?
Thank you.

per Sharon Jones on 5/25/2005 p. 2 of 2 is a blank page. JTW

CMS,1050rA

20-0
(2)
NWIS/AH/PPS/IPC

CMS-1500-P-11 **Changes to the Hospital Inpatient Prospective Payment Systems and FY 2006 Rates**

Hefter
Hartstein
Trung
Lefkowitz
- Ruiz

Submitter : Dr. Jonathan Ward **Date & Time:** 04/29/2005

Organization : Dr. Jonathan Ward

Category : Pharmacist

Issue Areas/Comments

GENERAL

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Withdrawal of pharmacy specialized residency training funding is a giant step backwards in the attempts to cut healthcare costs while providing safe and effective drug therapy and care. Specialized pharmacists provide proven value in the healthcare system, saving a great deal of money while limiting adverse drug reactions, another huge cost to the system. Withdrawing their support will paradixically cost the government more money in the long run.

Per Sharon Jones, CMS/OSORA on 5/25/2005 p. 2 of 2 is a blank page. DTW

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MAY 27 2005 Rec'd 5/23/05

DREWER.

19 May 2005

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

Reference: Formal comments on CMS-1500-P Inpatient Prospective Payment System Notice of Proposed Rulemaking (IPPS NPRM), Federal Register April 24, 2005.

Dear Dr. McClellan,

I am writing today to request your involvement in a significant healthcare and economic issue developing in the area of recovery of the natural heart from acute heart failure. I recognize the challenging endeavor you face in managing the Medicare payment system to appropriately balance clinical effectiveness, innovations in medical technology and improvements in related therapies against the economic impact to the program. With that challenge in mind, I want to formally bring to your attention that the current reimbursement for the technology to recover the natural heart from acute heart failure (**external ventricular assist device, ICD-9 37.65, DRG 525**) has not kept pace with the innovations in the technology nor the proven therapeutic use of the technology, and may actually be creating an incentive to forego recovery of the natural heart as a clinical option.

Our fundamental concern is the inadequacy of the reimbursement level in DRG 525 for external ventricular assist devices and the associated optimal clinical use of the technology in AMI (heart attack) patients. The underpayment for the use of external VADs is really at the root of the incentive to forego a "heart recovery" course of care, which in the long term costs the Medicare program significantly more. **Outdated information on hospital charges, length of stay and the large variation of ICD-9 codes within DRG 525 even historically are all contributing factors.**

On behalf of our hospital customers and their patients, we are providing you with additional financial and clinical data obtained directly from hospitals, a third-party analysis conducted by the Lewin Group, and Abiomed's own clinical patient registry to clearly document the inaccuracy of the current reimbursement for external VADs under DRG 525. Many hospital surgeons, CFOs, and CEOs will also be requesting resolution to this issue based on their own experiences. The data validates the following:

- Improvements in technology are providing patients in acute heart failure with no other treatment option the ability to recover their own hearts or go on to a transplant after attempting recovery. **The AMI patient population has ~50% survivability, and more than 60% of survivors go home with their own heart with no or limited reliance on the health system long term.**

- Recovery and the ability to go home with your own heart is now being seen on average at 4 weeks on support, 4 times the length previously considered. This is providing improved recovery, but is also i**ncreasing the average length of stay to 43 days , per the Lewin Group study**.

- **Average charges are 89-103% higher for the AMI patients** analyzed by the Lewin group than the average charge in DRG 525, even more so versus very old technology such as centrifugal pump in ICD-9 37.62 that was added to DRG 525 last year.

- The charge data provided in the **FY06 NPRM demonstrates ICD-9 37.65 was already 34% higher than other DRG 525 charges prior to advances in technology** as provided from the Lewin Group and described herein, and we would anticipate much larger differences when compared to ICD-9 37.62 specifically.

- **Recovery of the natural heart is the best clinical option**, allowing the patient to return to normal life after heart failure without dependence on a device or drug therapy.

- **Recovery is the least costly alternative,** estimated at 50% - 80% less than the cost of implantable devices or heart transplants with related drug therapy and multiple surgeries. At this time **there is no additional reimbursement when a patient recovers** and a 2nd surgery is required to remove the device, **or when a patient receives a heart transplant** after recovery is attempted.

- **Dozens of peer reviewed studies** have been published on the success of ventricular assist devices used for recovery, and is it considered a standard of care for most heart programs. It is also **preventative treatment, as success means one less chronic heart failure patient** or reliance on immunosuppressive drug therapy.

The following tables summarize key financial and LOS data from a study conducted by the Lewin Group. The full study is attached for further detail.

Comparison of Heart Recovery Charges to Charges for DRG 525 Cases by Procedure

Procedure		Medicare Cases	Average length of stay	Average total charge per case	Average standardize charge per case [1]
37.62	Insertion of non-implantable heart assist system	141	18.6	$193,054	$146,810
37.63	Repair of heart assist system	75	13.1	$166,250	$135,352
37.65	Implant of external heart assist system	121	12.5	$229,430	$188,200
	All DRG 525 procedures	337	15.2	$200,149	$159,121
	AMI Heart Recovery using Bi-Ventricular Assist Device Support	**n/a**	**44.1**	**$405,350**	**$285,690**
	AMI Heart Recovery	**n/a**	**43.2**	**$378,903**	**$267,050**

1/ Charges are standardized for differences in area wage levels, indirect medical education and DSH across hospitals.
DRG is based on the FY 2005 version of the Medicare DRG Grouper.
Source: Lewin Group analysis of 2003 Medicare Provider Analysis Review (MedPAR) data.

Actual Average Length of Stay and Charges for Heart Recovery Patients

	Cases	Average Length of Stay	Average Total Charges	Average Standardized Charges
Medicare Patients Only				
DRG 525	9	37	$578,431	$413,404
DRG 525 & 103	10	40	$614,256	$433,133
All Patients				
DRG 525	19	37	$515,167	$348,945
DRG 525 & 103	24	44	$572,206	$383,172

Cases submitted by seven hospitals from late 2004-2005.

Compounding the problem of underpayment for heart recovery therapy is the sizeable increase in the reimbursement for implantable (versus external) heart assist systems for FY05. By now paying for implantable heart assist devices out of the higher reimbursement DRG 103, CMS has inadvertently exacerbated an environment that already **discourages an initial attempt to recover the heart in patients with acute heart failure, such as heart attack/AMI**, prior to using an alternative implantable device or a heart transplant. Not only does this jeopardize access to a therapy that can afford patients a better clinical outcome by recovering their heart, it also creates a population of new chronic patients. Secondly, when a patient does recover and the assist device needs to be removed or when a patient goes on to heart transplant **there is no additional reimbursement for the additional surgeries required.** The final ruling for FY05 recognized this potential risk and agreed to annual reviews of DRG 525 and 103 accordingly.

The accompanying detailed clinical and financial data demonstrates that this is indeed a serious issue that is affecting patients and hospitals today. Our mission is simple; provide a surgeon the choice to offer the best clinical option for the patient while maintaining the goal of budget neutrality at CMS. Based on discussions with CMS, the Lewin Group and other industry experts there appear to be several options available to resolve the reimbursement gap.

- Based on the unique resource requirements for AMI patients, **create a new DRG for AMI patients** requiring heart assist devices. A combination of primary and secondary AMI diagnosis codes with a surgical procedure codes as is done today by CMS with defibrillators and other cardiac support devices.

- Map the same AMI patients to DRG 103

- Increase the overall weighting of DRG 525 to better align with new developments. Maintaining other old technology in 37.62 will make this difficult, as the increase required is significant to match the AMI patient charges.

- **To reduce overall CMS costs and incentive for additional surgeries,** allow second DRG payment or add-on payment for heart transplant if heart recovery is first attempted.

Abiomed Inc. is a small company dedicated to recovering, supporting or replacing the natural heart for over 20 years. We are fully committed to providing CMS with access to all of our in-depth knowledge of trends and a database of registered patients from hospitals across the country, to be able to evaluate this therapy as it is being used today. Our clinical and technical experts will provide any additional data for your team, and I would recommend discussing this directly with the Lewin Group. With the scale of impact this trend implies for our nation's healthcare, we request changes be made in the inpatient prospective payment system (IPPS) and that our recommendations to modify the reimbursement level for external VADs be included in the final ruling in August 2005. Thank you for your time and involvement is this matter, and I look forward to further discussions on this important topic.

Best regards,

Andrew J Greenfield
Vice President, Healthcare Solutions
Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01833

Enclosures:

Lewin Group Report
Abiomed CMS Presentation
AB5000 AMI Presentation and Abstract
Sample Publications

An Analysis of Medicare DRG Assignment for Heart Recovery Using External Heart Assist Devices

Final Report to:

Abiomed, Inc.

by:
Randy Haught
Jeannine Dollard
Allen Dobson, Ph.D.

The Lewin Group

May 9, 2005

Executive Summary

The purpose of this study is to examine hospital resource utilization for AMI heart recovery patients treated using external heart support and to assess the DRG assignment for this technology in terms of the clinical aspects of patients and their hospital resource utilization.

The key findings of the study are as follows:

- Patient length of stay and hospital charges for patients receiving AMI heart recovery treatment were substantially higher than other DRG 525 cases (***Table ES.1***).

Table ES.1 – Comparison of Heart Recovery Charges to Charges for DRG 525 Cases by Procedure

Procedure		Medicare Cases	Average length of stay	Average total charge per case	Average standardize charge per case [1]
37.62	Insertion of non-implantable heart assist system	141	18.6	$193,054	$146,810
37.63	Repair of heart assist system	75	13.1	$166,250	$135,352
37.65	Implant of external heart assist system	121	12.5	$229,430	$188,200
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1/ Charges are standardized for differences in area wage levels, indirect medical education and DSH across hospitals.
DRG is based on the FY 2005 version of the Medicare DRG Grouper.
Source: Lewin Group analysis of 2003 Medicare Provider Analysis Review (MedPAR) data.

- The substantially higher hospital resource usage may cause Medicare reimbursement for this technology to be inadequate when compared to the hospitals' cost of treating the patients using this technology.
- The changes by CMS to move implantable heart assist device procedures to DRG 103 has created incentives for hospitals to use the implantable heart assist device technology instead of the external heart recovery technology for financial reasons, since the base Medicare payment rate for the implantable device under DRG 103 is about 72 percent higher than the payment for the new heart recovery technology under DRG 525.
- The financial incentives created by Medicare payment policy to choose one technology over another may potentially lead to inappropriate clinical treatment decisions. In the design of the IPPS system, it is considered important that Medicare payment policy be "incentive neutral" so hospitals could make decisions for using one technology over another based solely on the best clinical outcomes for the patient.

- Based on precedent rulings by CMS on DRG reassignment of certain procedures, the average length of stay and charges for AMI heart recovery cases are sufficiently different from other DRG 525 cases for CMS to consider removing AMI heart recovery from DRG 525 and creating a separate DRG.
- If establishing a new DRG for AMI heart recovery is not appropriate, then we believe it should be moved to DRG 103 for the following reasons: 1) average length of stay and charges for AMI heart recovery are similar to those for DRG 103; 2) AMI heart recovery cases are clinically similar to implantable heart assist system cases; and 3) DRG 103 is the only DRG within MDC 5 (diseases and disorders of the circulatory system) with average charges that are higher than DRG 525. Therefore, there is no other appropriate place to put AMI heart recovery patients.
- A method that could be used to identify AMI heart recovery cases would include discharge records that include an ICD-9 procedure code of 37.65 (Implant of external heart assist system) and a principle diagnosis code of AMI (410.01, 410.11, 410,21, 410,31, 410.41, 410.51, 410.61, 410.71, 410.81, or 410.91).

I. Introduction

Ventricular assist devices (VAD) are used to assist or replace the pumping function of the heart in the presence of heart failure. VADs can be used to recover a heart that has failed temporarily (bridge to recovery), support the heart until transplant (bridge to transplant), or as permanent assistance for the natural heart (destination therapy). The patient population for use of VADs as a bridge to recovery of the natural heart is estimated to be 50,000 patients annually (10 percent of heart attack patients experiencing inability to pump blood known as cardiogenic shock). Current penetration of this market is a small percent of the potential to date (less than two percent). Health care facilities capable of using the VAD are open-heart centers (fewer than 1,000 nationwide, without transplant capability) and heart transplant centers (fewer than 100 nationwide).

The AB5000, produced by Abiomed, is one of two heart VADs approved by the FDA for use with acute myocardial infarction – cardiogenic shock (AMI-CS) patients. The device is attached to a mobile unit allowing for greater patient ambulation during recovery. The external pump design reduces the risk of bleeding and infection in the patient. Abiomed supplemental data indicates that 70 percent of AB5000 survivors recover and retain their natural hearts.

The AB5000 external heart assist device greatly improves a patient's chance of heart recovery after heart failure and shock when compared to other available heart assist technologies. The new technology has been used since September 2003 and the operating room procedure for inserting the device is coded under ICD-9 code 37.65 (implant of external heart assist system), which categorizes patients receiving this treatment under DRG 525 (other heart assist devices).

Although survival and recovery rates are greatly increased, the cost of these new devices are substantially higher than the cost of the older devices and the patient length of stay is significantly increased. Thus, hospital charges for AMI patients receiving heart recovery treatment using the new technology will be substantially higher than other DRG 525 cases. The substantially higher hospital resource usage may cause Medicare reimbursement for this technology to be inadequate when compared to the hospitals' cost of treating the patients using this technology. There are three primary reasons why payment may be inadequate for these cases:

1. Historical hospital charge data for the new heart recovery technology was not available to CMS at the time the FY 2005 rates were established. Medicare DRG relative weights were computed using FY 2003 (October 2002 – September 2003) hospital charge data.
2. The other heart assist device procedures included in DRG 525 are much less costly than the new technology. Thus the relative DRG weights are based on technologies with very different costs than the newer heart recovery technology.
3. In FY 2005 CMS moved implantable heart assist device procedures, which are similar in cost to this technology, from DRG 525 to DRG 103. Removing these higher-charge

procedures from DRG 525 had the effect of reducing the overall average charge for DRG 525, thus reducing DRG 525 relative payment weights.

In addition, the changes by CMS to move implantable heart assist device procedures to DRG 103 has created incentives for hospitals to use the implantable heart assist device technology instead of the external heart recovery technology for financial reasons, since the payment for the implantable device under DRG 103 is about 72 percent higher than the payment for the new heart recovery technology. The consequences of this could be the use of an implantable device when an external device would have been appropriate, which could have saved the patient's heart. The financial incentives created by Medicare payment policy to choose one technology over another may potentially lead to inappropriate clinical treatment decisions. It is important that Medicare payment policy be "financially incentive neutral" so that hospitals can make decisions for using one technology over another based solely on the best clinical outcomes for the patient.

II. Study Purpose and Methods

The purpose of this study is to examine hospital resource utilization for heart recovery patients and assess the DRG assignment for this technology based on the clinical aspects of the patients and the hospital resource utilization of the patients. In order to perform this analysis, The Lewin Group used the following data and analytic methods:

- Performed a review of Abiomed's current clinical data analyses and other information available regarding the AB5000 heart assist device patients;
- Performed a length of stay and average charge analyses for heart recovery versus other procedures in DRG 525, using supplemental data collected by Abiomed from hospitals currently using these devices, the Medicare Provider Analysis and Review file for 2003, and CMS Cost Reports for inpatient procedures;
- Reviewed peer literature on VAD use and outcomes;
- Reviewed the current and past CMS Final Rules for the Inpatient Prospective Payment System (IPPS); and
- Evaluated the appropriate DRG assignment for heart recovery patients based on length of stay and charge comparative analyses in perspective with past CMS rulings on DRG assignments for particular procedures.

The following sections present the results of our analyses and describe the methods we used.

III. Analysis of Abiomed Clinical Data for AMI Patients

The Lewin Group analysis of supplemental patient data provided by Abiomed for patients receiving the AB5000 heart assist device and who had a principal diagnosis of acute myocardial

infarction (AMI) as presented in ***Table III.1***. This table shows the outcome status, average days of support and average total days to recovery for 42 AMI patients whose data were voluntarily provided to Abiomed by advanced heart centers across the country who utilize the AB5000 device in their patient care.

Cardiogenic shock after acute myocardial infarction (AMI-CS) is associated with a very high mortality rate. The use of ventricular assist devices (VAD) for bridge to recovery is widely considered a standard of care for open heart centers and transplant centers offering advanced cardiac services for acute cardiac heart failure *(Alicia Sierra, et al v. McAllen Medical Center, Inc. et al)*. Survival rates of greater than 70 percent have been achieved by top performing institutions with proper protocols. The largest patient population with potential for heart recovery from cardiogenic shock is acute myocardial infarction (AMI), or heart attack. Approximately 865,000 AMI patients are treated in hospitals annually, with 7.5 percent, or more than 50,000, experiencing cardiogenic shock with potential for VAD use. An estimated 230 VADs were used with AMI patients in 2003 *(Health Research International, 2004)*.

The data show that all AMI heart recovery patients treated using this device have about a 50 percent survival rate with an average total length of stay of 43.2 days. On average the patient spends about 2.4 days in the hospital prior to the implantation of the device. For patients who survive and have the device removed, the average support time is about 31 days, which is followed by an additional 38 days in the hospital until discharge. When we average all patients, including those that expired, the average length of stay for all patients is about 43.2 days.

Table III.1 – Average Total Days by Patient Outcome and VAD Procedure Type, 2004 – 2005 (based on updated patient data received through May 10, 2005)

AMI Heart Recovery using BiVAD Support	Undetermined /2	n/a	n/a	n/a	n/a	n/a
	Expired	15	1.5	13.7	-	15.3
	Survived /3	9	2.8	38.8	54.5	96.1
All AMI Heart Recovery	Undetermined /2	1	1.0	8.0	n/a	n/a
	Expired	21	1.3	16.1	0.5	17.9
	Survived /3	20	3.6	31.2	37.9	72.7

1.Average excludes patients with undetermined outcomes.

2.Patients with undetermined outcomes are survivors that had completed support but have not yet reached 30 days. Also excludes three patients who have not yet ended VAD support.

3. Survived patients are defined as patients who survived for at least 30 days from end of device support.

Source: Abiomed, Inc. supplemental data voluntarily collected from heart hospitals and heart transplant centers which utilize the AB5000 device, September 2003 – March 2005

Based on information provided by Abiomed clinical experts, bi-ventricular assist device (BiVAD) support is becoming the protocol for heart recovery for patients with AMI. This approach requires two devices which support both sides on the heart. The use of these two devices greatly increases the cost of the patient's stay. Based on these findings, we also examine hospital resource utilization and charges for heart recovery patients with AMI and treated using bi-ventricular support.

a. Analysis of Average Charges for Heart Recovery Patients

In order compare the average charges for AMI heart recovery patients to these patients currently assigned to DRG 525, we first needed to determine the average charge per case for AMI heart recovery patients. Information on AMI heart recovery patients using the new devices were not available until September 2003, so the necessary charge data were unavailable in the 2003 MEDPAR data. Also, there is not a unique ICD-9 code for this technology so patients receiving it cannot be differentiated from other external heart assist technologies coded under ICD-9 code 37.65. Therefore, we had to estimate what the average per-case charge would be for these patients. The following sections describe the method we used for computing the average charges.

i. Estimated Average Accommodation Charges

Based on the analysis presented above, we estimated an average length of stay of 44.1 days for AMI heart recovery patients treated using BiVAD support and 43.2 days for all AMI heart recovery patients, based on Abiomed clinical data. We assumed that two-thirds of the days would be in an ICU or CCU and one-third would be general routine unit. This assumption was based on the proportion of ICU to total days for patients with implantable heart assist devices, which had similar average lengths of stay to the AMI heart recovery patients.

Average per-diem charge data were compiled from the Medicare hospital cost report data for FY 2003-04 for about 20 hospitals for which Abiomed had clinical data (***Table III.2***).

Table III.2 – Accommodation Charges per Day, 2003 - 2004

Type of Unit	Number Days	Cost per Day	Charge per Day
Routine Accommodations	2,958,580	$705	$1,728
ICU / CCU	435,122	$1,581	$3,774

Source: Lewin Group analysis of Medicare Hospital Cost Report data, FY 2003 -2004

Using these data, we estimate that the average accommodation charges of $136,387 for AMI heart recovery patients treated using BiVAD support and $133,604 for all AMI heart recovery patients as shown in ***Table III.3***. This is based on the average per-diem charge for hospitals that use these devices multiplied by the average number of inpatient days by type of unit.

Table III.3 – Estimated Average Accommodation Charges per Case

Unit Type	Charge Per Day	Average Days per Unit	Average Per-Case Charges
AMI Heart Recovery with BiVAD Support			
Routine Accommodations	$1,728	14.7	$25,376
ICU/CCU	$3,774	29.4	$111,011
Total Accommodation Charges	$3,092	44.1	$136,387
AMI Heart Recovery			
Routine Accommodations	$1,728	14.4	$24,858
ICU/CCU	$3,774	28.8	$108,746
Total Accommodation Charges	$3,092	43.2	$133,604

Source: Lewin calculation based on Medicare Cost Reports, 2003 -2004 and Abiomed supplemental data.

ii. Estimated Average Ancillary Department Charges

To estimate the average ancillary department charges for AMI heart recovery patients, we used the average charges for patients treated using other external heart assist devices (DRG 525 and ICD-9 code 37.65 and principle diagnosis of AMI) from the FY 2003 MEDPAR data as a proxy.

However for patients treated using BiVAD support, we substituted the medical/surgical equipment costs with the cost of two AB5000 devices, which have an average sales price of $40,306 each (based on Abiomed average sales price data). For AMI heart recovery patients treated with either left or right ventricular support, we used the cost for only one device. We also assumed that charges for these devices would be marked up by the hospitals by about 37 percent above costs based on an unpublished Lewin Study of hospital markups for high cost implantable devices. Medical supplies are usually marked up by hospitals at a much higher percentage above cost, usually about 200 percent. However, we have found that hospitals often markup high-cost items by a much lower amount. In addition, we added about $5,000 in average medical/surgical supply charges for other types of supplies including cardiac stents, other catheter lab supplies, and general medical/surgical supplies.

Based on these assumptions, we estimated average ancillary department charges of about $268,963 for AMI heart recovery patients treated with BiVAD support and about $245,299 for all AMI heart recovery patients (***Table III.4***). We found the average length of stay for patients in the MEDPAR data that met the above conditions was only about 9 days compared to an average length of stay of 43 to 44 days for AMI heart recovery patients. Therefore, our estimated ancillary department costs may be very conservative since during the longer length of stay the patient may require additional lab, pharmacy, radiology and other services.

Table III.4 – Estimated Average Ancillary Department Charges for Heart Recovery Patients in 2003

Ancillary Department	AMI Heart Recovery with BiVAD Support	AMI Heart Recovery
Pharmacy	$38,105	$38,105
BiVAD device /1	$110,438	$86,773
Physical Therapy	$174	$174
Occupational Therapy	$70	$70
Speech Pathology	$79	$79
Inhalation Therapy	$7,027	$7,027
Blood	$863	$863
Blood Administration	$17,687	$17,687
Operating Room	$36,677	$36,677
Cardiology	$14,588	$14,588
Anesthesia	$6,313	$6,313
Laboratory	$26,817	$26,817
Radiology	$2,764	$2,764
MRI	$169	$169
Outpatient	$95	$95
Emergency Room	$345	$345
ESRD	$413	$413
Clinic	$4	$4
Other Med/Surg Supplies (est.)	$5,000	$5,000
Other	$1,336	$1,336
Total Ancillary Charges	**$268,963**	**$245,299**

/1 Device charge for BiVAD support = ($40,306 Cost X 2 Units) + 37% Markup, for left or right ventricle support only, the charges for a single device = $40,306 + 37% markup.
Source: Lewin Group analysis.

We estimate that average total charges for AMI heart recovery patients treated using BiVAD support would be about $405,350 ($136,387 for accommodation charges and $268,963 for ancillary department charges). Average total charges for all AMI heart recovery patients is estimated to be about $378,903 ($133,604 for accommodation charges and $245,299 for ancillary department charges).

iii. Average Standardized Charge

CMS standardizes average charges to remove the differences of wage levels, teaching and disproportionate share across hospitals for developing the DRG relative weights. ***Table III.5*** shows the computation of the average standardized charge for BiVAD patients based on the average wage index, IME and DSH adjustment factors for hospitals for which Abiomed had collect clinical data.

