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Hefter
Hartstein
Brooks
Fagan
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Kelly
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DRG/Gen

DRG Reclassifications

Memo To: CMS

From: Stan Mendenhall
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Date: June 17, 2005

Subject: Proposed DRG changes and reclassification of lower joint replacements as reported in the May 4, 2005 Federal Register

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Summary:

1. I agree with your approach and recommendations to split primary joint replacement from revision joint replacement.
2. I disagree with some of the findings and data submitted by AAOS
3. I believe that CMS should include the price of medical devices in evaluating changes to the DRG system.
4. The new knee revision ICD-9-CM procedure codes should have an "includes note" to indicate that they include both bicondylar and unicondylar knee replacements.

1. I agree that primary and revision replacements should be split into 2 different DRGs:

I have been the editor and publisher of Orthopedic Network News for 15 years. I have also provided software services to hospitals to help them manage their joint replacement programs for about 10 years. There are currently 12 hospital systems [representing 43 hospitals, with about 70,000 cases from 1991-2004] utilizing my software. These hospitals submit blinded patient data, implant components and prices paid by the hospitals for their joint replacements. These data are then used to identify trends in implant cost as well as utilization. These hospitals are considered members of the "Orthopedic Research Network."

I saw your proposal to reclassify joint replacements into separate DRGs for "primary" and "revision" lower joint replacement in the May 4, 2005 Federal Register, based on data submitted by the American Academy of Orthopedic Surgeons (AAOS), Massachusetts General Hospital, Mayo Clinic, and San Francisco General Hospital.

Although the hospitals that provided data to you are well-known in the field of orthopedics – there is no hospital in the US that performs more revision cases than the Mayo clinic in Rochester -- I would argue that this data may be skewed toward the academic medical centers, while the 43 or so hospitals in the Orthopedic Research Network may be more representative of "community hospitals" where the bulk of joint replacements are performed.

Below is a table prepared from the 43 hospital in the Orthopedic Research Network. This data confirms the variation in charges cited by CMS in their rationale for splitting revision joint procedures from primary joint procedures:

Resource consumption of Joint replacements (DRG 209), ORN, 2004

Principal procedure	Cases	Average charge	Average implant costs
81.51 Total hip	3,441	$37,683	$6,341
81.52 Partial hip	1,477	$36,950	$2,929
81.53 Revision hip	714	$48,604	$5,485
81.54 Total knee	7,111	$34,963	$5,193
81.55 Revision knee	672	$44,685	$5,559

Source: Orthopedic Research Network, 2004 discharges, 43 hospitals

The average charges per case are significantly higher for revision hips and revision knees, supporting CMS' proposal to split primary from revision joint replacements into separate DRGs.

2. I disagree with some of the findings and data submitted by AAOS:
We have concentrated on collecting implant costs for several reasons. For one thing, implant costs are hugely variable between case types and hospitals, depending on the "contracted" price that hospitals are able to negotiate and the type of system being implanted. Secondly, hospital charges are a poor proxy for cost. We have also found that supply costs are reported to Medicare through UB-82 are distorted in two ways: (a) there is a variation in the markups that hospitals charge for the medical devices that they use, and (b) there is a variation in the prices that the hospitals pay for identical medical devices. Finally, hospitals see implant costs as more of a variable cost and savings in implant costs translate directly to savings to the institution.

For this reason, we view implant costs as "cost drivers". The variation in the number and types of implant components used on a case will often have more of an impact on resource consumption than other factors, since the post-operative care of many types of joint replacements and revisions is quite similar.

We have used a different approach toward classification of revisions, which is similar to, but not identical to that proposed by the AAOS. Specifically, we believe that one of the main cost drivers in revision joint replacements is which of the patient bones must be disrupted in order to perform a revision. For example, as was pointed out in the proposed rule, a liner, head, or patella exchange are relatively low in resource consumption, while

those cases requiring all of the components for a revision knee will be more resource consumptive. We believe that the higher resource consumption for complete knee revisions are because of both higher component costs and the more challenging surgical technique, since the femoral shaft, pelvis, tibia and femur will be disrupted. This surgery may create voids in the bones which may require bone grafts and substitutes to make up for the bone that is lost during the removal of the implant components.

In the proposed rule of page 23326, you state that "Among revision knee replacement procedures, patients who underwent complete revision of all components had longer operative times…., and significantly higher resource utilization, according to studies conducted by the AAOS. Revision of the isolated/modular tibial insert component was the next most resource-intensive procedure, and primary total knee replacement was the least resource-intensive procedures studied."

According to 2004 data from the Orthopedic Research Network, our experience is different than that provided by AAOS:

Resource consumption of knee revisions, ORN, 2004

Replaced femur? 	Replaced tibia? 	Replaced insert? 	Replaced patella? 	Cases	Average charge	Implant costs
Yes	Yes	Yes	Yes	157	$55,397	$8,727
No	No	Yes	No	143	**$33,682**	$1,448 L
Yes	Yes	Yes	No	82	$56,497 H	$9,633 H
Yes	No	Yes	No	55	$36,363	$5,647
No	No	Yes	Yes	45	**$33,565**	$2,546
No	No	No	Yes	27	**$24,066 L**	$2,073
No	Yes	Yes	Yes	19	$46,131	$10,845
Total primary knee				*6,531*	*$33,451*	*$4,778*

**Note: Total knees exclude bilateral knees assigned to DRG 471
Source: Orthopedic Research Network, 2004 discharges, 43 hospitals

In contrast to your statements, our data indicates that the most resource intensive (charges) were revisions involving both femur and tibia, and least were those involving the patella or insert exchanges. The least resource consumptive were those involving a patellar replacement only ($24,066).

Resource consumption of hip revisions, ORN, 2004

Replaced femoral stem? 	Replaced femoral head? 	Replaced Acetabular Shell 	Replaced Acetabular Liner 	Cases	Average charge	Implant costs
No	Yes	No	Yes	137	$32,176 L	$2,478
No	Yes	Yes	Yes	124	$44,247	$4,894
Yes	Yes	Yes	Yes	121	$67,428 H	$9,665 H
Yes	Yes	No	Yes	65	$61,160	$7,537
Yes	Yes	No	No	59	$55,754	$7,512
No	No	No	No	48	$40,151	$1,812 L
No	No	Yes	Yes	35	$43,926	$4,253
No	Yes	No	No	33	$42,403	$3,247
No	No	No	Yes	27	$39,442	$1,937
Yes	No	No	No	21	$64,006	$9,687 H
Yes	Yes	Yes	No	21	$57,617	$7,660
Total primary hip				*3,441*	*$37,683*	*$6,341*

Source: Orthopedic Research Network, 2004 discharges, 43 hospitals

A similar profile is evident for revision hip replacements. As can be seen the highest resource consumption (charges) is for revisions in which the femoral stem, head, shell, and liner were replaced, while the lowest consumption were for cases in which only the femoral head and liner were replaced. These "minimal" revisions were also the most frequently occurring cases in cases assigned 81.53 as a principal procedure. The lowest implant costs were associated with those cases in which none of the usual hip implant components were replaced (these could have been revision using bone graft, cable, or other misclassified components) and the highest were those in which the femoral stem or all components were replaced. (The high implant costs ($9,687) associated with the "femoral stem only" components were largely those for oncology cases in which a hip stem was replaced along with components used in the knee.)

In summary, the disparity in resource consumption which is based on patient charges is largely explained through variation in individual components used in joint replacement. The more parts that are replaced, the more the direct costs to the hospital, and generally the higher the charges are to Medicare. Reimbursing revisions of simple head and/or liner exchanges in hips, and patellar/insert exchanges may be over-reimbursing for these cases, and under reimbursing primary hip and knee procedures, where the number of components is greater, and more costly.

There are significant differences in some of the prices of the specialty components that are used in limb salvage surgery (generally oncology), and major differences in the prices of hinged knee/revision knee components from primary knee replacements. However, it

is not realistic to expect the hospitals to submit, or for Medicare to administer a program which requires the submission of part numbers to separately identify these components.

3. I believe that CMS should include the price of medical devices in the evaluation of DRG changes:

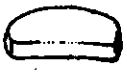
One of the constant themes in the comments provided to CMS in determining reimbursement to hospitals over the last 20 years has been the attempt by device and drug manufacturers to "lobby" for their specific DRG. They have tried to ensure that hospitals are paid sufficiently to justify the prices that the drug and device manufacturers charge to hospitals. I would urge CMS to consider the collection of price information from device manufacturers and other independent parties in order to verify the impact that device costs have on Medicare's budget. Since many of the device manufacturers are quite profitable, I believe that it is in the taxpayers' interest to ensure that Medicare is not overpaying device and drug companies through the hospital payment system. Although many manufacturers would argue that their device represent a relatively small portion of Medicare's cost and has improved the lives of many of these recipients, my fear is the profitability of these can drive sales and lead to inappropriate hospitalizations, surgeries, and utilization of resources. One can find data that suggests that the sales commissions for some implantable medical devices exceed the payment that Medicare gives to surgeons for implanting them. This may, in fact, lead to inappropriate surgeries, and hence, decrease the quality of life for the recipients, who may be marginal candidates for some of these devices in the first place.

4. Unicondylar (or unicompartmental) knee replacement

Unicondylar knee replacements replace one-half the knee (either medial or lateral condyles). Their design is similar to that of bicondylar knees in that they have a femoral component, a tibial component, and an insert:

Unicondylar femoral component

Unicondylar base component



Unicondylar tibial insert

In some hospitals reviewed by Orthopedic Network News, unicondylar knee replacements account for almost 25% of the knee replacements performed, although nationally, unicondylar knees represent about 4% of all knee replacements, and probably significantly less in the Medicare population. Currently there is no difference between the ICD-9-CM coding for bicondylar and unicondylar primary and revision knee replacements which are both assigned to ICD-9-CM 81.54 and 81.55. According to the most recent survey conducted by *Orthopedic Network News*, the average manufacturer list price for a unicondylar knee was $4,406 compared to $7,363 for the components of a cemented bicondylar knee replacement. One manufacturer (Zimmer/Centerpulse) also

markets a "Unispacer" which is basically a tibial base component with a list price of about $3,400.

According to the Orthopedic Research Network, a number of unicondylar knee replacements may be revised to total knees, or they may replace some of the components that have worn or become dislodged. Therefore, it would be helpful to have an "Includes note" for the new revision knee procedures to indicate that the code includes replacement of unicondylar components as well as bicondylar components.

LABOR S/N – KNIGHT
KRAEMER
SEIFERT
TREITEL
HEFTER
HARTSTEIN

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DELAWARE VALLEY HEALTHCARE COUNCIL
of The Hospital & Healthsystem Association of Pennsylvania

June 20, 2005

TRANSER – WALZ
HART

WI/OM – MILLER
Payment Rates/Outlier

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

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates; (70 Federal Register 23306), May 4, 2005.

Dear Dr. McClellan:

On behalf of the more than 150 member hospitals, health systems and other health related organizations in Southeastern Pennsylvania, Southern New Jersey and Delaware, I am writing to convey our views on the proposed rule "Medicare Program; Proposed changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates." Hospitals and health systems throughout the Delaware Valley are under severe financial pressure. This comes from a combination of such challenges as skyrocketing medical liability insurance costs, managed care/inadequate reimbursement, uncompensated care, the short supply and rising cost of workers, double-digit inflation in prescription medicines, the high cost of new technology, and the considerable costs associated with disaster preparedness. In order to ensure continued access to high quality health care for Medicare beneficiaries in Southeastern PA, adequate hospital payments under the Medicare Prospective Payment System (PPS) is critical. Our comments primarily focus on four specific aspects of the proposed regulation: the labor-related share, the outlier threshold, the post acute-care transfer policy and the occupational mix adjustment for the wage index.

The Delaware Valley Healthcare Council (DVHC) requests that the Centers for Medicare and Medicaid Services (CMS) modify the proposed rule to ensure that inpatient facilities receive adequate reimbursement for their services as follows:

LABOR S/N

Labor Share

According to the proposed rule, the DVHC hospitals as part of the Philadelphia Core Based Statistical Area (CBSA) would benefit from an increase in the area wage index from 1.0855 for federal fiscal year 2005 to 1.10 for federal fiscal year 2006. However, based on CMS' proposal to reduce the labor-related share from 71.1 percent to 69.7 percent, the improved reimbursement from the increased wage index is negated. Needless to say, this would adversely affect hospitals in our region that are under severe financial stress as has been previously described.

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http://dvhc.phillynews.com

DVHC agrees with the American Hospital Association's (AHA) position that CMS should leave the labor-related share at 71.1 percent. We are concerned with CMS' proposal to remove postage from the labor-related share, as it seems arbitrary to pick one item to remove that ultimately will result in penalizing hospitals in high wage areas. It would have a detrimental affect on high-wage area hospitals while diverting funds back to low-wage hospitals that have already been protected through the Medicare Modernization Act which specified that the labor-related share for hospitals with an area wage index of less than 1.0, would remain at 62 percent. Since CMS has been unable to discover a methodology for changing the labor-related share that is accurate, reliable and easy to apply, **DVHC recommends that CMS leave the labor-related share alone until such time that there is a broader plan to refine the methodology.**

Outlier Threshold

For the past two years, DVHC has argued against CMS' proposal to increase the outlier threshold and once again we strongly oppose CMS' proposed increase in the outlier threshold. The purpose of providing extra payments for cases with unusually high costs that are determined to be outliers is both to limit the hospitals' financial risk from extreme costs and to remove any financial disincentive for treating Medicare patients with especially serious conditions. Although CMS is proposing a more modest increase than what has been proposed in the past, we believe that an increase in the outlier threshold from $25,800 to $26,675 as proposed in the rule for FY 2006, will make it even more difficult for hospitals to qualify for outlier payments and will put them at greater risk when treating extraordinary cases. Furthermore, CMS has continued to under spend the 5.1% that is set-aside for outliers. It is estimated that in FY 2005 CMS under spent the funds set aside for outliers by an estimated $610 million. Given that CMS did not even spend the entire pool of funds set aside in FY 2005 with an outlier threshold of $25,800, we recommend that the outlier threshold be lowered not increased. It is critical that hospitals receive special payments to cover the extremely high-costs associated with extraordinary cases. **We urge CMS to guarantee that hospitals receive the full 5.1 percent of payments that will be withheld from base inpatient payments in 2005 by lowering the outlier threshold.**

OUTLIER

Transfer policy

We are disappointed that the rule proposes to expand the post-acute care transfer policy from 30 Diagnosis-related groups (DRGs) to 223 DRGs in FY 2006. The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare Prospective Payment System (PPS). The Medicare inpatient PPS is based on a system of averages. Cases with higher than average length of stay tend to be paid less than costs while cases with shorter than average lengths of stay tend to be paid more than costs. The expansion of this policy makes it impossible for hospitals to break even on patients that receive post-acute care after discharge. Hospitals lose" if a patient is discharged prior to the mean length of stay, and they "lose" if patients are discharged after the mean length of stay.

TRANSFERS

The proposal to expand the transfer policy would result in significant financial penalties to hospitals for making sound clinical judgments about the best setting of care for patients. For hospitals in Pennsylvania, it is estimated that the proposed expansion to 223 DRGs would mean a $50-$60 Million reduction in payments. CMS' proposal to expand the post-acute transfer policy is not in the best interests of patients or caregivers. It appears to be strictly a cost cutting measure that undermines clinical decision-making and penalizes hospitals for providing efficient care, at the most appropriate time and in the most appropriate setting. Therefore, **DVHC recommends that this provision be eliminated from the final rule.**

Occupational Mix Adjustment

As you know, the occupational mix adjustment was included with little discussion or debate by Congress as a part of Benefits Improvement and Protection Act (BIPA) of 2000. We understand the intent of the proponents of this provision was to redistribute Medicare payments among hospitals to increase payments to and address needs of rural hospitals. Aside from the fact that the needs of these hospitals were addressed directly in the Medicare Modernization Act (MMA), based on the data submitted to CMS it seems evident that in reality the impact of the proposed occupational mix adjustment is extremely inconsistent. In other words, it appears that the occupational mix adjustment is not having the desired or intended results. The fact that the occupational mix adjustment results run counter to their intended objectives suggests that there are flaws with the methodology. Perhaps more important, the methodology introduces financial incentives related to staffing that are not in the best interests of patient care.

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Since the occupational mix adjustment does not have the effect proponents intended and the MMA substantially improved payments to rural hospitals, **we support CMS' decision to limit the application of an occupational mix adjustment to no more than 10 percent of the wage index.**

Additional Comments

In addition to the previously mentioned modifications to the proposed rule, we want to support CMS' position with regard to specialty hospitals and the direct Graduate Medical Education (GME) policy for the initial residency period. We appreciate the clarification of the Medicare statutory definition of a "hospital" that was outlined in the proposed rule. We support the direction that CMS is taking by deciding not to process any further requests for Medicare provider numbers from limited-service hospitals until the completion of a review and revision of the procedures for evaluating such requests. We think it is important that CMS take the time to examine these types of facilities. Likewise, we agree with CMS' proposed change to the policy for the initial residency period. The change would allow hospitals to be paid an entire full-time equivalent (FTE), rather than half of an FTE for such residents until they are board eligible.

Thank you for the opportunity to express our views on this important regulation as it will greatly impact on hospital services received by Medicare beneficiaries in the Philadelphia area as well as other parts of the Commonwealth and the nation. If you or your staff needs further clarification of our views, please do not hesitate to contact me at (215) 735-3295 or Pamela Clarke, DVHC's Vice President of Managed Care at (215) 735-3265.

Sincerely,

Andrew Wigglesworth
President

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JUN 2 2 2005

ASTS

American Society of Transplant Surgeons

DRG/WEIGHTS- KRAEMER
TREITEL
ZEZZA
HUE
HEFTER
HARTSTEIN

June 21, 2005

DRG/OPPS - BROOKS
FAGAN
GRIEFER
KELLY

FEDERAL EXPRESS

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

IMPACT-

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

Dear Dr. McClellan:

The American Society of Transplant Surgeons (ASTS) is delighted to have the opportunity to comment on the proposed 2006 payment rule (the "Proposed Rule") for hospitals paid under the inpatient prospective payment system (IPPS). ASTS is an organization comprised of over 1,000 transplant surgeons, physicians and scientists dedicated to excellence in transplantation surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

DRG Weights

We understand that, every year, CMS recalibrates DRG weights based on charge data using the most current charge information available, and, this year, recalibration is based on charges occurring between October 1, 2003 and September 30, 2004 for all hospitals subject to the IPPS. We note that the Proposed Rule reflects a 6% reduction in the relative weight of the heart transplant DRG (DRG 103) and an 11% reduction in the

pancreas/kidney DRG (DRG 512). It is unclear to us from the preamble to the Proposed Rule whether these reductions may have resulted from a methodological change in the way organ acquisition costs are addressed in the weighting process, and would appreciate CMS's addressing this issue in its Final Rule.

DRG Reclassifications – Heart Assist Devices

We understand that CMS has decided not to propose a change urged by the manufacturer of the external heart assist system which would have placed implantation of an external heart assist system in the heart transplant DRG (DRG 103). While ASTS supported the reclassification of the insertion of an implantable heart assist system into DRG 103 last year, because hospital costs associated with this service were similar to costs associated with a heart transplant, we agree with CMS's decision not to include the implantation of external heart assist systems in DRG 103. We agree with CMS's assessment that the costs associated with implantation of an external heart assist system are considerably less than a heart transplant or insertion of an implantable heart assist system and moving it to DRG 103 would result in over-reimbursement for that service, and would result in a decrease of the relative weight of the heart transplant DRG, ultimately resulting in underpayment of heart transplant cases. We agree that the implantation of an external heart assist system will therefore stay in DRG 525 – "other heart assist system implant."

In this regard, we would like to take this opportunity to reiterate the concern set forth in our comments last year with respect to the reclassification of the insertion of implantable heart assist systems into DRG 103. We remain concerned that, because many of the hospitals that implant heart assist systems as destination therapy are not transplant centers, the classification of this procedure into DRG 103 will over time result in inappropriate reduction in the weight of this DRG.

DRG Reclassification – Islet Transplants

Islet transplants alone are classified into DRG 315 ("Other Kidney and Urinary Tract Procedures"), which is currently associated with a weight of 2.0861. Under the CMS proposal, the weight associated with this procedure would be reduced to 1.4005, a reduction of almost 33%. We continue to believe that this procedure is inappropriately classified, and again request that it be re-classified into DRG 513, the DRG used for Pancreas Transplants. As indicated in our prior comments, islet and solid organ (pancreas) transplants involve substantially similar patient populations and pancreas and islet transplants both serve the same clinical function: to free the patient from insulin-dependence. We request that, at a minimum, CMS identify those admissions included in DRG 315 that involved islet transplants and determine the actual relative costs involved to determine whether islet transplants should be reclassified.

Also, we remain extremely concerned about CMS policy disallowing the add-on payment for islet isolation costs when islets do not meet release criteria. CMS has taken the position that the current add-on payment of $18,848 takes into account the costs of isolating islets that do not meet release criteria. The islet isolation add-on payment costs were not determined based on a uniform and reliable cost accounting system, but rather were based upon an informal cost survey. We do not believe it likely that the respondents included in their per-procedure islet isolation costs all of the costs associated with isolating islets that ultimately were not transplanted. Nor do we believe it appropriate to include such isolation costs in the add-on payment, since different islet isolation facilities may have substantially different success rates in generating products that meet release criteria, depending on a number of factors that may not be within their control (including, for example, the condition of the pancreata that they have to work with).

In any event, we believe that the process used by CMS to determine the amount of the islet isolation add-on should be reviewed, updated, and standardized and we would be delighted to work with CMS on this project.

DRG Reclassification – Liver and/or Intestinal Transplants

In the FY 2005 IPPS final rule (69 FR 48976), CMS moved intestinal transplantation cases that were assigned to ICD–9–CM procedure code 46.97 (Transplant of Intestine) out of DRG 148 (Major Small and Large Bowel Procedures with CC) and DRG 149 (Major Small and Large Bowel Procedures Without CC) and into DRG 480 (Liver Transplant). CMS also changed the title for DRG 480 to ''Liver Transplant and/or Intestinal Transplant.'' It did so because its analysis demonstrated that the average charges for intestinal transplants are significantly higher than the average charges for other cases in DRGs 148 and 149. CMS indicated at the time that it would continue to monitor these cases. Based on its review of the FY 2004 MedPAR data, CMS is proposing to retain the classification of intestinal transplants in the same DRG as liver transplants. Based on the data provided by CMS in the Proposed Rule, we concur with this proposal with respect to intestinal transplants alone. However, as discussed below, we believe a separate DRG is needed for combined liver-intestinal transplants.

DRG Reclassification – Liver–Kidney Transplants

Both liver and liver-kidney transplants are included in the same DRG (DRG 480). We believe a separate DRG is needed to address the significantly higher costs associated with combined liver-kidney transplants just as there is a separate DRG for kidney-pancreas transplants.

With the implementation, in February 2002, of the model end stage liver disease (MELD) system to prioritize patients, there has been a substantial increase in the number of patients receiving liver-kidney transplants. This is due, in large part, to the fact that high creatinine levels

affect the MELD score more than other variables. Thus, many of the patients who are priority candidates for liver transplants also have impaired kidney function. In a study at one large transplant center, liver-kidney transplants were 6% (n=5) of the total number of liver transplants prior to implementation of the MELD system but 17% (n=22) post-MELD.[1]

In addition, at that same center, the overall length of stay (LOS) for a liver-kidney transplant was about 2.3 times that of a liver transplant alone – 28.4 days compared to 11.6 days – resulting in substantially higher costs. In addition, a substantial portion of liver-kidney transplants fell in the gap between the DRG payment and the outlier threshold which meant the hospital received no extra reimbursement for these more difficult cases.

We believe a separate DRG for liver-kidney transplants should be established. We note that CMS has already recognized the higher costs for double organ transplants in the case of kidney-pancreas transplants, which have their own DRG, and request that it treat liver-kidney transplants in the same fashion.

At the very least, we ask that CMS separately identify and analyze the charges and LOS for liver-kidney transplants compared to liver transplants alone and report this data in the final rule.

DRG Reclassification – Liver-Intestinal Transplants

For the same reasons as articulated above with respect to liver-kidney transplants, we believe a separate DRG is needed for combined liver-intestine transplants. Currently, liver transplants, intestinal transplants, and combined liver-intestinal transplants are all assigned to the liver transplant DRG (DRG 480). However, patients who need both a liver and intestinal transplant are generally sicker and more complicated and have longer LOS than patients who need only a liver transplant or an intestinal transplant. Consequently, we believe a separate DRG for liver-intestinal transplants is justified.

If CMS does not establish a separate DRG at this time, we ask that the agency separately identify and analyze hospital charges and LOS for liver-intestine transplants compared to liver transplants or intestinal transplants alone and report this data in the final rule.

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[1] Axelrod DA, et al., *The Economic Impact of MELD on Liver Transplant Centers*, accepted for publication in the American Journal of Transplantation (copy attached).