Table III.5 – Estimated Standardized Charges for BiVAD Cases

	AMI Heart Recovery with BiVAD Support	AMI Heart Recovery
Average Accommodation Charges	$136,387	$133,604
Average Ancillary Department Charges	$268,963	$245,299
Average Total Charge	$405,350	$378,903
Average Wage Index	1.0499	1.0499
Average COLA	1.0000	1.0000
Average IME Adjustment	0.2509	0.2509
Average DSH Adjustment	0.1200	0.1200
Step 1: Adj Charge = Avg Charge / (1+IME+DSH)	$295,682	$276,390
Step 2: Std Charge = (.711*Adj Charge)/wage index + (0.289*Adj Charge)/COLA	$285,690	$267,050

Wage index, IME and DSH adjustments based on FY 2005 standardizing file for 20 hospitals for which Abiomed had collect clinical data.

iv. Average Charge Data Submitted by Hospitals

As mentioned above, we believe these average charge estimates may be conservative. In order, to validate the charge estimates, Abiomed requested average charges and length of stay data from hospitals who are using the AB5000 heart assist system to treat heart recovery patients. Average charge data was received from seven hospitals, who responded to the request, for 24 heart recovery patients treated using the AB5000 heart assist system during 2004 and 2005. ***Table III.6*** shows the average length of stay, average charges and average standardized charges for these patients.

Table III.6 – Average Length of Stay and Charges for Heart Recovery Patients

	Cases	Average Length of Stay	Average Total Charges	Average Standardized Charges
Medicare Patients Only				
DRG 525	9	37	$578,431	$413,404
DRG 525 & 103	10	40	$614,256	$433,133
All Patients				
DRG 525	19	37	$515,167	$348,945
DRG 525 & 103	24	44	$572,206	$383,172

Cases may or may not include a principle diagnosis of AMI.

Although these charge data represent a more recent time period (i.e., 2004 and 2005), they show that average standardized charges for Medicare heart recovery patients treated using the AB5000 system were $413,404 and $348,945 for all heart recovery patients, which is substantially higher than our estimates of $267,000 to $285,000. Thus, in the following comparative analyses, the average charge estimates for AMI heart recovery patients presented in the tables should be viewed as conservative estimates.

IV. Comparison of Length of Stay and Average Charges for AMI Heart Recovery Patients to Patients Currently Assigned to DRG 525 or DRG 103

In order to determine if heart recovery using BiVAD support cases should remain in DRG 525, we compared average length of stay, average charges and average standardized charges for each DRG 525 procedure to those statistics for AMI heart recovery patients. Using the FY 2003 MedPAR inpatient data, patient observations were extracted for DRG 525 (Heart Assist System Implant) cases based on the FY 2005 version of the CMS DRG grouper. As shown in ***Table VI.1*** the average length of stay for all DRG 525 patients is 15.2 days and about 12.5 days for patients receiving an external heart assist system (ICD-9 code 37.65).

The average length of stay for AMI heart recovery patients using BiVAD support of 44.1 days would be 190 percent higher than current DRG 525 procedures. The average length of stay for all AMI heart recovery patients of 43.2 days would be 184 percent higher than current DRG 525 procedures.

In addition, average charges would be 103 percent higher for AMI heart recovery patients treated with BiVAD support ($405,350) compared to the average charge for all DRG 525 patients ($200,149), and average charges for all AMI heart recovery patients would be 89 percent higher ($378,903 compared to $200,149).

Table IV.1 – Comparison of AMI Heart Recovery Charges to Charges for DRG 525 Cases by Procedure

Procedure		Medicare Cases	Average length of stay	Average total charge per case	Average standardize charge per case
37.62	Insertion of non-implantable heart assist system	141	18.6	$193,054	$146,810
37.63	Repair of heart assist system	75	13.1	$166,250	$135,352
37.65	Implant of external heart assist system	121	12.5	$229,430	$188,200
	All DRG 525 procedures	337	15.2	$200,149	$159,121
	AMI Heart Recovery using BiVAD Support	**n/a**	**44.1**	**$405,350**	**$285,690**

	AMI Heart Recovery	**n/a**	**43.2**	**$378,903**	**$267,050**

DRG is based on the FY 2005 version of the Medicare DRG Grouper.
Source: CMS – Medicare Provider Analysis Review (MedPAR), 2003 for inpatient procedures.

However, the average length of stay of 41.9 days for all DRG 103 (Heart Transplant) patients is very similar to the average length of stay for AMI heart recovery patients of 43.2 days and 44.1 days for patient with BiVAD support (***Table IV.2***). Also, average charges for AMI heart recovery patients are more similar to DRG 103 cases than to DRG 525 cases. Overall, we found that average charges for AMI heart recovery patients would be only about 6 to 12 percent lower than the average charges for DRG 103 patients.

Table IV.2 – Comparison of Heart Recovery Charges to Charges for DRG 103 Patients by Procedure

	Procedure	Cases	Average length of stay	Average total charge per case	Average standardize charge per case
37.5	Heart Transplant	553	41.1	$403,340	$286,334
37.66	Insertion of implantable heart assist system	91	47.2	$575,343	$433,576
	Other DRG 103 procedures	6	38.2	$728,130	$559,093
	All DRG 103 procedures	650	41.9	$430,419	$309,465
	AMI Heart Recovery using BiVAD Support	**n/a**	**44.1**	**$405,350**	**$285,690**
	AMI Heart Recovery	**n/a**	**43.2**	**$378,903**	**$267,050**

DRG is based on the FY 2005 version of the Medicare DRG Grouper.
Source: CMS – Medicare Provider Analysis Review (MedPAR), 2003 for inpatient procedures.

Further analysis of the 2003 MedPAR data showed some potentially erroneous discharge data for implant of external heart assist system patients within DRG 525. These include nine patients that appear to have been discharged from the hospital after less than seven days, which seem to be impossible. The average charge for these patients was only $63,000.

V. Regulatory Precedent for Changes to DRG Classification and Relative Weights

Discharges from to hospital inpatient settings are classified into DRGs (diagnosis related groups) for payment under the IPPS (inpatient prospective payment system) based on the patient's principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the inpatient stay. Currently, patient cases are assigned to one of 510 DRGs in 25 major diagnostic categories (MDCs). The records of all Medicare hospital inpatient discharges are maintained in the Medicare Provider Analysis and Review (MedPAR) file. The

data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weight. On occasion, CMS will consider the feasibility of using particular non-MedPAR data when they are given sufficient time to evaluate and test the data.

We reviewed recent Medicare Inpatient Prospective Payment System Final Rules to identify CMS precedent for DRG reclassification and or re-weighting with regard to specific procedures. ***Table V.1*** presents the CMS precedent and their relevance to AMI heart recovery procedures.

Table V.1 - Summary of Regulatory Precedent for DRG Reclassification

CMS Decision	Relevance to Heart Recovery
CMS analysis of intercranial vascular procedures results in new DRG 528 – CMS found that patients with an intracranial vascular procedure and a principal diagnosis of an intercranial hemorrhage were **significantly more costly than other cases** in DRG 1 and 2. These patients have an **acute condition with a high severity of illness and risk of mortality**.. Based on their analysis, CMS created a new DRG 528. (68 FR 45353 August 1, 2003, IPPS Final Rule)	The average charges for intercranial vascular procedure cases were found to be much higher (116% higher) than the average charges for other procedures under DRG 1 and 2. Average charges for AMI heart recovery are estimated to be about 89-103 percent higher than charges for other procedures in DRG 525.
CMS proposed to split DRG 514 based on the presence or absence of AMI, hearth failure, or shock. Patients who are admitted with AMI, heart failure, or shock and have a cardiac catheterization are generally acute patients who require emergency implantation of a defibrillator. There are very high costs associated with these patients. Patients in DRG 515 were also reviewed for significant charge differences between the absence or presence of AMI, hearth failure, or shock. CMS split DRG 514 to DRG 535 w/AMI, heart failure, or shock and DRG 536 w/o AMI, heart failure, or shock. (68 FR 45356 August 1, 2003, IPPS Final Rule)	CMS found a relatively small number of patients in DRG 515 with AMI and a **less-than-10 percent charge difference**. However, in DRG 514, the split was approved because the **charge difference between AMI vs. non-AMI was found to be 24 percent** ($121k vs. $97k). Average charges for AMI heart recovery are estimated to be about 89-103 percent higher than charges for other procedures in DRG 525.
CMS removed procedure 37.64, an operative procedure to remove a heart assist device, from DRGs 478 and 479 and assigned to DRGs 110 and 111. CMS found that the average length of stay and the average charges were higher than the other procedures under DRGs 478 and 479. CMS indicated that the **surgical removal of a heart assist system is a major cardiovascular procedure** and therefore, more appropriately assigned to DGR 110 and 111. CMS indicates that this DRG assignment for this procedure is **more clinically and financially appropriate.** (68 FR 45356 August 1, 2003, IPPS Final Rule)	Average length of stay for procedure 37.64 was 74 percent higher (14.1 days vs. 8.1 days) and average charges were 92 percent higher ($105k vs. $55k). Average length of stay and average charges for AMI heart recovery are estimated to be about 184-190 percent and 89-103 percent higher than other procedures in DRG 525 respectively.

VI. Assessment of Analyses

The average length of stay for heart recovery AMI heart recovery patients was 184 to 190 percent higher than the average length of stay for current DRG 525 procedures. In addition, average charges are estimated to be 89 to 103 percent higher for AMI heart recovery patients as compared to the average charge for all DRG 525 patients. Based on the precedent rulings by CMS, presented above, the average length of stay and charges for AMI heart recovery cases are

sufficiently different from other DRG 525 cases for CMS to consider removing heart recovery procedures from DRG 525 and establishing a new DRG for AMI heart recovery.

In addition, the fact that CMS moved implantable heart assist device procedures to DRG 103 has created incentives for hospitals to use the implantable heart assist device technology instead of the external heart recovery technology for financial reasons over clinical reasons, since the two treatments require similar hospital resources but the payment for the implantable device under DRG 103 is about 72 percent higher than the payment for the new heart recovery technology. The financial incentives created by the Medicare payment policy to choose one technology over another may potentially lead to inappropriate clinical treatment decisions. In particular, use of the external system can recover the heart while use of the internal device cannot. In the design of the IPPS system, it is important that Medicare payment policy be "incentive neutral" so that hospitals can make decisions for using one technology over another based solely on the best clinical outcomes for the patient.

If establishing a new DRG for heart recovery is inappropriate, then we believe it should be moved to DRG 103 for the following reasons:

- Average length of stay and charges for heart recovery are similar to those for DRG 103;
- Heart recovery cases are similar to implantable heart assist system cases both clinically and resource intensity (average charges within 6-12 percent of DRG 103 cases, based on conservative estimates); and
- DRG 103 is the only DRG within MDC 5 (diseases and disorders of the circulatory system) with average charges that are higher than DRG 525. Therefore, there is no other appropriate place to put heart recovery patients.

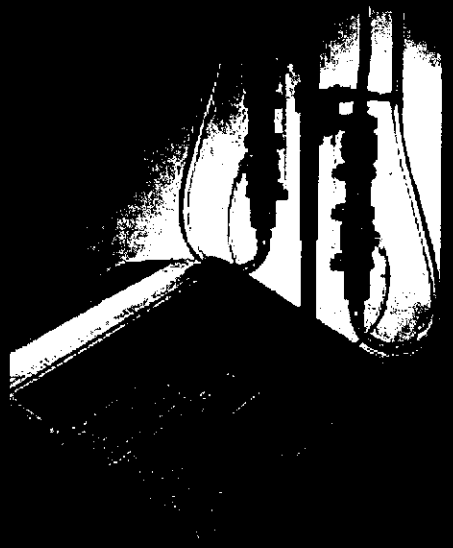
A method that could be used to identify AMI heart recovery cases would include discharge records that include an ICD-9 procedure code of 37.65 (Implant of external heart assist system) and a principle diagnosis code of AMI (410.01, 410.11, 410,21, 410,31, 410.41, 410.51, 410.61, 410.71, 410.81, or 410.91).

Recovery from Acute Heart Failure:

Reimbursement challenges and proposed solutions

Center for Medicare Management
Washington D.C.
12 May 2005

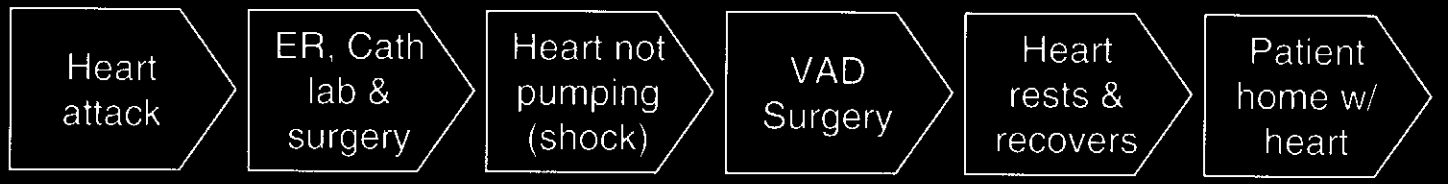
Abiomed Technology



Ventricular Assist Devices (VAD)

- External or implanted mechanical device that replaces or supports the pumping function of the heart
- Implantable devices (DRG 103) generally for patients needing longer term support prior to a transplant if not recovered. Usually left side support only.
- External devices (DRG 525) allow natural heart to rest while on support with least invasive surgery. Allows heart to recover, usually supporting both sides of the heart (bi-ventricular).

External Example



~70% of survivors on AB5000 external device have gone home with their own heart

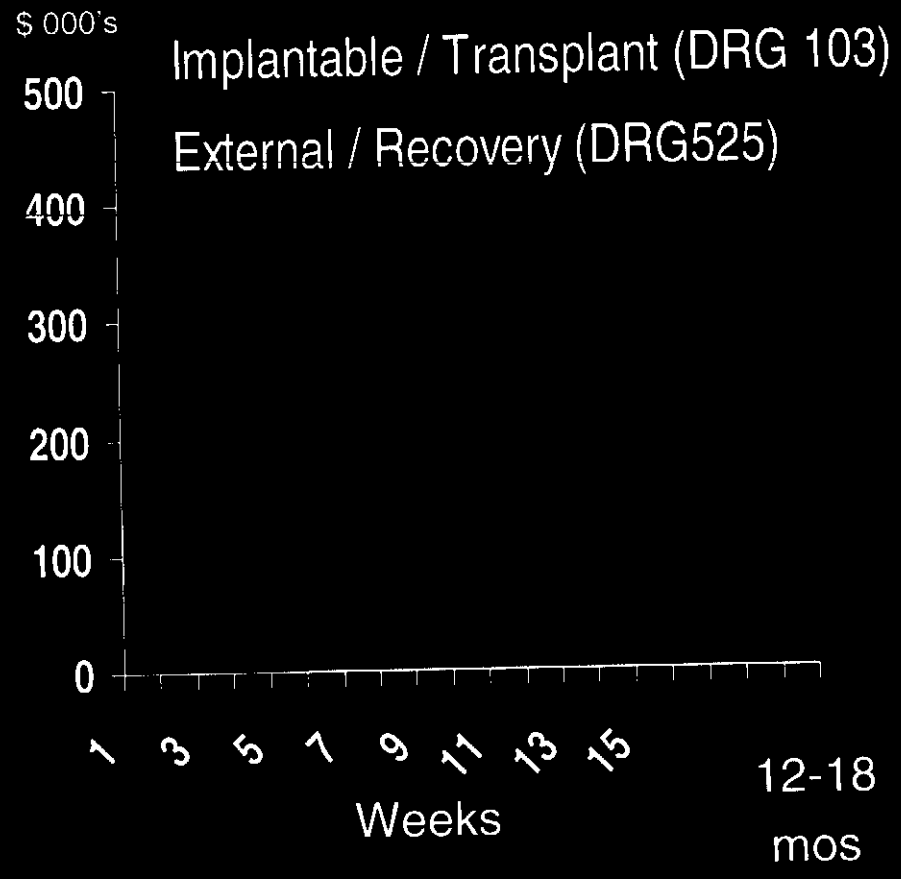
Why we are here today

- Requested validation of patient data from third party and current hospital charge data now available from Lewin Group analysis.
- Concerns reimbursement changes will add costs to Medicare. Reality = each patient recovered saves Medicare $50-$300k
- Recovery is prevention-based care for acute heart failure, reducing chronic care patients (transplant or long-term device)

- Changing recovery trends in length of support and outcomes from new technology not appropriately reimbursed within current DRG
- Requesting increased reimbursement for recovery from acute heart failure such as AMI (recommend new AMI VAD DRG)
- Recommend second DRG 103 payment or modifier if patient goes on to a transplant to eliminate need for additional surgery

Financial Impact Growing Quickly

CMS Payments/patient



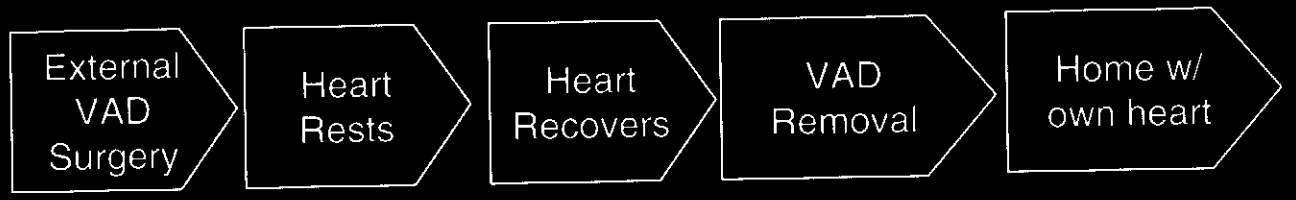
Additional Costs per 1000 Patients

~$300M annually

Example of Hospital Options - Heart Attack

Recovery → DRG does not cover costs

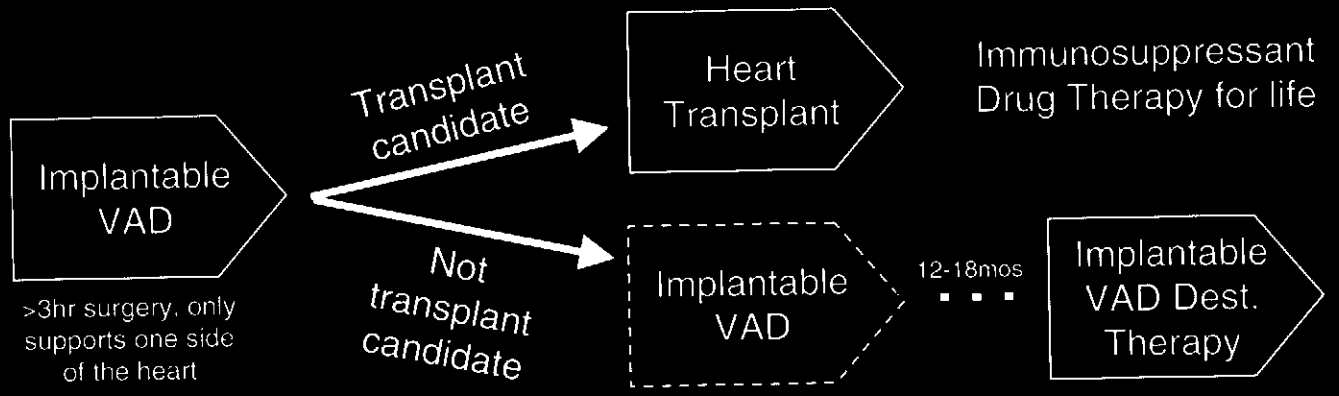
Est Ave Reimb



~$83k
(DRG 525)

<1hr surgery, supports both sides of the heart

Implantable → Financial incentive



~$260k
(DRG 103 x2)
$391k after 1 yr

Or

~$390k
(DRG 103 x3)

~$130k (DRG 103) — Discharge → ~$130k (DRG 103) — Discharge → ~$130k (DRG 103)

ABIOMED

AMI Patient Charges Higher than DRG 525

Lewin Group Charge Data Analysis

	Procedure	Average length of stay	Average total charge per case	Average standardize charge per case /1
37.62	Insertion of non-implantable heart assist system	18.6	$193,054	$146,810
37.63	Repair of heart assist system	13.1	$166,250	$135,352
37.65	Implant of external heart assist system	12.5	$229,430	$188,200
	All DRG 525 procedures	15.2	$200,149	$159,121
	AMI Heart Recovery using Bi-Ventricular Assist Device Support	**44.1**	**$405,350**	**$285,690**
	AMI Heart Recovery	**43.2**	**$378,903**	**$267,050**

89-103% higher ave. charges

1/ Charges are standardized for differences in area wage levels, indirect medical education and DSH across hospitals. DRG is based on the FY 2005 version of the Medicare DRG Grouper.
Source: Lewin Group analysis of 2003 Medicare Provider Analysis Review (MedPAR) data.

Multiple Sources Validate Reimbursement Gap

External VAD Surgery → Heart Rests → Heart Recovers → VAD Removal → Home w/ own heart

OR	$9k
RVAD	$45k
LVAD	$45k
Supplies	$1k

Length of Support 21 -28 days ave.

10-15 Days ICU ave. costs $1.500 – 3.000

11-15 Days step down unit $750 - 1000

OR Extraction $9k

Length of Stay 7 days

2 days ICU, ave. costs $1,500 – 3,000

5 Days step down unit $750 - $1,000

Sample Analysis of Costs

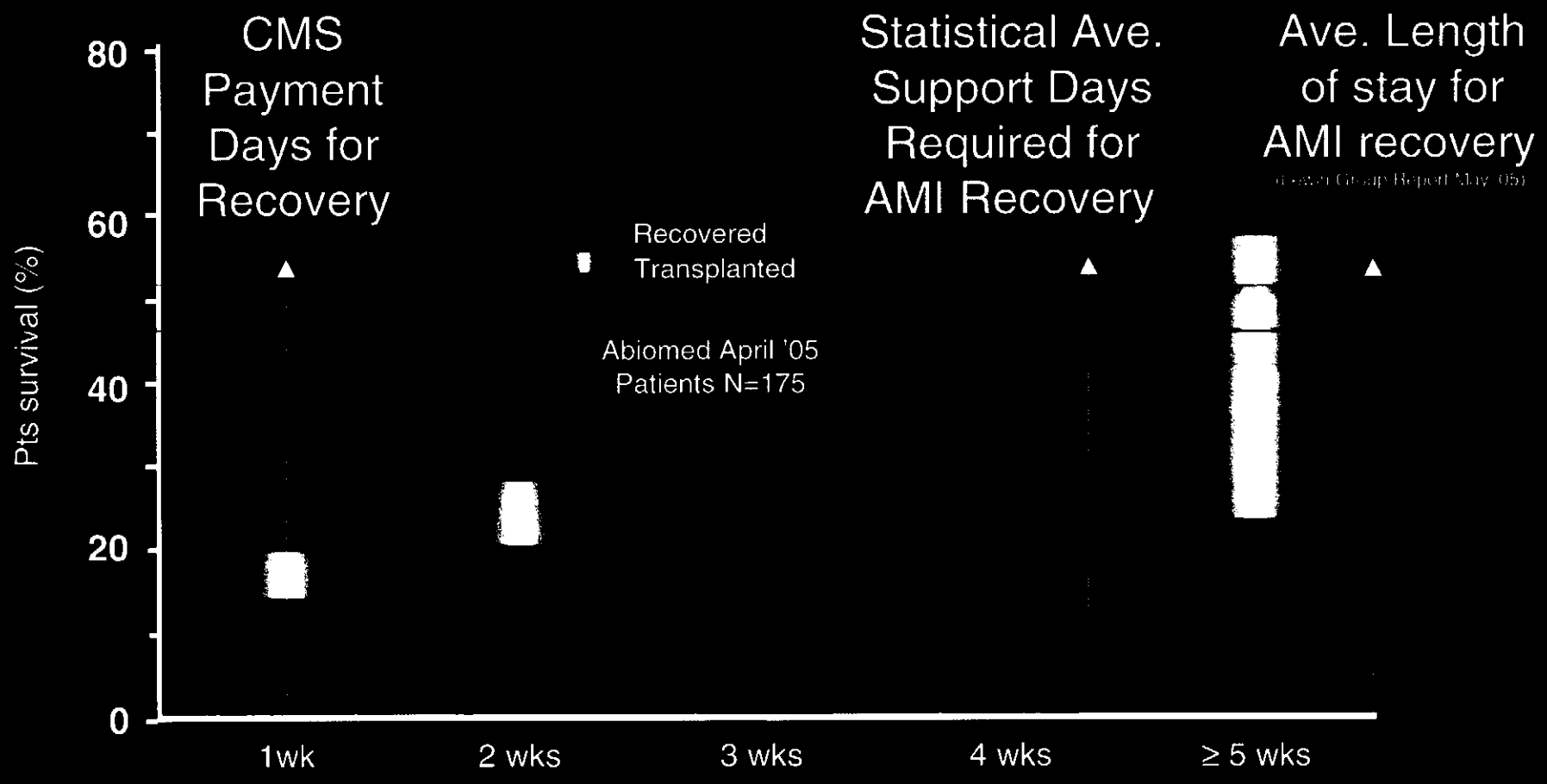
Hospital Resources Estimated Ave. **COSTS** =$140 -180k

Lewin Analysis of all AMI patients – Estimated ave. **CHARGES** =$267 - 405k

Sample 2004/2005 patients – **Actual** ave. hospital **CHARGES** =$349 – 515k

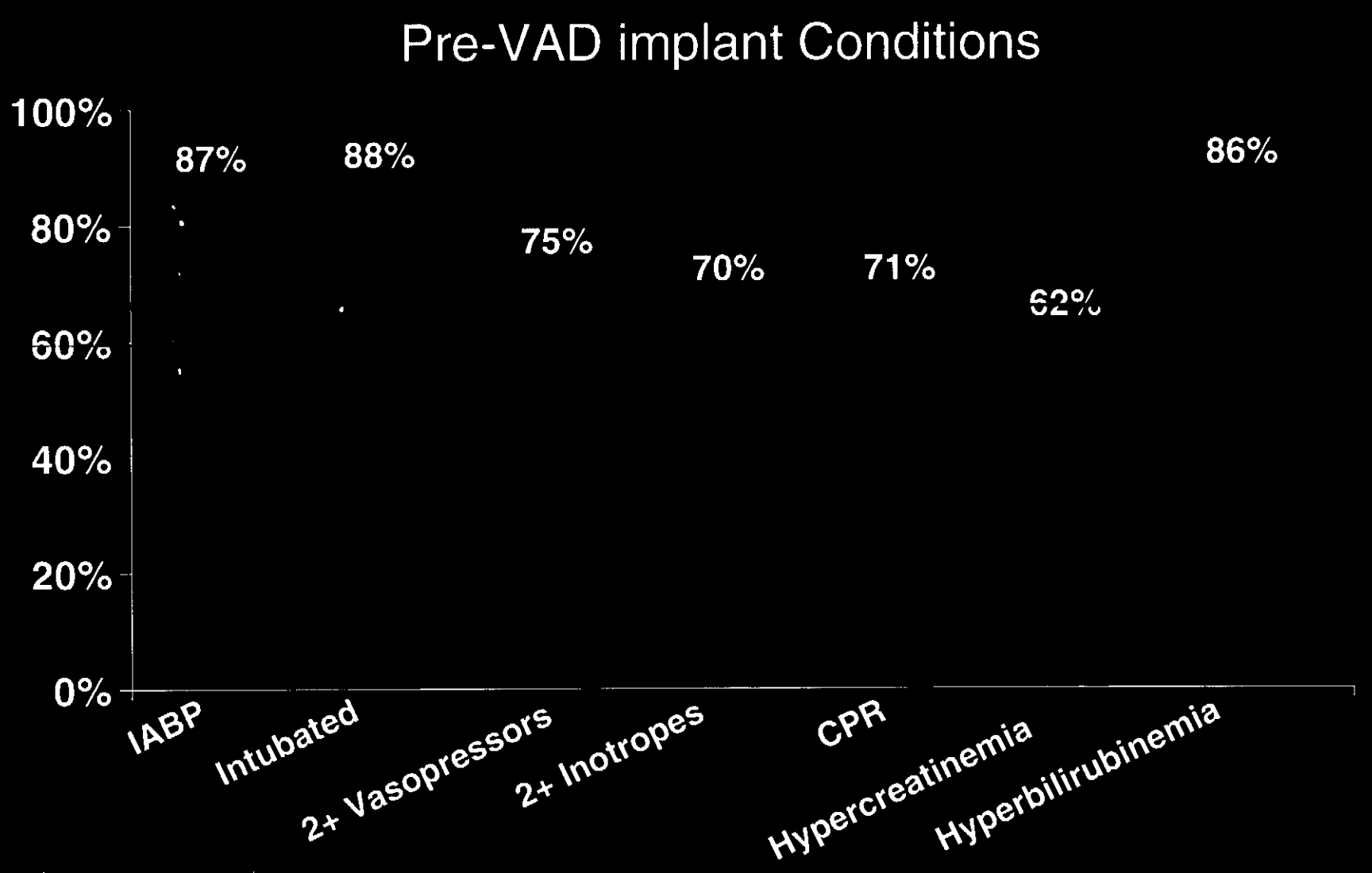
Recovery → DRG 525 does not cover costs Reimb. ~$83k

Historically Assumed Short Term Recovery

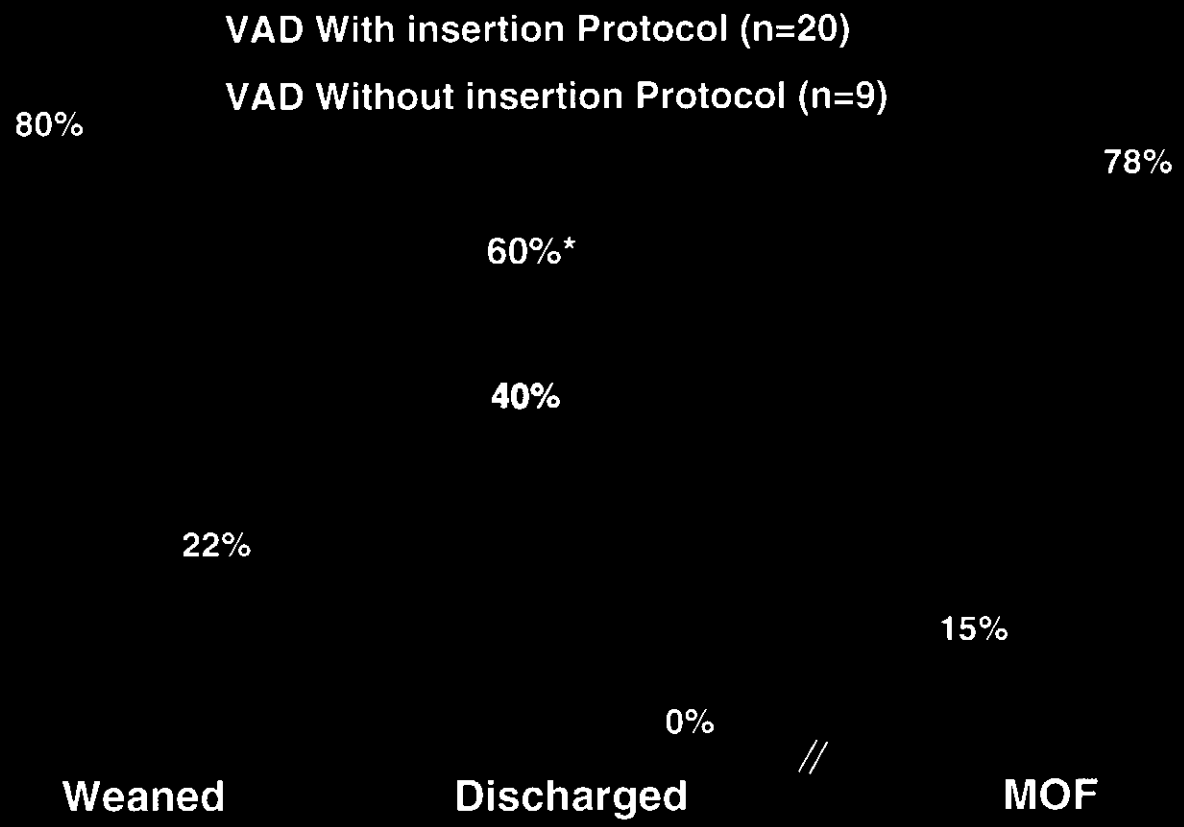


Hospitals lose money when enough time is provided to recover organs, and receive no coverage when going on to a heart transplant

Patient Condition - AMI Cardiogenic Shock



Proven Success with Heart Recovery



* Cardiol Clin. 2003 Feb;21(1):43-9

Recovery the Best Clinical Outcome

- Better quality of life with no tether to the hospital
- Prevention-based care for heart failure, reducing the number of chronic care patients in or soon to be in Medicare system
- Lower cost per patient vs. alternatives, reimbursement does not accurately match costs.
- Limited heart transplants available (only 2,200/yr), and related savings from lifetime immunosuppressant drug therapy (costs $20-50k yr).
- Evidence based … multiple peer reviewed publications on successful recovery with external ventricular assist devices, considered standard of care for heart failure programs.

Summary of Lewin Analysis

Current reimbursement discouraging recovery;

- Statistics show recovery takes >25 days on support, >43 days length of inpatient stay
- Charge data for AMI support 89-103% higher than other DRG 525 claims
- Data shows recovery patients under reimbursed for length of stay, especially AMI
- Hospitals have financial incentive to perform 2nd surgery on patients not recovering in order to discharge prior to transplant.

Recommended Solutions Based on Lewin Report

- Data demonstrates a patient population not appropriately reimbursed in current DRG structure.
- Create new DRG for acute external ventricular support patient population such as AMI with current diagnostic and procedure codes.
- Similar diagnostic/procedure codes map to DRG 103
- Increase relative weight to align with true hospital charges
- Provide 2nd payment or additional payment for heart transplant (DRG 103) and recovery (DRG 525) for those who do not recover to eliminate incentive for another device & surgery

Regulatory Precedent for DRG Change

Lewin Group - Historical CMS recommendations

CMS proposed to split DRG 514 based on the presence or absence of AMI, hearth failure, or shock. Patients who are admitted with AMI, heart failure, or shock and have a cardiac catheterization are generally acute patients who require emergency implantation of a defibrillator. Patients in DRG 515 were also reviewed for significant charge differences between the absence or presence of AMI, hearth failure, or shock. Two new DRGs would have the same procedures currently listed for DRG 514, but would split based on the presence or absence of AMI, heart failure or shock as a principle diagnosis. (68 FR 45356 August 1, 2003, IPPS Final Rule)

Also reference DRG 115 and DRG 116 for similar acknowledgement of increased resources required for AMI patients

CMS found a relatively small number of patients in DRG 515 with AMI and a **less-than-10 percent charge difference**. However, in DRG 514, the split was approved because the **charge difference between AMI vs. non-AMI was found to be 24 percent** ($121k vs. $97k).

Average charges for AMI heart recovery are estimated to be about 89-103 percent higher than charges for other procedures in DRG 525.

Proposal: Create new DRG for AMI patients for the same procedure codes such as 37.65 and presence of AMI diagnosis codes of 410.01, 410.11, 410,21, 410,31, 410.41, 410.51, 410.61, 410.71, 410.81, or 410.91.

Alternative: Route same patients to DRG 103 with similar LOS and charges

Broad Concern Across the U.S.

- Multiple hospitals responding to the NPRM including leading VAD programs, academic centers, community hospitals and specialty heart hospitals (sample):

  - –Lankenau Hospital (Philadelphia)
  - –St. Mark's Hospital (Salt Lake City)
  - –Beth Israel (Boston)
  - –Cleveland Clinic
  - –Indiana Heart Hospital
  - –Massachusetts General
  - –New York/Columbia Presbyterian
  - –Robert Wood Johnson (New Brunswick)
  - –Northern Iowa Mercy Health Center
  - –University of California San Diego
  - –Medical University of South Carolina
  - –Dayton Heart Hospital

- Hospital CEOs, CFOs, and surgeons all recognizing the critical need to offer recovery to patients, and the need to improve the reimbursement situation.

- Patients and patient families

- Multiple members of Congress and elected officials

Appendix

Lewin Analysis of AMI Patient Charges

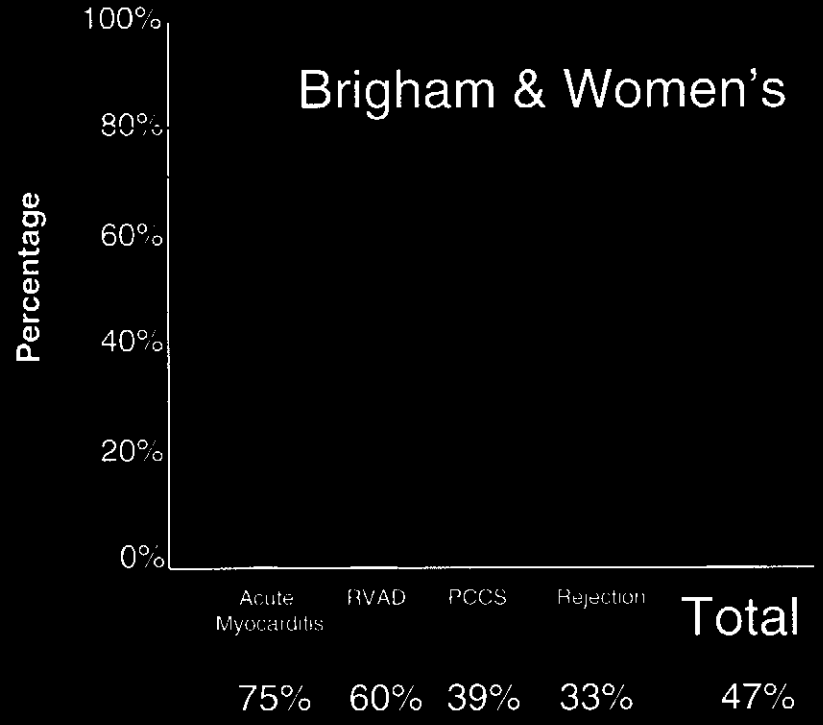
Ancillary Department	AMI Heart Recovery with BiVAD Support	AMI Heart Recovery
Pharmacy	$38.105	$38.105
BiVAD device	$110.438	$86.773
Physical Therapy	$174	$174
Occupational Therapy	$70	$70
Speech Pathology	$79	$79
Inhalation Therapy	$7,027	$7,027
Blood	$863	$863
Blood Administration	$17.687	$17.687
Operating Room	$36.677	$36.677
Cardiology	$14.588	$14.588
Anesthesia	$6.313	$6.313
Laboratory	$26.817	$26.817
Radiology	$2.764	$2.764
MRI	$169	$169
Outpatient	$95	$95
Emergency Room	$345	$345
ESRD	$413	$413
Clinic	$4	$4
Other Med/Surg Supplies (est.)	$5.000	$5.000
Other	$1,336	$1.336
Total Ancillary Charges	**$268,963**	**$245,299**

Unit Type	Charge Per Day	Average Days per Unit	Average Per-Case Charges
AMI Heart Recovery with BiVAD Support			
Routine Accommodations	$1.728	14.7	$25.376
ICU/CCU	$3.774	29.4	$111.011
Total Accommodation Charges	$3.092	44.1	$136.387
AMI Heart Recovery			
Routine Accommodations	$1.728	14.4	$24.859
ICU/CCU	$3.774	28.8	$108.746
Total Accommodation Charges	$3.092	43.2	$133.604

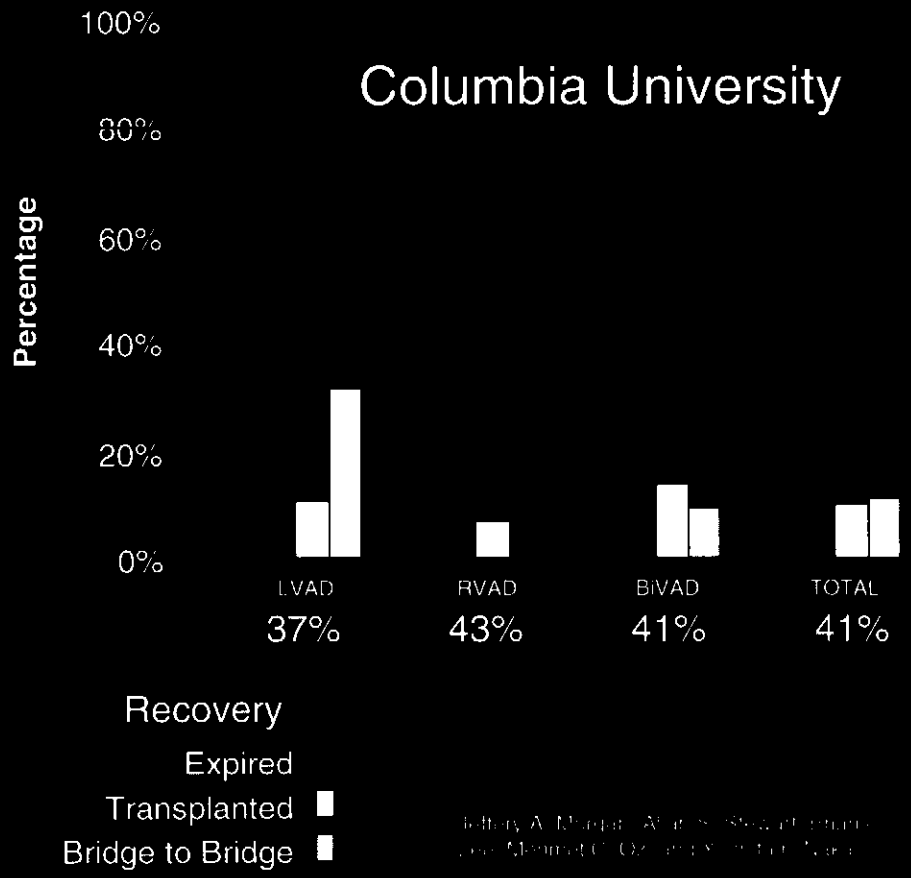
Table III.5 Standardized Charges	AMI with BiVAD Support	AMI All patients
Average Accommodation Charges	$136.387	$133.604
Average Ancillary Department Charges	$268.963	$245.299
Average Total Charge	$405.350	$378.903
Average Wage Index	1.0499	1.0499
Average COLA	1.0000	1.0000
Average IME Adjustment	0.2509	0.2509
Average DSH Adjustment	0.1200	0.1200
Step 1: Adj Charge = Avg Charge / (1+IME+DSH)	$295.682	$276.390
Step 2: Std Charge = (.711*Adj Charge)/wage index + (0.289*Adj Charge)*COLA	$285.690	$267.050

Proven Success with Heart Recovery

47% Recovery



41% Recovery



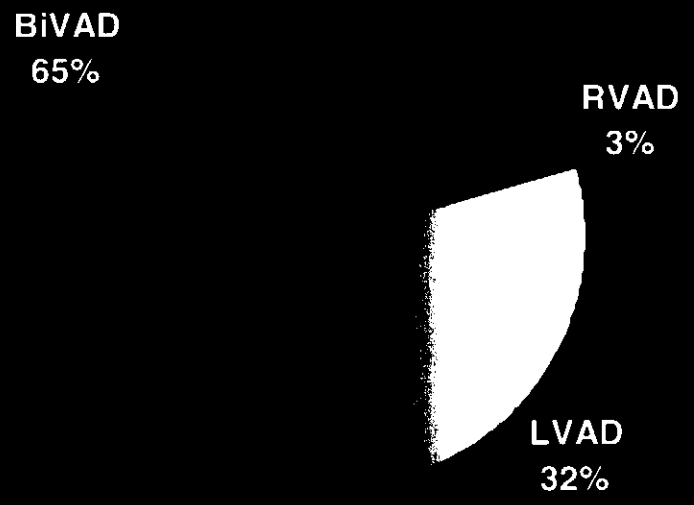
Benefits of Bi-ventricular Support

AMI Cardiogenic Shock
93 Patient Study
Mark B. Anderson, MD

Director, Cardiac Transplantation & Circulatory Support
UMDNJ / Robert Wood Johnson Medical School

	Left or right Side only	Bi-ventricular support
Number of patients	46	47
Survival to discharge	13	24

AMI Cardiogenic Shock
AB5000 Patient Registry
35 Patients - Jan 05



Timeline of Events

July '04 (Documented from NPRM & final ruling Aug.)

- Abiomed identified financial incentives that discourage recovery
- CMS final ruling understood concern and agreed to re-look at the issue

Aug - Dec '04

- Continued data collection, confirmed incentives to CMS Dec. 04

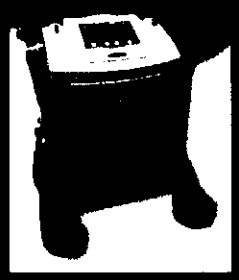
Jan - Feb '05

- Reviewed new technology/patient clinical data with CMS on recovery (2X recovery rate, but requires 28 days of support, 60 days total length of stay)

March '05

- Provide appropriate reimbursement for recovery of acute patients
- Requesting DRG 525 and 103 payment when transplant required

Abiomed, Inc.



- Develop and manufacture cardiac mechanical assist devices & the world's only Total Artificial Heart in Danvers, MA since 1981
- Products protect, recover or replace failing hearts
- Recovery = heart can rest and recover the cells (patients go home with their own heart), takes 4-6 wks
- 250+ employees, Nasdaq: ABMD
- Revenue FY05 $37M est.

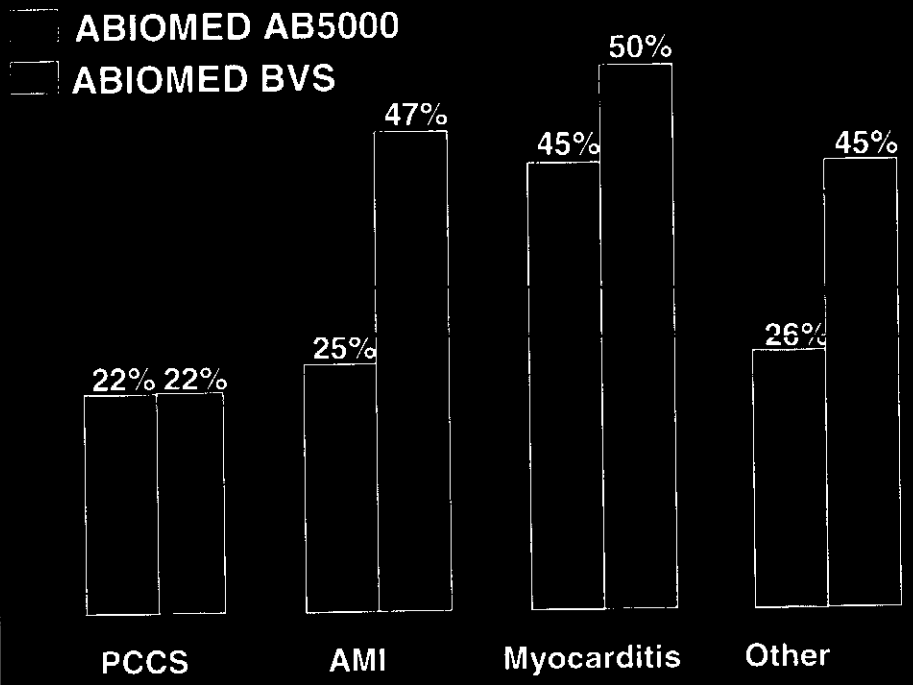
Clinical Excellence

using ABIOMED Technology

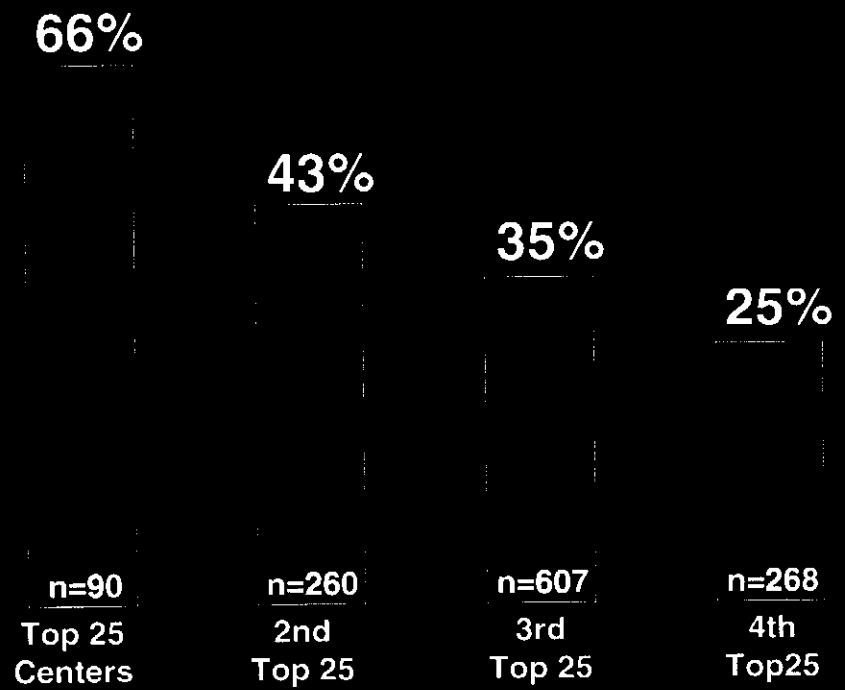
Karim Benali, M.D
Vice-President
Product Development

ABIOMED Survival Data

All Patients: Survival



Top Centers: Survival



*2 or more Patients

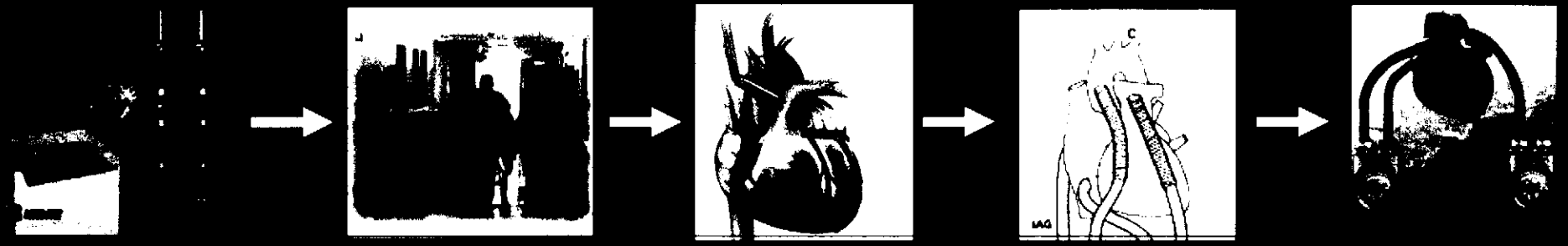
- ABMD Clinical Data Registry
- ID Best Practice Sharing Protocols

- BVS / AB Users in Data since '93
- >2200 Patients, >650 Centers

* ABIOMED AB5000 Patient Database
* ABIOMED BVS 5000 Patient Database

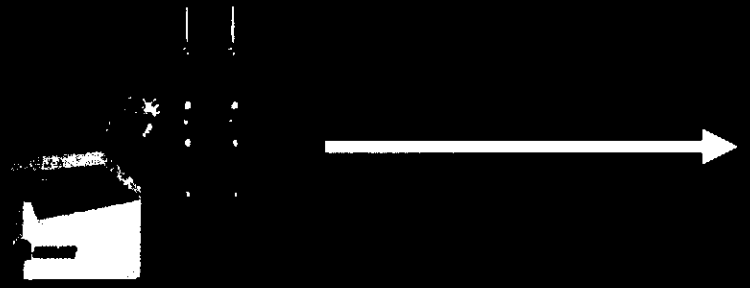
Avoid a Second Surgery

Before AB5000 ~ 2 hours



BVS Pump → New surgery → On by-pass → Re-cannulation → Other device

Now with AB5000 ~ 10 min.