We appreciate the opportunity to comment on the Proposed Rule. If you have any questions regarding our comments, please do not hesitate to call Katrina Crist, ASTS Executive Director, at 703-684-5990.

Sincerely yours,

A. Benedict Cosimi

A. Benedict Cosimi, M.D.
President

Enclosure

THE ECONOMIC IMPACT OF MELD ON LIVER TRANSPLANT CENTERS

David A. Axel, MD, MBA[1], Alan J. Koffron MD[1],
Talia Baker MD[1], Patrice Al-Saden RN[1], Irma Dixler, RN[2], Gwen McNatt RN[2],
Scott Sumner[2], Mike Vaci[2], and Michael Abecassis MD, MBA[1]

Division of Transplant Surgery
Department of Surgery

Feinberg School of Medicine
Northwestern University [1]

Kovler Transplant Center
Northwestern Memorial Hospital [2]
Chicago, IL

Word Count: 2384

Running: Economic Implications of MELD

Correspondence to:

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Chief, Division of Transplant Surgery
Feinberg School of Medicine
Northwestern University
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ABSTRACT

Adoption of the MELD system prioritized patients awaiting liver transplant (LT) by severity of illness including progressive renal dysfunction. Unfortunately, current reimbursement for LT is not adjusted by severity of illness or need for simultaneous liver-kidney transplantation (LKT). This study examines hospital cost and reimbursement for LT and LKT to determine the effect of MELD on transplant center (TC) financial outcomes given current reimbursement practices as well as DRG outlier threshold limits. LT was performed for 86 adults prior to and 127 following the implementation of MELD. Between the eras, there was a substantial increase in the average laboratory MELD score (17.1 to 20.7 $p=.004$) and percentage of LKTs performed (5.8% to 17.3% $p=.01$). Increasing MELD score was associated with higher costs ($4309 per MELD point $p<.001$) and decreasing TC net income ($1512 per MELD point $p<.001$). In patients not achieving the Medicare outlier status, predicted net loss was $17,700 for high MELD patients and $19,133 for those needing LKT. In conclusion, contractual reimbursement agreements that are not indexed by severity of disease may not reflect the increased costs resulting from the MELD system. Even with outlier thresholds, Medicare reimbursement is inadequate resulting in a net loss for the TC.

Introduction:

The adoption of a "sickest patient first" strategy for organ allocation for deceased donor liver transplantation (LT) has resulted in a profound shift in the liver transplant population. While adoption of the model for end stage liver disease (MELD) score to prioritize patients in February 2002 has led to a reduction in wait list mortality, particularly among patients with the highest MELD score, its impact on post transplant survival is less clear.(1) Furthermore, the increasing complexity and acuity of patients undergoing transplantation is likely to have a significant impact on hospital resource utilization and financial outcomes of the nation's transplant centers (TC).

Two groups of patients have been particularly favored by the current organ allocation system. Under the MELD system, patients with progressive renal impairment receive a very high priority and appear to constitute an increasing proportion of the patients undergoing transplantation. Previous investigations have demonstrated a significant relationship between the degree of renal impairment and the cost of transplant.(2) Thus, these patients are likely to have a profound effect on TC economics. Furthermore, an increasing number of these patients require a simultaneous liver-kidney transplant (LKT) which is currently reimbursed by Medicare under the same DRG as liver transplant alone(3).

The second group of patients who have benefited from the MELD score are patients to whom MELD scores are assigned based on exceptions to the MELD system, such as patients with hepatocellular carcinoma (HCC). It is important to differentiate between patients whose calculated MELD scores reflect hepatic decompensation and those that received MELD exceptions. The latter receive MELD point upgrades to facilitate early transplant, whereas the former are desperately ill, often with multi-organ failure. In order to assess the financial impact of the increased acuity of illness associated with a high MELD score while controlling for secular trends in the cost of care, the cost of LT/LKT in patients with high calculated MELD scores can be compared to those with high assigned MELD scores, but low calculated scores.

In this investigation, the clinical and financial records for 213 consecutive liver transplant recipients at a single TC spanning the implementation of MELD were assessed to examine the impact of the new organ allocation system on the cost of transplantation in the context of current contractual reimbursement agreements and determine the impact of MELD on the profitability of the TC.

Materials and Methods:

Patient population: Clinical and demographic data for all adult patients (N=229) undergoing liver transplantation (N=233) from January 2000 to December 2003 at a single institution were examined. This analysis included whole organ transplants from a deceased donor (DDLT), split liver transplants (SLT) including both segmental and lobe splits, and adult to adult live donor liver transplants (ALDLT). A combined liver-kidney transplant (LKT) was performed if the renal failure was thought to be irreversible. Alternatively, patients with renal insufficiency were maintained on dialysis through the peri-operative period until adequate return of renal function. Patients undergoing transplant for fulminant hepatic failure (N=11) or undergoing a combined LT and coronary artery bypass grafting procedure (N=5) were excluded from this analysis resulting in 213 transplant patients (216 LTs) for analysis..

MELD: MELD score was calculated using the last laboratory data available prior to transplant for all patients, including patients who were transplanted in the pre-MELD era. For patients on dialysis, a creatinine level of 4.0 was assigned and used to calculate the MELD score. The calculated MELD score was used in all patients. For patients who had been assigned a MELD score upgrade on the basis of a MELD exception granted by the Regional Review Board, the calculated MELD score was used to determine the severity of liver disease

Cost data: Financial records were extracted from the hospital cost accounting system for the hospital stay in which the transplant occurred. For the small number of patients who were re-transplanted during the same hospital stay (N=3) due to primary non-function or hepatic artery thrombosis, all costs were assigned to the first transplant. The cost of care was determined using the full allocated cost of care (fixed and variable components) net of organ acquisition cost. Net income reflects the actual difference between allocated cost and hospital revenue. Given the short time period of this analysis, cost data were not adjusted for inflation.

Medicare gap analysis: Using existing Medicare fee schedules for DRG 480 (Liver Transplant), all cases, regardless of payer, were examined to determine the expected reimbursement under Medicare.

For cases in which costs exceeded the outlier threshold, expected reimbursement was calculated using data from the current (2004) Medicare cost report. The outlier payment gap was defined as the amount between reimbursement for DRG 480 and the payment threshold which triggers outlier reimbursement.

Data analysis: Continuous and categorical variables were compared using student t-test and Chi squared analysis as appropriate. Multivariate linear regression was used to assess the independent affect of demographic and clinical variables. A p-value $<.05$ was considered significant. Patient outcome at one year was assessed using a chi-squared test. All analyses were conducted using Stata 8.0 (Stata Corporation College Station TX).

Human subjects review: This project was approved by the Northwestern University Institutional Review Board.

Results:

Liver transplantation was performed for 86 patients prior to and 127 patients following the implementation of the MELD system of organ allocation in February 2002. Patient characteristics including age, gender, and the incidence of hepatitis C were similar across the period of analysis (Table 1). There was a significant increase in the number of patients transplanted for HCC (31% vs. 15% p=.009) as a result of the MELD upgrade accorded to these patients. Overall, there was a 21% increase in mean calculated MELD score between patients transplanted before and after the MELD system (17.1 vs. 20.7 p=.004). Among patients receiving a whole organ DDLT (excluding live donor and split liver transplants), the average calculated MELD score increased by 28% (17.8 to 22.8 p<.001). Overall patient survival was comparable between eras (p=.20)

As a result of the emphasis placed on renal dysfunction in the MELD score, there was a significant increase in the number of LKTs after the implementation of MELD (Table 2). In the pre-MELD era, LKT represented 6% of transplants which increased to 17% in the post-MELD era (p=.01). There was also a trend toward a reduction in the number of whole organ DDLT accompanied by an increased use of live donor and split liver transplant in the post-MELD era.

The increasing severity of illness, as reflected in the higher MELD scores, was associated with dramatically higher costs of care and reduced margins for the TC. When compared to patients with low calculated MELD scores, patients with MELD scores greater than 15 had total inpatient costs which were 49% higher (p<.001).(Table 3). The major cost drivers for the increased cost of high MELD patients include higher room and board costs, as well as increased use of laboratory, radiology, and pharmacy services (Table 3). High MELD patients were associate with a significant increase in overall length of stay (16.9 vs. 8.1 days P< 0.001) as well as longer pre-transplant hospitalization (5.3 vs. 0.9 days p<.001). Despite the significant increase in resources needed to care for high MELD patients, hospital revenues increased by only 24%. Consequently, average net income was 114% less in high MELD patients (p=.02), resulting in a net loss for the TC.

Univariate analysis revealed that MELD score, diagnosis of HCC, a diagnosis of hepatitis C, and living donor liver transplant (p=.02) were significantly correlated with the cost of liver transplant (Table 4). However, in the multivariate analysis only the MELD score was found to correlate with cost, demonstrating an increase of $4309 per MELD point. Neither donor type nor diagnosis remained significant after adjustment for MELD score. Univariate analysis revealed that a diagnosis of HCC, MELD score, and LRD transplant were all significantly associated with TC income. However, in the multivariate analysis, only MELD score was associated with decreasing TC net income ($1512 reduction per MELD point p=.002).

The disparity between cost and revenue was particularly profound for patients who required LKT (Table 5). When compared with patients undergoing liver transplant alone, LKT patients did not differ based on age or gender. The overall LOS following LKT was markedly longer than for LT alone (28.4 days vs. 11.6 days p<.001). This difference was largely the result of a more complex pre-transplant course, characterized by pre-transplant LOS which was significantly longer (14.3 vs. 2.2. p<.001) As a result, the mean cost of LKT was 124% higher than for LT and revenues were often inadequate resulting in a net loss for the TC. Compared to LT alone, LKT was associated with a 388% reduction in net income.

An additional analysis was conducted to assess the impact of current Medicare reimbursement policy on TCs. Overall, Medicare was the primary payor for 16% of patients undergoing LT/LKT. Among high MELD patients, 25% met outlier thresholds under current Medicare guidelines, while an additional 19% fell in the gap in which costs exceed reimbursement but fail to qualify for outlier payment. For high MELD patients undergoing liver transplant alone, patients achieving outlier status resulted in a predicted let loss for the TC of $17,000 while those in the gap had a predicted net lossof $17,700. Under current Medicare reimbursement schedules, LKT are reimbursed as liver transplant alone. In LK cases achieving outlier status, the predicted loss per patient under current Medicare guidelines was $17,037. However, among LKT cases falling in the gap the loss was $19,133 per case.

Discussion:

The implementation of the MELD system of organ allocation has resulted in a shift in liver transplant recipients to patients with higher MELD scores and increased severity of illness. Patients with high MELD scores have longer hospital stays and, thus, incur higher hospital costs. Hospital revenues, however, are frequently either tied to Medicare DRG 480, or are reimbursed on a case rate based reimbursement that is not indexed to severity of illness. In either situation, outlier payments are meant to provide a safety net for high cost cases, but often result in payments that are either at the margin or below cost. This results in significant reductions in net income, and may lead to a net loss for TC. This disparity is particularly significant in patients undergoing LKT.

The objective of the MELD system is to transplant the patients with the highest likelihood of dying without receiving a transplant. Recent analysis of the MELD system has demonstrated a significant reduction in waitlist mortality among adult and pediatric recipients (>2 years old).(1) Among adults listed for transplant, there was a reduction in the deaths/1000 patient-years from 910 to 743. Despite the increased severity of illness in patients undergoing transplantation, overall patient and graft survival have improved in the post MELD era.(4) Even for patients with high MELD scores, the outcome of transplant is often favorable. Although MELD scores are a relatively poor predictor long term outcome, in patients with scores greater than 24, there is a only 7% reduction in 5 year survival when compared to scores less than 10.(5) Conversely, those patients with low calculated MELDs who are awarded upgrade points for HCC are likely to benefit significantly from early transplant.

While transplantation of patients with high MELD scores has been shown to be of substantial clinical benefit(6), this shift in the transplant population will, predictably, increase the cost of transplantation. Prior to the implementation of MELD, improvements in clinical care and reduction in hospital stay had led a reduction in the cost of care. From 1993 to 1998, the average cost of liver transplantation performed in the Medicare population decreased from $201,677 to $143,363.(7) In the

pre-MELD era, analyses of the cost of liver transplantation have identified several recipient factors that were associated with high costs. In a multi-center analysis, Showstack and colleagues demonstrated increased costs associated with older donor age, older recipient age, alcoholic liver disease, Child-Pugh class C cirrhosis, and hospitalized patients.(8) Markman and colleagues identified several additional variables in their large single center study including donor sodium level, recipient creatinine, and recipient ventilator requirement pre-transplant.(2) Thus, it is the patients most likely to be prioritized under the MELD system who can be expected to have the highest costs associated with liver transplantation. The cost of care is likely to be further increased by the increased reliance on older and marginal donors (e.g. non-heart beating DDLT), both of which have been associated with higher costs, and longer lengths of stay.

While reimbursement varies considerably depending upon contractual negotiations between TC and third party payers, many follow the current Medicare practice of case rate based reimbursement that is not adjusted for severity of illness. Current practice does allow for some reimbursement for true outliers. Outlier protection typically consists of a stepwise or incremental payment methodology whereby cases at the margin will receive no additional reimbursement or payment until a certain outlier threshold is met. Thus for patients who exceed this threshold, payment in addition to the case rate will be made to the TC based on a percentage of charges, whereas for those patients who fail to meet the threshold, the TC receives no additional payment. Unfortunately, a significant percentage of high MELD patients (19%) fell in the Medicare outlier gap between hospital cost and the outlier provision threshold. Even among those patients (25%) who exceed this threshold, revenues frequently failed to cover hospital costs. For LKTs, this problem is particularly severe with 19% falling in the outlier gap and 44% achieving outlier status. Outlier payments were often inadequate resulting in a calculated average per case loss of over $17,000 per LKT, while those in the gap resulted in a loss of more than $19,000.

This study is limited in its general applicability because of the use of a single center's cost accounting information. Changes in clinical practice may reflect local practice and as well as the known variations in MELD score at transplantation which occur between regions.(9) However, multiple studies have documented the relationship between increasing severity of illness and the cost of liver transplant. Thus, the conclusion that the MELD allocation system is likely to increase liver transplant costs is likely to be robust. In regard to reimbursement, by utilizing current Medicare guidelines in addition to actual TC experience to assess the impact of current reimbursement policies, including outlier threshold costs, on TC profitability our findings should be generalizable at least to this population nationwide.

In conclusion, the shift in the allocation policy for liver transplantation has resulted in the transplantation of patients with higher acuity of illness who incur significantly higher costs. The change to the MELD system has led to higher costs for LT and will negatively impact TC profitability unless current reimbursement policies are changed. A modified reimbursement policy to a system indexed by severity of illness is needed to protect TCs from financial losses due to the MELD policy. Specifically, a new DRG is needed for LKT that reflects the significant increase in costs associated with this procedure. Finally, TCs should consider case rate reimbursement contracts with third party payers that account for the higher costs incurred by the TC as a result of allocation policies that favor transplantation for the sickest patients first.

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Table 1: Patient Demographics and Transplant Results

	Pre-MELD	Post-MELD	P-Value
N	86	127	
Age (yrs)	50.8 ± 9	53.0 ± 10	P= 0.13
Male (%)	72%	68%	P= 0.49
DX of HCC	15%	31%	P= 0.009
DX of Hep C	39%	42%	P= 0.07
Average MELD	17.1	20.7	P= 0.004
% with MELD >15	59%	67%	P= 0.35
Total LOS (days)	16.1 ± 18	12.1 ± 15	P= 0.08
Pre TXP LOS, MELD <15	1.6 ± 5	0.3 ± 1	P= 0.09
Pre TXP LOS, MELD >15	7.3 ± 14	4.1 ± 9	P= 0.11
1 year patient survival	85%	91%	P= 0.20

Table 2: Procedures Performed Prior to and Following the Implementation of MELD

	Pre-Meld	Post Meld	P-Value
Liver Transplant Alone N (%)	81 (94%)	105 (83%)	P= 0.01
Deceased Donor	62 (76%)	71 (67%)	P= 0.18
Live Donor	13 (16%)	23 (22%)	P= 0.32
Split Liver	6 (7%)	11 (10%)	P= 0.47
Liver-Kidney Transplant N (%)	5 (6%)	22 (17%)	P= 0.01

Table 3: Impact of MELD score on Resource Utilization for Liver Transplantation

	Relative cost of High (>15) vs. Low (≤15) MELD LT	**P value**
Total Cost	49% increase	P< 0.001
Room and Board	135% increase	P< 0.001
Operating Room	11% increase	P= 0.09
Pharmacy	87% increase	P= 0.02
Laboratory	100% increase	P< 0.001
Radiology	92% increase	P= 0.007
Supplies	40% increase	P= 0.06
Overall LOS†	108% increase	P< 0.001
Pre-TXP LOS†	489% increase	P< 0.001
Net Income	114% **decrease**	P= 0.02

* MELD= Model for End Stage Liver Disease LT= Liver Transplant † Increase in days in the hospital

Table 4: Univariate and Multivariate Analysis of Cost Drivers

	Cost				Net Income			
Variable	Univariate	P-value	Multivariate	P-value	Univariate	P-Value	Multivariate	P-Value
Age	-271	0.64			-532	0.21		
HCC	-43,895	0.001			24,313	0.02		
Hep C	-22,291	0.05			8,768	0.33		
MELD	4,309	<.001	4,309	<.001	- 1,512	0.002	-1,512	0.002
Split	-2,689	0.89			- 11,170	0.49		
LRD	-35,432	0.02			25,640	0.03		
Pre-MELD	-8,102	0.47			-2,839	0.75		

Table 5: Differential in Resource Utilization for Liver-Kidney Transplant vs. Liver Transplant

	Ratio of LKT to LT alone	P-value
Total Cost	124% increase	P< 0.001
Net Income	388% decrease	P= 0.004
LOS (days)	144% increase	P< 0.001
Pre-TXP LOS	550% increase	P< 0.001

* LKT= liver-kidney transplant LT= liver transplant LOS= length of stay

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OSF HEALTHCARE
A commitment to life.

OSF STROKE NETWORK

DRG/GEN Hefter. Haitstein Brooks FASAN Gruber Kelly Hue

David Z. Wang, DO
Director

Jean A. Rose, RN, MS, CNRN
Associate Director

CMS, Dept. of Health and Human Services
CMS-1500-P, PO Box 8011

June 19, 2005

Dear Sir:

My name is David Wang, D.O. and I am currently the Director of OSF Stroke Network in Peoria, Illinois. I was recently appointment by the Governor to be a member of the Illinois Stroke Task Force. I have been taking care stroke patients for 12 years and I believe that it is critical for stroke care in this country if CMS can support the changes to Medicare hospital inpatient reimbursement for advanced stroke treatment in FY 2006.

As I am sure you are aware, stroke is the 3rd leading cause of death and the leading cause of adult disability in the United States. As one of the premier stroke centers in the nation and the first JCAHO certified primary stroke center in Illinois, we treat over 400 stroke patients every year. Despite the ongoing effort to offer the best stroke care to the population in central Illinois, the low reimbursement for stroke DRGs has placed significant financial pressure on our institution.

One indication of quality stroke care is the ability to administer IV-TPA, the one and only FDA approved clot buster, to patients with acute ischemic stroke within 3 hours. However, TPA is expensive and its cost is included in the stroke DRG. The use of TPA consumes nearly 40% of the DRG payment. Often the patient may have good outcome after receiving TPA, but the hospital suffers from financial loss. Offering TPA actually penalizes the healthcare institution financially. Therefore, we would like to strongly support the establishment of a separate DRG or payment code for the use of TPA or acute reperfusion therapy for acute ischemic stroke. At our institution, nearly 10% of stroke patients received TPA with nearly 50% of these treated patients was discharged to home. However, our relatively high percentage of TPA utilization contributed to the negative 2% financial gain in the past 5 years.

Furthermore, stroke is a devastating disease and time is brain. The current DRG payment cannot cover the comprehensive care provided to stroke patients. Typically when a stroke patient presents to the hospital emergency room, immediate assessment and implementation of the state-of-art diagnostic studies are critical in the determination of the acute treatment plan. Subsequently, stroke patients often require intensive care because of not only the damaged brain, but also the concomitant systemic failure and complications that come with the stroke. Such an approach is very costly. Any process considering further reduction in this care process will compromise the care of stroke patients. We therefore also support the process that will consider increase the overall payment to stroke DRG. We foresee that the low payment for stroke may soon discourage the healthcare institutions to provide the state-of-art stroke care or not provide the care at all, which will have a serious impact on the health of Americans.

If anyone would like to speak to me individually about these issues I discussed, please feel free to contact me at 309-624-9500 or via email dwang@uic.edu.

Sincerely,

D Wang

David Wang, D.O.,
Director, OSF Stroke Network

NATIONAL ASSOCIATION OF URBAN HOSPITALS

Private Safety-Net Hospitals Caring for Needy Communities

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Payment Rls/Outliers

June 20, 2005

Hefter
Hartstein
Treitel
Kraemer

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

Subject: Outliers

To Whom it May Concern:

I am writing on behalf of the National Association of Urban Hospitals to express our opposition to the increase in the outlier threshold that the Center for Medicare & Medicaid Services (CMS) has proposed for the Medicare inpatient PPS system for fiscal year 2006. We believe this increase will result in Medicare once again failing to pay out its statutorily required proportion of PPS funds as outlier payments for fiscal year 2006 and will cause serious harm to hospitals that incur significant costs from legitimate outlier cases.

Medicare Outliers: The Situation Today

Medicare recognizes that some hospital admissions fall so far outside the norms captured by its prospective payment system (PPS) that they must be paid in an entirely different manner. Consequently, it employs a system of what it calls outliers. Under this system, hospital cases involving selected medical services that exceed a specific Medicare cost threshold are reimbursed by Medicare on a cost basis, through additional payments above and beyond the Medicare PPS payment. These cases are known as outliers. While outlier reimbursement is said to be on a cost basis, outlier payments do not actually reimburse providers for the full cost of the care they provide in cases designated as outliers.

In the current fiscal year, the threshold for a qualified case to become a Medicare outlier is $25,000.

Medicare Outliers: The Proposed Change in Regulations

In the proposed fiscal year 2006 Medicare inpatient PPS regulation published in the *Federal Register* on May 4, 2005, CMS proposes raising the outlier threshold for the coming year from the current $25,000 to $26,675.

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Medicare Outliers: NAUH's Objections to the Proposed Policy Changes

NAUH believes that the proposed outlier threshold is too high and will result in Medicare failing, yet again, to meet its statutory requirement of paying out between five and six percent of its PPS payments as outliers. In 2004, with the outlier threshold at $31,000, outlier payments amounted to only 3.5 percent of PPS payments – well short of the statutory requirement. This year, with the threshold at $25,000, outlier payments are on a pace to constitute only about 4.4 percent of PPS payments – again, well short of the statutory requirement. It stands to reason, we believe, that if Medicare cannot fulfill its statutory minimum of five percent with a threshold of $25,000 this year, it is likely to fall even further from its statutory minimum, not draw closer to it, if that threshold is raised to $26,675 – even allowing for a generous increase in the overall cost of health care services. NAUH believes the outlier threshold should be decreased below the current $25,000, not increased.

Medicare's failure to pay an appropriate level of outliers has serious implications for hospitals. Even when it does pay out to an appropriate level, outlier payments themselves do not adequately compensate hospitals for the extraordinary costs they incur providing care to patients with extraordinary medical problems; they only help cushion the blow of such costs. Compounding this problem is that in today's environment, hospital margins are shrinking like never before, with more and more hospitals suffering negative margins. In some situations, just a few outlier cases can mean the difference between a hospital breaking even or losing money. This is especially true for large, private, non-profit urban safety-net hospitals such as those represented by NAUH because they care for higher proportions of low-income elderly and uninsured patients than other hospitals. Medicare's failure to live up to its statutory requirements has implications for hospitals nation-wide, and NAUH believes that Medicare should live up to its legal obligation to pay out at least the legally required minimum amount of payments as outliers. The threshold proposed for 2006 will not enable Medicare to achieve this goal.

In failing to meet its statutory requirement for outlier payments, Medicare is failing: it is failing to meet its obligation to Congress to spend an appropriate amount on outlier payments and it is failing to meet its obligation to hospitals to pay them for the extraordinary – and extraordinarily expensive – care they deliver to their seriously ill and severely injured outlier patients.

Medicare Outliers: NAUH's Proposed Solution

NAUH believes that CMS's current approach to calculating Medicare's outlier threshold does not work. While NAUH would welcome an opportunity to work with CMS officials to develop a better methodology, we believe the agency's first priority at this time should be to develop a more appropriate threshold for fiscal year 2006 – a threshold that will enable Medicare to meet its statutory obligation. We all know that the proposed threshold of $26,675 will not achieve this end and will keep Medicare out of compliance with the statutory requirement yet again.

For this reason, NAUH suggests an interim approach: CMS should use a ratio, based on the current threshold and its likely percentage of overall PPS payouts, to revise the threshold and ensure that outliers constitute at least 5.1 percent of overall PPS payments. This would enable CMS to use projections instead of a formula that clearly is not working and would lead to a decrease, instead of an increase, in the FY 2006 threshold.