BVS Pump → ABMD Ventricle

More than 1 in 4 *(43/161)patients transitioned from the BVS (SPOKE to HUB)*

AB5000 increases Chance of Recovery by Reducing Surgery, Bleeding and Infection

ABIOMED SHOCK Registry using AB5000 Technology

A Retrospective Study on post AMI Cardiogenic Shock including 21 US Centers: Preliminary Results

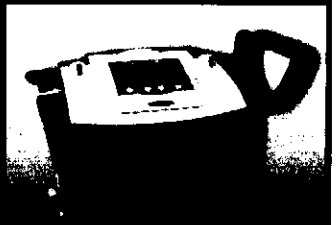
ABIOMED AB5000 System Performance

Ventricle:

BVS 5000 (ALOS)	5 ± 5 days
AB5000 (ALOS)	15 ± 5 days
AB5000 Patient (longest LOS)	153 days
Lab Testing	> 365 days

Ventricles after 95 days of support on a Bi-VAD patient @ Mayo clinic

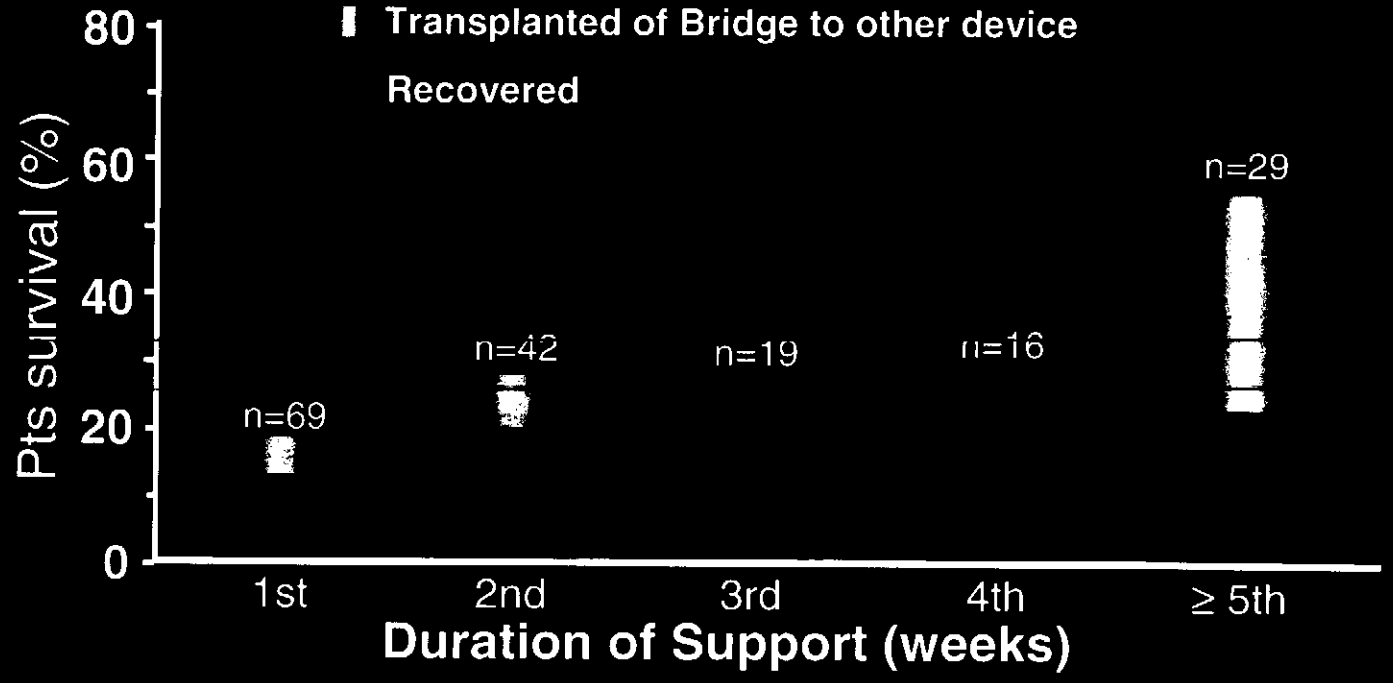
Console:



- More than 120 consoles installed and 10 years cumulated function
- More than 17 months Lab-test with zero failure for Console
- ~3500 hours of continuous clinical support on a single patient

Excellent Hemocompatibility and Reliability of the System

Recovery as a Function of Time



- Majority of patients recover after 1 week on support
- 70% of saved patients recover native heart function
- Transplant becomes an alternative when no recovery of native heart function.

Recovery After First Week is Practical

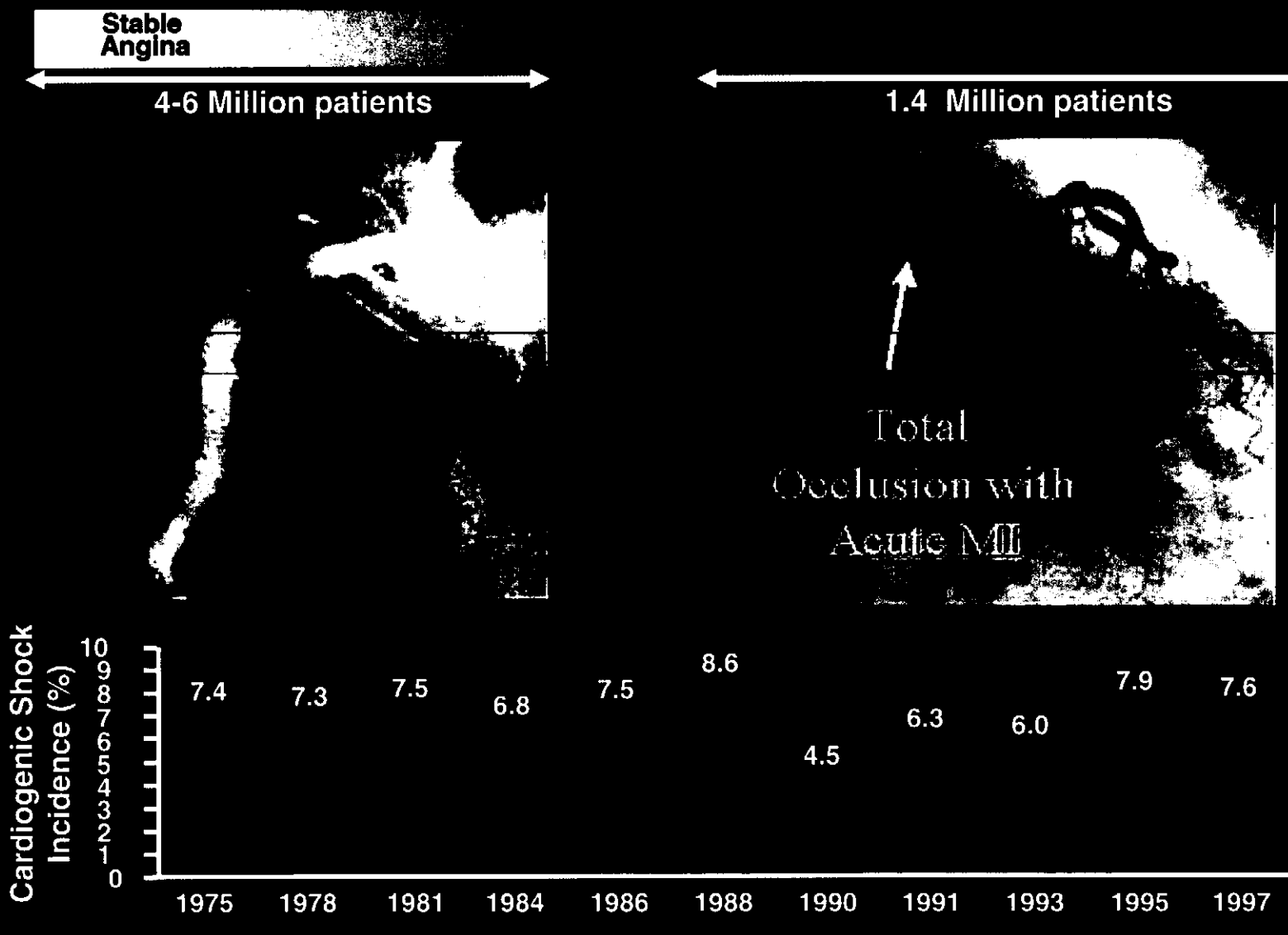
ABIOMED Voluntary Data Registry for AB5000 as of April 2005.

Cardiogenic Shock

after

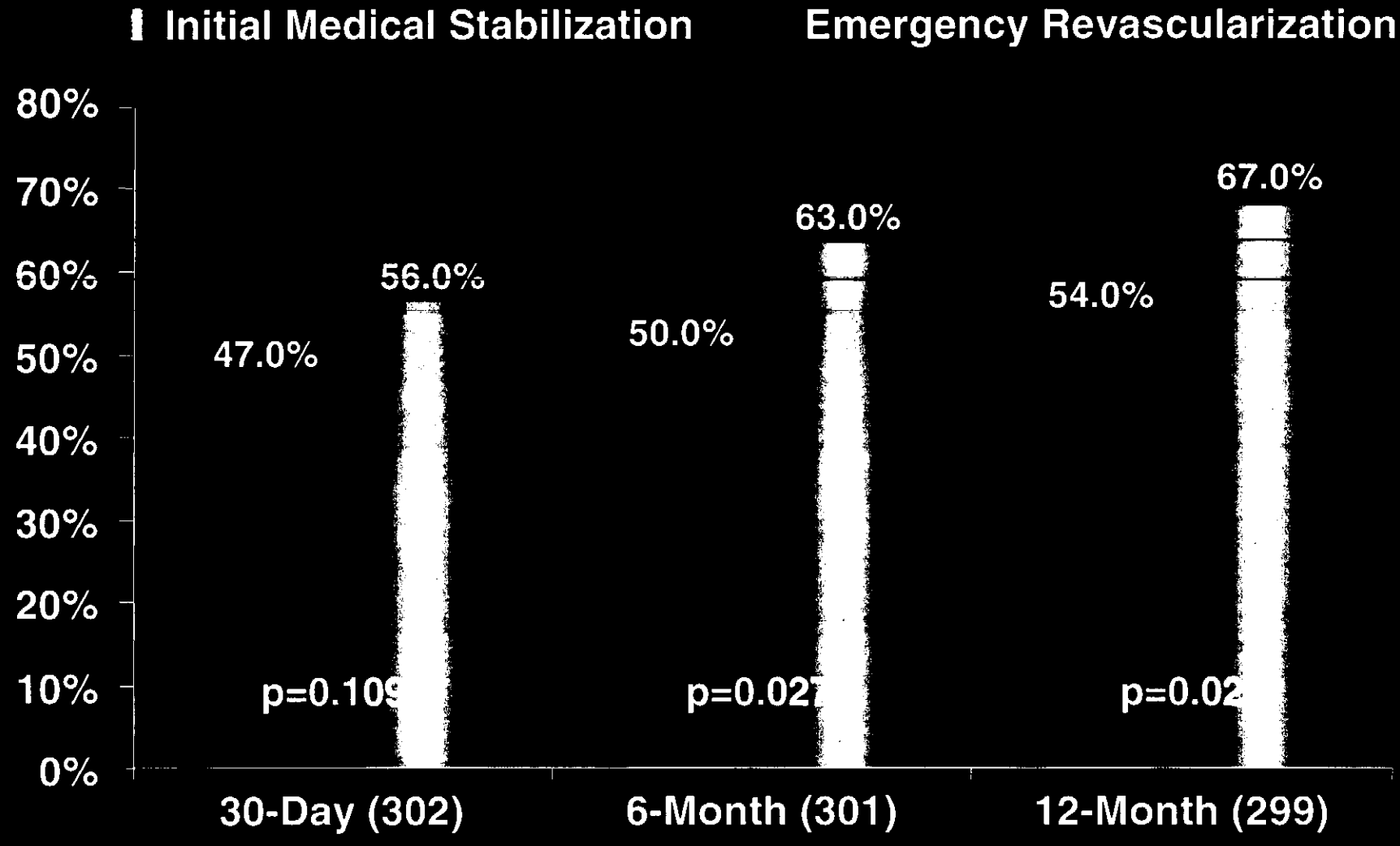
Acute Myocardial Infarction

Clinical Spectrum of Cardiogenic Shock



Goldberg et al. NEJM 1999; 340:1162

SHOCK Trial: 12-Month Mortality



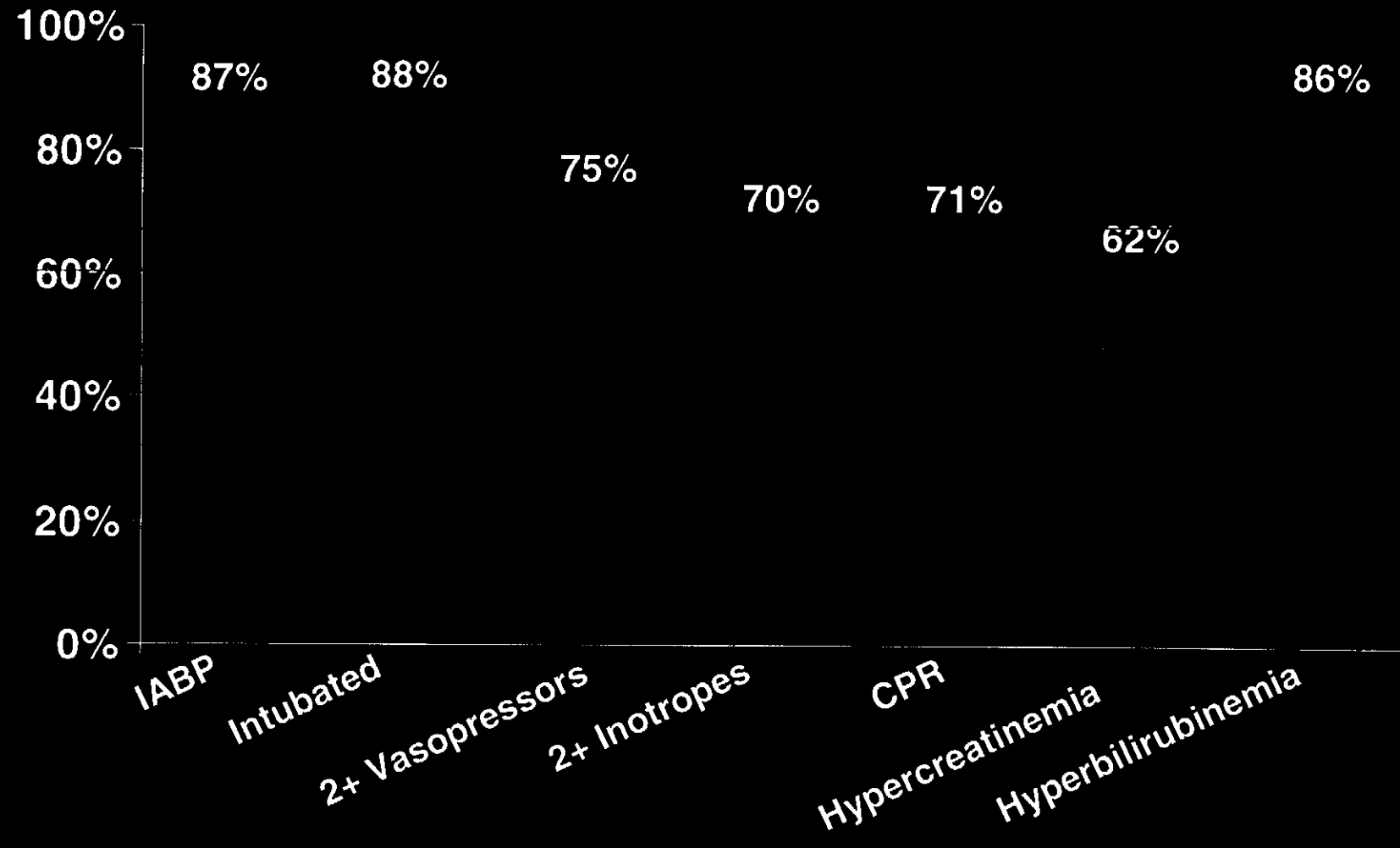
Hochman, JAMA 285: 190, 2001

ABIOMED AB5000 SHOCK Registry: Patients Population (n=45)

Patient Characteristics	Mean [Min - Max] or %
Age (yrs)	53 [33 - 85]
Gender (Male in %)	73 %
History of:	
HTN	56%
Diabetes	25%
Prior MI	38%
CHF	31%
ST Elevation	92%
Revascularization: . Lytic	71%
. Mechanical (r/PTCA,Stent,CABG)	88%
Bi-VAD Support	59%
Onset of Shock to VAD implant (hrs)	45.6 [1 - 180]

ABIOMED AB5000 Data Registry for AMI Cardiogenic Shock as of April 8th, 2005

ABIOMED AB5000 SHOCK Registry: Pre-VAD implant Conditions

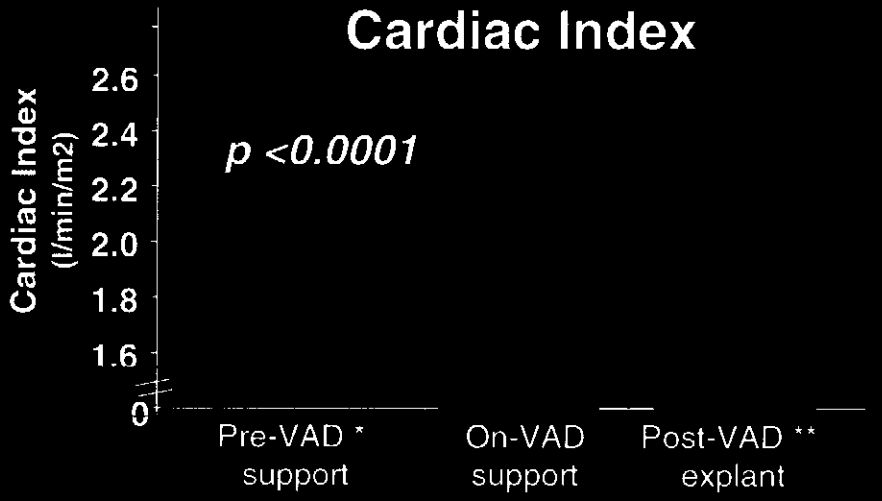


N ≤ 29 depending on variable

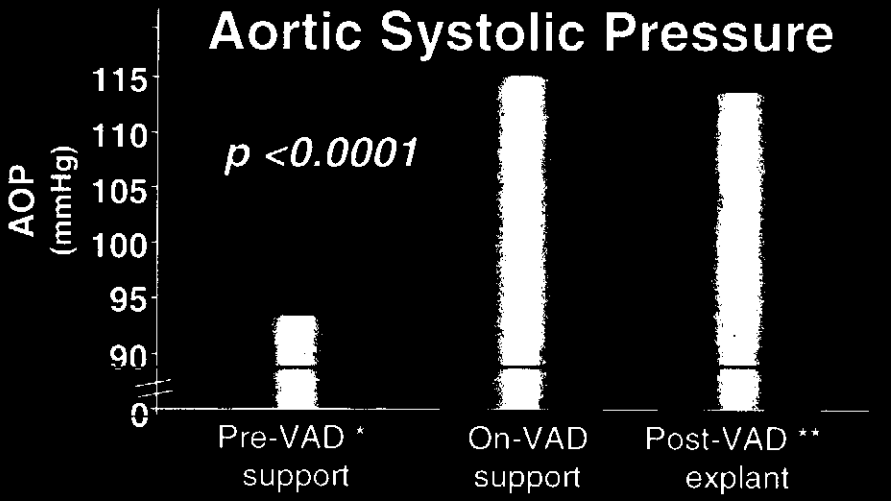
ABIOMED AB5000 Data Registry for AMI Cardiogenic Shock as of April 8th, 2005