An alternative would be to calculate what the outlier threshold would need to be for the current (FY 2005) year to enable outlier payments to account for at least 5.1 percent of Medicare PPS payments and then to use that figure as the FY 2006 threshold.

About the National Association of Urban Hospitals

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

* * *

We appreciate your attention to the concerns we have expressed about the proposed increase in the Medicare outlier threshold for fiscal year 2006 and welcome any questions you have about our organization, this issue, or our rationale for the positions we have stated in this letter.

Sincerely,

Ellen J. Kugler, Esq.
Executive Director

AANS/CNS CEREBROVASCULAR SECTION

American Association of Neurological Surgeons

A Section of the
American Association of Neurological Surgeons
and
Congress of Neurological Surgeons

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Hefti
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

June 3, 2005

DRG/Gen

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

Dear Sir/Madam:

My name is Robert H. Rosenwasser, M.D., F.A.C.S., and I am currently the Chairman of the Section on Cerebrovascular Disease of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons. Our academic and clinical mission is the diagnosis and treatment of all neurovascular disorders including hemorrhagic and ischemic stroke. I am writing you on behalf of our National Organization to support changes to the Medicare Hospital Inpatient Reimbursement for advanced stroke treatment in fiscal year 2006.

Stroke, as you know, is the third leading cause of death and disability in the United States behind cancer and heart disease. It often affects patients during very productive years of their life and, if treated appropriately, can reduce long-term care at either nursing homes or physical rehabilitation facilities. It is clear from all of the data to date that reestablishment of circulation within the occluded vessel is necessary to improve outcome, and technology is improving at a rapid pace to fulfill this prophecy and concept. If patients are admitted to institutions and cared for with intra-arterial and other endovascular techniques, patient outcomes and length of hospital stay should be reduced, ultimately leading to significant savings within the healthcare system.

Additional reimbursement for endovascular treatment which will lead to reperfusion therapy will result in improved care for patients suffering from stroke. The infrastructure and protocols required to maintain an effective system are costly and labor intensive. Hospitals that administer reperfusion therapies incur higher costs than those that do not provide this type of management. This creates a significant disincentive to institutions to supply the necessary infrastructure to provide best available care for stroke patients.

We respectfully request that CMS support changes to medicare hospital reimbursement for the management of such stroke patients. Perhaps the creation of a new DRG for acute stroke management with reperfusion therapy could be considered. Our national neurovascular coalition, which consists of vascular neurologists, vascular neurosurgeons, and interventional neuroradiologists, would be willing to work with your organization on such a project.

We thank you for your continued work on behalf of medicare beneficiaries and the special attention that you have given to the needs of all stroke patients.

If I can be of any further assistance in this matter, please contact me at 215-503-7004 or my pager at 215-401-3720. My e-mail address is robert.rosenwasser@jefferson.edu.

Thank you for your kind consideration in this matter.

Sincerely,

Robert H. Rosenwasser, M.D., F.A.C.S.
Professor and Chairman of Neurosurgery
Section on Cerebrovascular Disease
American Association of Neurological Surgeons
Congress of Neurological Surgeons

RHR/mts/jw

THE UNIVERSITY
OF KANSAS HOSPITAL
KUMED

Health System Finance
Budget, Reimbursement,
and Cost Accounting

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June 10, 2005

HEFTER
HARTSTEIN

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

TRANSFERS - WALZ
HART

Dear Sir or Madam:

The University of Kansas Hospital appreciates the opportunity to comment on CMS's proposed FY 2006 inpatient PPS rule. We are a 475-bed teaching hospital with approximately 400 residents.

The proposed rule states that effective October 1, 2005, 193 additional DRGs will be added to the post-acute care transfer policy. We believe that this conflicts with the principal of a Prospective Payment System, which calculates costs based on averages. Some cases will cost less than the DRG payment, while others will cost more. TRANSFERS

If there are hospitals that are discharging to post-acute care before it is medically advisable in order to maximize revenue and minimize expenses, these hospitals should be individually penalized. If hospitals are simply discharging patients to receive care in the most appropriate setting, then the DRG payment calculation (based on averages) will take this reduction in hospital costs into consideration.

Thank you.

Sincerely,

Sally Enevoldson

Sally Enevoldson
Director of Reimbursement

4720 Rainbow Boulevard | Shawnee Mission, Kansas 66205 | Phone (913) 588-0845 | Fax (913) 588-0846 | www.kumed.com

Hosp Redes – Kenby
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SCH – Smith
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June 17, 2005

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

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

Dear Sir or Madam:

Please accept these comments regarding Hospital Redesignations and Reclassifications (70 *Fed. Reg.* at 23,376), the Out-migration Adjustment (70 *Fed. Reg.* at 23,381) and Critical Access Hospitals (70 *Fed. Reg.* at 23,450). Specifically, these comments urge the Centers for Medicare and Medicaid Services ("CMS") to permit hospitals qualifying for reclassifications under Social Security Act § 1886(d)(8)(B) ("Lugar Reclassifications") to waive or reject the reclassification if the reclassification proves to be detrimental or otherwise undesirable to the qualifying hospital.

CAH/
LUGAR

A. The existing policy is problematic for an increasing number of providers, and disadvantaging hospitals in ways that were unforeseen when Lugar Reclassification was created.

Congress intended for Lugar Reclassifications to benefit hospitals in eligible counties, and most affected hospitals in fact do benefit from the reclassification. However, some hospitals are disadvantaged by Lugar Reclassification and the "urban" status that goes along with it. For example, hospitals with special designations, such as Rural Referral Centers ("RRCs"), Sole Community Hospitals ("SCHs"), Medicare Dependent Hospitals ("MDHs"), and Critical Access Hospitals ("CAHs"), where their status is dependent on being located in a rural area, lose their special designation when they are reclassified to an urban area.

When first implemented for fiscal year 1989, only 37 counties qualified for Lugar Reclassification. Now, after CMS has implemented the changes made by § 402 of the *Balanced Budget Refinement Act of 1999* (Public Law 106-113) and new metropolitan areas for fiscal year 2005, many more hospitals are affected by the Lugar Reclassification provisions. Nearly 100 counties and 75 hospitals are reclassified by the Lugar Reclassification provisions.

Additionally, there are now more ways for hospitals to be affected by Lugar Reclassification. In 1987, when Congress established the Lugar Reclassification opportunity, there was no such thing as

MDH or CAH status. Today, hospitals designated as MDH and CAH lose their special designation when the Lugar Reclassification provisions move them into urban areas.

Historically, Lugar Reclassification affected few counties and providers. Now, as Lugar Reclassification touches more counties, and there are more ways in which providers can be adversely impacted by reclassification to an urban area, there is more need to provide a mechanism to opt out of Lugar Reclassification.

B. The solution CMS utilizes to address this problem is inadequate.

CMS directs providers that are adversely impacted by Lugar Reclassification to reclassify back to the rural area in which they are geographically located through 42 C.F.R. § 412.103. However, this solution is inadequate for two reasons. First, not all affected providers can satisfy the criteria for reclassification under § 412.103. Section 412.103 expressly contemplates RRCs and SCHs, and provides a ready mechanism to restore "rural" status to RRCs and SCHs that are reclassified to an urban area by Lugar. However, § 412.103 does not provide a similar path for MDHs that are reclassified to an urban area by Lugar. Moreover, while CMS has created an opportunity for CAHs that were moved to an urban area by the new metropolitan area definitions to regain rural status, this opportunity does not necessarily cover CAHs that were reclassified by Lugar to an urban area, particularly if those providers are redesignated by Lugar after fiscal year 2005. As such, the § 412.103 reclassification opportunity is not available to all affected providers.

Second, § 412.103 reclassification is an imperfect solution because it does not fully restore the provider to its pre-Lugar reclassification status. There are consequences to § 412.103 reclassification that leave providers that reclassify in this manner worse off than before they were reclassified by Lugar. For example, hospitals that must use § 412.103 reclassification to regain rural status are then blocked from seeking wage index reclassification under § 1886(d)(10), and from qualifying for the out-migration wage index adjustment under §1886(d)(13). A hospital located in a rural area that is reclassified by the Lugar provisions, and then uses § 412.103 to return to its rural origin should not have to forfeit other wage index adjustments for which the provider is otherwise eligible and should benefit.

Third, § 412.103 reclassification forces the provider into a cumbersome and unnecessary regulatory process. CMS has interpreted §1886(d)(13) as allowing a provider that has § 1886(d)(8)(B) and (E) reclassifications to waive those reclassifications to accept a §1886(d)(13) wage index adjustment. However, the provider and CMS could achieve the same result far more efficiently if the provider were allowed to reject Lugar Reclassification. If so, affected providers would not be forced to undergo the § 412.103 reclassification process, and to add this additional layer of compliance burden to the process.

Finally, waiving § 1886(d)(8)(B) and (E) reclassifications for a §1886(d)(13) wage index adjustment may be only a temporary and partial solution for the provider. CMS has not specified whether the opportunity to waive §§ 1886(d)(8)(B) and (E) to accept a §1886(d)(13) wage index adjustment is available only so long as the provider is eligible for the §1886(d)(13) wage index adjustment. If so, as soon as the provider's county no longer qualifies for a §1886(d)(13) wage index adjustment, the provider would then again be reclassified by the Lugar provision, and forced

to again go through the § 412.103 process to return to its rural area. CMS could avoid this yo-yo phenomenon by permitting affected hospitals to generally waive Lugar Reclassification, rather than making waiver contingent on eligibility for a §1886(d)(13) wage index adjustment.

C. Recommendations

In the very limited instances where a provider is potentially disadvantaged by Lugar Reclassification, or otherwise prefers not to be moved to an urban area, CMS should permit the hospital to waive or reject the Lugar Reclassification. CMS should make this opportunity available to affected providers during the 45-day period following publication of the proposed update to the inpatient prospective payment system, just as it permits hospitals to reject other geographic reclassifications and wage index adjustments during that period.

If CMS rejects this recommendation, the Agency should at the very least clarify its policy with respect to hospitals that waive §§ 1886(d)(8)(B) and (E) reclassifications to accept a §1886(d)(13) wage index adjustment. Under current policy, a hospital that has §§ 1886(d)(8)(B) and/or (E) reclassifications may waive those reclassifications to accept a § 1886(d)(13) wage index adjustment. However, it is not clear what becomes of those waivers if the provider at some point in the future no longer qualifies for the wage index adjustment, either because the provider's county does not meet the specified commuting threshold or the provider subsequently seeks wage index reclassification under § 1886(d)(10). If CMS chooses not to implement the solution proposed above, it should at the very least provide that hospitals that waive §§ 1886(d)(8)(B) and/or (E) reclassifications to accept a § 1886(d)(13) wage index adjustment may perpetuate the reclassification waiver for so long as the provider chooses, regardless of whether the provider continues to receive a § 1886(d)(13) wage index adjustment.

D. CMS has the authority to make the recommended changes.

CMS has the authority to make the changes proposed above. Although § 1886(d)(8)(B) establishes a mandatory requirement that "the Secretary shall treat a hospital located in a [qualifying] rural county... as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute," this mandate does not necessarily mean that the Secretary cannot establish an opportunity for hospitals to opt out of the reclassification. The statute is completely silent on the question of whether hospitals wishing to opt out of the reclassification may do so. Nowhere in this section did Congress expressly or implicitly provide that hospitals disadvantaged by Lugar Reclassification could not waive it. Where Congress is silent on a question, the Secretary has the authority to fill the gaps.

The Secretary has similarly established waiver or cancellation opportunities under mandatory reclassification provisions before. Section 1886(d)(8)(E), for example, provides "the Secretary shall treat the [qualifying] hospital as being located in the rural area...of the State in which the hospital is located." This provision directs the Secretary comparably to § 1886(d)(8)(B). HOSP REDES Nonetheless, CMS established a mechanism for hospitals to cancel reclassifications under § 1886(d)(8)(E). *See* 42 C.F.R. § 412.103(g). Likewise, § 1886(d)(13) expressly permits eligible hospitals to waive the wage index adjustment. However, this legislation says nothing about allowing hospitals to waive § 1886(d)(8)(B) reclassifications to accept the out-migration wage

index adjustment. Nonetheless, CMS appropriately permits hospitals to waive § 1886(d)(8)(B) reclassifications, if they prefer to receive the out-migration wage index adjustment. In both instances, CMS established opportunities for hospitals to waive or cancel reclassifications where it made policy sense to do so, and the statute was silent on the matter.

Moreover, § 1886(d)(5)(I)(i) provides the Secretary with broad authority to make adjustments and exceptions under the inpatient prospective payment system. The Secretary could certainly use that authority to create an exception in this instance that allows hospitals to waive Lugar Reclassifications.

CMS also is not barred by its own regulations from establishing a waiver opportunity. Section 412.64(b)(3) describes the process by which CMS will identify eligible counties, and the reclassification applicable to hospitals in eligible counties. Like the statute, § 412.64(b)(3) does not expressly or implicitly address waiver or cancellation. The regulation is completely silent on this point. CMS may wish to supplement the Medicare regulations to establish a waiver opportunity, but it likely would not be obligated to do so. CMS established the opportunity for hospitals to waive § 1886(d)(8)(B) reclassifications to accept the out-migration wage index adjustment without articulating this policy anywhere in regulations.

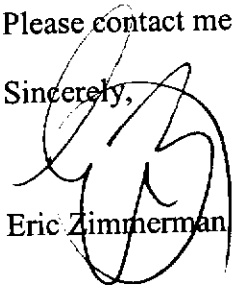
Congressional intent supports an opportunity for disadvantaged hospitals to reject Lugar Reclassification. Congress enacted the Lugar Reclassification policy to benefit eligible providers. Congress appropriately reasoned that hospitals in qualifying counties would be more favorably reimbursed if treated as urban providers. Subject to limited exceptions, such as where a hospital has CAH or SCH status, aggregate Medicare reimbursement most often is higher for urban hospitals. Congress most certainly did not intend to disadvantage hospitals when it enacted the Lugar Reclassification provisions. Congressional intent would be served if CMS established an opportunity for disadvantaged hospitals to reject Lugar Reclassification.

CMS will not encounter any opposition to a waiver opportunity. Most hospitals are advantaged by Lugar Reclassification; very few are disadvantaged. Those that are disadvantaged would support a proposal by CMS to create a waiver opportunity. It is highly unlikely that any stakeholder would find cause or inclination to object if CMS established a waiver opportunity.

* * * * *

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

Sincerely,



Eric Zimmerman

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June 14, 2005

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

Re: Hold-Harmless provision for Sec 401(a) redesignations and
Wage index corrections for Sec 401(a) redesignations.

To whom it may concern:

In the Proposed Rules for Inpatient services in the May 4th, Federal Register, pages 23376 & 23377, CMS has proposed a new policy to Hold-Harmless rural areas and urban areas for wage index purposes. This policy is for urban and rural areas which are impacted by an urban hospital being redesignated under Sec 401(a) of Public Law 106-113 to a rural area.

Specifically CMS is stating that if a hospital is granted redesignation under the Statute Section 1886(d)(8)(E) of the Act, that its wages are always included in the urban area where it is located, and is also included in the rural area to which it seeks redesignation, if it increases the rural area wage index, and is excluded if it decreases it wage index. This would Hold-Harmless both the urban and rural areas for wage index issue.

We agree with CMS's logic to purpose this change, in that it would be consistent with prior policy that it has on other reclassifications. **We encourage and support CMS in this proposed policy change.**

In a related matter, this Commentator wishes to comment on the effective date of the wage index change for the rural area, to which a Sec 401 redesignation takes place. CMS policy as stated in the May 4th, Federal register on the above Hold-Harmless issue, and in a Program Memorandum-intermediares, Transmittal A-00-27 dated May 2000, is that a hospital that receives redesignation under Sec 401 is considered rural for all payment purposes including the wage index. This is consistent with the intent of the Statute Section 1886(d)(8)(E) and the regulation 412.103(d). HOSP REDES

The timing of the wage index change for the rural area can be an important issue. Hospitals can file an application under Sec 401 to be redesignated at any time during the

Federal Fiscal year. According to the Statute, and the regulation, CMS has to review and give a determination within 60 days. If approved, according to the regulation, it is effective the date CMS receives the application from the Hospital. **Thus if approved per regulation 412.103(d), "CMS will consider a hospital..... As being located in the rural area of the State in which the hospital is located as of that filing date".**

Under current operating policy, CMS pays the redesignated hospital, the current published rural wage index excluding the hospitals wage data until the beginning of the next Federal fiscal year. CMS does not include the hospital's wage data into the rural area to calculate the revised rural wage index until the next Federal Fiscal year begins on Oct 1st. Thus, redesignated hospitals would receive a rural wage index that does not include their wage data from the time they are approved for redesignation until the beginning of the next Federal Fiscal year to which it can be included beginning Oct 1st. **In addition, all of the hospitals located in the rural area as well as the redesignated hospital are in effect excluded from receiving the increased wage index for that period.**

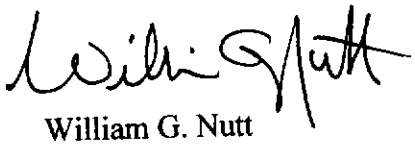
An example of how the timing of including the redesginated hospitals wages in the rural area, will show how this could work. A hospital request redesignation in June, and is approved 60 days later in August. Since the wage data is already finalized by the time of the August Federal Register Final rule, the hospitals wage data would not be included in the current FFY starting that Oct 1st, under current CMS policy, but be included in the rural wage data the following Federal Fiscal year on Oct 1st. The hospital and the other rural hospitals would be paid the old published rural wage index without including the redesignated hospitals wage data, from June until the subsequent Oct or roughly 15 months.

Rural hospitals located in a rural area receive the rural MSA wage index that includes their wages. The Statute and the regulation clearly state, that a redesignated hospital is considered as being located in the rural area of the State, at the time of the effective date of the redesignation. The effective date is the CMS receipt date of the application. Since rural hospitals physically located in the state get a MSA wage index including their wages so should the redesignated hospital at the time of the effective date. It is only fair for payment purposes to both the physically located rural hospitals and the redesignated hospital as well.

We strongly recommend that CMS change its policy to conform to the correct meaning of the statute and the regulation on this wage index adjustment timing issue. CMS has a policy and regulation (412.64(K)) that addresses mid-year corrections of the wage index, which could be used in this case to facilitate the timing of wage index corrections for Sec 401(a) redesignated urban hospitals.

As a practical matter we realize that doing a mid year process of recalculating the entire wage index for nearly 4000 PPS hospitals is very time consuming and creates fiscal budgetary and planning issues for all PPS hospitals. As an alternative, we suggest that CMS could adjust just the redesignated hospital and the state rural hospitals wage index at the effective date, and then make the national adjustment the next Oct 1st.

Sincerely yours,



William G. Nutt
President

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TRANSFERS — WALZ
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HARTSTEIN

June 13, 2005

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

RE: CMS-1500-P

We are writing to urge you to re-consider changes to the Centers for Medicare & Medicaid (CMS) proposed rules that would expand the post acute transfer provision under the inpatient prospective payment system (PPS). As written, the rules would hurt hospitals like UMass Memorial Medical Center, a not-for-profit hospital in Worcester, Massachusetts, as well as many other hospitals that provide care for extraordinarily high cost injuries and ensure patients receive care in the most appropriate setting. TRANSFERS

This proposal would effectively reduce DRG payments for any hospital discharge that has less than the average length of stay and where the patient receives post-acute care after discharge. Hospitals would be penalized across the country for making good clinical decisions in discharge planning. This policy contradicts the premise of the inpatient prospective payment system. In a system of averages, there will be cases with an average length of stay below, and above the average. By reducing hospitals' payment for cases below the average, CMS inhibits hospitals' ability to break even in the discharge of patients to gain a post-acute care payment have already been allayed. Significant cutbacks in Medicare payments and the shift to PPS for home health skilled nursing, and other post-acute care have removed any previous incentive that may have been in place for early discharge. **As a result, no further expansion of the transfer provision should be made, and we ask that the proposal be removed from the final rule.** If this rule were passed, UMass Memorial would see payments drop by an additional $4.3 million in 2006.

This decrease in reimbursement, coupled with other reimbursement changes, have added further stress to hospitals trying to operate in an already difficult financial environment.

Thank you for your attention to our concern, and we strongly urge you to give this your full consideration.

Sincerely,

Todd Keating
VP/CFO
cms5527.doc

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CAH Reloc

Hefter
Hartstein
Collins
Morey
Smith

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

Subject: Critical Access Hospitals

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

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

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

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

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

Sincerely,

Dennie Burchett

Dennie Burchett
Treasurer of Selby General Hospital Board of Trustees
120 Winters Drive
Marietta, OH 45750

cc: U.S. Representative Ted Strickland

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MORTON HOSPITAL AND MEDICAL CENTER

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Geo Reclass

Hefter
Hartstein
Kenly
Miller

June 14, 2005

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

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

To Whom it May Concern:

The Morton Hospital and Medical Center believes that the Bristol County hospitals were denied an opportunity to reclassify for Medicare wage index purposes last year because of a very narrow interpretation of the FY 2005 Medicare inpatient prospective payment regulation by the Medicare Geographic Classification Review Board. We believe that our appeal for reclassification into the Boston wage index area should have been approved by the review board and request that the Centers for Medicare & Medicaid Services (CMS) revise this year's proposed FY 2006 Medicare inpatient prospective payment regulation to clarify its original intent and enable us to secure this reclassification.

For this to be possible, three steps are needed:

1. Revise the rule to state that area wage reclassification based on the 1990 census proximity standard using CMSAs should also include New England County Metropolitan Areas (NECMA) for New England hospitals.
2. Exercise the CMS Administrator's discretion, based on the clear qualification of Bristol County hospitals to reclassify into the Boston wage index area, and reclassify us into that area for fiscal years 2006, 2007, and 2008.
3. Eliminate from the proposed FY 2006 rule, the proposed provision that calls for eliminating the 1990 proximity standard as grounds for enabling hospitals to qualify for wage index reclassification.

Background

After more than two decades in the Boston wage index area, the Morton Hospital and Medical Center, like the other hospitals in Bristol County, was reassigned to the Providence wage index area in 2005. Our application for a county-wide reclassification into the Boston wage index area was denied because the Medicare Geographic Classification Review Board concluded that we failed to meet the proximity requirement; our appeal of this rejection was denied as well.

We believe the review board reached an incorrect conclusion. It is clear to us that if the demographic circumstances in which we find ourselves were in evidence anywhere else in the nation except for

New England, we would have been found to meet the standard established in the proximity requirement and our appeal for reclassification into the Boston wage index area would have been approved. We now seek a remedy for this situation.

The Case for Reclassification

Last year's Medicare inpatient PPS rule, which created new, nation-wide wage index areas, stated that hospitals could satisfy the proximity requirement, one of the key criteria for wage index area reclassification, if they met either the Consolidated Metropolitan Statistical Area (CMSA) standard established by the Office of Management and Budget (OMB) in 1990 or the Consolidated Statistical Area (CSA) standard established by that same office in 2003. OMB created these standards to ensure that applicants for reclassification were sufficiently related to the areas into which they sought reclassification to justify their requests for such actions. In retaining the 1990 CMSA proximity standard, CMS was taking steps to ensure that hospitals that had long been part of a CMSA, and therefore of a wage index area, had a reasonable means of appeal if the nation-wide reclassification of hospitals left them in a new wage index area that they thought was disadvantageous and inappropriate.

This is the situation that Morton and the hospitals of Bristol County found ourselves in last year: in a new wage index area – the Providence area – that we felt would cause considerable harm to our financial health. Believing that we met the CMS criteria for reclassification into the Boston wage index area, we worked together and filed for a county-wide reclassification, citing the 1990 CMSA standard as proof that we met the proximity requirement. The Medicare Geographic Classification Review Board, however, rejected our application and subsequent appeal, ruling that we met neither the 1990 CMSA standard nor the 2003 CSA standard for proximity.

We believe that these decisions reflect an inadequate understanding of both the concept of proximity and the unique qualities of the manner in which New England local governments are organized and that, had the same demographic conditions existed anywhere else in the country, our application for reclassification would have been approved.

At the heart of the review board's rejection of our county-wide application and appeal was its specific rejection of our use of data based on New England County Metropolitan Areas, or NECMA, rather than CMSA or CSA data, in our appeal. The NECMA designation was created by OMB and adopted by CMS to reflect a fundamental difference in the manner in which New England political subdivisions are organized: whereas in most of the country the primary unit of political subdivision for census and other purposes is the county, in New England the primary units of political subdivision are cities and towns. CMS used NECMAs to create a level playing field: to have consistent groupings for nation-wide comparisons. When CMS adopted the Core-Based Statistical Area (CBSA) system following the 2003 census, however, the review board apparently concluded that it no longer needed to accept NECMA data – a surprising conclusion in light of the regulation's preservation of the 1990 proximity requirement as a criterion for qualifying for reclassification. For New England hospitals, NECMA data would have to be the primary means through which to demonstrate compliance with the 1990 proximity requirement, and now, that avenue had been closed off to us. In other parts of the country, hospitals that had been part of the same CMSA still could reclassify if they met all of the other reclassification criteria. Only hospitals in New England, based on the narrow interpretation of the Medicare Geographic Classification Review Board, had been singled out and denied an equivalent opportunity in this manner. (In fact, had NECMAs not been used, according to the chief geographer of the U.S. Census Bureau, Bristol County almost certainly would have been designated a part of the Boston CMSA. A copy of his letter attesting to this is

attached.) We believe this is wrong and unfair and led to a bad public policy decision – a decision that we now ask CMS to remedy.