ABIOMED AB5000 SHOCK Registry: Improved Patient Hemodynamics

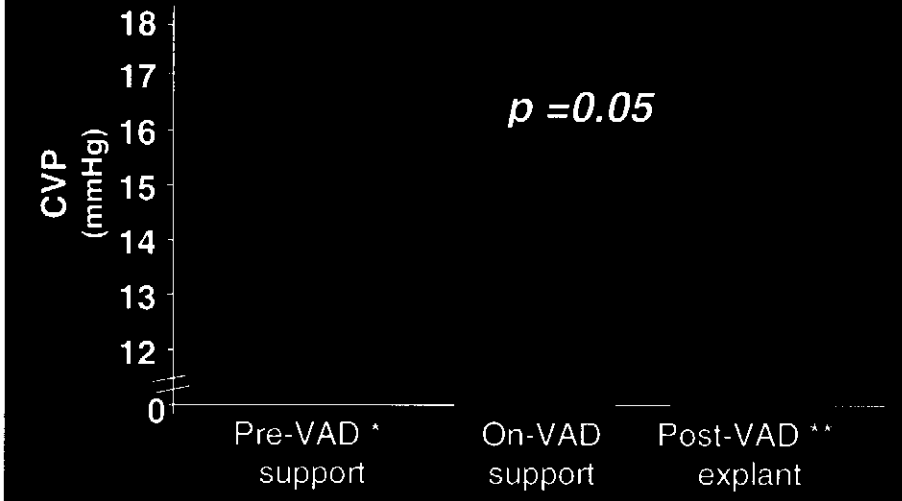
Cardiac Index



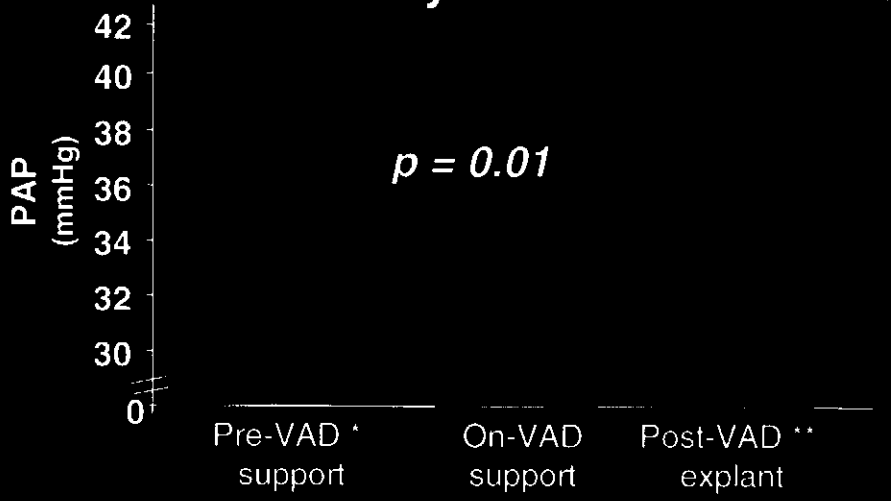
Aortic Systolic Pressure



Central Venous Pressure



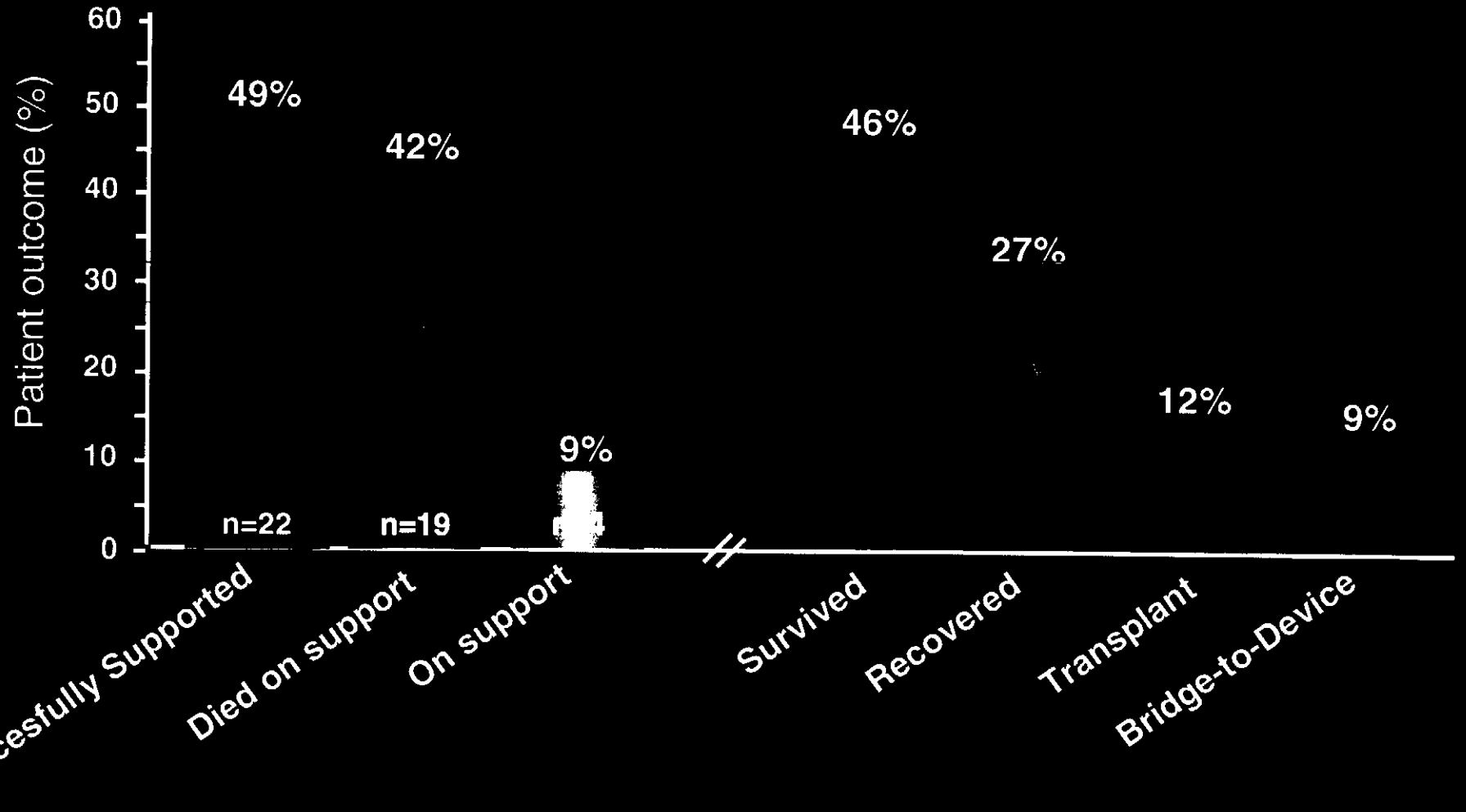
Pulmonary Arterial Pressure



* with Optimal Medical Management and drugs; ** Only for patients that recovered.

ABIOMED AB5000 Data Registry for AMI Cardiogenic Shock as of April 8th, 2005

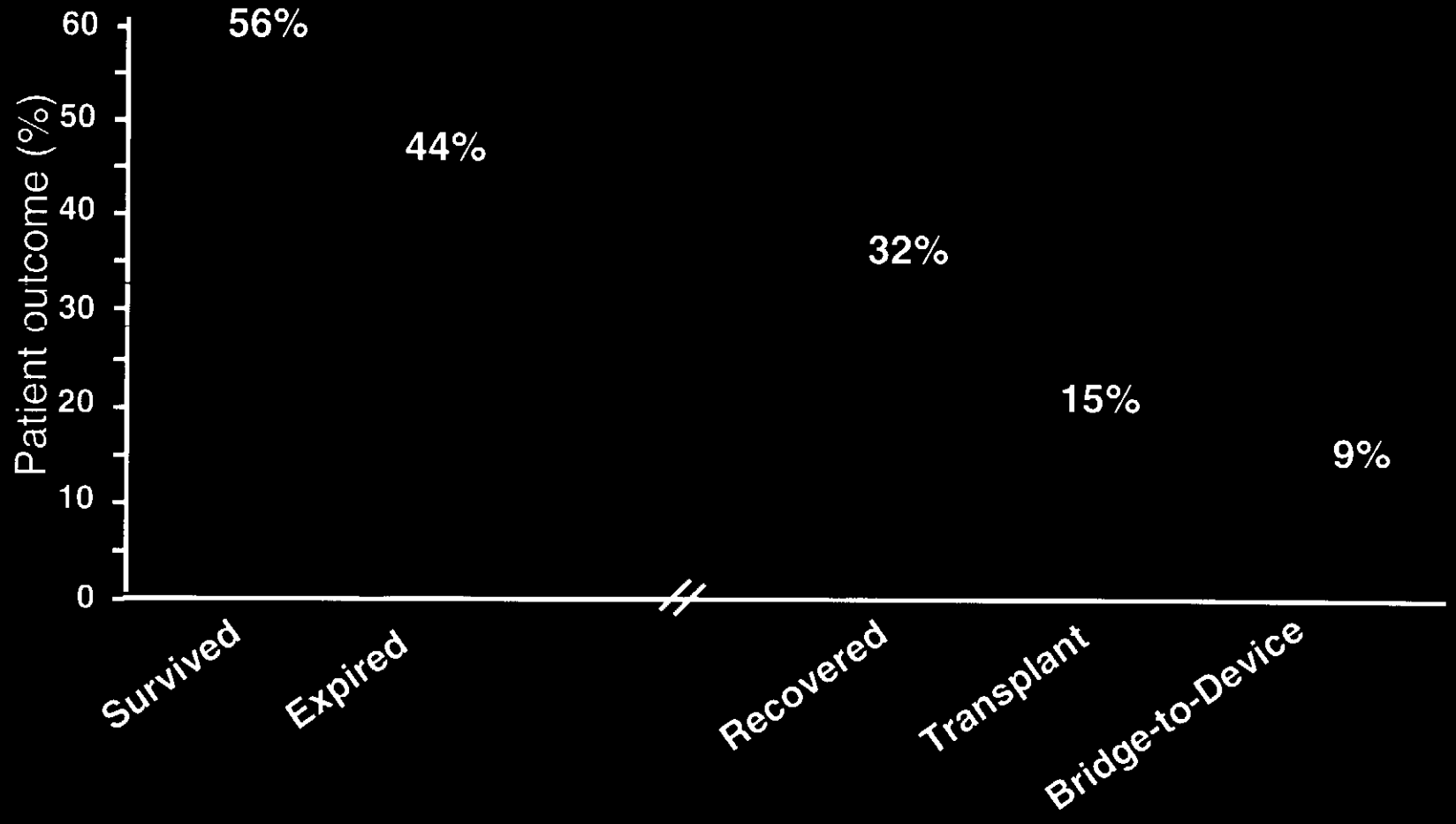
ABIOMED AB5000 SHOCK Registry: Patients Outcome*



*Includes every single patient identified and every center between up to April 8th, 2005 (N=45). Not best practices.

ABIOMED AB5000 Data Registry for AMI Cardiogenic Shock as of April 8th, 2005

ABIOMED AB5000 SHOCK Registry: Patients Outcome**



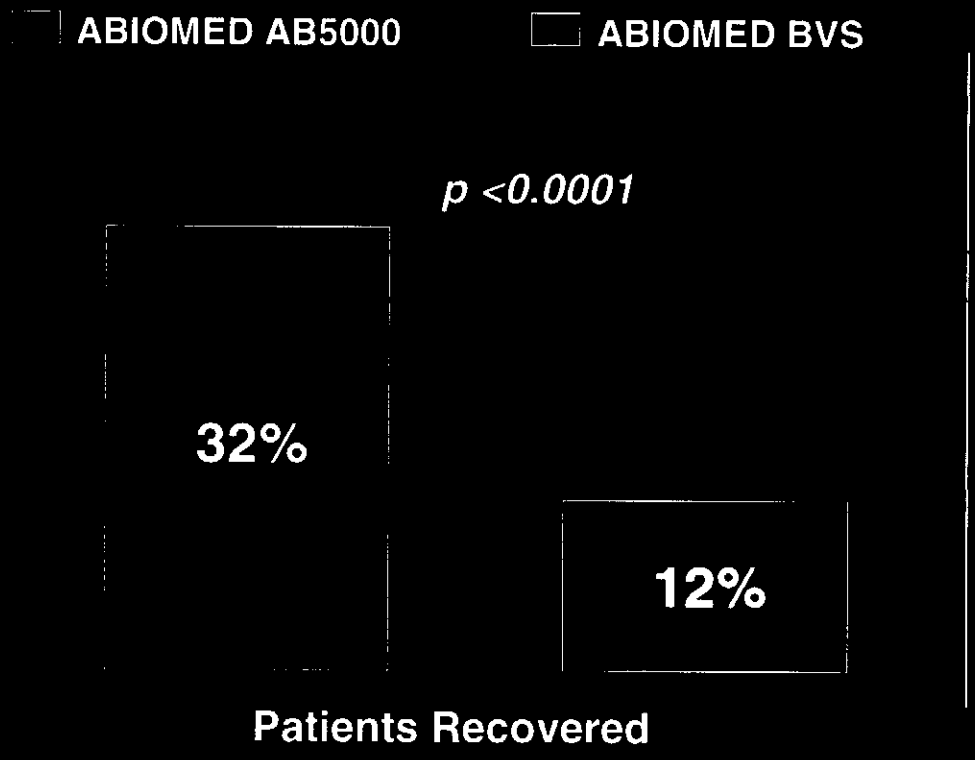
~ 60% of survivors recover native heart function

**Includes all sites but one (outlier, ~10% survival). Not best practices.

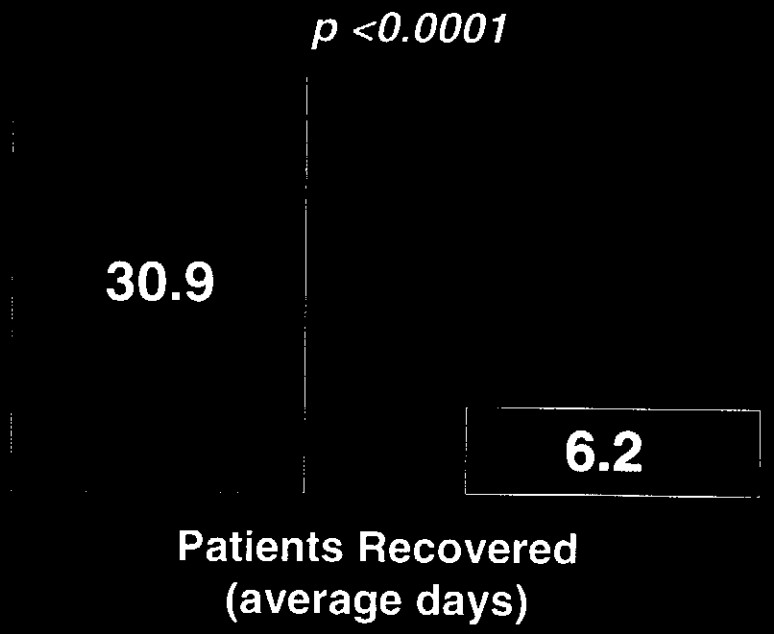
ABIOMED AB5000 Data Registry for AMI Cardiogenic Shock as of April 8th, 2005

ABIOMED AB5000 SHOCK Registry: Length of Support impacts Outcome

Patients Recovered



Length of Support



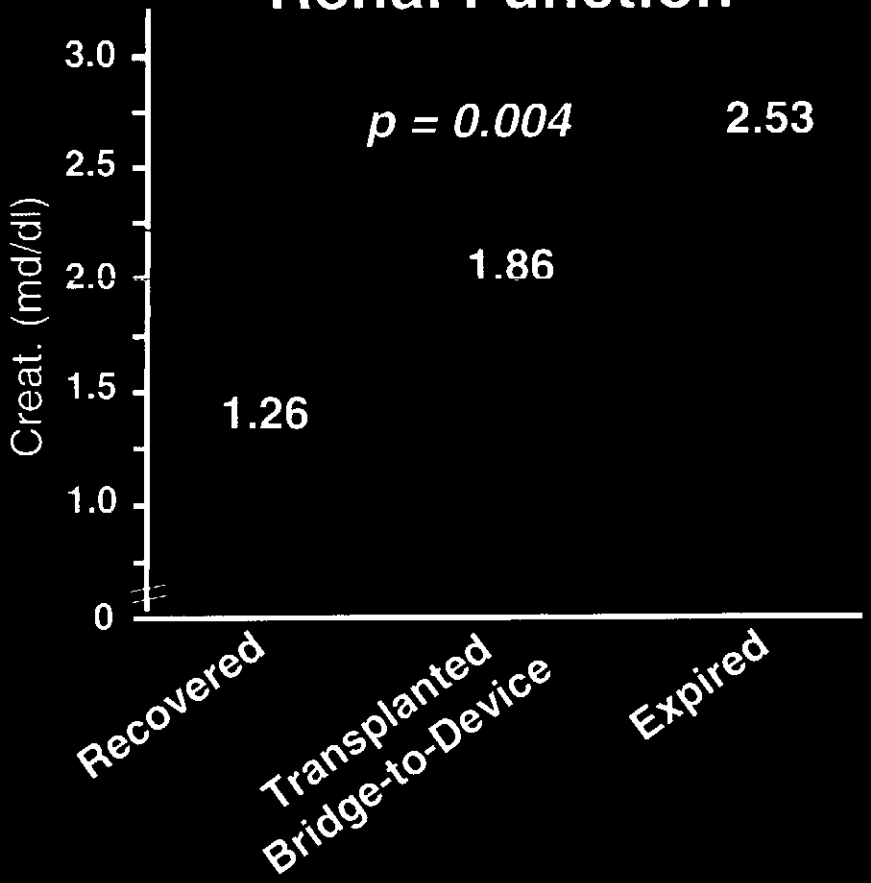
Early weaning may reduce the chance of recovery

Stunned Myocardium may need more time to recover than expected

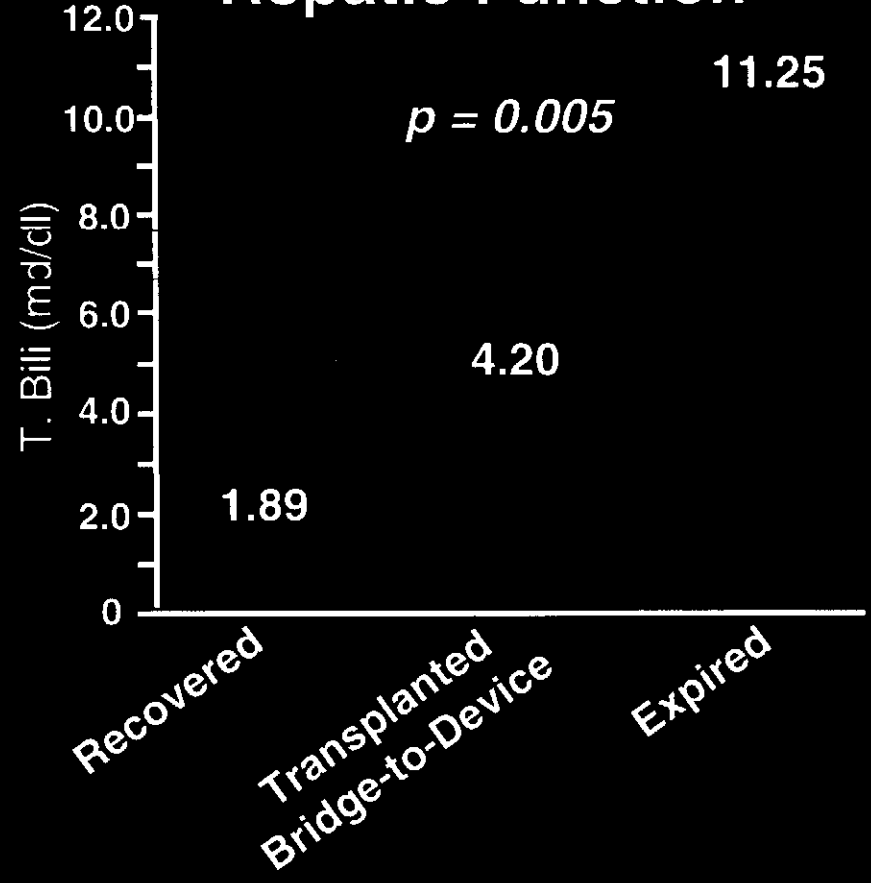
ABIOMED AB5000 Data Registry for AMI Cardiogenic Shock as of April 8th, 2005

ABIOMED AB5000 SHOCK Registry:
Pre-implant Condition impacts outcome

Pre-implant Renal Function



Pre-implant Hepatic Function

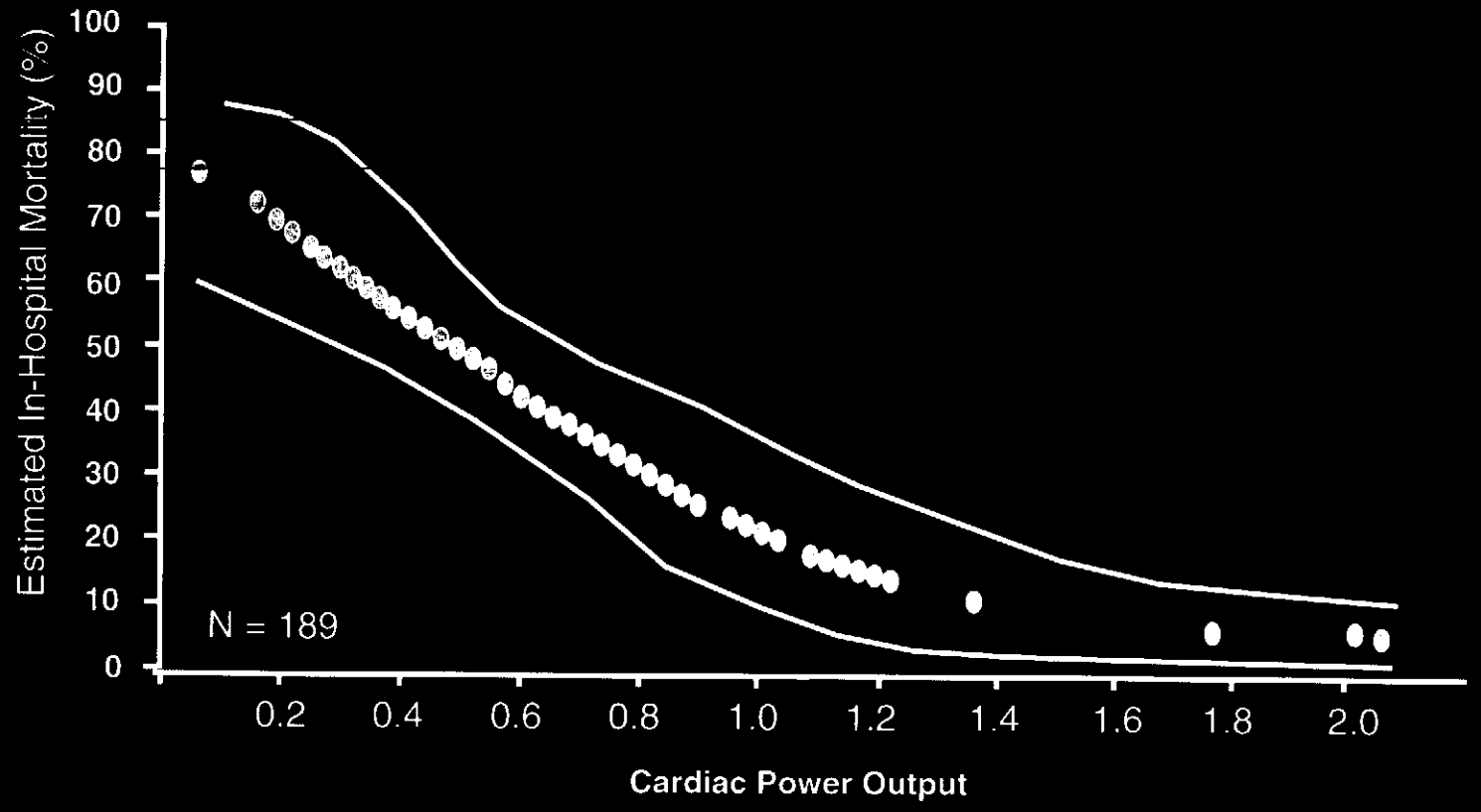


Early VAD implant would limit other organs failure and improve chance of recovery

ABIOMED AB5000 Data Registry for AMI Cardiogenic Shock as of April 8th, 2005

Cardiogenic Shock

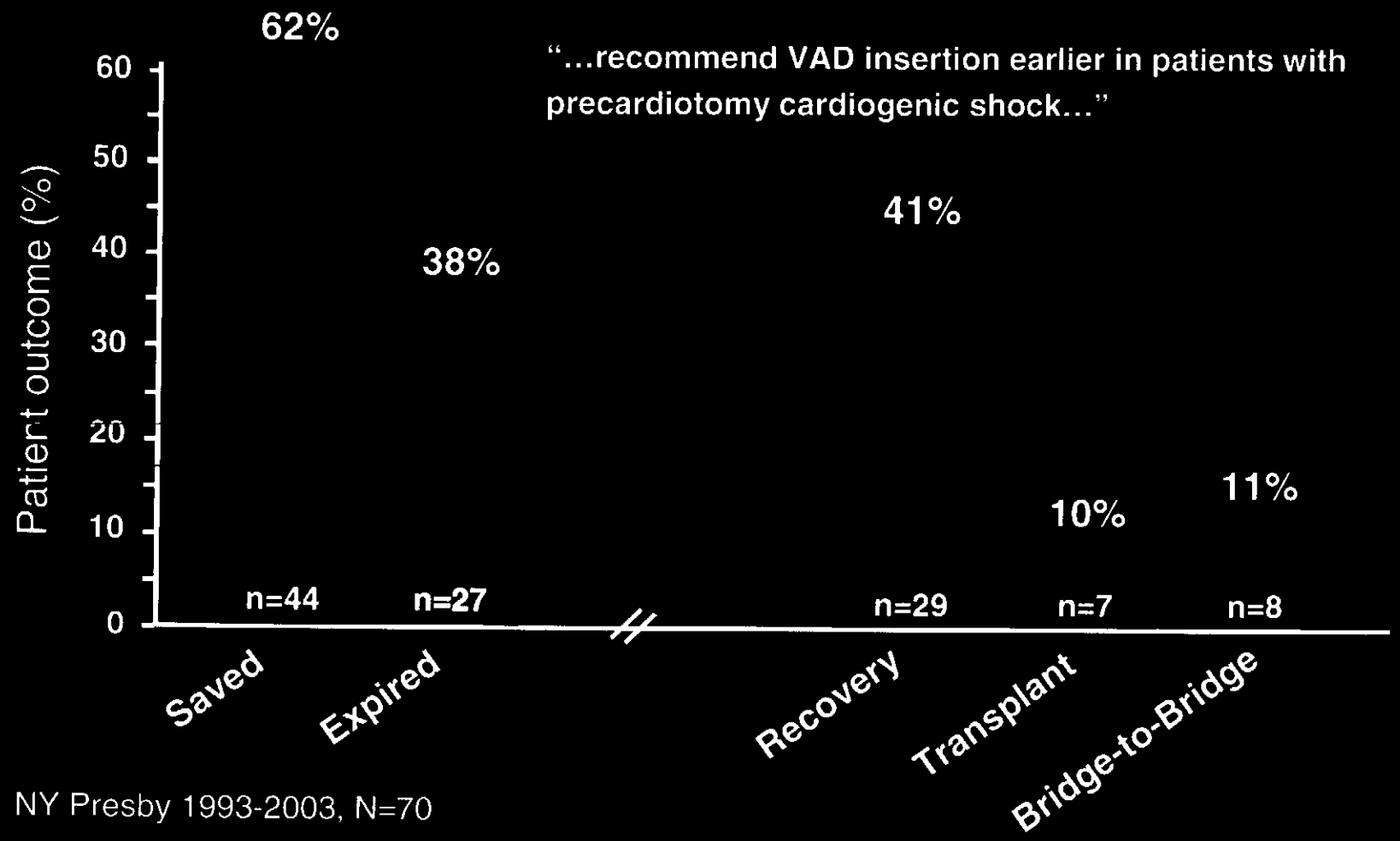
Cardiac Power: The Strongest Hemodynamic Correlate of Mortality in Cardiogenic Shock



Fincke R et al. JACC 2004 Vol 44, n2: 304-8

Bridge to Recovery on BVS

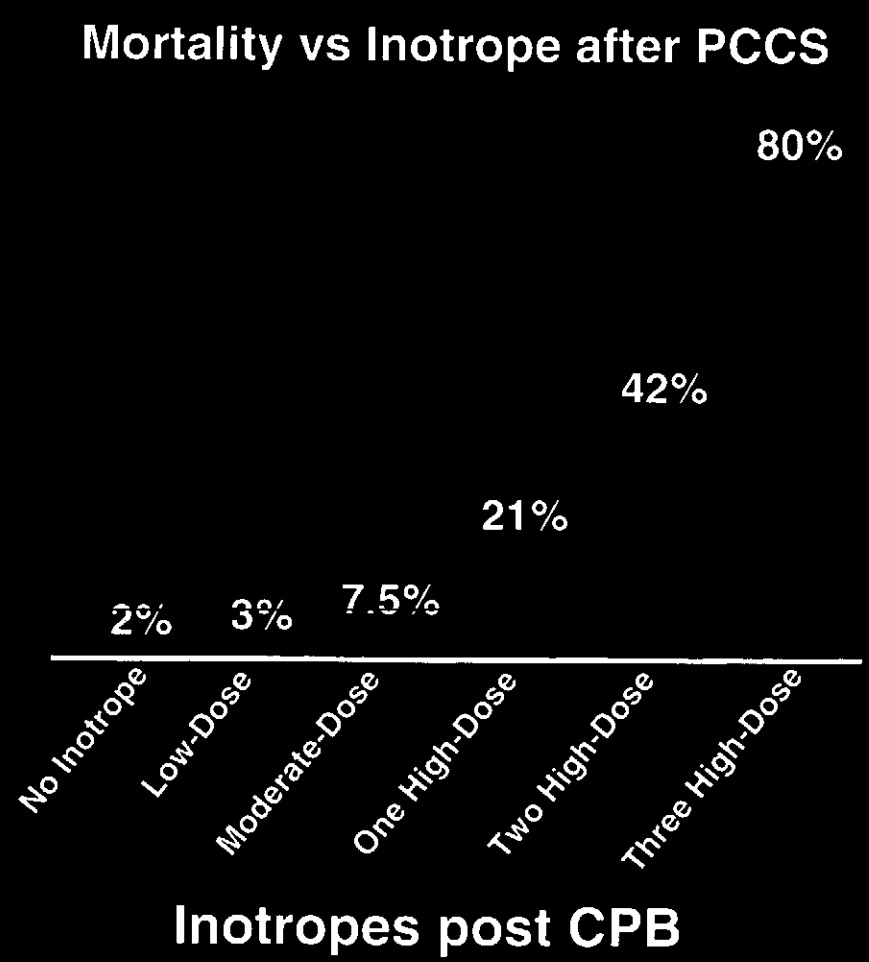
41 % Recovery on BVS

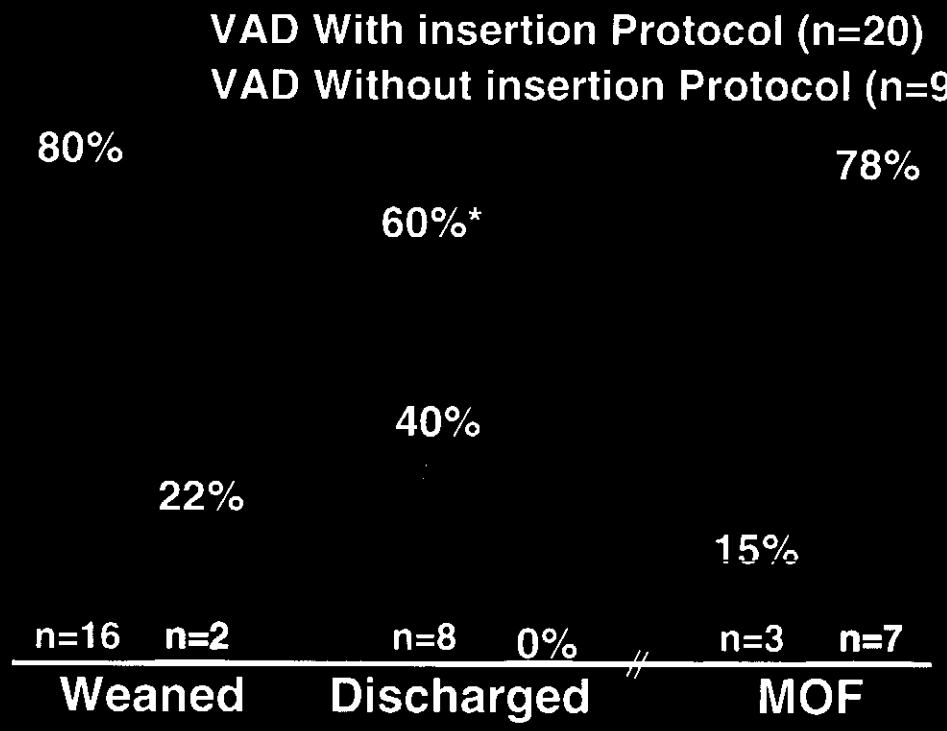


NY Presby 1993-2003, N=70

J Morgan et al. ASAIO J. 2004, Jul/Aug 50(4):360-3

Management of Acute Heart Failure using BVS





Samuels at al J. Card. Surg 1999:14(4):288-93
**Cardiol Clin. 2003 Feb;21(1):43-9*

Pharmacological criteria for ventricular assist device insertion following postcardiotomy shock: experience with the Abiomed BVS system Samuels LE & al . J Card Surg. 1999 Jul-Aug;14(4):288-93. N=29. 100%. Post-CS n=29). 1996-1999

Conclusion:

ABIOMED cumulative data, as well as third party published data seem to suggest that the recovery success rate is dependent on:

- Time to VAD insertion (the earlier the better)
- Length of support (chance of recovery increases after 1 week)
- Lower rate of adverse events (bleeding, infection, ...)

Role of the Abiomed BVS 5000 Device for Short-Term Support and Bridge to Transplantation

JEFFREY A. MORGAN, ALLAN S. STEWART, BRIAN J. LEE, MEHMET C. OZ, AND YOSHIFUMI NAKA

Over the last 10 years, we have gained experience implanting the Abiomed BVS 5000 (Abiomed, Inc., Danvers, MA) device for short-term mechanical support. We retrospectively reviewed our experience with this device. From April 1993 through January 2003, 71 patients underwent implantation of an Abiomed BVS 5000 device. This included 19 left ventricular assist devices (LVADs), 30 right ventricular assist devices (RVADs), and 22 biventricular assist devices (BIVADs). Demographics of device recipients, conditions for mechanical support, and outcome were evaluated for each device type.

Devices were inserted for postcardiotomy cardiogenic shock in 53 (74.6%) patients and precardiotomy cardiogenic shock in 18 (25.4%) patients. Mean duration of support was 4.9 ± 4.1 days, with 64 (90.1%) patients supported for fewer than 10 days. Twenty-nine (40.8%) patients were successfully weaned from support after myocardial recovery: 7 (36.8%) LVADs, 13 (43.3%) RVADs, and 9 (40.9%) BIVADs. Eight (11.3%) patients received devices as a "bridge to bridge," undergoing implantation of a long-term HeartMate LVAD (Thoratec, Pleasanton, CA): six (31.6%) LVADs and two (9.1%) BIVADs. Seven (9.9%) Abiomed patients were successfully bridged to transplantation: two (10.5%) LVADs, two (6.7%) RVADs, and three (13.6%) BIVADs. Overall, 44 (62.0%) patients survived support: weaned, "bridged to bridge," or transplanted.

The Abiomed BVS 5000 can be used effectively for short-term stabilization and for bridging to transplant in select patients. *ASAIO Journal* 2004; 50:360–363.

The advent of implantable ventricular assist devices (VADs) has significantly affected the treatment of heart failure.[1] Mechanical devices can be used for short-term, intermediate-term, and long-term support as a bridge to recovery, bridge to transplant, and destination therapy.[2–5] In this report, we review our experience with the Abiomed BVS 5000 (Abiomed, Inc., Danvers, MA) device for short-term mechanical support in patients with cardiogenic shock.

Over the last 10 years, we have gained experience using the Abiomed BVS 5000 for short-term mechanical univentricular support in the form of a left ventricular assist device (LVAD) and right ventricular assist device (RVAD), as well as for biventricular support in the form of a biventricular assist device (BIVAD). The mode of circulatory support—univentricular or biventricular—is primarily a function of the indication for support.[2] We retrospectively reviewed our 10 year experience using the Abiomed BVS 5000 for short-term mechanical support in patients with postcardiotomy and precardiotomy cardiogenic shock.

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Submitted for consideration August 2003, accepted in revised form February 2004.

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DOI: 10.1097/01.MAT.0000130680.63196.7b

Patients and Methods

We began implanting the Abiomed BVS 5000 in April 1993. At that time, all recipients met the preoperative requirements outlined by Abiomed's advisory council, as well as the US Food and Drug Administration for postcardiotomy shock. These conditions have since been amended to include any patient who requires cardiac support for a potentially reversible condition, including patients with precardiotomy cardiogenic shock. Accordingly, patients with myocarditis, myocardial infarction, cardiomyopathy, and arrhythmias also have become potential candidates for the Abiomed BVS 5000 for short-term support.

From April 1993 through January 2003, 71 patients underwent implantation of an Abiomed BVS 5000 device at our institution. This included 19 LVADs for left ventricular support, 30 RVADs for right ventricular support, and 22 BIVADs for biventricular support. Demographics of device recipients, conditions for mechanical support, and outcomes were evaluated for each device type.

Device

The BVS 5000 is a dual chamber, temporary external pulsatile VAD powered by a pneumatic console that may operate one or both pumps simultaneously and that can be used for isolated univentricular or biventricular support.[6–8] Patients are managed with either the standard or high flow console. The size of the inflow and outflow cannula can be personalized to accommodate each patient.

Anticoagulation

Patients are not anticoagulated in the first 24 hours after surgery; however, heparin therapy is used thereafter for the duration of mechanical support.

Antibiotics

Our antibiotic regimen includes standard gram positive coverage with cefazolin or vancomycin until all drains are removed. Antibiotic coverage is broadened if there are signs of infection postoperatively.

Table 1. Clinical Characteristics of Device Recipients

Variable	LVAD	RVAD	BIVAD	Overall	p^a
Mean age (Yrs)[b]	54.4 ± 17.3	53.7 ± 10.4	45.7 ± 22.0	51.4 ± 16.8	0.159
Gender					
Male	13 (68.4%)	22 (73.3%)	15 (68.2%)	50 (70.4%)	0.900
Female	6 (31.6%)	8 (26.7%)	7 (31.8%)	21 (29.6%)	
Race					
Caucasian	13 (68.4%)	19 (63.3%)	15 (68.2%)	47 (66.2%)	0.909
African American	0 (0.0%)	5 (16.7%)	2 (9.1%)	7 (9.9%)	0.161
Other	6 (31.6%)	6 (20.0%)	5 (22.7%)	17 (23.9%)	0.643
Etiology of heart failure					
CAD	16 (84.2%)	20 (66.7%)	11 (50.0%)	47 (66.2%)	0.108
ICM	2 (10.5%)	7 (23.3%)	7 (31.8%)	16 (22.5%)	0.277
Other	1 (5.3%)	3 (10.0%)	4 (18.2%)	8 (11.3%)	0.810
Duration of support (days)[b]	4.2 ± 3.5	5.3 ± 4.2	5.1 ± 4.4	4.9 ± 4.1	0.657
Range (days)	0–11	0–17	0–20	0–20	

LVAD, left ventricular assist device; RVAD, right ventricular assist device; CAD, coronary artery disease; ICM, idiopathic cardiomyopathy.
[a] p values from ANOVA testing and Chi square analysis.
[b] Mean ± standard deviation.

Data Analysis

Data were represented as frequency distributions and percentages. Values of continuous variables were expressed as a mean ± standard deviation. Continuous variables were compared using analysis of variance (ANOVA-Bonferroni), whereas categorical variables were compared by means of Chi square tests. For all analyses, a p of less than 0.05 was considered statistically significant. All data were analyzed using SPSS 11.5 (SPSS Inc., Chicago, IL).

Results

Clinical Demographics of Abiomed Recipients

From April 1993 to January 2003, 71 patients underwent implantation of an Abiomed BVS 5000 device at our institution: 50 (70.4%) male patients and 21 (29.6%) female patients with a mean age of 51.4 ± 16.8 years (**Table 1**). There were 19 (26.8%) LVADs, 30 (42.3%) RVADs, and 22 (31.0%) BIVADs.

Conditions for Abiomed Implantation

Devices were inserted for postcardiotomy shock in 53 (74.6%) patients and precardiotomy shock in 18 (25.4%) patients. A summary of the conditions for VAD implantation is outlined in **Table 2**.

Duration of Abiomed Support

The overall mean duration for VAD support was 4.9 ± 4.1 days, with a mean of 4.2 ± 3.5 days for LVADs, 5.3 ± 4.2 days for RVADs, and 5.1 ± 4.4 days for BIVADs (**Table 1**). In total, 64 (90.1%) patients were supported for fewer than 10 days.

Outcome After Implantation of Abiomed

Overall, 29 (40.8%) patients were successfully weaned from support after myocardial recovery, including 7 (36.8%) LVADs, 13 (43.3%) RVADs, and 9 (40.9%) BIVADs (**Figure 1**). Eight (11.3%) patients received devices as a "bridge to bridge," undergoing implantation of a long-term HeartMate LVAD: six (31.6%) LVADs and two (9.1%) BIVADs. Seven (9.9%) Abiomed patients were successfully bridged to transplantation. This included two (10.5%) LVADs, two (6.7%) RVADs, and three (13.6%) BIVADs. Overall, 44 (62.0%) patients survived support: weaned, "bridged to bridge," or transplanted. Post-transplant 1 and 5 year survival rates were 50.0% and 50.0%

Table 2. Conditions for ABIOMED Implantation

Condition	LVAD	RVAD	BIVAD	Overall	Duration	PI Survival
Postcardiotomy shock						
s/p CABG	12 (63.2%)	2 (6.7%)	2 (9.1%)	16 (22.5%)	5.46 ± 3.07	1.06 ± 2.78
s/p CABG/MVr	0 (0.0%)	2 (6.7%)	2 (9.1%)	4 (5.6%)	8.67 ± 6.13	0.06 ± 0.06
s/p CABG/AVR	1 (5.3%)	1 (3.3%)	2 (9.1%)	4 (5.6%)	3.00 ± 2.94	0.74 ± 1.44
s/p OHT	2 (10.5%)	5 (16.7%)	6 (27.3%)	13 (18.3%)	4.23 ± 2.62	2.16 ± 3.59
s/p LVAD	0 (0.0%)	16 (53.3%)	0 (0.0%)	16 (22.5%)	5.00 ± 4.55	1.16 ± 2.57
Precardiotomy shock						
Postacute myocardial infarction	1 (5.3%)	1 (3.3%)	2 (9.1%)	4 (5.6%)	4.33 ± 1.15	0.25 ± 0.42
Myocarditis	0 (0.0%)	2 (6.7%)	1 (4.5%)	3 (4.2%)	3.00 ± 1.00	2.39 ± 4.11
Intractable ventricular arrhythmia	1 (5.3%)	1 (3.3%)	2 (9.1%)	4 (5.6%)	9.50 ± 9.47	4.31 ± 3.79
ICM	2 (10.5%)	0 (0.0%)	5 (22.7%)	7 (9.9%)	3.71 ± 3.40	7.13 ± 2.60

LVAD, left ventricular assist device; RVAD, right ventricular assist device; BIVAD, biventricular assist device; PI, postimplant, s/p, status post; CABG, coronary artery bypass grafting; MVr, mitral valve repair; AVR, aortic valve replacement; OHT, orthotopic heart transplantation; ICM, idiopathic cardiomyopathy.

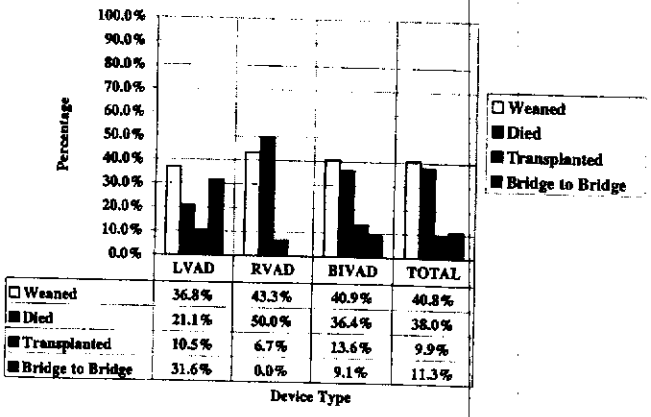

Figure 1. Outcome after implantation of an Abiomed BVS 5000. LVAD, left ventricular assist device; RVAD, right ventricular assist device; BIVAD, biventricular assist device.

for LVAD patients, 50.0% and 50.0% for RVAD patients, and 37.5% and 37.5% for BIVAD patients, respectively.

Causes of Death While on Mechanical Support

Causes of death while on the device included multisystem organ failure (MSOF), sepsis, stroke, and bleeding. These are outlined in **Table 3**. The incidence of stroke and transient ischemic attack while on the device was 4.2% (n = 3) and 2.8% (n = 2), respectively (**Table 4**).

Discussion

Over the last decade, there have been significant advancements in the treatment of cardiogenic shock.[9] These improvements have primarily involved medical therapies such as lytic therapy and antiplatelet agents, more effective and longer lasting interventional techniques, and cardiac assist devices.[10] Mechanical support has an established, well documented role in stabilization of patients with cardiogenic shock, both postcardiotomy and precardiotomy patients, refractory to medical and interventional therapies.[6–8,11–16]

In this series, we outlined our 10 year experience with the Abiomed BVS 5000 for short-term support as a bridge to recovery, bridge to bridge, and bridge to transplant. In patients with acute cardiogenic shock, the Abiomed BVS 5000 is our preferred device for short-term stabilization. This device has gained widespread popularity for cardiogenic shock for a variety of reasons.[17] It is relatively easy to implant, can be managed at the bedside by the nursing and medical house staff, and provides pulsatile flow, which has been demonstrated to improve end organ perfusion and function in acute cardiogenic shock.[13,18] Anticoagulation can be withheld for the first 24 hours to minimize bleeding. In addition, the device is an asynchronous unit; the pump output is a function of preload and afterload and is independent of cardiac rhythm, enabling the device to provide support during potentially fatal arrhythmias.[19] The Abiomed BVS 5000 has generally been limited to short-term support; several series have demonstrated a relatively high incidence (40%) of MSOF and sepsis associated with its long-term use.[13] The Abiomed BVS 5000 is not the preferred device for bridging patients with end-stage heart failure to transplantation given its high associated morbidity and limitations of mobility.

Table 3. Causes of Deaths for Patients Who Died on Mechanical Support

Cause of Death	LVAD	RVAD	BIVAD	p^a
MSOF	0 (0.0%)	4 (26.7%)	0 (0.0%)	0.153
Sepsis	0 (0.0%)	1 (6.7%)	1 (12.5%)	0.728
CVA	0 (0.0%)	3 (20.0%)	3 (37.5%)	0.322
Bleeding	0 (0.0%)	3 (20.0%)	2 (25.0%)	0.562
Other				
PGF	2 (50.0%)	1 (6.7%)	1 (12.5%)	0.660
Arrhythmia	2 (50.0%)	2 (13.3%)	0 (0.0%)	0.395
CHF	0 (0.0%)	1 (6.7%)	1 (12.5%)	0.728

LVAD, left ventricular assist device; RVAD, right ventricular assist device; BIVAD, biventricular assist device; MSOF, multisystem organ failure; CVA, cerebrovascular accident; PGF, primary graft failure; CHF, congestive heart failure.
[a] *p* values from Chi square analysis.

Table 4. Incidence of CVA and TIA While on Mechanical Support

Neurologic Complication	LVAD	RVAD	BIVAD	p^a
CVA	1 (5.3%)	1 (3.3%)	1 (4.5%)	0.913
TIA	2 (10.5%)	0 (0.0%)	0 (0.0%)	0.060

LVAD, left ventricular assist device; RVAD, right ventricular assist device; BIVAD, biventricular assist device; CVA, cerebrovascular accident (stroke); TIA, transient ischemic attack.
[a] *p* values from Chi square analysis.

Our preferred device for bridging patients with end-stage heart failure to transplant is the HeartMate (Thoratec, Pleasanton, California). Over the last 12 years, we have had a greater than 70% success rate in bridging patients with end-stage heart failure to transplantation using the HeartMate.[20] Patients can be discharged from the hospital to wait for their transplant at home without significant limitations in mobility.[21,22] Additionally, anticoagulation is not required with the HeartMate.[23]

There are data to suggest that timing of VAD insertion significantly affects survival and successful bridging to recovery or transplant.[17] Early insertion of a mechanical assist device in the setting of cardiogenic shock unresponsive to medical therapy can favorably affect outcome.[10,17] Thus, we have made an effort to insert the Abiomed BVS 5000 relatively early in patients with postcardiotomy shock. In patients who cannot be weaned from cardiopulmonary bypass, we often place an Abiomed within the first hour after failed weaning attempts with maximal inotropic support and the use of an intraaortic balloon pump. In addition, we have encouraged our referring cardiologists to recommend VAD insertion earlier in patients with precardiotomy cardiogenic shock (acute myocarditis, myocardial infarction, and intractable arrhythmia) because implantation of a mechanical device earlier in the process is associated with improved survival in this cohort.[17] This is similar to our results in patients with end-stage heart failure who are bridged to transplant with an LVAD. Patients with higher LVAD implantation scores at the time of LVAD insertion, with a higher score correlating with more severe systemic manifestations of heart failure, demonstrate significantly decreased survival and bridging to transplant success.[24]

Limitations of this study include those related to a retrospectively performed analysis. Clinical data were obtained by chart review, which has inherent limitations, such as access and accuracy of the data. Additionally, as a retrospective observational study, it is subject to selection bias and incomplete data collection. Finally, extrapolation of the results regarding bridging patients to recovery, bridge to bridge, and bridging to transplant with the Abiomed BVS 5000 is limited because of interinstitutional variability in clinical practice.