We believe it is entirely appropriate for reclassification applicants to use NECMA data to demonstrate compliance with a proximity requirement that uses NECMA data as its foundation. Below, we will address how to ensure that this can be done in the future. We also wish to note that addressing this problem would amount to a relatively minor refinement, not a large-scale, nation-wide reclassification movement. The conditions that affect us can be found only in New England – predominantly in Massachusetts and possibly in a few parts of New Hampshire; Rhode Island hospitals, for example, would not be able to reclassify into the Boston wage index area.

The Cost of Our Inability to Reclassify

The Morton Hospital and Medical Center, long a part of the Boston wage index area, is paying a high price for our classification into the Providence wage index area. Annually, the reduction in payment across all of Morton's Medicare services as a result of being moved to the Providence wage area approximates 1.5 million dollars. Reclassification of Morton into the Boston wage area, since reclassification applies only to inpatient and outpatient PPS services, will restore about $500,000, or one-third, of this revenue loss.

The two nearest hospitals to Morton (both are just 15 miles away) are included in the Boston wage area. Nurses at Morton and these neighboring hospitals are represented by collective bargaining agreements with the same union. So, even with reclassification, Morton will face the very difficult challenge of competing for health care professionals seeking Boston wages, but doing so without the necessary financial resources. Without reclassification, it is very likely that Morton will be unable to offer wages that are competitive in our labor market and will be unable to retain the workforce necessary to provide the services needed by our community.

The purpose of the Medicare wage index system is to help Medicare reimburse hospitals accurately and appropriately based on the varying cost of living, and employing workers, throughout the country. Simply put, workers with comparable skills are paid different amounts of money in different parts of the country, and the wage index system helps ensure that hospitals are neither overpaid nor underpaid but are fairly paid for the services of these workers.

Classification in the Boston wage index area is so important for us because we are very much a part of the Boston labor market – far more so than of the Providence labor market. Of the 250,000 working adults who reside in Bristol County, nearly a quarter – 22.1 percent – travel to work in Boston. By comparison, only a little more than one-third of that figure – 8.5 percent – travel to Providence for work. Among Bristol County residents who work in hospitals, however, even more – 27 percent, according to the Census Bureau's Bureau of Economic Analysis – commute to other Massachusetts counties, primarily in the Boston area, for work. This tells us that these workers are willing to commute – and do commute – in search of higher wages.

Clearly, this demonstrates that the Morton Hospital and Medical Center and Bristol County are very much more a part of the economic life of the Boston area and that we meet any reasonable standard of proximity to the Boston wage index area.

Recommended Regulatory Changes

We urge CMS to correct this injustice in the final version of the FY 2006 Medicare inpatient rule. This can be done through three specific steps.

Step One: Revise the Regulation to Make Clear that NECMA Data Can Be Considered in Reclassification Applications Based on the 1990 Proximity Requirement

The Morton Hospital and Medical Center asks CMS to revise the regulation to clarify to hospitals that they can use NECMA data to support applications for reclassification based on the 1990 proximity standard and to direct the Medicare Geographic Classification Review Board that it must consider NECMA data when evaluating applications for reclassification based on that 1990 proximity requirement. To effect this change, we recommend that CMS add, after "CMSA" in 42 CFR 412.234(a)(3)(ii), the phrase "or in the case of New England, New England County Metropolitan Area, or NECMA."

Step Two: Exercise the Administrator's Discretion to Reclassify Us Immediately

Section 1886(d)(5)(l)(i) authorizes the CMS Administrator to make unilateral exceptions to wage index classifications, and we request that the CMS Administrator do exactly that and reclassify our hospital into the Boston wage index areas right away for fiscal years 2006, 2007, and 2008. Because the Medicare Geographic Classification Review Board ruled too narrowly on our appeal and its decision could cause serious harm to us, we believe this is an appropriate use of the Administrator's discretion.

Step Three: Preserve Use of the 1990 Proximity Requirement Standard as a Criterion for Reclassification Eligibility

The proposed regulation includes a provision that would eliminate the 1990 proximity standard as a criterion for reclassification. Since the 1990 standard is the only reasonable means through which hospitals like ours can demonstrate that we truly are part of the community into which we seek reclassification, we strongly urge CMS to preserve this criterion and not to remove it from the regulation. We have been an integral part of this community for decades, and we should continue to remain so.

The Bristol County Hospitals Meet the Other Criteria for Reclassification

To qualify for reclassification, applicant hospitals must fulfill three criteria: they must be in a county contiguous to the CMSA into which they seek reclassification; they must meet the proximity requirement; and they must meet the wage requirement. The Morton Hospital and Medical Center believes that we meet all three of these requirements:

1. Bristol County, in which we are located is immediately adjacent to the Boston CMSA and wage index area.
2. As this letter demonstrates, we believe we meet the proximity requirement.
3. All hospitals based in Bristol County, as defined by CMS, as well as all hospitals with operations in the county, meet the wage requirement. The Medicare Geographic Classification Review Board confirmed the former in its review of our county-wide application last year, and documentation of this compliance accompanies this letter.

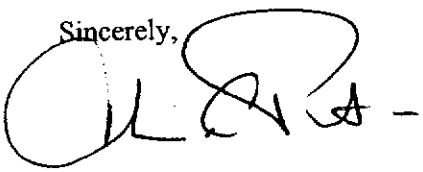
Conclusion

We recognize the considerable challenge CMS faced in crafting new wage index areas for the entire country based on the results of the 2000 census. This was an enormous undertaking, and CMS has appropriately given hospitals opportunities to appeal its classification decisions. We believe that the decision of the Medicare Geographic Classification Review Board to reject the appeal of the Bristol County hospitals for reclassification was an unfortunate one – and that it should be corrected. We clearly have demonstrated that we are part of the Boston area, we have long been reimbursed by Medicare as part of the Boston area, and we should continue to be viewed and treated in this manner in the future.

CMS can accomplish this by revising the FY 2006 Medicare inpatient PPS regulation to make clear that NECMA data can be considered in reclassification applications based on the 1990 proximity requirement; by exercising the CMS Administrator's discretion to reclassify us immediately; and by preserving the use of the 1990 proximity requirement as a criterion for reclassification eligibility.

We appreciate your consideration of our comments and welcome any questions you may have about them.

Sincerely,



Thomas C. Porter
President

Enclosures

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

February 4, 2005

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

Dear Mr. Baker,

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

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

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

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

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

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

Sincerely,

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

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

Group Name: Bristol (MA) Hospital Group

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

Average Hourly Wage for Group: $25.8252

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

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

25.8252 / 29.1519 x 100 = 88.5883%

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

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

Group Name: Bristol (MA) Hospital Group

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

Average Hourly Wage for Group: $26.0839

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

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

26.0839 / 29.1519 x 100 = 89.4758%

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

163

MMI Healthcare Consulting, LLC

Geo Reclas

June 13, 2005

Hefter
Hartstein
Kenly
Miller

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

To Whom It May Concern:

In response to the proposed rule as published in the May 4, 2005, Federal Register (70 FR 23306), we submit the following comment for your consideration:

Geographic Reclassifications – File Code CMS-1500-P

It has been noted that the regulation at 42 CFR § 412.63(b)(1) defines *a hospital reclassified as rural* to include a reclassification that results from an urban hospital applying for reclassification as rural under §412.103. However, the definition at 42 CFR § 412.64(b)(ii)(D) makes no mention of hospitals reclassified under §412.103.

Clarification is sought as to whether §412.64(b)(ii)(D) was meant to intentionally exclude hospitals reclassified as rural under §412.103 from the definition of *hospitals reclassified as rural* and, if so, the reasoning for such exclusion. It would seem that if hospitals reclassified under §412.103 were not included in the definition at §412.64(b)(ii)(D), they would potentially be entitled to the capital DSH adjustment at §412.320 (assuming they meet the 100 bed criterion). We noted no direct explanation for this exclusion in the May 18, 2004 proposed rule (69 FR 28196) and apologize for our oversight in not commenting on this issue at that time.

We appreciate any consideration you can give to this issue. Should you have any questions, please feel free to contact us at 812-353-5819.

Sincerely,

Michael L. Craig
President

4112 Bill Mallory Blvd., Bloomington, IN 47401
812-353-5819

HUDSON HOSPITAL

Exceptional Care — Close to Home

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JUN 23 2005
BY:.....

1624

CAH Reloc

Hefter
Hartstein
Collins
Morey
Smith

June 14, 2005

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

Reference: CMS-1500-P

Dear Sir/Madam:

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

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

Our basis for this position is as follows:

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

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

3. Many rural hospitals are located on a small campus in the middle of residential neighborhoods with relocation being the most appropriate, and sometimes only, alternative.

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

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

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

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

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

Respectfully submitted,

Marian M. Furlong
President and Chief Executive Officer
Hudson Hospital

MMF:ljb

CMS-1500-P-585

165 (new)

Date: 06/23/2005

BODDEN
KRUSHAT
HEFTER
HARTSTEIN

Submitter : Dr. Nicki Will

Organization : Lower Keys Medical Center

Category : Hospital

Q DATA

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-585-Attach-1.DOC

Attachment 585

June 16, 2005

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

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

Dear Sir or Madam:

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

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

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

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

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

It seems unjust that for the delinquency of 5 charts, a hospital that served 6,554 patient days to 1,200 Medicare patients in 2004 would have to see a decrease of any kind in its reimbursement. We incurred $17,000 in expenses in 2004 to have an outside audit agency review 100% of the inpatient charts that were sent to Medicare for reimbursement. This agency ensured that there were no coding errors on our submission. Our charges are also run through a third party editor to ensure that charges not allowed by Medicare are not included in our bills. We provided nearly $13 Million in care to the indigent in this community. We maintain a licensed Laboratory and Psych department, along with our participation in the JCAHO program. The delinquency of 5 charts is in no way an indicator of the level of service provided to patients in this community.

The long term impact to facilities, particularly Sole Community Providers, can be devastating. To base such a severe ramification on the review of 5 charts seems unfair. The CMS proposal places a tremendous burden on Sole Community Providers and we request that CMS delay until FY 2007, implementation of their proposal tying the market basket update to the validation assessment to allow rural hospitals adequate notice.

Thank you in advance for your consideration of our comments in making decisions relative to the CMS proposed rules.

Sincerely,

Nicki L. Will, PhD
Chief Executive Officer

166

Health Alliance™

3200 Burnet Avenue
Cincinnati, OH 45229
513-585-6000

RECEIVED
JUN 23 2005
BY:

Hafter
Hartstein
Walz
Treitel

TRANSFERS
Payment Rats/Outlier

June 15, 2005

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

To Whom It May Concern:

The Health Alliance of Greater Cincinnati is an alliance of six acute care hospitals, located in the greater Cincinnati area. Two of the hospitals are located in Northern Kentucky, three in Cincinnati and one hospital in Hamilton, Ohio. One of the Cincinnati hospitals is the University Hospital, which is the safety-net hospital for the greater Cincinnati area.

Our comments are prompted by our concerns over the financial impact of the proposed changes to the Prospective Payment System (PPS) for inpatient operating costs; specifically, changes to the expansion of the transfer payment policy and the proposed changes to the outlier payment policy. These proposed changes are outlined in the Federal Register/Volume 70, 85/Wednesday, May 4, 2005/Proposed Rules-Page 23305 through 23774.

The proposed rule would increase the fixed-loss cost threshold for outliers from $25,800 to $26,675, or a 3.4% increase. The perspective payment rules mandate that outlier payments be funded through a 5.1% reduction in the PPS standardized payment amount. Based on your own data, outlier payments in fiscal year 2004 were 3.5% of the total PPS payments and in fiscal year 2005 you are estimating that outlier payments will reach 4.4% of total payments. Since your policy regarding outlier payments does not allow a retroactive increase in payments in any given year, and actual outlier payments have fallen short for two consecutive years of the 5.1% reduction in PPS payments, it's not clear to us why the fixed-loss threshold should increase in 2006. Based on the experience of our own six hospitals, outlier payments as a percent of gross PPS payments have steadily declined over the last five years from a high of 8.99% in fiscal year 2001 to a low of 3.76% in fiscal year 2005. These numbers would suggest that a reduction in the fixed-loss threshold would not be logical. We ask that you re-evaluate your current proposed fixed-loss threshold and lower the threshold to achieve the mandated 5.1% payment level.

Post-Acute Care Transfer Payment Policy:

We believe that CMS should not implement an expansion of the Post-Acute Care Transfer Policy. The fundamental problem with the transfer policy is that it penalizes hospitals that

properly place their Medicare patients in the appropriate setting during the continuum of care. In addition, it undercuts the fundamental principle of PPS, which is a system based on averages. Analysis of the average length-of-stay in our six hospitals shows a very slight increase from 5.06 to 5.31 in the average length-of-stay over the last five years. In fact, the average length-of-stay at University Hospital has decreased only slightly from 5.14 days to 4.82 days over the last five years. This safety-net hospital is the hospital most financially damaged by the expansion of this policy and is just one more example of the many deductions in funding from both the local, state and federal level, which is eroding the financial stability of this safety-net hospital. A recent OIG report found that hospitals do not always comply with the transfer policy. The implication of this report is many of these errors were intentional. Since this report was prepared, CMS took steps to detect over-payments from the hospitals post-acute care transfers, by implementing edits in the common working file to detect this improper coding. These edits were put in place January 1, 2004. As a result of these edits our hospitals received a significant number of corrections to our disposition codes. The majority of these resulted from situations where the patient's initial discharge is to home and after a day or two, the patient on their own or the physician's initiative, is admitted to a skilled nursing facility or has initiated services with a home health agency. Our discharging hospitals have no way of knowing that these services are now being acquired. The expansion of the transfer rule to 223 DRG's will only exacerbate this situation.

In summary, we expect that the proposed expansion of the transfer rule will reduce the Medicare reimbursement for our alliance by $4.7 million or 1.4% of our total Medicare reimbursement. The impact on the University Hospital is $2 million. We are concerned that the reduction in reimbursement caused by this rule change will impact University Hospital's ability to continue to serve the indigent population of the greater Cincinnati area.

Sincerely,

Ronald R. Long
Executive Vice President & Chief Financial Officer

cc: Ken Hanover, President and CEO – Health Alliance
The Honorable Mike DeWine – U.S. Senate
The Honorable George V. Voinovich – U.S. Senate
The Honorable John A. Boehner – U.S. House of Representatives
The Honorable Steven J. Chabot – U.S. House of Representatives
The Honorable Ted Strickland – U.S. House of Representatives

167

Date: 06/16/2005

Submitter :

Organization : American Health Information Management Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-363-Attach-1.DOC

ICD-9-CM
DRG | Gen
(Stroke
AICD
Cor. Stents
Spinal Fusion

MCE
CC List
Transfers
Q Data
MedPAC

Hefter
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue
Walz
Treitel
C. Bodden
M. Krushat
J. Hart

AHIMA
American Health Information Management Association

Attachment to #363

June 15, 2005

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

Dear Dr. McClellan:

The purpose of this letter is to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed changes to the Medicare Hospital Inpatient Prospective Payment Systems (IP-PPS) and fiscal year 2006 Rates, as published in the May 4, 2005 *Federal Register*. The American Health Information Management Association (AHIMA) is a professional association representing more than 50,000 educated health information management (HIM) professionals who work throughout the healthcare industry. HIM professionals serve the healthcare industry and the public by managing, analyzing, and utilizing data vital for patient care and making it accessible to healthcare providers and appropriate researchers when it is needed most.

Consistency in medical coding and the use of medical coding standards in the United States is a key issue for AHIMA. As part of this effort, AHIMA is one of the Cooperating Parties, along with CMS, the Department of Health and Human Services' (HHS) National Center for Health Statistics (NCHS), and the American Hospital Association (AHA). The Cooperating Parties oversee correct coding rules associated with the *International Classification of Diseases Ninth Revision, Clinical Modification* (ICD-9-CM). AHIMA also participates in a variety of coding usage and standardization activities in the United States and internationally.

Our desire for consistency in medical coding and data integrity leads AHIMA to advocate for immediate adoption and coordinated implementation of ICD-10-CM and ICD-10-PCS as quickly as possible in the United States. It is very clear in reading these proposed rules and the MedPAC recommendations, that CMS should actively be seeking these same goals. The sooner the healthcare industry and CMS begin to use and collect data more closely representing actual diagnoses and procedures, the clearer and more accurate will be the depiction of our health and healthcare services which will lead to more accurate reimbursement and less administrative burden on healthcare providers and on CMS.

730 M Street, NW, Suite 409, Washington, IL 20036
phone (202) 659-9440 · *fax* (202) 659-9422 · www.ahima.org

II-B: DRG Reclassifications

Unless otherwise noted, AHIMA supports CMS' proposed DRG modifications.

II-B-3a: Strokes (70FR23315)

AHIMA shares CMS' concern regarding the possible underreporting of ICD-9-CM code 99.10, Injection or infusion of therapeutic or prophylactic substance, because it currently does not affect DRG assignment. Our members are encouraged to report all appropriate diagnosis and procedure codes, regardless of the impact on reimbursement. We believe complete and accurate coding is necessary not only to ensure appropriate refinements to reimbursement systems, but also to ensure a quality database for other purposes, such as measuring quality of care, provider profiling, and conducting research. AHIMA's Standards of Ethical Coding state, "Coding professionals are expected to support the importance of accurate, complete, and consistent coding practices for the production of quality healthcare data."

AHIMA believes that, even given the small number of cases in the MEDPAR database, it would be reasonable to split stroke cases with and without use of a reperfusion agent into separate DRGs.

II-B-4a: Automatic Implantable Cardioverter/Defibrillator (70FR23316)

AHIMA supports CMS' proposal to remove code 37.26 from the list of cardiac catheterizations for DRGs 535 and 536. Once the coding issues have been resolved and consistent data are being collected, the appropriate DRG assignment(s) for code 37.26 can be re-examined.

We also agree that there has been considerable confusion as to the proper use of code 37.26. In addition to confusion as to whether code 37.26 should be reported when an electrophysiologic study (EPS) is performed as part of a defibrillator implantation, there has also been confusion as to whether this code should be reported for defibrillator device checks. Advice in *Coding Clinic for ICD-9-CM* regarding the use of code 37.26 has also changed over the past few years, further contributing to inconsistent data regarding the reporting of this code. Until 2003, *Coding Clinic* advised that code 37.26 should be reported in conjunction with the code for insertion of an automatic implantable cardioverter/defibrillator (AICD) when an EPS is performed during the implantation of the device. Then in 2003, *Coding Clinic* changed this advice and stated that no additional code should be reported for an EPS performed during the implantation of an AICD. However, diagnostic EP studies done prior to or following insertion of the AICD should be coded separately and assigned to code 37.26.

Up until 2003, *Coding Clinic* advised to assign code 37.26 for bedside evaluations of an automatic implantable cardioverter/defibrillator (AICD). In 2003, *Coding Clinic* changed its advice to indicate that code 89.59, Other nonoperative cardiac and vascular measurements, should be assigned for a bedside evaluation. In 2004, a new code (89.49) was created for an AICD check.

So, even when coders were coding correctly, in accordance with current *Coding Clinic* advice, the reporting of code 37.26, and the services this code represents, has been inconsistent.

II-B-4b: Coronary Artery Stents (70FR23318)

We support CMS' proposal to restructure the coronary stent DRGs such that the cases are split on the basis of the presence or absence of a CC. We agree that these DRGs shouldn't be restructured to account for multiple stent insertion until sufficient data has been collected using the new ICD-9-CM procedure codes that will go into effect this October. We also concur with CMS' recommendation that coders should code as accurately as possible, assigning as many codes as necessary to describe each case.

However, since the October 2005 ICD-9-CM revisions require three separate code assignments for angioplasty with coronary stent insertion, and since CMS only uses the first six reported procedures in the DRG classification process, we are concerned that significant procedures (including some of the newly-created codes) may be missed in future DRG analysis data because they are not sequenced within the first six procedures. **AHIMA recommends that CMS use all reported diagnoses and procedures, not just the first nine diagnoses and six procedures, in their DRG analysis and DRG classification process.** With more care being provided on an outpatient basis, hospital inpatients tend to be sicker than in the past. There has also been an increasing demand for greater coding specificity. Both of these trends mean higher numbers of reportable diagnoses and procedures for many hospital inpatient cases.

II-B-6c: Multiple Level Spinal Fusion (70FR23328)

For the proposed new DRG for non-cervical spinal fusions with a principal diagnosis of curvature of the spine or malignancy, codes 737.40-737.43 are included in the list of applicable principal diagnoses. However, these codes are manifestation codes, and, according to ICD-9-CM conventions, can never be sequenced as the principal diagnosis. The underlying etiology would be sequenced as the principal diagnosis. **Therefore, these codes should not be included in the list of principal diagnoses for proposed DRG 546.**

II-B-9a: Newborn Age Edit (70FR23331)

While we agree that comprehensive edits for pediatric admissions are more appropriately developed outside of the Medicare program, nevertheless, there is a newborn age edit in the MCE. As long as this edit exists, it should be accurate, up-to-date, and not include codes that could appropriately be assigned to older children and adults. If there are errors in this edit, an adult Medicare claim could be rejected due to inappropriate triggering of the newborn age edit. The introduction for Chapter 15 in ICD-9-CM states that this chapter includes conditions, which have their origin in the perinatal period even though death or morbidity occurs later. Some of the conditions included in this chapter may potentially persist into adulthood. **CMS should utilize the necessary expertise to develop and maintain pediatric edits on an up-to-date basis, or consider deleting this edit from the MCE.**

II-B-11b: CC List (70FR23332)

We support CMS' plans to perform a comprehensive review of the CC list. As noted in an earlier comment, AHIMA recommends that all reported diagnoses, not just the first nine, should be included in CMS' DRG analysis and in the DRG classification process. Therefore, CMS' review of the CC list

should encompass all reported diagnoses. We also recommend that CMS examine the impact of multiple CCs on hospital resource consumption and length of stay.

As part of CMS' efforts to improve the DRG system to better recognize severity, we recommend that CMS seriously consider adoption of a refined DRG system that accounts for variations in severity of illness, and, as noted above, also consider changing its system and requirement to allow providers to submit all appropriate diagnoses and procedures associated with the claim.

V-A: Postacute Care Transfers

V-A2: Changes to DRGs Subject to the Postacute Care Transfer Policy (70FR23411)

AHIMA opposes CMS' proposal to significantly expand the list of DRGs subject to the postacute transfer policy. In order to identify patients meeting the home health criteria, hospitals must often contact patients to determine if they have received home health services within three days after discharge. This is an extremely labor-intensive process, delays claims submission, and an incorrect discharge status code may still end up being reported if hospital personnel are unable to reach the patient to determine whether the home health criteria have been met. A major expansion in the number of DRGs included in this policy, without any changes to the home health criteria, will place a tremendous administrative burden on hospitals because of the increased number of patients subject to this cumbersome process.

V-B: Hospital Quality Data

V-B1: Background (70FR23424)

We commend CMS for its plans to create a system or mechanism for reporting clinical quality data directly from electronic health records (EHRs) to a CMS data repository. This will greatly relieve the hospitals' administrative burden in reporting this data and result in the realization of a tangible benefit from EHR implementation. Eliminating duplicate data entry will also increase the accuracy of reported data. CMS should also consider the impact of diagnoses and procedure information in determining quality. A combination of electronic quality data indicators, combined with a contemporary classification system, instead of ICD-9-CM, would significantly impact on any understand of quality, value, or process and enhance and expedite any pay-for-performance process CMS might introduce into the Medicare program.

IX: MedPAC Recommendations

IX-B: Physician-Owned Specialty Hospitals (70FR23454)

AHIMA agrees with MedPAC that the current DRG system needs to be refined to more fully capture differences in severity of illness and we encourage CMS to adopt a DRG system that better accounts for severity, such as APR-DRGs. Also, in order to better capture differences in severity of illness, CMS

should include all reported diagnoses, not just the first nine, in its DRG analysis, classification, and refinement processes. We further recommend that the Secretary take the necessary steps (NPRM and final rule) to permit final implementation of adopt ICD-10-CM and ICD-10-PCS as soon as possible. These necessary upgrades to ICD-9-CM will provide CMS with modern classification systems that will greatly improve the quality of data needed to identify differences in severity of illness and to support an improved DRG system that better accounts for patient severity.

Conclusion

We appreciate the opportunity to comment on the proposed modifications to the Medicare Hospital Inpatient PPS program for fiscal year 2006. It is clear to AHIMA, in reviewing the proposed rule, that CMS must actively promote HHS' adoption and implementation of the ICD-10-CM and ICD-10-PCS coding systems, if appropriate, consistent, and accurate clinical information that is reflective of patients' medical conditions and care provided is to be available to support this country's healthcare data needs, including the foundation of CMS' IP-PPS reimbursement system and necessary refinements to better recognize variances in severity of illness. The structure of ICD-9-CM is not sufficiently flexible to continue to accommodate revisions needed to identify the use of new medical technology or incorporate the increasing demands for greater specificity. Making needed changes to the ICD-9-CM coding systems, particularly the procedural component, has become increasingly difficult each year. The limitation of the four-digit structure of ICD-9-CM's procedural coding system allows little room to make substantive changes. Soon, needed updates will no longer be possible, jeopardizing the ability to compare outcomes and efficacy between older and newer technologies, identify costs associated with the new technology, or revise reimbursement policies to appropriately reflect the cost of patient care when the new technology is used.

If AHIMA can provide any further information, or if there are any questions or concerns with regard to this letter and its recommendations, please contact either Sue Bowman, RHIA, CCS, AHIMA's director of coding policy and compliance at (312) 233-1115 or sue.bowman@ahima.org, or myself at (202) 659-9440 or dan.rode@ahima.org.

Sincerely,

Dan Rode, MBA, FHFMA
Vice President, Policy and Government Relations

cc: Sue Bowman, RHIA, CCS

168

Date: 06/16/2005

Submitter : Dr. Yoshifumi Naka

Organization : New York Presbyterian Hospital

Category : Physician

DRG/Gen

Hefler
Hartstein
Brooks
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Gruber
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Issue Areas/Comments

GENERAL

GENERAL

June 16, 2005

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

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

Dear Administrator McClellan,

As a surgeon who was involved in the CorCap CSD US Randomized Trial, I am very concerned that hospital payment for the new CorCap procedure code 37.41 (implantation of prosthetic cardiac support device around the heart), under DRGs 110 and 111 will not be adequate to cover the cost of implanting the cardiac support device.

Without adequate payment for the CorCap procedure, neither patients nor payers will have the opportunity to benefit from this break though in heart failure treatment. As the Director of Cardiac Transplantation and Mechanical Circulatory Support Programs at Columbia University Medical Center, New York Presbyterian Hospital which is one of the largest heart transplant center in the world, I have seen numerous advanced heart failure patients who might have benefit from the CorCap. The proposed DRG payments do not appropriately account for the resources consumed resulting in a disincentive for hospitals to use the CorCap. If the device is not implanted, the Medicare program stands to miss an opportunity to limit future costs by preventing the need for LVADs and heart transplants.

I urge you to seriously consider the comments submitted by Acorn Cardiovascular that provide further detail as to the dissimilarities between the CorCap CSD implant procedure and those assigned to DRGs 110 and 111 as well as the rationale for reassignment to DRG 108. Reassigning this novel procedure to DRG with other similar techniques will ensure that payment does not serve as an obstacle to the health of Medicare beneficiaries and the Medicare Trust fund.

Sincerely,

Yoshifumi Naka M.D., Ph.D.
Director, Cardiac Transplantation and Mechanical Circulatory Support Programs
New York Presbyterian Hospital, Columbia University Medical Center

169

Date: 06/16/2005

Submitter : Mr. Michael Karuschak, Jr.

Organization : Amery Regional Medical Center

Category : Critical Access Hospital

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Issue Areas/Comments

GENERAL

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To CMS:

The Centers for Medicare & Medicaid Services proposed rules will make it virtually impossible for Critical Access Hospitals like Amery Regional Medical Center to replace our current facility now or at any time in the future.

Under the proposed rules, CAHs that have been determined to by "necessary providers" by the State of Wisconisn would need to build a replacement facility within 250 years of our existing building unless we can demonstrate that construction plans were under development prior to December 8th, 2003. Otherwise ARMC runs the risk of losing our CAH designation.

I understand that CMS is concerned that CAH could build a new facility outside of the rural community they currently serve. However one of the criteria included in the proposed rules would require Critical Access Hospital that build a replacement facility to demonstrate that they will continue to serve a minimum of 75 % of the same population they are currently serving while providing a comparable level of service and access as they have provided at their current site. This requirmemnt itself would eliminate the potential of a CAH moving outside their current service area while maintaining their CAH designation.

The 250 yard restriction as well as the arbitary date of December 8, 2003 are unnecessary and only prevent the appropriate replacement of facilities that for the most part were built in the 1950's and will need to be replaced at some time.

In the case of Amery Regional Medical Center, the proposed rules would prevent ARMC from building a new facility within 1 mile of our current location. However, we would be allowed to spend as much money to renovate and expand our present facility at its' current location. If the proposed rules are finalized, ARMC will be forced to stay at our current site and build around part of our structure that is over 50 years old. The final building would not be as efficient as a new facility and we would be severely land locked requiring us to purchase homes in our immediate area that would be demolished in order to provide visitor and employee parking. In addition, during the renovation of our current facility it would be very disrupting to maintain easy access to our services for our patients.

The 250 yard requirement and the December 2003 date are unnecessary to achieve the goals of CMS. I would urge CMS to eliminate these requirements from the proposed rules.

Thank you.

Michael Karuschak, Jr., FACHE
Chief Executive Officer

170

Date: 06/16/2005

Submitter : Dr. Alexandre de Moura

Organization : New York Spine Institute

Category : Physician

NT

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Issue Areas/Comments

GENERAL

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Please be advised that the Charite Artificial disc is an excellent operation for people suffering from intractable low back pain. Patients that are on medicare disability and have back problems will be candidates for the new procedure. Although patient older that 65 will all be candidated for this procedure the younger population on disability will. It is in the public interest that medicare recognize this operative procedure.

CMS-1500-P-375

Date: 06/16/2005

Submitter : Dr. John J Demakas

Organization : Inland Neurosurgery

Category : Physician

NT

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Issue Areas/Comments

Issues

New Technology Applications

Re: CHARITE Artificial Disc.

Although I have not placed an artificial disc (TDR-total disc replacement) in a patient older than 60 years of age, I have done interbody fusions and surgical decompressions of the spine in elderly patients, over a 30+ year career; additionally, I have been involved in an IDE study for a different artificial disc. In my experience, the presence of significant softening of the bone in patients over the age of 60 has not been so common that it precludes them from being managed surgically with fusions and instrumentation of the spine. I have always assessed their bone density and proceeded accordingly. In those patients who have qualified for interbody fusion and/or pedical screw fixation, I would not have hesitated to perform TDR, if indicated.
Rather than treating according to age, would it not be more prudent and medically appropriate to treat according to medical necessity and clinical/study findings? In that regard, female patients over the age of 40 and male patients over the age of 50 should be considered for DEXA scan. Based on those findings, patients would be considered appropriate candidates for TDR, if they met, among other considerations, set standards of bone density.
Overall, we are talking about a patient population of approximately less than 5% of Medicare eligible people. The impact, in dollars, would not be extraordinary, and for that small percentage of patients, allow for a speedier recovery and greater mobility

Thank you.

(4) 1720

Date: 06/16/2005

Submitter : Miss. Penelope Solis

Organization : American Heart Association

Category : Association

Issue Areas/Comments

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"See Attachment"

CMS-1500-P-378-Attach-1.PDF

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Attachment #378

American Stroke Association
A Division of American Heart Association

American Heart Association
Learn and Live

Advocacy Department
Office of Legislative and Regulatory Affairs
1150 Connecticut Ave., NW Ste 300
Washington, DC 20036
Tel 202.785.7900
americanheart.org

June 16, 2005

VIA E-MAIL

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

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

To whom it may concern:

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

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

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

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

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

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

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

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

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

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

I. Background

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

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

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

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

[7] 70 Fed. Reg. at 23315.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[13] Level 1A means:

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

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

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

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

IV. Establishment and Maintenance of Primary Stroke Centers

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

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

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

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

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

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

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

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

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

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

V. Conclusions & Recommendations

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

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

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

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

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

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

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

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

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

Sincerely,

Ellen Magnis
Vice-President

Marc Mayberg, MD
Chairman
Stroke Council Leadership Committee

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

Ralph Sacco, MD
Incoming Chairman
ASA Advisory Committee

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

173

Date: 06/16/2005

Submitter : Mr. Dean Verret

Organization : Terrebonne General Medical Center

Category : Other Health Care Professional

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Issue Areas/Comments

GENERAL

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Considering the difficulties we are currently experiencing with the validation process for 3rd quarter and some of you are experiencing with submission of validation records for 4th quarter CMS is requested to change it's validation language to provide more time than what is being stated.

M. Krushat

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MEDPAC Medicare Payment Advisory Commission

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M/B/H
Impact

June 23, 2005

JUN 24 2005

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Box 8011
Baltimore, Maryland 21244-1850

Re: File Code CMS-1500-P

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled *Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2006 Rates*, Federal Register Vol. 70, No. 85, pages 23305-23774 (May 4, 2005). We appreciate your staff's ongoing efforts to administer and improve the payment system for acute inpatient services, particularly considering the agency's competing demands. We have comments on several of the issues addressed in the proposed rule, and where applicable we have included the captions specified in the rule.

MedPAC recommendations on physician-owned specialty hospitals

After an extensive analysis of Medicare hospital inpatient claims and cost data, the Commission concluded that the IPPS payment rates are badly distorted, resulting in Medicare paying too much for some types of patients and too little for others. These price distortions and resulting profits send inappropriate signals to hospitals and reward or penalize individual providers based on the mix of patients they treat rather than their efficiency of treatment. We see this as an urgent issue and recommended four payment policy changes that should be implemented to substantially improve Medicare's hospital payments. We also want to be clear that the policies we recommended are not new. All four policies have been described, analyzed, and discussed for at least a decade. Our estimates suggest that adopting these policies would change Medicare inpatient payments for many hospitals. We interpret the impact of these changes as a strong indication of why payment reforms are so urgently needed.

We are pleased that CMS shares our objective of improving the accuracy of the IPPS payment rates. We are concerned, however, that CMS may not go far enough to redress the distortions that we have identified. The menu of analyses that CMS listed in its response to our recommendations is long and broad, raising the risk that some analyses might not be completed in time to support proposals for payment policy changes in fiscal year 2007. Further, CMS's

responses suggest that it did not fully understand one of our recommendations. We discuss our specific concerns below.

Refinement of diagnosis related groups (DRGs)

CMS indicates that it expects to make changes to the DRGs to better reflect differences in severity of illness among patients. It then discusses three options that are under consideration.

Comprehensive review of the comorbidities and complications (CC) list—CMS proposes to make a comprehensive review and revision of the CC list.[1] This may be a desirable improvement. However, we do not expect that even a major revision to the list would greatly improve the extent to which the IPPS payment rates capture the effects of differences in patient severity of illness.

The CC distinction is based only on the presence or absence of any CC, implicitly assuming that all CCs have equal effects on severity of illness and costs. Even if the CC review process were to correctly identify all secondary diagnoses that significantly affect hospitals' costs, our research and CMS's earlier work have shown that simply distinguishing between patients with and without CCs fails to capture large, predictable differences in costs among patients. Further differentiation is necessary to make the most effective use of information about patients' secondary diagnoses and help to minimize opportunities for hospitals to benefit financially from patient selection.

Selective review of DRGs—CMS proposes to review selected DRGs that are overpaid or those with substantial variation in charges per discharge. Focusing on DRGs in which Medicare's payment rates may be set too high would miss the large number of equally problematic DRGs in which payment rates appear to be set too low. Our analysis showed that the problem of differences in relative profitability is widespread among and within DRGs. About two-thirds of the DRGs showed relative profitability ratios that were more than 5 percent higher or lower than the average for all cases in fiscal year 2002. Differences in relative profitability among severity classes within DRGs were often substantially greater than 5 percent. Moreover, using a criterion based on the variation in charges among cases also may not help identify DRGs to revise because most DRGs have substantial variation in charges, partly reflecting unmeasured differences in illness severity among patients.

Evaluation of alternative DRG systems—CMS proposes to examine alternative DRG systems, such as the all patient refined DRGs (APR-DRGs), to better capture severity. However, CMS notes two concerns with making extensive changes in the DRGs. First, adopting an alternative system might improve payment accuracy, but it also could substantially alter the distribution of payments among hospitals. As we stated earlier, we interpret the potential redistribution of payments among hospitals as strong evidence that the current payment system is distorted and

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[1] The CC list identifies secondary diagnoses that qualify as comorbidities (coexisting conditions present at hospital admission) or complications (conditions that develop during the stay) that, when present, affect patient severity of illness and are expected to significantly increase the cost of care.

that is why our payment recommendations should be adopted quickly. Maintaining the status quo—especially in the face of evidence that some hospitals benefit from distorted payment rates while others are disadvantaged—should not be an objective.

The Commission recognizes that such payment changes can be disruptive to hospitals. Thus, we recommended that the Congress and the Secretary implement our payment policy recommendations through a transitional period so that hospitals do not face abrupt changes in Medicare payments.

CMS's second concern is that significantly expanding the number of DRGs could lead to changes in hospitals' case-mix reporting that may cause inappropriate increases in Medicare payments. We recognized in our report that major DRG refinements will affect hospitals' reporting and coding behavior in ways that could increase Medicare payments. Under the law, the Secretary has discretion to make a prospective adjustment to the national base payment amounts to offset expected increases in payments resulting from changes in hospitals' case-mix reporting. The Secretary also has the means to carry out this policy by using data from reabstracted medical records that are collected in Medicare's quality assurance program. CMS also has other tools to address this problem, such as:

- Excluding from any refined DRG secondary diagnoses (for example, history of cancer) that might be too easily used to overstate a patient's severity of illness and obtain higher payment,

- Issuing guidance to remind hospitals that diagnoses should be reported on the claim only if they materially affect the course of the patient's inpatient care, and

- Monitoring case-mix changes for individual hospitals and using the measured changes to select hospitals for review and audit of medical records and claims.

We will continue to work with CMS as it considers these and other options for mitigating inappropriate increases in payments resulting from changes in hospitals' case-mix reporting.

Changing the way CMS sets DRG relative weights

CMS raises concerns about each of MedPAC's recommendations for improving the accuracy of the DRG relative weights—using estimated costs instead of charges, calculating weights based on the national average of hospital-specific relative values (HSRV), and adjusting the relative weights for differences in the prevalence of outlier payments across DRGs. While we agree that no method of setting relative weights will be perfect, the current method is far from perfect and must be improved.

Using estimated costs—CMS notes that cost estimates for services must be derived by applying a hospital's average departmental or other cost-to-charge ratios to the associated service charges it reports on its Medicare claims. Cost measurement errors may occur because hospitals report their costs for departments that include many services with potentially different markups and

hospitals differ in the level of departmental detail in their cost reports. As a result, cost estimates may be biased in certain circumstances.

Both charge-based and cost-based relative weights will contain some error because of hospitals' charge-setting practices and the limitations of available data on accounting costs. We conclude, however, that cost-based weights would better track the true relative costliness of DRGs than charge-based weights because one large, systematic source of errors would be removed.

It is clear that hospitals' charges contain substantial error—as a basis for estimating the relative costliness of services or different types of cases—because hospitals' charge markups are highly varied both among and within hospitals.[2] In our survey of hospitals' charge-setting practices, hospitals told us that they often did not look at costs when they were setting charges.[3] Our analysis of hospitals' claims and cost reports shows that average markup levels differ substantially among hospitals. Further, charge markups show a strong pattern among hospital departments, with relatively low markups for routine and intensive care services and high markups for ancillary departments, such as radiology, operating room, laboratories, and supplies. These differences in markup levels will result in varying amounts of distortion in charge-based relative weights at the DRG level, depending on the mix of services typically used in treatment for patients in each DRG.

The available evidence also suggests that hospitals' markups often differ among services within departments. CMS correctly points out that these differences would introduce errors in cost estimates for individual services because hospitals' departmental average cost-to-charge ratios are too high for some services and too low for others. But mark-ups differing among individual services causes the same problem with charge-based weights. The difference is that in the cost-based weights, substantial differences in markup levels across departments are removed, while in the charge-based weights, they are included.

CMS also correctly notes that cost data are not as timely as charges from claims. Thus, estimated cost weights may trail changes in relative costliness more than would charge-based weights. We suggested in our report a method for recalibrating the relative weights that would mitigate the timeliness problem, and reduce the burden of annually re-estimating costs. Under that method, CMS would recalibrate the weights using cost estimates only periodically (for example, every third or fifth year). In each such year, CMS would also calculate charge-based weights and the relationships between the cost-based weights and the charge-based ones. In the intervening years, CMS would use charge-based weights, but adjust them to account for the latest available estimates of the relationship between cost and charge weights.

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[2] See, for example, "California Hospitals Open Books, Showing Huge Price Differences", Wall Street Journal, December 27, 2004, available at http://online.wsj.com/article/0,,SB110410465492809649,00.html

[3] See Worzala, C. and J. Ashby. 2004. Survey of hospital charge-setting practices. Presentation to Medicare Payment Advisory Commission meeting, September 10, Washington, DC. http://www.medpac.gov.

Calculating weights using the national average of hospital-specific relative values—In the hospital-specific relative value (HSRV) method, relative weights are based on the national average of relative values calculated within each hospital. CMS notes that a 1993 RAND study showed some evidence that charge-based weights calculated by the HSRV method were compressed—undervaluing high-cost DRGs and overvaluing low-cost DRGs. The compression observed in this study, however, may not hold today. The RAND study used sample claims data for fiscal years 1985 through 1989. If we are correctly interpreting the results, the inferred compression in the HSRV weights was not caused by the method itself, but primarily by the pattern of cross-subsidies in charge mark-ups by hospitals that performed the majority of major cardiac surgeries. Charge markups, however, were much smaller 15 years ago than they are today and cardiac surgeries were performed by a narrower group of hospitals. Thus, the same results may not hold with current data or with weights based on the HSRV method applied to estimated costs.

We view the HSRV method as an important adjunct to using estimated costs as the basis for the relative weights. Using estimated costs removes distortions in the relative weights caused by differences in hospitals' markups across departments. But the level of costs still differs, sometimes dramatically, among hospitals. The HSRV method removes distortions that arise because certain kinds of cases (sophisticated surgical DRGs, for example) are treated primarily in high-cost hospitals. The HSRV method addresses this problem by removing the effects on the relative weights of differences in the level of charges or costs across hospitals regardless of their source.

Another way to look at it is that the HSRV method is a more effective way (than the current method CMS uses) of removing the effects on the weights of differences in the level of costs or charges among hospitals. CMS's method—standardizing hospitals' charges—accounts for differences in charges that are presumed to be associated with certain payment factors included in the IPPS:

- Market input price levels as measured by the wage index and cost of living adjustment (applied in Alaska and Hawaii);
- Teaching activity as measured by the indirect medical education (IME) adjustment; and,
- Service to low-income patients as measured by the disproportionate share hospital (DSH) adjustment.

Given the known limitations of these factors (particularly that the IME and DSH adjustments are poorly related to the cost impact of teaching and treating low-income patients), standardized charges or costs are likely to be at least somewhat distorted. But even if this method worked perfectly, standardized charges or costs would still differ substantially across hospitals because of differences in hospital costliness.

Adjusting the DRG weights for differences in the prevalence of outlier payments—CMS's discussion of this recommendation suggests some misunderstanding of our proposal. The

Commission recommended that CMS reduce the relative weight for each refined DRG to reflect the estimated prevalence of outlier payments in that category.[4] This policy would replace the current policy of reducing the national base payment amounts by the estimated national average prevalence of outlier payments (5.2 percent), thereby making relative profitability more uniform across DRGs. We determined that removing the current outlier adjustment to the national base payment amounts would require legislation because this adjustment is specifically required in current law.

Under current policy, a single percentage—5.2 percent—is withheld from each DRG payment to form the outlier pool. The policy also calls for a national "fixed-loss" threshold—the amount of loss that any case must exceed to qualify for outlier payments. DRGs with high DRG weights and payment rates tend to have greater variation in costs, making them more likely to meet the threshold and trigger outlier payments. This can lead to differences in profitability across DRGs because DRGs with high weights get more outlier payments than were withheld for them in the outlier pool. DRGs with low weights get lower outlier payments than were withheld.

A related problem is that the high standardized charges for the cases paid as outliers are included in calculating the relative weight for each DRG. Including these very high charges tends to overstate the true relative costliness of typical cases in DRGs that have lots of outlier cases. The overstatement is greatest in DRGs with high weights.

Together, the current policies for financing outlier payments and calculating relative weights create differences in relative profitability among DRGs. These differences in relative profitability, in turn, create opportunities and financial incentives for patient selection and payment inequities among hospitals. Under our recommendation, outlier payments in each DRG would be financed out of the aggregate payments in the DRG. This would reduce the distortion in the relative weights that comes from including the outlier cases in the calculation of the weight and it would correct the differences in profitability that stem from using a uniform outlier offset for all cases. Thus, our recommendation would help to make relative profitability more uniform across DRGs.

Revising the IPPS through a transitional period

As we mentioned above, the estimated impact of our recommendations suggested to us the need for a transition period to cushion the impact for some hospitals that would face substantial changes in Medicare patient revenues. We also recognize that a transition from one DRG payment system to another might be complicated. We will continue to work with CMS to develop ways to mitigate the complexity and burden of a transition mechanism.

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[4] Prevalence of outlier payments is measured by the proportion that outlier payments represent of DRG payments: outlier payments divided by the sum of regular DRG payments plus outlier payment (excluding IME and DSH payments).

Critical access hospitals

On the issue of allowing critical access hospitals (CAHs) to relocate, the rule should provide CAHs with the flexibility to build a new facility within the same community when rebuilding is the most economical option.

The proposed rule states that a CAH will lose its necessary provider status (and cost-based reimbursement) if it relocates to a new location (defined as being more than 250 yards from its current site) unless the new building fulfills all of the following criteria:

- meets the same necessary provider criteria that were in place when the hospital became a CAH;
- serves the same service area;
- improves access to care; and
- was in the process of being developed prior to December 8, 2003.

The last of the four criteria will prevent virtually all CAH relocations that were not underway in 2003. Due to these criteria, a CAH may choose to remodel an aging facility even when building a new facility would be less expensive—just to retain cost-based reimbursement. In addition, the criteria for serving the same service area and improving access appear somewhat vague and cumbersome to administer.

We suggest that CMS adopt alternative criteria for relocations—that the new CAH building must be located:

- within 2 miles of the current location; or
- within 5 miles of the current location provided that the nearest hospital is more than 15 miles away.

These two alternative criteria would require the CAH to continue serving the same community and prevent it from moving significantly closer to another hospital's core market area. The criteria would be much simpler to administer and yet would provide enough flexibility so that hospital boards can find a suitable site for a new facility when new construction is more economical than renovation.

Low-volume hospital payment adjustment

By applying the same percentage adjustment to all hospitals qualifying as low-volume providers, CMS's low-volume adjustment may pay hospitals treating similar numbers of patients quite differently. We believe that a continuous adjustment (that is, one with an adjustment rate that declines as volume increases) would work better, but because few PPS hospitals are receiving

this payment adjustment, we acknowledge that developing a new payment formula will not be CMS's highest priority in the coming year.

The MMA requires CMS to develop an empirically justifiable adjustment formula based on the relationship between hospitals' costs per discharge and volume of discharges. Based on the results of a multivariate analysis, CMS last year adopted a 25 percent adjustment for all hospitals with fewer than 200 all-payer discharges. This year CMS updated its analysis of the effect of discharge volume on Medicare costs per case and also estimated the impact of volume on Medicare inpatient margins. Based on these analyses, the agency proposes to continue the formula adopted last year and to again reevaluate the adjustment based on updated data next year.

The low-volume adjustment should be based on the empirically established relationship between the number of all-payer discharges and Medicare cost per discharge. Reliance on margins analysis appears to have caused CMS to structure the adjustment such that all hospitals below the size threshold receive the same 25 percent adjustment while those above the threshold receive no adjustment. This payment "cliff" would create highly inequitable payment for a hospital with just over 200 discharges compared with one with just under that number, as well as extreme payment changes from one year to the next for a hospital whose discharge volume averages in the neighborhood of 200 discharges. We strongly suggest that CMS adopt a simple linear formula that starts with a 25 percent adjustment at the hypothetical level of one discharge and phases out at some point beyond 200 discharges. This structure, however, should not increase the aggregate level of spending CMS proposes in its NPRM.

It is not necessary to update the analysis and the formula for the low-volume adjustment every year. Measurements of the effect of volume differences on unit costs are sensitive to changes in sample size, and the number of hospitals available for analysis has been dropping steadily due to conversions to the critical access hospital program. The adjustment should reflect the long-term relationship between volume and costs, which should not change significantly from year to year.

Wage index

CMS computes a hospital wage index to adjust Medicare payments for differences in underlying wage levels across the country. A value is computed for each metropolitan statistical area (MSA) in the country and another value for all counties not in MSAs in each state. For 2006, CMS proposes few major changes from 2005 policy. We comment on two policies below.