In conclusion, acute cardiogenic shock continues to present a medical and surgical challenge. The Abiomed BVS 5000 is an effective device for short-term support of patients with acute cardiogenic shock. Our challenge is to continue to improve device design as well as preoperative and postoperative management so that we can continue to improve outcome in these complex patients.

Acknowledgment

Dr. Yoshifumi Naka, MD, PhD, is Herbert Irving Assistant Professor of Surgery at Columbia University, College of Physicians and Surgeons.

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Mechanical Circulatory Support in Profound Cardiogenic Shock Post Acute Myocardial Infraction: A US Multicenter Study

Background:

In-hospital mortality of patients with Acute Myocardial Infarction (AMI) complicated by profound cardiogenic shock (CS) remains high despite revascularization procedures, inotropic and intra-aortic balloon pump therapy. Ventricular Assist Devices (VAD) could be an alternative to help these patients recover or bridge them to other alternatives such as heart transplantation when conventional therapies have failed.

Methods:

We report a multicenter US experience for treating patients with profound circulatory failure post AMI and unresponsive to conventional resuscitation. Since November 2003, 45 patients were supported in 21 US centers using AB5000 VAD technology (ABIOMED, Inc). Preimplant conditions included IABP 87%, mechanical ventilation 88%, cardiopulmonary resuscitation 71%, 2 or more vasopressors 75%, 2 or more inotropes 70%, hyperbilirubinemia 86%, hypercreatinemia 62%. Bi-VAD support was required in 53% of the patients. The average time from onset of CS to VAD implant was 45.6 hrs (range 1-180 hrs).

Results:

VAD implantation instantly stabilized hemodynamics with significant improvements in cardiac index (1.57±0.5 vs 2.5±0.5 l/min/m2, $p<0.0001$), systolic aortic pressure (94±14 vs 115±7mmHg, $p<0.0001$), central venous pressure (17±5 vs 14±5mmHg, $p=0.05$) and pulmonary arterial pressure (41±11 vs 31±7mmHg, $p=0.01$). Of the 41 patients with known outcomes, 46% survived. Of all survivors, 58% recovered and were discharged, 21% were transplanted and 21% were bridged to other devices. The average length of support for patients that recovered was 31 days (range 2-96 days) versus 44 days for those who were transplanted (range 4-95 days).

Conclusion:

The ABIOMED AB5000 technology can be successfully used to improve outcomes in this population with extremely high risk for mortality when all conventional therapies have been exhausted.

Abstract being submitted for publication, author list not yet final

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Transfers

CMS-1500-P-54 **Changes to the Hospital Inpatient Prospective Payment Systems and FY 2006 Rates**

Hefter

Submitter : M.B. Schuh **Date & Time:** 05/11/2005

Organization : St. Anthony's Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Postacute Care Transfer:A request I have made during several of the hospital Open Door Forums is that CMS provide education to the provider community for reporting of patient status since this single UB-92 reporting field has as much impact on correct reimbursement as does correct DRG assignment. A review of the FAQ's posted on the website of the Uniform Bill Committee on the subject of patient status reveals how much confusion exists. The proposed expansion of the number of DRGs under the postacute care transfer policy will only intensify the need for accurate consistent reporting among all providers under the IPPS. I believe this can only be accomplished by CMS providing the necessary education.

MAY 27 2005 23-0 (9)

MEMORIAL COMMUNITY HOSPITAL
313 Stoughton Road, Edgerton, Wisconsin 608-884-3441

May 10, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

Re: Proposed CMS Rule Change Dated 4/25/05 Regarding Replacement of Critical Access Hospital (CAH) Facilities

Please be advised that our entire hospital administration, management and Governing body of Memorial Community Hospital, a critical access hospital in Edgerton, WI, are adamantly opposed to the new rule changes proposed by CMS on April 25, 2005. The new rules as proposed would effectively signal the ultimate demise of our hospital by condemning us to remain on a site, which has been deemed unsuitable for expansion.

We are of the opinion that Congress never intended the Medicare Modernization Act (MMA) to be used as a mechanism to throttle the growth plans and undermine the local control of rural hospitals. As proposed, the new rule would prohibit any CAH operating with a "Necessary Provider Designation" from relocating its hospital unless the move is completed by January 1, 2006. The only exception permitted under the rule would allow a CAH that had construction plans under development as of December 3, 2003. By enacting such a rule with the intent of enforcing it retroactively, you will have succeeded in limiting the replacement of any CAH hospital in the future.

Our present circumstances make it imperative that we challenge these new rules. We occupy a building that varies in age from 35 to 45 years old and does not meet existing Life Safety and ADA standards. Its been estimated that basic repairs and upgrades would cost the hospital over $6 million over the next 4 years, not one dime of which would improve health care. A replacement of the entire facility on-site is estimated to cost more than building a new hospital off-site. At the time the new rules were published, we were active engaged in planning a replacement facility on a site 2 miles from our present location, but still inside the city limits. An option on the land had already been secured and bids had been solicited for a project scope analysis. If allowed to pass, the new rules would stop our relocation plans dead in their tracks forcing the ultimate demise of our facility.

We believe the new rule is an over-reactionary provision to enforce a simple statement in the MMA that would require a replacement CAH "to service the same community and operate essentially the same services with essentially the same staff". This standard if allowed to stand, would set a new precedent treating CAHs differently than other hospitals. We find it totally incredulous that CMS would write a rule that a legitimate plan by a locally controlled board to build a new hospital to address safety and environmental concerns that does not conform with the rule, will be deemed to "constitute a cessation of business and loss of provider number". There is no precedent in law to support such a rule.

If this rule change is allowed to stand, what will the next phase of regulations include? Will CMS later expand the rule to include major renovations to an existing facility, new equipment purchases, and acquisitions of provider-based clinics? We are deeply concerned about the extent of these rule changes and the unbridled expansion of powers of an already powerful bureaucratic organization that may or may not conform with the intent of Congress.

We respectfully request that the proposed rules be rescinded as written and appropriate provisions be allowed for CAHs like Memorial Community Hospital with "Necessary Provider Designation" status to replace their aging facilities. The loss of our hospital in this community will result in a major economic recession and force its residents to drive long distances for essential medical care.

Respectfully submitted,

Board of Trustees of Memorial Community Hospital

Robert T. Borremans, E.d.D. Board Chairman	Dorothy Gunderson Vice Chair	Mari Anne Warren Secretary
Melva Sue Larson Treasurer	John Wollaeger, MD Board of Trustee	Kenneth Betts, MD Board of Trustee
Lawanna Schieldt Board of Trustee	Steven Thompson Board of Trustee	James Schultz Board of Trustee

cc: Senator Herbert Kohl
Senator Russ Feingold
Representative Tammy Baldwin
Representative Paul Ryan
Tim Size, RWHC
Steve Brenton, WHA

24

MAY 27 2005

CAH/Rural
Hefter
Hamstead
Collins
Nurse
Molley Smith

Eldon and Bette McCormick
PO Box 186
Holyoke, CO 80734

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

Dear Sirs:

RE: Medicare Construction Ban on Critical Access Hospitals

As an introduction, I have worked for Melissa Memorial Hospital in Holyoke, CO for 46 years. I was here when the present hospital was built in 1965, with the majority of the financing provided by a local banker, and the land on which it sets, part of his former gardens next to his house, which is now the local library. We have no room for parking and little room to expand. We are in desperate need for more efficient space to work. We have been excited about the prospect of building a new hospital in our community at a site where there would be room for expansion and where there would be easy access and plenty of parking space.

My husband, Eldon, is Mayor of our small town and is also very interested in good health care for our community.

We are now told that CMS interprets a "rule" stating that, because we are within 36 miles of another Critical Access hospital, we would lose our critical access status if we were to build more than 750 yards away from the present site. This "rule" is impeding the progress of health care in rural America. Efficiently run health care systems should be able to build a new facility without losing Critical Access status.

I would ask that you reconsider this "rule" in the interest of good health care in rural America.

Sincerely,

Bette Lou and Eldon McCormick

Bette Lou McCormick Eldon McCormick

25

May 23, 2005

MAY 27 2005
CAH/Kelle

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

Hefley
Hamstein
Collins
Money
Molly Smith

To: CMS

I am the president of the board for Community Hospital Association of Southeast Kansas. I have recently been made aware of a proposed ruling by CMS in relation to limitations in the building of replacement Critical Access Hospitals, such as ours. This information dismays me and my fellow board members. If I understand the proposed ruling correctly, the changes limit a hospital's ability to maintain its CAH status if a needed replacement facility is built at a different location.

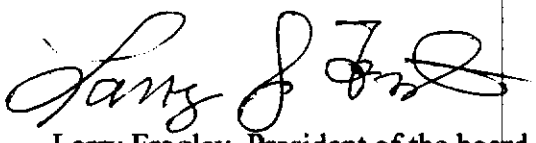
Several years ago, the City of Oswego approached a for-profit company with the option of purchasing the hospital here in Oswego, Kansas. The company agreed to the purchase in the hopes of serving the community by improving the operations of the hospital and by providing the needed quality health care services for this area. The future plans were to turn the hospital back over to the community as a non-profit corporation. The hospital in Oswego has experienced growth in the volume of patients and has made improvements and expanded health care services in this area. For some time now, the current owners of the hospital have been working towards returning the operation of the hospital back to the community. They have also been actively helping in beginning the process of building of a needed replacement hospital for our community. The company, the board and the city are currently in the process of making these changes. In this effort, we have established Community Hospital Association and are in the process of obtaining a not-for-profit status. This newly founded non-profit corporation is made up of volunteer members from Oswego and other surrounding communities. We are currently in the process of converting Oswego Medical Center from its for-profit status over to the newly formed non-profit corporation. Additionally, we are in the process of accessing the capital necessary to build a needed replacement hospital for our area.

The Critical Access Hospital in Oswego is old and outdated. It is in a very out-of-the-way location, on a very small piece of property, with no real opportunity for expansion. Our intent is to build a replacement hospital at a new, more efficient, more convenient location, with a much needed improved physical plant that is up-to-date with current standards. This would also include a much needed medical building, which the current location does not have. The selected site, which is an ideal location for a replacement hospital in our community, would be less than 2 miles northwest of our current site. This location is still within the city limits of Oswego, along Interstate 59, increasing the accessibility to our services for those who live in surrounding communities. The City of Oswego has committed to this project and has agreed to

donate a 17 acre piece of property as the campus for the needed replacement hospital and new medical building.

It seems to me that this new CMS policy assumes that a current hospital and its location will be indefinitely adequate to meet the healthcare needs of the populous it serves. I do not see any logical basis for this type of policy. In the long run, it will only hurt the delivery of health care in rural areas such as ours. Please do not jeopardize our ability to provide the quality health care services we wish to have in our community by establishing such nonsensical and detrimental policies.

Thank you for taking the time to consider these comments.



Larry Frogley, President of the board
Concerned community member

MAY 27 2005

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MARILYN N. MUSGRAVE
MEMBER OF CONGRESS
4TH DISTRICT, COLORADO

1507 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
202-225-4676
FAX: 202-225-5870

http://www.house.gov/musgrave

Congress of the United States
House of Representatives
Washington, DC 20515–0604

COMMITTEES
AGRICULTURE
EDUCATION AND THE WORKFORCE
RESOURCES
SMALL BUSINESS
CHAIRMAN, SUBCOMMITTEE ON WORKFORCE EMPOWERMENT AND GOVERNMENT PROGRAMS

May 20, 2005

CAH/Reloc
Hefter, Hartstein, Collins, Macy, Molley Smith

Dr. Mark McClellan
CMS Administrator
Centers for Medicaid and Medicare Services
PO Box 8011
Baltimore, MD 21244-1850

Dear Dr. McClellan,

RE: Critical Access Hospitals
CMS-1500-P

I am writing regarding a proposed CMS rule that will impact two **Critical Access Hospitals** in northeastern Colorado.

It has come to my attention that the Medicare Modernization Act, passed by Congress and signed into law in December 2003, eliminated the "Necessary Provider" provision of the Critical Access Hospital (CAH) regulations, effective January 1, 2006. As I understand it, a proposed CMS rule would grandfather any CAH licensed under the Necessary Provider provision prior to January 1, 2006, allowing them to maintain licensure as a CAH. However, if a hospital builds a replacement facility in a different location and construction is complete after January 1, 2006, the hospital may lose its CAH designation.

These proposed regulations have implications for two hospitals within my district. Both of these hospitals are planning to build new facilities to replace their current facilities. By providing efficient, high-quality healthcare, these hospitals have seen growth and increased utilization that demand greater space to better serve the community.

- **Yuma District Hospital (Yuma, CO)** – Has plans to build a new site within **850 yards** of current site.

- **Melissa Memorial Hospital (Holyoke, CO)** – Has been preparing to build a new facility since April 2004, being very careful to ensure that finances, plans, and community perceptions are being considered in all details. The proposed sites are within **one mile** of the existing CAH facility.

According to the proposal, as stated in the Federal Register, the decision whether to continue to consider the hospitals Critical Access Hospitals may be determined on a case-by-case basis. *"The regulations...(do) not address the situation where the CAH is no*

longer the same facility due to relocation, cessation of business, or a replacement facility. Currently, CMS Regional Offices make the decision for continued certification following relocation of a certified facility on a case-by-case basis."

The proposed rule states that a "replacement" facility is one in which construction is undertaken within 250 yards of current building. *"We will consider a construction of the CAH to be a replacement if construction was undertaken within 250 yards of the current building, as set by prior precedence in defining a hospital campus."*

As representative of these two facilities, I consider it my responsibility to ensure that these facilities have every opportunity to serve the growing community. **I recommend that this distance be changed to three miles or within the same zip code.** There are many factors that could prevent a hospital from replacing itself on the exact location – lack of parking, lack of land availability, resistant community. However, a facility built within three miles or within the same zip code will most certainly serve the same population and continue to operate as the same entity.

Whether deemed to be a "replacement" or "relocation", I urge you to ensure that both Yuma District Hospital and Melissa Memorial Hospital receive continued CAH status and are enabled to continue serving their rural communities.

I am sure it was not the intent of Congress or CMS regulators to punish rural hospitals for their efficiency and success nor to hinder them from growth and expansion. It is my recommendation that you modify these regulations to ensure that hospitals such as these are able to continue to serve rural populations.

Please notify both of these hospitals regarding the steps they must take to ensure continued CAH status and please keep me informed as to the progression of these regulatory decisions.

Thank you for your prompt attention to this matter.

Sincerely,

Marilyn Musgrave

Congresswoman Marilyn Musgrave (CO-04)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 405, 412, 413, 415, 419, 422, and 485
[CMS-1500-P]
RIN 0938-AN57
Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates
AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.
ACTION: Proposed rule.
SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems. In addition, in the Addendum to this proposed rule, we describe the proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. We also are setting forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the IPPS that are paid in full or in part on a reasonable cost basis subject to these limits. These proposed changes would be applicable to discharges occurring on or after October 1, 2005, with one exception: The proposed changes relating to submittal of hospital wage data by a campus or campuses of a multicampus hospital system (that is, the proposed changes to §412.230(d)(2) of the regulations) would be effective upon publication of the final rule. Among the policy changes that we are proposing to make are changes relating to: the classification of cases to the diagnosis-related groups (DRGs); the long-term care (LTC)-DRGs and relative weights; the wage data, including the occupational mix data, used to compute the wage index; rebasing and revision of the hospital market basket; applications for new technologies and medical services add-on payments; policies governing postacute care transfers, payments to hospitals for the direct and indirect costs of graduate medical education, submission of hospital quality data, payment adjustment for low-volume hospitals, changes in the requirements for provider-based facilities; and changes in the requirements for critical access hospitals (CAHs).
DATES: Comments will be considered if received at the appropriate address, as provided in the "ADDRESSES" section, no later than 5 p.m. on June 24, 2005.
ADDRESSES: In commenting, please refer to file code CMS-1500-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of three ways (no duplicates, please):
1. Electronically
You may submit electronic comments to **http://www.cms.hhs.gov/regulations/ecomments** (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).
2. By Mail
You may mail written comments (one original and two copies) to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1500-P,
P.O. Box 8011,

Baltimore, MD 21244-1850.
Please allow sufficient time for mailed comments to be received before the close of the comment period.
3. By hand or courier
If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, S.W.
Washington, DC 20201, or
7500 Security Boulevard,
Baltimore, MD 21244-1850.
(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping in and retaining an extra copy of the comments being filed.)
Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.
Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website. Written comments received timely will be available for public inspection as they are received, generally beginning approximately 4 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.
For comments that relate to information collection requirements, mail a copy of comments to the following addresses:
Centers for Medicare & Medicaid Services,
Office of Strategic Operations and Regulatory Affairs,
Security and Standards Group,
Office of Regulations Development and Issuances,
Room C4-24-02
7500 Security Boulevard
Baltimore, Maryland 21244-1850.
Attn: James Wickliffe, CMS-1500-P; and
Office of Information and Regulatory Affairs,
Office of Management and Budget,
Room 3001, New Executive Office Building,
Washington, DC 20503,
Attn: Christopher Martin, CMS Desk Officer, **[insert filecode],**

Christopher_Martin@omb.eop.gov. Fax (202) 395-6974.

FOR FURTHER INFORMATION CONTACT:

Marc Harstein, (410) 786-4539, Operating Prospective Payment, Diagnosis-Related Groups (DRGs), Wage Index, New Medical Services and Technology Add-On Payments, Hospital Geographic Reclassifications, Postacute Care Transfers, and Disproportionate Share Hospital Issues

Tzvi Hefter, (410) 786-4487, Capital Prospective Payment, Excluded Hospitals, Graduate Medical Education, Critical Access Hospitals, and Long-Term Care (LTC)-DRGs, and Provider-Based Facilities Issues

Steve Heffler, (410) 786-1211, Hospital Market Basket Revision and Rebasing

Siddhartha Mazumdar, (410) 786-6673, Rural Hospital Community Demonstration Project Issues

Mary Collins, (410) 786-3189, Critical Access Hospitals (CAHs) Issues

Dr. Mark Krushat, (410) 786-6809, Quality Data for Annual Payment Update Issues

Martha Kuespert, (410) 786-4605 Specialty Hospitals Definition Issues

VII. Proposed Changes for Hospitals and Hospital Units Excluded from the IPPS
A. Payments to Excluded Hospitals and Hospital Units
1. Payments to Existing Excluded Hospitals and Hospital Units
2. Updated Caps for New Excluded Hospitals and Units
3. Implementation of a PPS for IRFs
4. Implementation of a PPS for LTCHs
5. Implementation of a PPS for IPFs
B. Critical Access Hospitals (CAHs)
1. Background
2. Proposed Policy Change Relating to Continued Participation by CAHs in Lugar Counties
3. Proposed Policy Change Relating to Designation of CAHs as Necessary Providers
a. Determination of the Relocation Status of a CAH
b. Relocation of a CAH Using a Waiver to Meet the CoP for Distance

B. Critical Access Hospitals (CAHs)
[If you choose to comment on issues in this section, please include the caption "Critical Access Hospitals" at the beginning of your comment.]
1. Background
Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation (CoPs) under 42 CFR Part 485, Subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR Part 413.
2. Proposed Policy Change Relating to Continued Participation by CAHs in Lugar Counties
Criteria for the designation of a CAH under the MRHFP at section 1820(c)(2)(b)(i) of the Act require that a hospital be located in a rural area as defined in section 1886(d)(2)(D) of the Act or be treated as being located in a rural area in accordance with section 1886(d)(8)(E) of the Act. The regulations at §485.610 further define "rural area" for purposes of being a CAH. Under §485.610(b), a CAH must meet any one of the following three location requirements. First, a CAH must not be located in an MSA as defined by the Office of Management and Budget, not be deemed to be located in an urban area under 42 CFR 412.63(b), and not be reclassified by CMS or the MGCRB as urban for purposes of the standardized payment amount, nor be a member of a group of hospitals reclassified to an urban area under 42 CFR 412.232. Second, if a CAH does not meet the first criterion, if located in an MSA, a CAH will be treated as rural if it has reclassified under 42 CFR 412.103. Third, as we stated in the FY 2005 IPPS final rule, if the CAH cannot meet either of the first two requirements and is located in a revised labor market area (CBSA) under the standards announced by OMB on June 6, 2003 and adopted by CMS effective October 1, 2004, it has until September 30, 2006, to meet one of the other classification requirements without losing its CAH status. Under section 1886(d)(8)(B) of the Act, hospitals that are located in a rural county that is adjacent to one or more urban counties are considered to be located in the urban

MSA to which the greatest number of workers in the county commute, if certain conditions, specified in section 1886(d)(8)(B) of the Act, are met. Regulations implementing this provision are set forth in 42 CFR 412.62(f)(1) (for FY 1984), 42 CFR 412.63(b)(3) (for FYs 1985 through 2004), and at 42 CFR 412.64(b)(3) (for FY 2005 and subsequent fiscal years). The provision (section 1886(d)(8)(B) of the Act) is referred to as the "Lugar provision" and the counties described by it are referred to as the "Lugar counties."

As explained more fully in the FY 2005 IPPS final rule (69 FR 48916), certain counties that previously were not considered Lugar counties were, effective October 1, 2004, redesignated as Lugar counties as a result of the most recent census data and the new labor market area definitions announced by OMB on June 6, 2003. Some CAHs located in these newly designated Lugar counties are now unable to meet the rural location requirements described above, even though they were in full compliance with the location requirements in effect at the time they converted from short-term acute care hospital to CAH status.

We have received comments that suggest that it would be inappropriate for a facility to be required to terminate participation as a CAH and resume participating as a short-term acute care hospital because of a change in county classification that did not result from any change in functioning by the CAH. After consideration of these comments, we are clarifying our policy with respect to facilities located in Lugar counties. As we noted in the FY 2005 IPPS final rule, we believe it is appropriate to allow facilities located in counties that began to be considered part of MSAs effective October 1, 2004, as a result of data from the 2000 census and implementation of the new labor market area definitions announced by OMB on June 6, 2003, an opportunity to obtain rural designations under applicable State law or regulations from their State legislatures or regulatory agencies. Similarly, we believe that when a CAH's status as being located in a Lugar county occurs as a result of changes that the CAH did not originate and that were beyond its control, such as a change in the OMB standards for labor market area definitions, it is appropriate for the CAH to be allowed a reasonable opportunity to reclassify to rural status. Thus, we are clarifying our policy to note that CAHs in counties that were designated as Lugar counties effective October 1, 2004, because of implementation of the new labor market area definitions announced by OMB on June 6, 2003, are to be given the same reclassification opportunity. Of course, the opportunity to reclassify would not be available to a CAH if the CAH itself were to initiate some change, such as a redesignation as urban rather than rural under State law or regulations, which would invalidate a prior §412.103 reclassification. As a result, we are proposing to make changes to §485.610(b) of the regulations that would permit CAHs located in a county that, in FY 2004, was not part of a Lugar county, but as of FY 2005 was included in such a county as a result of the new labor market area definitions, to maintain their CAH status until September 30, 2006. These changes, if adopted in final form, would permit CAHs in newly designated Lugar counties to continue participating in Medicare as CAHs until September 30, 2006. We expect that this will provide these CAHs with sufficient time to seek reclassification as rural facilities under the current regulations at §412.103. In other words, after October 1, 2006, these facilities must meet at least one of the criteria in §412.103(a)(1) through (a)(3) to be eligible to reclassify from urban to rural status. Once the §412.103 reclassification is approved, the facilities

undertaken within 250 yards of the current building, as set by prior precedence in defining a hospital campus. In addition, if the replacement is constructed on land that is contiguous to the current CAH, and that land was owned by the CAH prior to enactment of Pub. L. 108-173, and the CAH is operating under a State-issued necessary provider waiver that is grandfathered by Pub. L. 108-173, we would consider that construction to be a replacement of the existing provider and the provisions of the grandfathered necessary provider designation would continue to apply regardless of when the construction or renovation work commenced and was completed.