Occupational mix adjustment

CMS proposes continuing policy from 2005, which uses a blended wage index—10 percent adjusted for occupational mix and 90 percent unadjusted. It also states that ". . . for future data collections, we would revise the occupational mix survey to **allow** hospitals to provide both wage and hours data for each of the employment categories. . ." We support collecting wage as well as hours data—doing so could make the calculation of skill mix and adjustment of hospitals' average hourly wages more straightforward and accurate, as we observed last year.

Therefore, we suggest that CMS require—not allow—hospitals to provide both wage and hours data.

Exclusion of critical access hospital wage data

CMS does not now collect wage data from critical access hospitals (CAHs), and excludes historical data for hospitals now classified as CAHs from wage index calculations. We continue to believe that CAHs should be included in the wage index.

The wage index should ideally reflect the market labor compensation rates faced by all providers offering similar services and employing similar occupations as hospitals covered by Medicare's inpatient and outpatient PPSs. CAHs are similar in these respects to other small rural hospitals, and in many cases they are located close enough to hospitals remaining under prospective payment to compete for the same workers. With five hundred hospitals converting to CAH status in just the last three years, CAHs now dominate the rural labor market in a number of states. In these cases, data from CAHs may become critical to obtaining an accurate representation of rural wage levels, and it is important to remember that this representation determines payments for several other types of providers (skilled nursing facilities, home health agencies, ambulatory surgical centers, inpatient rehabilitation facilities, and long-term hospitals) in addition to acute care hospitals. Because there is a long lag between when wage and hours data are collected and when they can be reflected in the wage index, CMS should begin to collect the required data from CAHs this year.

Hospital market basket

Section 404 of the MMA requires CMS to revise the market basket weights and the labor share in the market basket to reflect the most current data available more frequently than once every five years. CMS's past practice has been to monitor the appropriateness of the market basket every year and to rebase and revise the index when necessary. CMS's analysis shows that updating the weights more frequently than every five years would make only small differences in its market basket forecasts, and some of the data used (specifically, data from the Bureau of Economic Analysis) are only available on a five-year cycle. Consequently, the Commission concludes that updating the weights more often than once every five years is unnecessary and potentially counterproductive.

Rebasing the market basket requires CMS to devote a significant amount of resources. Given how stable the market basket numbers remain under different base year weights, it seems unproductive for CMS to rebase more often than every five years. In fact, the four-year rebasing schedule CMS proposes could make the market basket weights even more out of date due to the timing of the BEA data. For example, rebasing in a given year could dictate use of old data for the weights that will apply for the next four years, while waiting one more year to rebase would allow much newer data to be used for three of those four years.

In the Commission's view, CMS should rebase the hospital market basket in years that new BEA data become available, combining these data with the most recent Medicare cost report data

available at that time. This essentially means that market baskets would be rebased every five years, unless CMS found some other compelling reason to either revise or rebase the market basket sooner. The Secretary should propose legislation to repeal Section 404 of the MMA requiring the more frequent updating of the market basket.

Hospital quality data

In the MMA, the Congress directed CMS to reduce hospitals' update for services covered by the acute inpatient PPS by 0.4 percent if they fail to report information on the quality of patient care provided to Medicare beneficiaries. MedPAC supports the concept of the Medicare program obtaining more information on quality of care from providers, including hospitals. In our March Report to the Congress this year, we recommended that the Congress establish a quality incentive payment policy for hospitals, and this type of reporting helps build the infrastructure to implement such a program. However, Medicare should not have to financially reward or penalize providers based on whether they report data. It is reasonable for Medicare to expect, as a condition for receiving payments, that information on the quality of care be provided to beneficiaries and the program.

Nonetheless, any system for reporting quality data must ensure that Medicare is able to obtain the best and most useful information possible on hospital quality. Pursuant to that goal, we comment on CMS's proposal for ensuring the reliability of the quality data hospitals report and we suggest that this rule provides an opportunity to require hospitals to report additional data on the hospital claim form that are needed to support quality improvement initiatives.

Ensuring the reliability of quality data

For fiscal year 2005, the first year of mandated reporting, CMS required only that hospitals submit data for the 10 specified quality indicators covering the first quarter of calendar year 2004 by no later than August 1, 2004. For fiscal year 2006, CMS is proposing that hospitals must continuously submit data for the 10 measures on a quarterly basis, achieve an 80 percent reliability score on a chart-audit process, and have at least two consecutive quarters of data published.

We support CMS's efforts to review the data submitted through a chart audit process and to impose stringent standards for data accuracy. Data meeting high standards of completeness and accuracy will be essential to their use in a pay for performance system. We are concerned that a sample of five charts for each hospital may be insufficient to accurately establish the reliability of the data individual hospitals submit. But we plan to wait until the Government Accountability Office completes its analysis of the reliability of the quality data submitted to date before we consider the need for more specific comments on CMS's procedures.

Improving quality data

This rule provides an opportunity for CMS to implement another Commission recommendation that would greatly expand Medicare's ability to measure the safety of hospital care using

administrative data. In our March 2005 Report to Congress, we recommended that CMS require hospitals to identify which secondary diagnoses were present on admission on the inpatient payment claims.[5] The National Uniform Billing Committee has included a field on the UB04 to accommodate this information, and two states already require that hospitals report the information.

Adding information to the claim on secondary diagnoses present at admission would make important data available for a far wider range of quality improvement applications. For example, it would enable a quality measure to distinguish between a patient population that has a high rate of infections when they enter the hospital from a population that frequently acquires infections during their hospital stay.

We believe that either the proposed rule on conditions of participation (70 Federal Register 15266, March 25, 2005) or this rule on payment policy could provide an opportunity for CMS to implement this recommendation, and we have suggested it in both contexts.

Conclusion

MedPAC appreciates the opportunity to comment on the important policy problems and proposals crafted by the Secretary and CMS. The Commission also values the willingness of CMS's staff to provide relevant data and to consult with us concerning technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director.

Sincerely,

Glenn M. Hackbarth, J.D.
Chairman

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[5] On page 4 of this letter, we suggest that as one strategy for dealing with changes in case-mix reporting that inappropriately increase payments after the number of DRGs is expanded, CMS could exclude from any refined DRG secondary diagnoses (for example, history of cancer) that might be too easily used to overstate a patient's severity of illness and obtain higher payment. That approach involves CMS's use of secondary diagnoses in defining DRGs; it would not affect how hospitals report secondary diagnoses on the claims as discussed here.

175

Submitter : Dr. Kenneth Pettine

Date: 06/17/2005

Organization : RMA Ortho

Category : Physician

NT

Issue Areas/Comments

Issues

New Technology Applications

CHARITE Artificial Disc, see attached document

CMS-1500-P-393-Attach-1.DOC

Hefter
Hartstein
Walz
Treitel

Attachment to #393

June 17, 2005

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

Re: CMS-1500-P CHARITÉ Artificial Disc New Technology Application

This letter is a request for reassignment of the CHARITE Artificial Disc to the fusion DRG's 497/498. I am Kenneth A. Pettine, M.D., an orthopedic spine surgeon who practices in Loveland, Colorado. I have three patents on a separate artificial disc and have been working on the project of artificial disc replacement since 1992. I was among the first group of twenty surgeons in the United States to be trained on the CHARITÉ disc.

As you are aware the current treatment for a patient with a degenerative disc disease is a lumbar fusion. While lumbar fusion has benefited millions of patients, it continues to have some major drawbacks. Fusion patients face lengthy recovery periods of up to twelve months or longer and the probability of future lumbar surgery due to overloading and premature degeneration of adjacent levels associated with lumbar fusion.

The recovery period for a CHARITÉ Artificial Disc is approximately six weeks, which is a major improvement over lumbar fusion which can range up to twice as much as a disc replacement, primarily due to extended hospital stays and implant costs.

Candidates for artificial disc replacement are patients with degenerative disc disease who have good bone density and active lifestyles. Because people are continuing to be more active, health conscious, and are receiving excellent medical care, I feel the percentage of Medicare patients who qualify for artificial disc replacement will continue to rise. I also believe this surgery would be of great benefit to those people who are disable and have Medicare coverage, by allowing them the chance to possibly regain a normal life and return to work.

Because the current classification of the CHARITÉ Artificial Disc does not take into consideration the technique required for this surgery and the cost of the

implant, Medicare patients will be denied access to this technology and be forced to endure an inferior procedure such as fusion. It is my opinion, Medicare patients should be afforded this motion-preserving technology and I again ask you to consider reassigning the CHARITÉ Artificial Disc to the fusion DRGs of 497/498.

Sincerely,

Kenneth A. Pettine, M.D.

cc:
Mr. Marc Hartstein
Deputy Director of the Division of Acute Care
Centers for Medicare and Medicaid Services
7500 Security Blvd
Room C4-25-11
Mail Stop C4-03-06
Baltimore, MD 21244-1850
(410) 786-4539
Marc.hartstein@cms.hhs.gov

176

Date: 06/17/2005

Submitter : Ms. Leisa Oglesby

Organization : LSU Health Sciences Center

Category : Hospital

Q DATA

Issue Areas/Comments

GENERAL

GENERAL

Problems encountered with Vendor uploads to the CMS Data Warehouse need to be resolved prior to increasing the reimbursement or pay for performance program.

Hefter
Hartstein
C. Bodden
M. Krushat

177

Submitter : Dr. Nicholas Smedira

Date: 06/17/2005

Organization : Cleveland Clinic Foundation

Category : Physician

DRG | Gen

Heffler
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

Issue Areas/Comments

GENERAL

GENERAL

June [], 2005

VIA: ELECTRONIC MAIL

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

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

Dear Administrator McClellan,

This letter is to respectfully request that you reconsider the decision to group the new procedure code 37.41-Implantation of prosthetic cardiac support device to DRG 108 instead of DRGs 110 and 111 as proposed. The proposed DRGs will not adequately account for the cost of performing the procedure or device use that could negatively impact adoption of this important breakthrough treatment in the management of heart failure.

I served as a principal investigator on the CorCap CSD US Randomized Trial in which 7 CorCap devices were implanted at my center. In my experience, if the device is placed as sole therapy the procedure is quite similar to and utilizes similar stabilizing devices as off pump coronary artery bypass grafting. If used as an adjunct to a mitral valve procedure the additional complexity of the case is similar to adding a maze procedure to the mitral valve intervention. This supports placing the implantation of prosthetic cardiac support device in DRG 108-Other cardiothoracic procedures. Thus, 37.41 should also group to DRG 108 as well. I would be happy to discuss this with you or your staff.

Sincerely,

Nicholas Smedira, M.D.
Department of Thoracic and Cardiovascular Surgery
Cleveland Clinic Foundation
216-445-7052

178

Date: 06/17/2005

Submitter : Stan Mendenhall
Organization : Orthopedic Network News
Category : Media Association

DRG | Gen
(Hip/Knee)

Hefler
Hartstein
Brooks
Fagan
Gruber
Kelly
Hue

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1500-P-400-Attach-1.DOC

CMS-1500-P-400-Attach-2.DOC

Attachment to #400

DRG Reclassifications

Memo To: CMS

From: Stan Mendenhall
Editor and Publisher, Orthopedic Network News
orthonet@aol.com
Bus. 734.741.4710
Fax 734.741.7277

Date: June 17, 2005

Subject: Proposed DRG changes and reclassification of lower joint replacements as reported in the May 4, 2005 Federal Register

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Summary:

1. I agree with your approach and recommendations to split primary joint replacement from revision joint replacement.
2. I disagree with some of the findings and data submitted by AAOS
3. I believe that CMS should include the price of medical devices in evaluating changes to the DRG system.
4. The new knee revision ICD-9-CM procedure codes should have an "includes note" to indicate that they include both bicondylar and unicondylar knee replacements.

1. I agree that primary and revision replacements should be split into 2 different DRGs:

I have been the editor and publisher of Orthopedic Network News for 15 years. I have also provided software services to hospitals to help them manage their joint replacement programs for about 10 years. There are currently 12 hospital systems [representing 43 hospitals, with about 70,000 cases from 1991-2004] utilizing my software. These hospitals submit blinded patient data, implant components and prices paid by the hospitals for their joint replacements. These data are then used to identify trends in implant cost as well as utilization. These hospitals are considered members of the "Orthopedic Research Network."

I saw your proposal to reclassify joint replacements into separate DRGs for "primary" and "revision" lower joint replacement in the May 4, 2005 Federal Register, based on data submitted by the American Academy of Orthopedic Surgeons (AAOS), Massachusetts General Hospital, Mayo Clinic, and San Francisco General Hospital.

Although the hospitals that provided data to you are well-known in the field of orthopedics – there is no hospital in the US that performs more revision cases than the Mayo clinic in Rochester -- I would argue that this data may be skewed toward the academic medical centers, while the 43 or so hospitals in the Orthopedic Research Network may be more representative of "community hospitals" where the bulk of joint replacements are performed.

Below is a table prepared from the 43 hospital in the Orthopedic Research Network. This data confirms the variation in charges cited by CMS in their rationale for splitting revision joint procedures from primary joint procedures:

Resource consumption of Joint replacements (DRG 209), ORN, 2004

Principal procedure	Cases	Average charge	Average implant costs
81.51 Total hip	3,441	$37,683	$6,341
81.52 Partial hip	1,477	$36,950	$2,929
81.53 Revision hip	714	$48,604	$5,485
81.54 Total knee	7,111	$34,963	$5,193
81.55 Revision knee	672	$44,685	$5,559

Source: Orthopedic Research Network, 2004 discharges, 43 hospitals

The average charges per case are significantly higher for revision hips and revision knees, supporting CMS' proposal to split primary from revision joint replacements into separate DRGs.

2. I disagree with some of the findings and data submitted by AAOS:
We have concentrated on collecting implant costs for several reasons. For one thing, implant costs are hugely variable between case types and hospitals, depending on the "contracted" price that hospitals are able to negotiate and the type of system being implanted. Secondly, hospital charges are a poor proxy for cost. We have also found that supply costs are reported to Medicare through UB-82 are distorted in two ways: (a) there is a variation in the markups that hospitals charge for the medical devices that they use, and (b) there is a variation in the prices that the hospitals pay for identical medical devices. Finally, hospitals see implant costs as more of a variable cost and savings in implant costs translate directly to savings to the institution.

For this reason, we view implant costs as "cost drivers". The variation in the number and types of implant components used on a case will often have more of an impact on resource consumption than other factors, since the post-operative care of many types of joint replacements and revisions is quite similar.

We have used a different approach toward classification of revisions, which is similar to, but not identical to that proposed by the AAOS. Specifically, we believe that one of the main cost drivers in revision joint replacements is which of the patient bones must be disrupted in order to perform a revision. For example, as was pointed out in the proposed rule, a liner, head, or patella exchange are relatively low in resource consumption, while

those cases requiring all of the components for a revision knee will be more resource consumptive. We believe that the higher resource consumption for complete knee revisions are because of both higher component costs and the more challenging surgical technique, since the femoral shaft, pelvis, tibia and femur will be disrupted. This surgery may create voids in the bones which may require bone grafts and substitutes to make up for the bone that is lost during the removal of the implant components.

In the proposed rule of page 23326, you state that "Among revision knee replacement procedures, patients who underwent complete revision of all components had longer operative times…., and significantly higher resource utilization, according to studies conducted by the AAOS. Revision of the isolated/modular tibial insert component was the next most resource-intensive procedure, and primary total knee replacement was the least resource-intensive procedures studied."

According to 2004 data from the Orthopedic Research Network, our experience is different than that provided by AAOS:

Resource consumption of knee revisions, ORN, 2004

Replaced femur? 	Replaced tibia? 	Replaced insert? 	Replaced patella? 	Cases	Average charge	Implant costs
Yes	Yes	Yes	Yes	157	$55,397	$8,727
No	No	Yes	No	143	**$33,682**	$1,448 L
Yes	Yes	Yes	No	82	$56,497 H	$9,633 H
Yes	No	Yes	No	55	$36,363	$5,647
No	No	Yes	Yes	45	**$33,565**	$2,546
No	No	No	Yes	27	**$24,066 L**	$2,073
No	Yes	Yes	Yes	19	$46,131	$10,845
Total primary knee				*6,531*	*$33,451*	*$4,778*

**Note: Total knees exclude bilateral knees assigned to DRG 471
Source: Orthopedic Research Network, 2004 discharges, 43 hospitals

In contrast to your statements, our data indicates that the most resource intensive (charges) were revisions involving both femur and tibia, and least were those involving the patella or insert exchanges. The least resource consumptive were those involving a patellar replacement only ($24,066).

Resource consumption of hip revisions, ORN, 2004

Replaced femoral stem? 	Replaced femoral head? 	Replaced Acetabular Shell 	Replaced Acetabular Liner 	Cases	Average charge	Implant costs
No	Yes	No	Yes	137	$32,176 L	$2,478
No	Yes	Yes	Yes	124	$44,247	$4,894
Yes	Yes	Yes	Yes	121	$67,428 H	$9,665 H
Yes	Yes	No	Yes	65	$61,160	$7,537
Yes	Yes	No	No	59	$55,754	$7,512
No	No	No	No	48	$40,151	$1,812 L
No	No	Yes	Yes	35	$43,926	$4,253
No	Yes	No	No	33	$42,403	$3,247
No	No	No	Yes	27	$39,442	$1,937
Yes	No	No	No	21	$64,006	$9,687 H
Yes	Yes	Yes	No	21	$57,617	$7,660
Total primary hip				*3,441*	*$37,683*	*$6,341*

Source: Orthopedic Research Network, 2004 discharges, 43 hospitals

A similar profile is evident for revision hip replacements. As can be seen the highest resource consumption (charges) is for revisions in which the femoral stem, head, shell, and liner were replaced, while the lowest consumption were for cases in which only the femoral head and liner were replaced. These "minimal" revisions were also the most frequently occurring cases in cases assigned 81.53 as a principal procedure. The lowest implant costs were associated with those cases in which none of the usual hip implant components were replaced (these could have been revision using bone graft, cable, or other misclassified components) and the highest were those in which the femoral stem or all components were replaced. (The high implant costs ($9,687) associated with the "femoral stem only" components were largely those for oncology cases in which a hip stem was replaced along with components used in the knee.)

In summary, the disparity in resource consumption which is based on patient charges is largely explained through variation in individual components used in joint replacement. The more parts that are replaced, the more the direct costs to the hospital, and generally the higher the charges are to Medicare. Reimbursing revisions of simple head and/or liner exchanges in hips, and patellar/insert exchanges may be over-reimbursing for these cases, and under reimbursing primary hip and knee procedures, where the number of components is greater, and more costly.

There are significant differences in some of the prices of the specialty components that are used in limb salvage surgery (generally oncology), and major differences in the prices of hinged knee/revision knee components from primary knee replacements. However, it

is not realistic to expect the hospitals to submit, or for Medicare to administer a program which requires the submission of part numbers to separately identify these components.

3. I believe that CMS should include the price of medical devices in the evaluation of DRG changes:

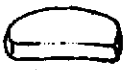
One of the constant themes in the comments provided to CMS in determining reimbursement to hospitals over the last 20 years has been the attempt by device and drug manufacturers to "lobby" for their specific DRG. They have tried to ensure that hospitals are paid sufficiently to justify the prices that the drug and device manufacturers charge to hospitals. I would urge CMS to consider the collection of price information from device manufacturers and other independent parties in order to verify the impact that device costs have on Medicare's budget. Since many of the device manufacturers are quite profitable, I believe that it is in the taxpayers' interest to ensure that Medicare is not overpaying device and drug companies through the hospital payment system. Although many manufacturers would argue that their device represent a relatively small portion of Medicare's cost and has improved the lives of many of these recipients, my fear is the profitability of these can drive sales and lead to inappropriate hospitalizations, surgeries, and utilization of resources. One can find data that suggests that the sales commissions for some implantable medical devices exceed the payment that Medicare gives to surgeons for implanting them. This may, in fact, lead to inappropriate surgeries, and hence, decrease the quality of life for the recipients, who may be marginal candidates for some of these devices in the first place.

4. Unicondylar (or unicompartmental) knee replacement

Unicondylar knee replacements replace one-half the knee (either medial or lateral condyles). Their design is similar to that of bicondylar knees in that they have a femoral component, a tibial component, and an insert:

Unicondylar femoral component

Unicondylar base component



Unicondylar tibial insert

In some hospitals reviewed by Orthopedic Network News, unicondylar knee replacements account for almost 25% of the knee replacements performed, although nationally, unicondylar knees represent about 4% of all knee replacements, and probably significantly less in the Medicare population. Currently there is no difference between the ICD-9-CM coding for bicondylar and unicondylar primary and revision knee replacements which are both assigned to ICD-9-CM 81.54 and 81.55. According to the most recent survey conducted by *Orthopedic Network News*, the average manufacturer list price for a unicondylar knee was $4,406 compared to $7,363 for the components of a cemented bicondylar knee replacement. One manufacturer (Zimmer/Centerpulse) also

markets a "Unispacer" which is basically a tibial base component with a list price of about $3,400.

According to the Orthopedic Research Network, a number of unicondylar knee replacements may be revised to total knees, or they may replace some of the components that have worn or become dislodged. Therefore, it would be helpful to have an "Includes note" for the new revision knee procedures to indicate that the code includes replacement of unicondylar components as well as bicondylar components.

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Date: 06/17/2005

Submitter : Mr. Paul Beach
Organization : Quallion LLC
Category : Device Industry

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Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-1500-P-401-Attach-1.DOC

Attachment to #401

QUALLION LLC

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

Implantable Rechargeable Li Ion Batteries for Cardiac Rhythm Applications

Comment

June 17, 2005

Prepared by:
Paul M. Beach

In reviewing the following document, the reader should consider the following key points:

- Li ion is now the predominant rechargeable chemistry in the commercial market (p.1)
- Rechargeable batteries have been used in pacemakers in the past (p.4) and are now being used in neurostimulation applications
- Patient care issues with rechargeable batteries are largely similar to those faced by primary chemistries (p.5)
- Batteries can be reasonably sized to allow for a 15-20 year device with a 6 month to one year recharge regime (pp.5-6), thereby greatly r educing the number of replacement implants
- Recharging times may be as short as 20 minutes and at the longest 2 hours (p.6)
- Discharge curves for lithium ion are highly reliable and predictable, allowing for more precise end of life detection capabilities (pp. 5-6)
- Wireless communication capabilities will allow for fuel gauge notification to doctors, mitigating concerns over patient recharging (p. 6)
- State-of-the-Art (SOA) lithium ion technology can delivery over 3000 cycles (at 40% DOD) over two years time and still have 92% retained capacity (pp.6-8)
- SOA lithium ion technology showing improved calendar fade of 20% after two years at 100% state of charge (pp. 8-9)
- SOA lithium ion technology demonstrating recoverable self discharge of 6.7% after two years of storage (pp. 9-10)
- SOA lithium ion technology has demonstrated 75% retained capacity after 104,000 40 joule pulses (pp. 10-11)
- New lithium ion technology allows for deep discharge of battery without impacting performance (pp. 11-12)
- New lithium ion technology enhances safety (pp. 12-13)

IMPLANTABLE RECHARGEABLE LI ION BATTERIES FOR CARDIAC RHYTHM APPLICATIONS

Paul M. Beach

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ABSTRACT

With the expanding use of implantable medical devices, there is an increasing demand for long lasting implantable batteries to improve performance, enhance capabilities and ultimately reduce costs. Thus far, the majority of implantable batteries have been primary cells. With demands for more energy and other improvements such as longer life and smaller size, however, the merits of a rechargeable battery system have become more evident. An implantable power source for medical applications should have the following characteristics: hermeticity, high safety, long cycle life, long calendar life and low self-discharge. For neurostimulation applications, devices require low currents at the microampere to milliampere level. On the other hand, in most cardiovascular applications, more power is necessary, and high rate pulses of ampere-level currents may be needed. Quallion LLC has designed and tested rechargeable Li ion cells to meet all of these requirements.

INTRODUCTION

A. A Short History of Li ion Chemistry

Pioneering work for the lithium battery began in 1912 by G. N. Lewis but it was not until the early 1970's when the first non-rechargeable lithium batteries became commercially available. Lithium was considered an ideal candidate for batteries as it is the lightest of all metals, has the greatest electrochemical potential and provides the largest energy content. Rechargeable batteries using lithium metal as the negative electrodes (anode) are capable of providing both high voltage and excellent capacity, resulting in an extraordinary high energy density.

For many years, the Nickel Cadmium (NiCd) was the only suitable battery for portable applications such as wireless communications and mobile computing. In 1990, the Nickel Metal Hydride (NiMH) and Lithium Ion (Li ion) emerged as competing chemistries, each offering higher capacities and claiming better performance and smaller sizes.

In 1991, the Sony Corporation commercialized the first Li ion battery designed in part by Dr. Hisashi Tsukamoto. Today, Li ion has supplanted all other chemistries to become the dominant chemistry for most commercial applications. Li ion is currently the gold standard for all laptop, cell phone and PDA applications. In addition, due to enhancements in rate capability, Li ion is now being utilized in high power applications such as power tools, electric bikes and HEVs. In total, over 1.5B cells are produced annually for sale in the mainstream markets.

B. Adaptability of Li ion for Use in Medical Implants

The number of implantable medical devices has increased rapidly in recent years, with some sectors seeing a 30% growth rate. In 2005, the sales for pacemakers and implantable cardioverter defibrillators (ICDs) alone is expected to exceed $6.8 billion, representing a combined total of over 1M pacemakers and ICD implants. To date, primary chemistries have served as the predominant power source for such devices, with specifications typically indicating a useful life of up to 7 years for the batteries. Studies have shown, however, that in real usage, these primary batteries are lasting an average of only 3-5 years, depending on battery performance. This high rate of replacement, combined with an increasing demand for more powerful medical devices, has created a "power gap" that primary chemistries will be pressed to close, even if cell size is increased. This "power gap" is being addressed, however, through the use of commercial lithium ion rechargeable technology.

Using rechargeable batteries to power implants is not novel. Some thirty years ago, nickel-cadmium (Ni-Cd) cells were introduced into the pacemaker market. Some of those patients are believed to still be alive today using their original devices with a working Ni-Cd cell. If they had decided to use a device with a primary battery, those patients could have had up to 10 additional operations since their initial implant. Ni-Cd cells were limited in power and energy density, and ultimately, primary batteries became the de facto norm for the industry. Li ion cells have greatly improved upon Ni-Cd cells in these respects and offer a compelling alternative to primary batteries.

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To date, lithium ion has played a relatively minor role in the implantable medical device market. This may be due, in part, to patient concerns. Can a patient be relied upon to recharge the device in a timely manner before the battery reaches end-of-life? Will a patient be willing to accept a charging requirement? What are the liabilities associated with a failure to charge the battery in a timely manner? Other concerns are technical. What is the cycle life, calendar fade and self discharge of the battery? What happens if the battery over discharges? While valid questions, they are not insurmountable. Indeed, many of these issues were and remain just as relevant to primary chemistries. And just as these issues were addressed satisfactorily for primary chemistries, solutions exist for lithium ion.

1. Patient Care Issues

A fundamental issue for using a rechargeable battery in a life sustaining application is recharging the battery's energy before it is fully depleted. In effect, once a rechargeable battery has fully discharged, it has reached its end-of-life (EOL) (this is to contrast the general industry understanding of "end-of-life" which is reached after a certain number of cycles is achieved). This EOL issue is not exclusive to rechargeable batteries, primary batteries also have an EOL. The solution to date has been to predict a battery's EOL by monitoring, in most part, the cell voltage. Once a certain voltage is reached, an EOL indicator is triggered, alerting the doctor that the device needs to be explanted. Using this same method, lithium ion can provide a much more reliable discharge curve for predicting EOL than primary chemistry systems. Unlike most primary chemistries that have a flat discharge profile until the very end of life, lithium ion tapers over time. The figure below shows the standard charge of a lithium ion chemistry:

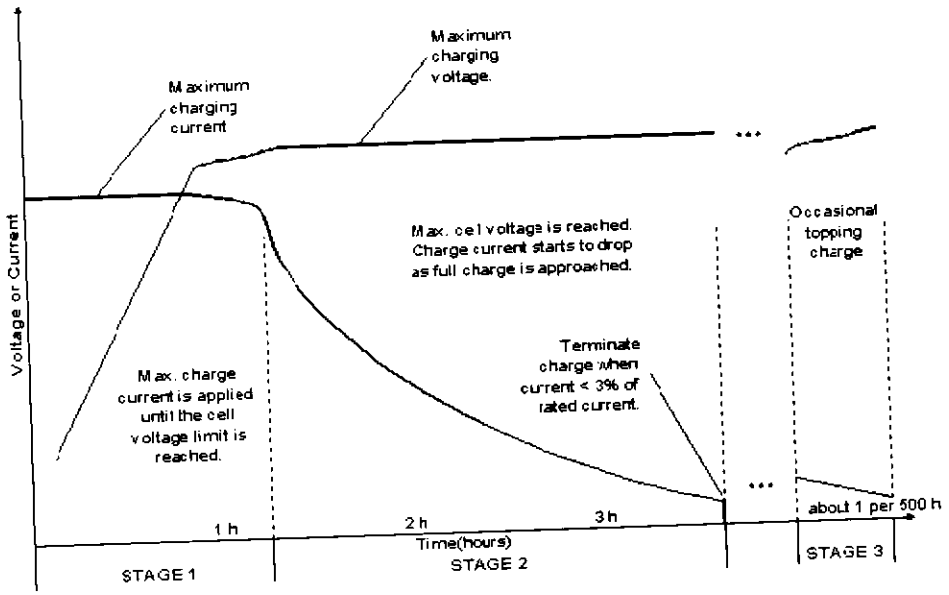

Figure 1: Standard charge stages of a Li-ion Battery.

Such a discharge profile allows for high fidelity battery management capabilities for measuring remaining capacity. These technologies are widely used today in commercial devices (e.g. laptops) to provide precise fuel gauges that inform the user of not only the remaining percentage of capacity, but also remaining time of use.

As for patient acceptance of a recharge, this has become less of a concern as shown by the growing patient population in the neurostimulation field using rechargeable batteries. Moreover, lithium ion could be sized to allow for a recharge once every 3 years, thereby equating to the current primary batteries. Yet, instead of the cost and burden of another

operation to replace the device, the patient would simply have to recharge the device. On the other hand, companies may wish to take advantage of the ability to shrink the size of the battery packaging. In doing so, the patient will be required to recharge the device more frequently, perhaps once every 6 months during their regular check up. The battery could be sized accordingly so that recharges last approximately 15-30 minutes. When compared to a replacement explant every 3-5 years, the option of a recharge once every 6 months over the course of 15-20 years would appear a reasonable option (particularly when considering that these devices are being implanted in children and young adults).

Finally, rechargeable batteries could be used to mitigate potential liabilities associated with battery failures. Device manufacturers recently introduced wireless telemetry to allow for realtime connectivity to the patient's doctor's office. Such devices could be set to alert the doctor and patient to a low battery. Using lithium ion, with its highly reliable and predictable chemistry, would be ideal under these circumstances. In the end, the quality of life issues and reduced cost associated with using lithium ion in a pacemaker and/or ICD greatly outweigh any concerns with recharging.

2. Technical Issues

When assessing the merits of a Li ion rechargeable system for a medical implant, it is critical to examine three key parameters: cycle life, calendar life and self discharge. In addition to these factors, pulsing or rate capability must be evaluated specifically when looking at a rechargeable battery for an ICD. Underpinning all of these issues is reliability and safety. Advancements in Li ion technology have enhanced all of these characteristics to the point where Li ion is not only a viable alternative to primary batteries, but in some applications, is superior.

a. Cycle Life

Typical cell phone and laptop applications call for a 500 cycle life requirement. This "industry standard" may be more than sufficient for some applications (e.g., cardiac applications), and deficient in others (e.g., neurostimulation). In general, however, the robustness of a rechargeable chemistry's cycle life is indicative of its other performance characteristics, such as calendar fade and self discharge which are critical for all medical applications. Quallion specifically designed a long-life chemistry for use in medical implants.

The chart below shows the accelerated cycle performance of this chemistry. Cells were cycled at various conditions, to determine their cycle life performance at 37°C. For this test a 200 mAh cell was tested. The cells were cycled to various depths of discharge (DODs): 20%, 40%, 80%, and 100%. For all DODs, the cells were charged to 4.1V with constant current at a 0.5C rate, and then a constant voltage charge at 4.1V till a 0.05C cutoff current. Then, for 100% DOD, the cells were discharged to 2.5V at a 0.5C rate. This cycle of charge and discharge was repeated at 37°C. At every 100 cycles, a full capacity check was performed for all cells at room temperature. Similarly, the cells tested at other DODs were cycled at 37°C, however, the discharge conditions were

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different. Instead of discharging completely to 2.5V, the discharge of the cells was stopped at the different DODs, as specified: 20%, 40%, 80% and 100%

Data for the intermediate capacity checks of the cells at every 100 cycles is plotted and shown in Figure 2. The capacity retention for each type of DOD is shown in Table 1. It is evident that using lower DODs greatly improves cycle life performance and capacity retention for the cells. Even by using a DOD of 80% versus 100%, the capacity retention of the cell can be improved from 76.5% to 88.6% retention after about 2100 cycles.

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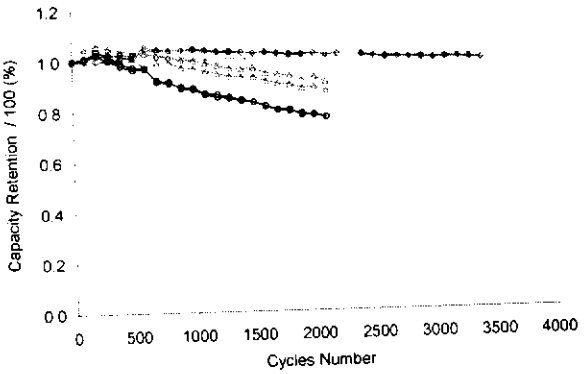
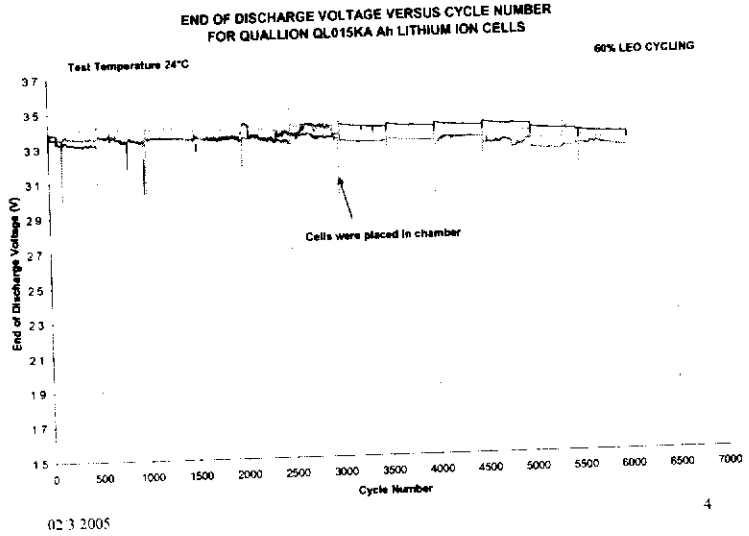


Figure 2. Cycle life of 200mAh cells cycling at 37°C at different depth of discharges (DODs): 20% (diamonds-◇), 40% (squares-□), 80% (triangles-△) and 100% (circles-○).

DOD (%)	Cycle Number	Capacity Retention (%)
20	3700	97.5
40	3700	92.5
80	2100	88.6
100	2100	76.5

Table 1. Capacity retention for cycle life at different DODs.

Even longer cycle life testing has been demonstrated in Quallion's satellite batteries utilizing the same chemistry:



Based on this performance, with proper sizing, a rechargeable battery for a pacemaker or ICD would be capable of thousands of cycles prior to EOL. Assuming a recharge regime of once over 6 months, such a battery would certainly outlast the patient. Indeed, other components such as leads would then become the determinant for explant.

b. Calendar Life

For some low-rate applications with less frequent cycling, such as pacing or ICDs (assuming a conversion is not attempted), performance can be evaluated more accurately by calendar life than cycle life. Calendar life, or calendar fade as it is also known, is defined as the irreversible loss of capacity that occurs in a rechargeable battery over time, regardless of cycling. As most commercial applications anticipate a battery's useful life to be less than 5 years, technology was not developed to address long-life applications. Quallion's chemistry, however, has been engineered to last for 15-20 years (a typical low earth orbit satellite specification calls for a 15 year useful life).

The calendar life testing summarized below was performed at 37°C. For these tests, a 200mAh cell was used. Cells were stored at 37°C at 100% state of charge (SOC), in this case at 4.1V. This tested the calendar performance of the cells considering the worst-case scenario, where the cells are stored continuously at the highest potential they are cycled to. In real use, the cells would most likely not be stored continuously at such a high SOC, rather, they would be cycling between 2.5 and 4.1V (calendar fade degradation lessens at lower voltages). In order to gauge the capacity retention of the cells while stored in this condition, the capacity of the cells was checked every month by use of a standard cycle from 2.5 to 4.1V at room temperature. The results are plotted in Figure 3, with capacity retention versus storage time, showing data after 23 months. This data

closely follows a logarithmic trend, fitting with an R^2 value of about 0.85. By extrapolation of the logarithmic fit, it is expected that the cells will have over 60 % retention after 6 years of storage at 37°C.

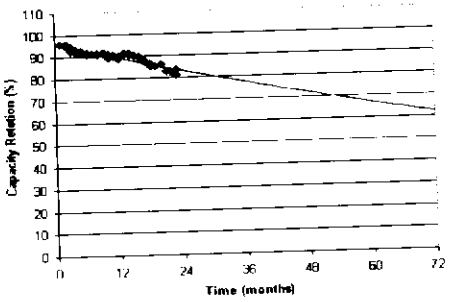


Figure 3. Calendar life of 200mAh cells stored at 37°C at 100% state of charge (4.1V).

Assuming a pacing or ICD would not be maintained at 100% SOC, the calendar fade would be significantly less than that demonstrated in the above-referenced test, thereby extending an implant's expected battery life to 15-20 years.

c. Self Discharge

Self-discharge behavior becomes important for cases where the battery will be stored for long periods of time between discharges. For example, self-discharge should be minimal for an ICD power source, since most of the time, the battery is performing maintenance and sensory operations which require very little energy. Whenever a pulse therapy is needed by the patient, the battery should have available capacity to discharge energy quickly to charge the capacitor of the device. Li ion cells show very good self-discharge results in addition to the good long term storage performance.

Figure 4 shows data from a 200mAh cell fully charged at 4.1V and then stored at 37°C. The voltage was checked at various intervals, and after 23 months the voltage had slowly dropped to 3.998V. The following plot (Figure 5) shows a very slow (C/200) discharge of a similar cell. At C/200, the voltage profile closely approximates the open circuit voltage (OCV) of the cell. Therefore, one can correlate the amount of capacity discharged to the cell OCV. This voltage corresponds to a self-discharge of about 6.7% of the cell capacity. Taking into account an approximate 80% capacity retention based on storage data for two years, if left fully charged, the cell would have approximately 73 % capacity retention after about two years of storage fully charged at 37°C. Since the capacity loss due to storage at high temperature can be approximated by a logarithmic fit, further loss of capacity after the first year would be much less.

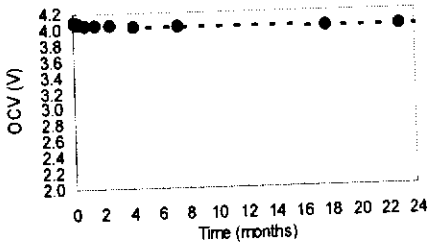


Figure 4. Voltage profile of a cell stored at 37°C, charged to 4.1V. The OCV of the cell was measured periodically.

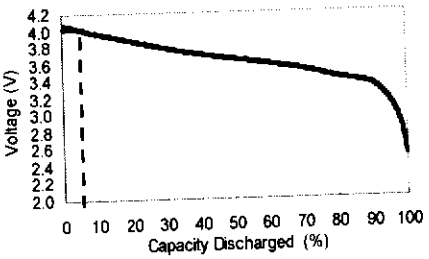


Figure 5. Voltage profile of a cell discharge at C/200 rate. After 6 months storage at 37°C, the OCV decreases to 4.0V, corresponding to 5% capacity discharged.

d. Pulsing Capability for ICDs

Typical Li ion commercial applications require a relatively low rate of discharge. These rates are acceptable for most medical device applications. ICDs, however, require 1.5—2 Ahr discharge pulses in under 10 seconds. Such high rates would tend to degrade the performance of a standard Li ion cell. To address this issue, Quallion designed a high rate cell for ICDs.

A 165mAh cell was tested for its ability to discharge pulses many times over by doing pulse cycling. The cell was tested by a protocol with characteristics for an ICD application. The cell was charged at 30mA to 3.8V, followed by constant voltage charge with a 7mA cutoff. After 5 minutes rest, it discharged 4 pulses at 1.3A (to get approximately 40J energy per pulse) with 10 second pulses alternating with 10 second rests. After resting 5 minutes, the charging to 3.8V was repeated. The cell was repeatedly cycled in this manner at 37°C. Periodically, the capacity of the cell was checked using a standard cycle protocol. Figure 6 shows a voltage profile of the cell during the four pulse sequence. Figure 7 shows the amount of energy per four pulses delivered over 26,000 cycles, which corresponds to over 104,000 pulses. Even after thousands of cycles, the cell is still capable of delivering 160 J per four pulses, just as it did at the beginning of life. Moreover, the pulsing has not impacted cycle performance as the cell maintained most of its initial capacity during a full discharge.

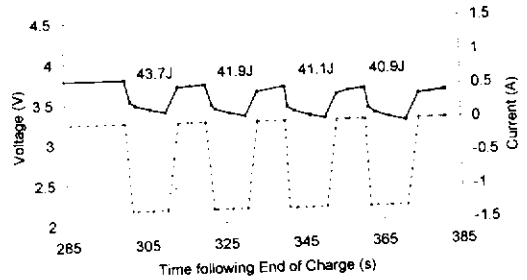


Figure 6. Four pulse discharge profile, voltage (solid line) and current (dashed line) shown. Energy for each pulse is also shown above each pulse.

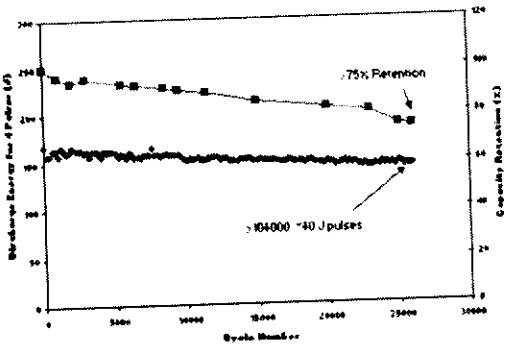
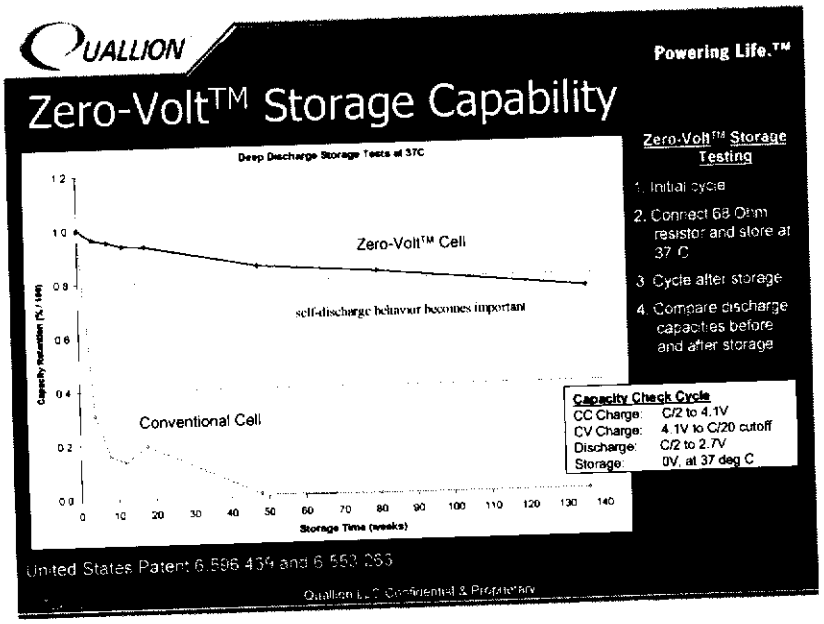


Figure 7. Cycle life data at 37°C for 4 pulse discharge. Discharge energy shown as sum of each set of 4 pulses. Also shown is the capacity retention for a full cycle of the cell.

e. Reliability

Conventional Li ion batteries cannot survive a deep discharge to low voltages. Capacity retention will suffer once the battery voltage drops below approximately 2 volts. Consequently, Li ion cells are typically discharged to 2.6 volts at which point the battery management c ircuit w ill cut-off t he discharge. D uring prolonged storage (which can occur in an implant that is not recharged), a discharge below this voltage level is possible due to calendar fade and self discharge. To mitigate this possibility, Quallion has designed a cell that can be fully discharged to zero volts without impacting performance.

The results of this effort are shown in Figure 8 where capacity degradation is presented as a function of storage time at zero volts at 37°C. The batteries were discharged to 2.5V and then connected to a resistive load to further discharge the battery down to zero volts. The batteries were stored at 37°C and were "awakened" periodically to check the full capacity. This capacity retention is plotted versus storage time at zero volts. Unlike conventional batteries, the Quallion Zero-Volt™ shows no degradation due to the zero volt condition (the degradation is due to calendar fade).



f. Safety

To reduce the risks associated with Li ion batteries, Quallion has focused on two fault mechanisms that comprise the greatest risk for battery failure. The first fault mechanism occurs when a battery develops an internal short circuit which cannot be resolved with external safety devices such as PTCs or battery management circuits. Such internal shorts typically develop from dendritic growth of Lithium caused by an electrode containing a form of impurity, such as iron. Lithium deposition and dendritic growth occur on the iron particle instead of intercalating into the electrode, posing a risk of a short. The second fault mechanism occurs when a battery develops a leak during usage and the leaking electrolyte corrodes the surrounding electronic circuits, resulting in a malfunctioning battery management circuit. The failed circuit can result in a battery overcharge and eventually a thermal run away situation.

i. SaFE-LYTE ™ Electrolyte System

Much effort has been made to improve the safety of the non-aqueous electrolyte system used in most Li ion batteries. Much of this previous work has focused on the use of flame retardant additives in the battery electrolyte. The flame retardant additives, when added to the electrolyte, reduce the electrolyte's flammability. While these technologies have contributed to advanced battery safety to some extent, none of them are widely used due to the resulting degradation in battery performance at elevated temperatures. The flame retardant additive, which is mixed into the electrolyte, tends to become spontaneously reactive at high temperature with the charged electrolyte, and in most cases it significantly reduced battery storage or operating performance over 40C and in some cases, it even worsened safety because of its exothermic reactivity. Quallion's new approach to the flammable organic electrolyte issue departs from this previous body of

work. Quallion's SaFE-LYTE ™ solution calls for the introduction of a liquid halogen compound into the battery which is a flame retardant material and substantially immiscible in the electrolyte. By adding this flame retardant, yet immiscible liquid into the battery, Quallion succeeded in achieving enhanced battery safety without compromising electrochemical performance.

ii. He/GC-MS Micro-Leak Test

For battery and capacitor manufacturers, it is of utmost importance from a safety and reliability standpoint, that the product case be properly sealed. A variety of commercially available leak testing apparatus and methods exist that attempt to measure leak rates including electronic sensors, helium leak detectors, pH measurement devices and visual inspection. Electronic sensors typically have detection limits in the parts per ten thousand ranges and are usually complex and not practical for high volume processing. High-end helium leak detectors have detection limits of 10^{-10} cc-atm/sec. However, if the leak opening is greater than the helium atom, but smaller than the molecules of the leak component of interest, helium easily escapes the product container and the test results in a false negative. On the other hand, if there is a gross leak and the He escapes before testing, results will show false positives. Another method measures chemical behavior that can be differentiated along the pH scale. This method is qualitative and limited to small families of chemicals that are pH sensitive. Finally, the traditional method of visual inspection, either by the naked eye or through optical microscope, is magnification and speed limited. For example, the conventional visual inspection method involves placing batteries in a controlled temperature environment for several days or weeks. Signs of leakage would typically show as marks of residual chemical corrosion on the surface of the battery case emanating from the leakage point. In mass production, this method is labor +intensive and not conclusive as the test results are very subjective.

Quallion has developed a new technology called the He/GC-MS Micro-Leak Test. Quallion uses this process to test for all manner of leaks, but specifically allows for the detection of micro-leaks in high volume operations. The method is a combination of helium leak test and direct solvent detection by GC-MS (gas chromatography and mass sector) analysis. The current standard for Quallion's leak test is less than 2ppm. In applying this method to commercially available batteries such as prismatic cell phone batteries and cylindrical lap top computer batteries, all evidenced one to two orders of magnitude of higher leakage. The leakage rates were also found to be very inconsistent, even amongst similar models.

#180

Date: 06/09/2005

Submitter : Mr. James Rainey

Organization : Mr. James Rainey

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1500-P-206-Attach-1.PDF

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Hefter
Hartstein
Kealey
Miller

VIA ELECTRONIC & HAND DELIVERY
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1500-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS – 1500 – P; Retroactive Wage Index Data Corrections for October 1, 2004 – December 31, 2004

INTRODUCTION

Baker & McKenzie LLP, on behalf of the following hospitals listed below and located in Palm Beach County, Florida, is pleased to submit these comments on the above referenced proposed regulation for the Medicare hospital Inpatient Prospective Payment System ("IPPS") governing the fiscal period October 1, 2005-September 30, 2006 ("FY 2006"):

- JFK Medical Center
- Palms West Hospital
- Columbia Hospital
- St. Mary's Medical Center
- Delray Medical Center
- Good Samaritan Medical Center
- West Boca Medical Center
- Bethesda Medical Center
- Glades General Hospital
- Boca Raton Community Hospital
- Jupiter Medical Center
- Wellington Regional Medical Center (collectively, the "Palm Beach Hospitals").