(2) Relocation of a CAH. Under our proposed approach, if the CAH is constructing a new facility in a location that does not qualify the construction as replacement of an existing facility in the same location under the criteria in the preceding paragraph, we would need to determine if this building would be a relocation of the current provider or a cessation of business at one location and establishment of a new business at another location. In the event of relocation, the CAH must ensure that the provider is functioning as essentially the same provider in order to operate under the same provider agreement. A provider that is changing location is considered to have closed the old facility if the original community or service area can no longer be expected to be served at the new location. The distance of the moved CAH from its old location will be considered, but it will not be the sole determining factor in granting the relocation of a CAH under the same provider agreement. For example, a specialty hospital may move a considerable distance and still care for generally the same inpatient population, while the relocation of a CAH at a relatively short distance within a rural area may greatly affect the community served.

In the event that CMS determines the rebuilding of the CAH in a different location to be a relocation, the provider agreement would continue to apply to the CAH at the new location. In addition to the relocation being within the same service area, serving the same population, the CAH would need to be providing essentially the same services with the same staff; that is, at least 75 percent of the same staff and 75 percent of the range of services are maintained in the new location as the same provider of services. We are proposing the use of a 75-percent threshold because we believe it indicates that the CAH that is relocating demonstrates that it will maintain a high level of involvement, as opposed to just a majority involvement, in the current community. We note that CMS has also used a 75-percent threshold in other provider designation policies such as the provider-based policies at §413.65(e)(3)(ii).

In all cases of relocation, the CAH must continue to meet all of the CoPs found at 42 CFR Part 485, Subpart F, including location in a rural area as provided for at §485.610.

(3) Cessation of business at one location. Under existing CMS policy, if the CAH relocation results in the cessation of furnishing services to the same community, we would not consider this to be a relocation, but instead would consider such a scenario a cessation of business at one location and establishment of a new business at another location. Cessation of business is a basis for voluntary termination of the provider agreement under 42 CFR Part 489. If the proposed move constitutes a cessation of business, the CMS Regional Office may assist the provider in obtaining an agreement to participate under a new provider number. Furthermore, in such a situation, the regulations require the provider to give advanced notice to CMS and the public regarding its intent to stop providing medical services to the community. There is no appeals process for a voluntary termination. Under our current

policies, the cessation of business by a CAH automatically terminates the CAH designation, regardless of whether the designation was obtained through a necessary provider determination.

b. Relocation of a CAH Using a Necessary Provider Designation to Meet the CoP for Distance

Once it has been determined that constructing a new facility will cause the CAH to relocate, the second step is to determine if the CAH that has a necessary provider designation can maintain this designation after relocating.

We recognize that §485.610 (c) relating to location relative to other facilities or necessary provider certification states that, after January 1, 2006, the "necessary provider" designation will no longer be used to waive the mileage requirements. In addition, CMS policy regarding a change of size or location of a provider states that there may be situations where the facility relocation is so far removed from the originally approved site that we would conclude that this is a different provider or supplier, for example, it has different employees, services, and patients. Furthermore, the language of section 1820(c)(2)(i) of the Act allows a State to waive the mileage requirement and designate a facility as a necessary provider of health care services to residents in the area. We have interpreted "services to residents in the area" to mean that the necessary provider designation does not automatically follow the provider if the facility relocates to a different location because it is no longer furnishing "services to patients" in the area determined to need a necessary provider.

We do not intend to change this policy. Our proposal, noted below, is intended to establish a methodology to be used by all CMS Regional Offices in making such a decision consistent with the statutory provisions concerning necessary provider designation.

In this proposed rule, we are proposing to amend the regulations at §485.610 to set forth the criteria by which those relocated CAHs designated as necessary providers that embarked on a replacement facility project before the sunset provision was enacted on December 8, 2003, but find that they cannot be operational in the replacement facility by January 1, 2006, can retain their necessary provider status. As required by statute, no additional CAHs will be certified as a necessary provider on or after January 1, 2006. We recognize that the statute refers to a facility designated as a CAH while relocation of a facility may result in a different building. However, to provide flexibility for a facility designated as a CAH whose location may change, but is essentially the same facility in a different location, we are proposing to amend the regulations to account for this scenario. Essentially, we recognize that the necessary provider designation may need to be applied to certain relocated CAHs. To this end, we are proposing to use the specified relocation criteria as the initial step to determine continuing necessary provider status. Specifically, in this proposed rule, we are proposing that, when a CAH is determined to have relocated, it may nonetheless continue to operate under its necessary provider designation that exempts the distance from other providers only if the following conditions are met:

(1) The relocated CAH has submitted an application to the State agency for relocation prior to the January 1, 2006, sunset date. If the CAH is applying under a grandfathered status under section 1820(h)(3) of the Act, the following items would need to be included in the application:

- A demonstration that the CAH will meet the same State criteria for the necessary provider designation that were established when the waiver was originally issued. For

example, if the location waiver was granted because the CAH was located in a health professional shortage area (HPSA), the CAH must remain in that HPSA.

- Assurance that, after the relocation, the CAH will be servicing the same community and will be operating essentially the same services with essentially the same staff (that is, a demonstration that it is serving at least 75 percent of the same service area, with 75 percent of the same services offered, and staffed by 75 percent of the same staff, including medical staff, contracted staff, and employees). This is essentially the same criteria used in determining whether the CAH has relocated.
- Assurance that the CAH will remain in compliance with all of the CoPs at 42 CFR Part 485 in the new location. Compliance will be established with a full survey in the new location to include the Life Safety Code and would include any off-site locations and rehabilitation or psychiatric distinct part units.
- A demonstration that construction plans were "under development" prior to the effective date of Pub. L. 108-173 (December 8, 2003) in the application the CAH submits to continue using a necessary provider designation. Supporting documentation could include the drafting of architectural specifications, the letting of bids for construction, the purchase of land and building supplies, documented efforts to secure financing for construction, expenditure of funds for construction, and compliance with state requirements for construction such as zoning requirements, application for a certificate of need, and architectural review. However, we recognize that it may not have been feasible for a CAH to have completed all of these activities noted above as examples prior to December 8, 2003. Thus, we expect the CMS Regional Offices to consider all of the criteria and make case-by-case determinations of whether a relocated CAH continues to warrant necessary provider status. We note that we have also used the above documentation guidelines in Publication 100-20 for grandfathered specialty hospitals to determine if construction plans were "under development."

In proposing these criteria, our intent in clarifying the sunset of the necessary provider designation provision is to allow CAHs to complete construction projects that were initiated prior to the enactment of Pub. L. 108-173, which we believe is consistent with the statutory language of section 405(h) of Pub. L. 108-173.

(2) In the application, the CAH demonstrates that the replacement will facilitate the access to care and improve the delivery of services to Medicare beneficiaries. We are soliciting comments on how a necessary provider CAH should demonstrate that the replacement will improve access to care.

These guidelines are meant to be applied to the relocated CAH that meets the CoP in the new location and wishes to maintain a necessary provider designation in order to meet the distance requirement at §485.610(c). They are not meant to preclude a CAH from relocating at any time if the CAH does not seek to maintain the necessary provider designation. Any CAH may relocate at any time if the CAH meets the definition of relocation and can meet all the CoPs at 42 CFR Part 485, Subpart F, as determined by the CMS Regional Offices on a case-by-case basis.

Accordingly, we are proposing to revise §485.610 of the regulations by adding a new paragraph (d) to incorporate this proposal. Specifically, the proposed new paragraph (d) would specify that a CAH may maintain its necessary provider certification provided for under §485.610(c) if the new facility meets the requirements for either a replacement facility that is constructed within 250 yards of the current building or contiguous to the current CAH on land owned by the CAH prior to December 8, 2003; or as a relocated CAH if, at the

relocated site, the CAH provides essentially (75 percent) the same services to the same service area with essentially the same staff. The CAH that plans to relocate must provide documentation demonstrating that its plans to rebuild in the relocated area were undertaken prior to December 8, 2003. We are also proposing that if a CAH that has a necessary provider certification from the State places a new facility in service on or after January 1, 2006, and does not meet either the requirements for a replacement facility or a relocated facility, as specified in the regulations, the action will be considered a cessation of business.

§485.610 Condition of participation: Status and location.

In order to be considered a relocation, we are proposing under §485.610(d)(2)(ii) to require a CAH to provide documentation demonstrating that its plans to rebuild in a relocated area were undertaken prior to December 8, 2003. This requirement does impose an information collection requirement. However, because this burden would be imposed on less than 10 CAHs, under 5 CFR 1320.2(c), these requirements are exempt from the PRA.

§412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) * * *

(1) The hospital is located in a rural census tract of a Metropolitan Statistical Area (MSA) as determined under the most recent version of the Goldsmith Modification, the Rural-Urban Commuting Area codes, as determined by the Office of Rural Health Policy (ORHP) of the Health Resources and Services Administration, which is available via the ORHP website at: **http://www.ruralhealth.hrsa.gov** or from the U.S. Department of Health and Human Services, Health Resources and Services Administration, Office of Rural Health Policy, 5600 Fishers Lane, Room 9A-55, Rockville, MD 20857.

* * * * *

(4) For any period after September 30, 2004 and before October 1, 2006, a CAH in a county that, in FY 2004, was not part of an MSA as defined by the Office of Management and Budget and was not considered to be urban under §412.64(b)(3) of this chapter, but as of FY 2005 was included as part of an MSA or was considered to be urban under §412.64(b)(3) of this chapter as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, may be reclassified as being located in a rural area for purposes of meeting the rural location requirement under §485.610(b) of this chapter if it meets any of the requirements in paragraphs (a)(1), (a)(2), or (a)(3) of this section.

§485.610 Condition of participation: Status and location.

* * * * *

(b) * * *

(3) Effective only for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or paragraph (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Budget Management and was not considered to be urban under §412.63(b)(3) of this chapter, but as of FY 2005 was included as part

of such an MSA or was considered to be urban under §412.64(b)(3) of this chapter, as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003.

* * * * *

(d) Standard: Relocation of CAHs with a necessary provider designation. A CAH that has a necessary provider certification from the State and places a new facility in service after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider certification only if the new facility meets either the requirement for replacement in the same location in paragraph (d)(1) of this section or the requirement for a relocation of a CAH in paragraph (d)(2) of this section.

(1) A new construction of a CAH will be considered as a replacement facility if the construction is undertaken within 250 yards of the current building or contiguous to the current CAH on land owned by the CAH prior to December 8, 2003.

(2) A new facility CAH will be considered as a relocation of a CAH if, at the relocated site--

(i) 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); and

(ii) The CAH provides documentation demonstrating that its plans to rebuild in the relocated area were undertaken prior to December 8, 2003.

(3) If a CAH that has a necessary provider certification from the State places a new facility in service on or after January 1, 2006, and does not meet either the requirements in paragraph (d)(1) or paragraph (d)(2) of this section, the action will be considered a cessation of business as described in §489.52(b)(3).

I. Impact of Proposed Policy on CAH Relocation Provisions

In section VII.B.3.of the preamble to this proposed rule, we discuss the proposed change to the necessary provider provision as it applies to CAHs. As required by statute, no additional CAHs will be certified as a necessary provider on or after January 1, 2006. We are proposing to revise the regulations to allow some flexibility for those CAHs previously designated as necessary providers that embarked on a replacement facility project before the sunset provision was enacted on December 8, 2003, but find that they cannot be operational in the replacement facility by January 1, 2006. We are proposing that, when a CAH is determined to have relocated, it may continue to operate under its existing necessary provider designation that exempts CAHs from the distance from another provider requirement only if certain conditions are met. The proposed clarification to the sunset of the necessary provider provision is intended to allow CAHs to complete construction projects that were initiated prior to the enactment of Pub. L. 108-173. The Health Resources Services Administration (HRSA) estimates that this proposal will apply to fewer than six CAHs nationwide. The average cost of construction of a new 25 bed CAH is approximately $25 million. Given a depreciation schedule based on a 25 useful life and Medicare utilization of approximately 50 percent, the additional capital costs for six CAHs would be $3 million. However, the actual cost to the program would be further reduced since those 6 CAH are currently being reimbursed for their existing capital costs and also the increased operating costs

that are associated with operating an aged facility. Accordingly, the budgetary impact for the proposed change on the affected CAHs is estimated at between $1 million and $2 million. Expressed on a per-facility basis, the budgetary impact of this proposed change is estimated at between $167,000 and $333,000 per CAH.

CMS-1500-P-78 **Changes to the Hospital Inpatient Prospective Payment Systems and FY 2006 Rates**

Submitter : Mrs. Marilyn Musgrave **Date & Time:** 05/20/2005

Organization : United States House of Representatives

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1500-P-78-Attach-1.DOC

27-0
(3)

NB/H

CMS-1500-P-70 **Changes to the Hospital Inpatient Prospective Payment Systems and FY 2006 Rates**

Helen Hamilton Knight Sellers

Submitter : Mrs. Patricia Eaves **Date & Time:** 05/18/2005

Organization : Beauregard Memorial Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

The proposed changes should be carefully re-evaluated before they become law. In regard to the full-market basket components there are several areas that need careful attention and assurrance that all parts are working smoothly. That currently is not the case. The appeal process is not functioning correctly. There are many problems related to this process: communication and accessability by the organization being evaluated. THIS NEEDS TO BE FIXED prior to determining denial of payment.
The second area of great concern is the alleignment of JCAHO and CMS for the national quality measures. This did not become operational until the first of 2005 and still has gliches.
June 6, 2005 should be posponed
The state QIO of LA is working very hard to assist us in meeting all deadlines and appeals. The problems occurring are outside thier area of authority. Please listen to all the state QIO's concerns. They are the ones who know what is really happening on the front line.

28

UWHealth

University of Wisconsin
Hospital and Clinics

600 N. Highland Ave.
Madison, WI 53792

MAY 27 2005

Nurse/AH/Pharm
Hefler
Hartstein
Truong
Lefkowitz
DME

May 18, 2005

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

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

Dear CMS:

I am writing this letter to urge CMS to restore funding for second-year, specialized pharmacy residency programs. This has an enormous impact on the availability of specialty residency programs and would thereby decrease the clinical skills of pharmacists caring for patients in all areas of health care.

I am currently the Director of the Critical Care Residency program at the University of Wisconsin Hospital and Clinics. My residency program undergoes accreditation by the American Society of Health System Pharmacists (ASHP) every 7 years to make sure it fulfills the standards set forth for all critical care residencies. My residents have gone on to work in critical care clinical pharmacy positions and to teach other pharmacy students at Schools of Pharmacy. It is important to have pharmacists practicing at higher levels because critical care pharmacy experts have been shown to decrease costs and decrease adverse drug events (Leape LL, et al. JAMA 1999). Physicians and nurses of the Society of Critical Care Medicine (SCCM) included in their position paper on critical care pharmacy services that critical care pharmacists should be involved in the teaching of pharmacy residents (SCCM/ACCP. Pharmacotherapy 2000).

Residents I trained have done numerous activities to benefit patients, staff and the hospital. An example of how critical care residents impact patient care is one resident noticed a patient was hypoglycemic and was started on a new medication that was recently found to cause this adverse reaction. After the offending medication was stopped, the patient's blood sugars stabilized and they were transferred out of the intensive care unit. My residents have also instructed physicians and nurses about many topics including venous thromboembolism prophylaxis, common intravenous medications used in the intensive care unit, treatment of upper gastrointestinal bleeds, and treatment of hyperkalemia. Residents are also involved in developing and implementing clinical guidelines for better patient management and to promote use of the most cost effective treatments. Some of the guidelines we have worked on include sedation and stress ulcer prophylaxis.

I completed a specialized pharmacy residency/fellowship after obtaining my Doctor of Pharmacy degree. This advanced training allowed me to step right into an intensive care

unit and practice at a high level. Without this advanced training, I could not have accomplished this step without more training from the department and the hospital.

I hope you reconsider the restoration of funding for second-year, specialized pharmacy residency programs to allow for more advanced training of pharmacists to meet the high demands of the health care industry. In this era of tight hospital budgets, I feel that without the CMS funding, a lot of the second-year, specialty residency training programs will be unable to continue. Thank you.

Sincerely,

Jeffrey Fish

Jeffrey Fish, Pharm.D., BCPS
Senior Clinical Pharmacist/Clinical Assistant Professor
Director of Critical Care Pharmacy Residency Program
University of Wisconsin Hospital and Clinics, Madison, WI

Cc: Russell Feingold, Herb Kohl, Tammy Baldwin

(3) 29-0

NURS/AH/Pharm

MAY 27 2005

NORTH MISSISSIPPI
MEDICAL CENTER

May 26, 2005

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear CMS:

North Mississippi Medical Center, a 650-bed regional referral center in Tupelo, holds the distinction of being the largest hospital in Mississippi and the largest non-metropolitan hospital in the United States. The medical center serves more than 650,000 people in 22 counties in North Mississippi, Northwest Alabama, and portions of Tennessee.

Area residents have access to a medical staff representing more than 40 medical specialties, as well as centers of excellence in cancer treatment and research, neurology, neurosurgery, cardiac surgery, cardiology, pulmonology, rehabilitation, chemical dependency, kidney and neonatal programs. In addition, the NMMC Home Health Agency serves patients in 17 counties in North Mississippi and offers many complex and extremely high-tech procedures that can be performed in the home setting. Several affiliate clinics to NMMC provide another avenue for patients to receive quality care.

NMMC currently offers Pharmacy Practice Residencies (PGY1) and Specialized Pharmacy Residency (PGY2) positions. The services offered through these positions are vital to the Clinical Pharmacy Team at NMMC. With preparation for Medication Therapy Management offered under Part D Medicare, access to the expertise of clinical pharmacist on an inpatient (hospital) and outpatient (clinic) level is particularly important.

As a Residency Director, a Pharmacy Practice Resident, and a Specialized Pharmacy Resident, we feel the nature and value of our services are assets to our facilities future. Collaborative care is the backbone of our medical system, and our patients rely on our input to best manage their health.

For example, a 65 year old female, and patient at our clinic has her blood drawn and analyzed for adjusting her blood thinner medication. Our Pharmacy Practice Resident interviews the patient and discovers several problems with her medication regimen. She corrects a duplication of therapy, recommends a daily supplement for the patient, and increased her blood thinner due to sub-therapeutic levels. Our Infectious Disease Specialized Resident works closely with physicians to analyze bacteria susceptibility in our facility. She plays a vital role in the

Affiliated with North Mississippi Health Services
830 South Gloster Street
Tupelo, Mississippi 38801
(662) 377-3000

NORTH MISSISSIPPI
MEDICAL CENTER

development of our anti-biogram which is a reference for medical professionals and aids in determining choice of antibiotics for the patients.

The impact of Pharmacy Residency training on a Medicare patient is extremely significant, and we urge CMS to continue full funding of this role. The American Society of Health-Systems Pharmacists submitted survey data to CMS in a timely manner in 2004 and 2005 to show that most hospitals require or prefer to employ clinical pharmacy specialists who have completed second-year specialty residency programs. Please use this information and the personal accounts mentioned in our letter as you finalize decisions regarding residency funding.

Sincerely,

Kristie Gholson

Kristie Gholson, B.S., Pharm. D., FASHP
Residency Director

Kim McCrory

Kim McCrory, Pharm. D., PGY2
Specialized Pharmacy Resident

Jillian Foster

Jillian Foster, Pharm. D., PGY1
Pharmacy Practice Resident

cc: Gary C. Stein, Director of Federal Regulatory Affairs, American Society of Health-Systems Pharmacists

Affiliated with North Mississippi Health Services
830 South Gloster Street
Tupelo, Mississippi 38801
(662) 377-3000

30

Nursing/Pharm

MAY 27 2005

ST. Joseph's/Candler
Live smart.

Hefler
Holtstein
Thomas
Heinrich
Ruiz

May 17, 2005

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

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

Dear CMS:

I am writing to you as Director, Clinical Pharmacy, Research & Pulmonary Medicine for the St. Joseph's/Candler Health System (SJ/C) in Savannah, Georgia. We are a community-based health system that has offered post-graduate pharmacy residency training for 6 years. I have the responsibility to develop the pharmacy residency program and assure that it satisfies the needs of our hospitals as well as needs for advanced-trained pharmacists in the State and region.

We are appreciative of the recent decision to continue CMS funding for first-year pharmacy practice residencies and believe this was the right decision for U.S. health care. However, we are disappointed that second-year, specialized pharmacy residency programs were not included. We urge you to reverse this decision and restore this funding.

At SJ/C we employ 9 clinical pharmacy specialists who practice in oncology (2), infectious diseases (1), critical care (2), and medicine (4). All of these individuals are required to have specialized residency training and be certified in their respective pharmacy practice specialties. Without sufficient numbers of specialized pharmacy practice residencies in the country we would not have been able to fill these important positions.

The State of Georgia is engaged in various initiatives through the Georgia Cancer Coalition to improve the care of our citizens who have cancer. We believe that one critical area of needed improvement is the availability of clinical pharmacists who have advanced training in cancer. Therefore, we plan to offer a specialized residency in oncology pharmacy practice starting next year. Elimination of CMS funding for second-year, specialized residencies will have an adverse effect on this plan and ultimately negatively effect the advancement of cancer care in Georgia.

St. Joseph's Hospital
11705 Mercy Boulevard
Savannah, Georgia 31419
(912) 925-4100

Candler Hospital
5353 Reynolds Street
Savannah, Georgia 31405
(912) 692-6000

Given the requirement for medication therapy management as part of the new Medicare drug benefit, it is particularly important that CMS take actions that support the continued availability of adequately trained pharmacy professionals to provide this level of care.

We look forward to your reconsideration and restoration of funding for specialized pharmacy residencies.

Sincerely yours,

Ray R. Maddox, PharmD
Director, Clinical Pharmacy, Research & Pulmonary Medicine

\rrm

cc: Senator Saxby Chambliss
Senator Johnny Isakson
Representative Jack Kingston

31-O
(387)
Nurs/AH/Pharm

CMS-1500-P-13 **Changes to the Hospital Inpatient Prospective Payment Systems and FY 2006 Rates**

Heffer
Hartstein
Truong
Leftwitz
Ruiz

Submitter : **Dr. Anne Denham** **Date & Time:** **04/29/2005**

Organization : **Kaiser Permanente**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Dear CMS:

My name is Anne Denham and I am a Clinical Pharmacy Specialist who is also a Board Certified Pharmacotherapy Specialist (BCPS). I completed two residency programs: a Pharmacy Practice Residency at the University of Colorado and a Specialty Residency at the Medical University of South Carolina. These experiences were able to prepare me for my current position at Kaiser Permanente's Clinical Pharmacy Cardiac Risk Service. This is a case-managament clinical service that helps control cardiac risk factors in patients with a history of heart disease. This service manages over 10,000 patients and my personal panel consists of around 800 of these patients. I am also the Residency Director of our Cardiology Residency Program.

I am writing today to urge you to restore funding for second-year, specialized pharmacy residency programs. Specialty residents not only help provide clinical services and help propel quality initiative programs, but they also are training to become clinical minds of the future. Experts agree the best health care model includes a multi-disciplinary team approach in order to improve patient care in the most cost-effective manner. This training will become even more important as the pharmacy community is preparing to implement medication therapy management programs as part of the new Medicare drug benefit. Failure to restore funding will limit Medicare beneficiaries' access to the expertise of clinical pharmacy specialists and will lead to increased Medicare spending for health care.

As a residency preceptor, second-year specialty residents are a vital part of our health care system. They not only provide support to our providers (physicians, nurse practitioners, etc), but also have a role in providing direct patient care. Patient safety and quality improvment research projects to improve patient care are also key components to the residency. Currently, Kaiser Permanente-Colorado is Denver's largest area Medicare provider. In the Cardiac Risk Service where I work, an estimated 70% of our 10,000 patients that we help to manage and prevent additional heart events are Medicare patients. As a former resident, my second-year specialty residency training provided the patient care tools and experience needed to care for my patients today.

In order to obtain a clinical pharmacy specialist position in our health care system, specialty residency experience is required. In addition, ASHP submitted survey data to CMS in 2004 and 2005 to show that most hospitals require or prefer to employ clinical pharmacy specialists who have completed second-year specialty residency programs.

Sincerely,

Anne M. Denham, Pharm.D., BCPS

31-0

Clinical Pharmacy Specialist
Director of Cardiology Specialty Residency
Kaiser Permanente- Colorado Region
Clinical Pharmacy Cardiac Risk Service
16601 E. Centretech Parkway
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