On May 4, 2005, the Centers for Medicare and Medicaid Services ("CMS") published the proposed regulation governing IPPS for FY 2006. As part of these proposed rules, CMS proposes, in the preamble, to allow for a retroactive correction to an error in the wage index data affecting certain hospitals for the period covering October 1, 2004 through December 31, 2004.[1] The proposed, one time, retroactive correction does not, however, address the

[1] 70 Fed. Reg. 23306, 23384 (May 4, 2005). The correction is proposed to affect four hospitals.

circumstances of the Palm Beach Hospitals listed above. The Palm Beach Hospitals should be included in the proposed retroactive adjustment because, as described, below, the circumstances of the Palm Beach Hospitals is similar in all material respects to that of the hospitals to which the retroactive correction is being made.

Briefly, CMS made an error in tabulating the wage index data for Palm Beach County when it incorrectly categorized St. Mary's Medical Center ("St. Mary's"), one of the Palm Beach Hospitals listed, above, as a hospital in the Miami-Dade County core based statistical area ("CBSA") in the IPPS final rule for the period October 1, 2004 – September 30, 2005 ("FY 2005") (the "Error").[2] St. Mary's (Medicare Provider Number 100288) is actually located in Palm Beach County and in the West Palm Beach CBSA.

The Error had the effect of improperly and incorrectly lowering the wage index for Palm Beach County, in which St. Mary's is physically located, and inflating the wage index for Miami-Dade County, in which it is not. In December 2004, CMS corrected the Error prospectively for the period beginning January 1, 2005.

The Error clearly was the result of a clerical mistake by CMS. Additionally, the Palm Beach Hospitals could not have known of the Error prior to the release of the IPPS rules for 2005. The Palm Beach Hospitals informed CMS upon learning of the Error before October 1, 2004, and prior to that date, CMS clearly recognized that St. Mary's is a hospital located in Palm Beach County. Therefore, as with the hospitals for which CMS proposes to correct a mistake in the FY 2005 wage index retroactive to October 1, 2004, CMS should also correct the wage index for the Palm Beach Hospitals listed above, retroactive to that same period.

DISCUSSION

A. Proposed Regulation

In the proposed IPPS rule, CMS proposes to revise its current regulation located at 42 C.F.R. § 412.64(k)(2) which allows for a midyear, prospective correction to a hospital's wage index data under certain circumstances.[3] The proposed regulation would allow for a retroactive adjustment to the wage index to the beginning of the Federal fiscal year under the following circumstances:

(1) the fiscal intermediary ("FI") or CMS made an error in tabulating a hospital's wage index data;

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[2] *See* 69 Fed. Reg. 48916 (Aug. 11, 2004).

[3] CMS's rules currently provide that CMS makes a midyear correction to the wage index for an area "only if a hospital can show that (1) the intermediary or CMS made an error in tabulating its data; and (2) the hospital could not have known about the error, or did not have the opportunity to correct the error, before the beginning of the federal fiscal year." 42 C.F.R. § 412.64(k)(1).

(2) the hospital informed the FI or CMS, or both, about the error following the established schedule (which is at least before the beginning of the Federal fiscal year to which the rule applies) and process for requesting corrections to its wage index data; and

(3) CMS agreed before October 1 that the FI or CMS made an error in tabulating the hospital's wage data and the wage index should be corrected.[4]

Most importantly, the preamble to the proposed rules states that CMS proposes to apply these same criteria to make a retroactive correction to the wage index data of certain hospitals for FY 2005.[5] According to the preamble, CMS previously corrected the error that affected those hospitals in the corrections to the IPPS rule for FY 2005 that it published on December 30, 2004 for the period January 1, 2005 – September 30, 2005. 70 Fed. Reg. 23306, 23384 (May 4, 2005). CMS now proposes to correct that error retroactive to October 1, 2004.[6]

B. The Error by CMS

St. Mary's is a hospital that is physically located in Palm Beach County. The wage index public use file ("PUF") posted on CMS's website on May 13, 2004, correctly identifies St. Mary's as a hospital included in Palm Beach County. Thus, the data in the PUF that were available to the Palm Beach Hospitals during the period in which they would be expected to bring errors to the attention of CMS and/or the FI showed St. Mary's as being located in the correct county. *See* Exhibit A. The Error was made in the final rule, which erroneously included St. Mary's wage data in the Miami-Dade County CBSA. Consequently, the first opportunity that St. Mary's and the other Palm Beach Hospitals had to bring the error to the attention of either CMS or the FI occurred after the publication of the FY 2005 IPPS final rule.

Because it was correctly listed in the May 11, 2004 PUF as being located in Palm Beach County, St. Mary's did not have a reason to follow any established procedure for correcting mistakes and errors. The process for resolving substantive wage index data corrections is

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[4] Proposed 42 C.F.R. §412.64 (k)(2), 70 Fed. Reg. at 23461.

[5] 70 Fed. Reg. at 23384.

[6] CMS proposes to do so under what it describes as its discretionary authority under the Section 903(a) of the Medicare Modernization Act, stating that the failure to apply such a correction would be contrary to the public interest. Similarly, the failure to correct the Error retroactively for the Palm Beach Hospitals would be both unlawful and contrary to the public interest.

primarily intended for errors that are identified before the publication of the IPPS final rule in August of each year. Here, the Error was made in the final rule, itself.

Upon discovering the error, the Palm Beach Hospitals, through their representative, Ernst & Young ("E&Y), notified CMS of the Error in a letter dated September 20, 2004. *See* Exhibit B. On the same date, representatives of E&Y also spoke with CMS by telephone, to verbally communicate the Error and to request an immediate correction.[7] In response, CMS by telephone, indicated that it was unable to correct the Error by October 1, 2004, the effective date of the FY 2005 IPPS final rule.

CMS clearly was aware, prior to October 1, 2004, of the fact that St. Mary's is located in Palm Beach County. In a letter, dated August 30, 2004, from CMS to E&Y responding to E&Y's request for a list of hospitals located in Palm Beach County, CMS correctly identified St. Mary's as such a hospital.[8] *See* Exhibit C; *see also* the May PUF data at Exhibit A. Thus, it is clear that CMS was aware of the Error by September 20, 2004.

CMS did not correct the Error by October 1. Rather, CMS corrected the Error in the publication of the December 30 corrections to the IPPS rule for 2005, and did so prospectively only, beginning January 1, 2005.

C. Resolution of CMS's Error

The Palm Beach Hospitals believe that the circumstance involving the St. Mary's Error, described above, clearly is one of those limited situations that warrants a retroactive correction. While we do not know the precise facts involved in the circumstance that CMS proposes to correct retroactive to October 1, 2004 for the four hospitals, it appears that the situation of the Palm Beach Hospitals is similar in all material respects.

Apparently, like the situation for which CMS proposes to make corrections, St. Mary's was not at fault for causing the Error. Rather, the Error was made by either CMS or the FI. In fact, the Error involved not information for which CMS was dependant upon the Palm Beach Hospitals, but rather a demographic fact that was part of public information and totally within the domain of CMS.

The Palm Beach Hospitals could not have known about the Error during the established schedule for bringing errors to the attention of the FI or CMS, because it appears that the

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[7] Richard Kolaska of E&Y spoke with Valerie Miller of CMS in this telephone call. Ms. Miller, in turn, referred Mr. Kolaska to, Margo Blige Holloway, who informed Mr. Kolaska that day that CMS would be unable to make any corrections before October 1.

[8] E&Y made that request for reasons unrelated to the Error. However, it was through that letter and subsequent review that the Hospitals and E&Y discovered the Error.

Error was not made until ***after*** that period had ended. However, the Palm Beach Hospitals notified CMS regarding the Error as soon as reasonably feasible, and prior to October 1, 2004. Finally, CMS clearly was aware, prior to October 1, 2004, that St. Mary's was located in Palm Beach and the West Palm Beach CBSA, and therefore, that an error was made. Thus, under any reasonable and fair application of the criteria proposed by CMS to correct errors in wage index data retroactive to the beginning of the period, the Error that affects the Palm Beach Hospitals should also be corrected retroactive to October 1, 2004. This is especially so given that CMS is proposing what appears to be a similar correction for four other hospitals.

CONCLUSION

In short, the Palm Beach Hospitals submit that it is unfair and unlawful to penalize them for a mistake made by CMS or the FI over a ministerial fact easily within CMS's domain, especially when CMS was given notice of the Error, and CMS, itself, had been in possession of the correct information since at least May 2004. We, therefore, request that CMS correct the Error to the FY 2004 wage index for the Palm Beach Hospitals retroactive to October 1, 2004, as it proposes to do for the other hospitals described in the proposed rule.

Respectfully submitted on behalf of the hospitals listed, above,

Michael H. Cook

MHC/tlo

Enclosures

St. Mary's

*	100288				
	100289				
	110001	HAMILTON MEDICAL CENTER			
	110002	UPSON REGIONAL MEDICAL CENTER			
	110003	SATILLA REGIONAL MEDICAL CENTER			
	110004	HUTCHESON MEDICAL CENTER, INC.			
	110005	BAPTIST MEDICAL CENTER CUMMINGS			
	110006	ST. MARY'S HEALTH CARE SYSTEM, INC.			
	110007	PHOEBE PUTNEY MEMORIAL HOSPITAL			
	110008	NORTHSIDE HOSPITAL-CHEROKEE, INC.			
	110010	EMORY UNIVERSITY HOSPTIAL			
	110011	TANNER MEDICAL CENTER			
	110015	TANNER MEDICAL CENTER - VILLA RICA			
	110016	WEST GEORGIA MEDICAL CENTER			
	110018	NEWTON GENERAL HOSPITAL			
	110020				
	110023				
	110024	CANDLER HOSPITAL, INC.			
	110025	SOUTHEAST GEORGIA REG MED CTR			
	110026	ELBERT MEMORIAL HOSPITAL			
	110027	COBB MEMORIAL HOSPITAL			
	110028	UNIVERSITY HEALTH SERVICES, INC.			
	110029	NORTHEAST GEORGIA MEDICAL CENTER			
	110030				
	110031				
	110032	STEPHENS COUNTY HOSPITAL			
	110033	EMORY NORTHLAKE REGIONAL MEDICAL CEN			
	110034	MEDICAL COLLEGE OF GEORGIA HOSPITAL			
	110035	KENNESTONE HOSPITAL			
	110036	MEMORIAL MEDICAL CENTER			
	110038	JOHN D. ARCHBOLD MEMORIAL HOSPITAL			
	110039	ST JOSEPH HOSPITAL			
	110040	BJC MEDICAL CENTER			
	110041	HABERSHAM COUNTY MEDICAL CENTER			
	110042	PAULDING MEDICAL CENTER			
	110043	ST. JOSEPH'S HOSPITAL, INC.			
	110044	SUMTER REGIONAL HOSPITAL			

Palm Beach

20010706	20020531	20031202	8960	52280
20010707	20020531	20031202	2680	52280
20001001	20010930	20040325	11	00101
20010101	20011231	20040210	11	00101
20010101	20011231	20040209	11	00101
20001001	20010930	20031229	1560	00390
20010101	20011231	20040202	0520	00101
20010101	20011231	20040130	0500	00101
20010801	20020731	20040128	0120	00101
20001001	20010930	20040409	0520	00101
20010901	20020831	20040211	0520	00101
20010701	20020630	20040130	0520	00101
20010701	20020630	20040210	0520	00101
20001001	20010930	20040127	11	00101
20010101	20011231	20040209	0520	00101
20010101	20011231	20040206	0520	52280
20010101	20011231	20040209	11	00090
20010701	20020630	20040211	7520	00101
20001001	20010930	20040127	11	00101
20010701	20020630	20040204	11	00101
20010101	20011231	20040120	11	00101
20010101	20011231	20040326	0600	00101
20001001	20010930	20040325	11	00101
20001001	20010930	20040206	0520	52280
20010401	20020331	20040210	0520	52280
20001001	20010930	20040209	11	00101
20010801	20020731	20040319	0520	00101
20010701	20020630	20040202	0600	00101
20010701	20020630	20040126	0520	00101
20010101	20011231	20040319	7520	00101
20001001	20010930	20040209	11	00101
20010701	20020630	20040202	0600	00101
20010701	20020630	20040202	11	00101
20010701	20020630	20040128	11	00101
20010701	20020630	20040120	0520	00101
20010701	20020630	20040210	7520	00101
20001001	20010930	20040203	11	00101

EXHIBIT A

ERNST & YOUNG

Ernst & Young
Phillips Point, West Tower
Suite 1200
777 South Flagler Drive
West Palm Beach, Florida 33401

Phone: 561-655-8500
Fax: 561-838-4191

September 20, 2004

Ms. Valerie Miller
Centers for Medicare and Medicaid Services
Center for Medicare Management
Hospital and Ambulatory Policy Group
Division of Acute Care
Mail Stop C4-07-07
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Ms. Miller:

This letter serves to notify the Centers for Medicare and Medicaid Services ("CMS") of a misclassification of wage data in the Miami-Miami Beach-Kendall, Florida and the West Palm Beach-Boca Raton-Boynton Beach, Florida core based statistical areas ("CBSAs"). Specifically, the wage data for St. Mary's Medical Center, provider number 10-0288, has been erroneously included in the Miami-Miami Beach-Kendall, Florida CBSA.

The wage data for St. Mary's Medical Center should be included in the West Palm Beach-Boca Raton, Boynton Beach, Florida CBSA since this hospital is physically located in Palm Beach County (Exhibit 3). Exhibit 1 documents the misclassification of St. Mary's Medical Center wage data and Exhibit 2 illustrates the wage index factors for the aforementioned CBSAs when St. Mary's Medical Center is properly classified in the West Palm Beach-Boca Raton-Boynton Beach, Florida CBSA.

We appreciate your prompt correction of this issue as it will affect payments to all hospitals in Miami-Miami Beach-Kendall, Florida and the West Palm Beach-Boca Raton-Boynton Beach, Florida CBSAs beginning October 1, 2004. If you have any questions, please call Mark Nichols at (561) 838-4172, Mike Smith at (561) 653-3072, or Rick Kolaska at (614) 229-5016.

Very Truly Yours,

Ernst & Young LLP

cc: Palm Beach County Hospitals

EXHIBIT B

Data Source: File FY03_FY05_WAGEDTA.xls (Mike Zezza - CMS)

EXHIBT 1

AS-PUBLISHED WAGE INDEX FACTOR FOR WEST PALM BEACH, FLORIDA

100002	48424 - West Palm	$ 72,073,336	3,257,274	$22.1269	$758,739,174	28,649,691	$26.4833
100010	48424 - West Palm	$ 82,321,390	3,054,761	$26.9486	$758,739,174	28,649,691	$26.4833
100080	48424 - West Palm	$ 101,446,035	3,848,541	$26.3596	$758,739,174	28,649,691	$26.4833
100130	48424 - West Palm	$ 11,746,614	514,472	$22.8324	$758,739,174	28,649,691	$26.4833
100168	48424 - West Palm	$ 101,043,022	3,873,399	$26.0864	$758,739,174	28,649,691	$26.4833
100176	48424 - West Palm	$ 47,390,672	1,588,552	$29.8326	$758,739,174	28,649,691	$26.4833
100234	48424 - West Palm	$ 26,222,780	1,038,220	$25.2574	$758,739,174	28,649,691	$26.4833
100253	48424 - West Palm	$ 41,095,416	1,683,888	$24.4051	$758,739,174	28,649,691	$26.4833
100258	48424 - West Palm	$ 71,020,975	2,227,952	$31.8772	$758,739,174	28,649,691	$26.4833
100262	48424 - West Palm	$ 48,091,426	1,821,960	$26.3954	$758,739,174	28,649,691	$26.4833
100268	48424 - West Palm	$ 43,529,919	1,459,322	$29.8289	$758,739,174	28,649,691	$26.4833
100269	48424 - West Palm	$ 35,356,906	1,396,250	$25.3228	$758,739,174	28,649,691	$26.4833
100275	48424 - West Palm	$ 24,976,758	1,027,601	$24.3059	$758,739,174	28,649,691	$26.4833
100287	48424 - West Palm	$ 52,423,925	1,857,499	$28.2229	$758,739,174	28,649,691	$26.4833
		$ 758,739,174	28,649,691				

Calculated AHW	$26.4833
Published West Palm AHW - Tables $4A_1$ & $4A_2$	$26.4833
Difference	$ 0.0000
National AHW (August 11, 2004 Federal Register)	$26.3570
Calculated WIF	1.00479
Published West Palm WIF - Tables $4A_1$ & $4A_2$	1.00460
Difference	0.00019

EXHIBIT B

Data Source: File FY03_FY05_WAGEDTA.xls (Mike Zezza - CMS)

EXHIBT 1

AS-PUBLISHED WAGE INDEX FACTOR FOR MIAMI, FLORIDA

100008	33124 - Miami	$ 179,534,697	6,975,560	$25.7377	$1,664,465,765	62,996,806	$26.4214
100009	33124 - Miami	$ 87,585,096	3,579,783	$24.4666	$1,664,465,765	62,996,806	$26.4214
100020	33124 - Miami	$ 37,369,329	1,582,737	$23.6106	$1,664,465,765	62,996,806	$26.4214
100022	33124 - Miami	$ 408,200,584	14,050,716	$29.0519	$1,664,465,765	62,996,806	$26.4214
100029	33124 - Miami	$ 46,147,491	1,713,561	$26.9308	$1,664,465,765	62,996,806	$26.4214
100034	33124 - Miami	$ 138,470,803	5,673,552	$24.4064	$1,664,465,765	62,996,806	$26.4214
100050	33124 - Miami	$ 26,847,296	1,297,643	$20.6893	$1,664,465,765	62,996,806	$26.4214
100053	33124 - Miami	$ 47,598,880	1,741,109	$27.3383	$1,664,465,765	62,996,806	$26.4214
100061	33124 - Miami	$ 81,445,008	3,042,701	$26.7673	$1,664,465,765	62,996,806	$26.4214
100076	33124 - Miami	$ 36,718,066	1,742,035	$21.0777	$1,664,465,765	62,996,806	$26.4214
100114	33124 - Miami	$ 49,584,691	1,787,394	$27.7413	$1,664,465,765	62,996,806	$26.4214
100125	33124 - Miami	$ 30,190,481	1,190,795	$25.3532	$1,664,465,765	62,996,806	$26.4214
100131	33124 - Miami	$ 51,707,042	2,001,695	$25.8316	$1,664,465,765	62,996,806	$26.4214
100154	33124 - Miami	$ 101,088,613	3,833,427	$26.3703	$1,664,465,765	62,996,806	$26.4214
100172	33124 - Miami	$ 17,294,288	936,591	$18.4651	$1,664,465,765	62,996,806	$26.4214
100181	33124 - Miami	$ 10,489,272	537,851	$19.5022	$1,664,465,765	62,996,806	$26.4214
100183	33124 - Miami	$ 27,572,825	1,029,248	$26.7893	$1,664,465,765	62,996,806	$26.4214
100187	33124 - Miami	$ 69,321,142	2,651,974	$26.1395	$1,664,465,765	62,996,806	$26.4214
100208	33124 - Miami	$ 30,727,899	1,229,834	$24.9854	$1,664,465,765	62,996,806	$26.4214
100209	33124 - Miami	$ 59,375,964	2,367,670	$25.0778	$1,664,465,765	62,996,806	$26.4214
100240	33124 - Miami	$ 22,368,977	952,560	$23.4830	$1,664,465,765	62,996,806	$26.4214
100277	33124 - Miami	$ 3,754,380	79,222	$47.3906	$1,664,465,765	62,996,806	$26.4214
100284	33124 - Miami	$ 17,196,885	761,170	$22.5927	$1,664,465,765	62,996,806	$26.4214
100288	33124 - Miami	$ 83,876,056	2,237,978	$37.4785	$1,664,465,765	62,996,806	$26.4214
		$ 1,664,465,765	62,996,806				

Calculated AHW	$26.4214
Published Miami AHW - Tables $4A_1$ & $4A_2$	$26.4214
Difference	$ 0.0000
National AHW (August 11, 2004 Federal Register)	$26.3570
Calculated WIF	1.00244
Published Miami WIF - Tables $4A_1$ & $4A_2$	1.00220
Difference	0.00024

EXHIBIT B

EXHIBT 2

CORRECTED WAGE INDEX FACTOR FOR WEST PALM BEACH, FLORIDA

100002	48424 - West Palm	$ 72,073,336	3,257,274	$22.1269	$842,615,230	30,887,669	$27.2800
100010	48424 - West Palm	$ 82,321,390	3,054,761	$26.9486	$842,615,230	30,887,669	$27.2800
100080	48424 - West Palm	$ 101,446,035	3,848,541	$26.3596	$842,615,230	30,887,669	$27.2800
100130	48424 - West Palm	$ 11,746,614	514,472	$22.8324	$842,615,230	30,887,669	$27.2800
100168	48424 - West Palm	$ 101,043,022	3,873,399	$26.0864	$842,615,230	30,887,669	$27.2800
100176	48424 - West Palm	$ 47,390,672	1,588,552	$29.8326	$842,615,230	30,887,669	$27.2800
100234	48424 - West Palm	$ 26,222,780	1,038,220	$25.2574	$842,615,230	30,887,669	$27.2800
100253	48424 - West Palm	$ 41,095,416	1,683,888	$24.4051	$842,615,230	30,887,669	$27.2800
100258	48424 - West Palm	$ 71,020,975	2,227,952	$31.8772	$842,615,230	30,887,669	$27.2800
100262	48424 - West Palm	$ 48,091,426	1,821,960	$26.3954	$842,615,230	30,887,669	$27.2800
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100275	48424 - West Palm	$ 24,976,758	1,027,601	$24.3059	$842,615,230	30,887,669	$27.2800
100287	48424 - West Palm	$ 52,423,925	1,857,499	$28.2229	$842,615,230	30,887,669	$27.2800
100288	33124 - Miami	$ 83,876,056	2,237,978	$37.4785	$842,615,230	30,887,669	$27.2800
		$ 842,615,230	30,887,669				

Calculated AHW	$27.2800
Published West Palm AHW - Tables $4A_1$ & $4A_2$	$26.4833
Difference	$ 0.7967
National AHW (August 11, 2004 Federal Register)	$26.3570

Published West Palm WIF - Tables $4A_1$ & $4A_2$	1.00460
Difference	0.03042

EXHIBT B

EXHIBT 2

CORRECTED WAGE INDEX FACTOR FOR MIAMI, FLORIDA

100008	33124 - Miami	$ 179,534,697	6,975,560	$25.7377	$1,580,589,709	60,758,828	$26.0142
100009	33124 - Miami	$ 87,585,096	3,579,783	$24.4666	$1,580,589,709	60,758,828	$26.0142
100020	33124 - Miami	$ 37,369,329	1,582,737	$23.6106	$1,580,589,709	60,758,828	$26.0142
100022	33124 - Miami	$ 408,200,584	14,050,716	$29.0519	$1,580,589,709	60,758,828	$26.0142
100029	33124 - Miami	$ 46,147,491	1,713,561	$26.9308	$1,580,589,709	60,758,828	$26.0142
100034	33124 - Miami	$ 138,470,803	5,673,552	$24.4064	$1,580,589,709	60,758,828	$26.0142
100050	33124 - Miami	$ 26,847,296	1,297,643	$20.6893	$1,580,589,709	60,758,828	$26.0142
100053	33124 - Miami	$ 47,598,880	1,741,109	$27.3383	$1,580,589,709	60,758,828	$26.0142
100061	33124 - Miami	$ 81,445,008	3,042,701	$26.7673	$1,580,589,709	60,758,828	$26.0142
100076	33124 - Miami	$ 36,718,066	1,742,035	$21.0777	$1,580,589,709	60,758,828	$26.0142
100114	33124 - Miami	$ 49,584,691	1,787,394	$27.7413	$1,580,589,709	60,758,828	$26.0142
100125	33124 - Miami	$ 30,190,481	1,190,795	$25.3532	$1,580,589,709	60,758,828	$26.0142
100131	33124 - Miami	$ 51,707,042	2,001,695	$25.8316	$1,580,589,709	60,758,828	$26.0142
100154	33124 - Miami	$ 101,088,613	3,833,427	$26.3703	$1,580,589,709	60,758,828	$26.0142
100172	33124 - Miami	$ 17,294,288	936,591	$18.4651	$1,580,589,709	60,758,828	$26.0142
100181	33124 - Miami	$ 10,489,272	537,851	$19.5022	$1,580,589,709	60,758,828	$26.0142
100183	33124 - Miami	$ 27,572,825	1,029,248	$26.7893	$1,580,589,709	60,758,828	$26.0142
100187	33124 - Miami	$ 69,321,142	2,651,974	$26.1395	$1,580,589,709	60,758,828	$26.0142
100208	33124 - Miami	$ 30,727,899	1,229,834	$24.9854	$1,580,589,709	60,758,828	$26.0142
100209	33124 - Miami	$ 59,375,964	2,367,670	$25.0778	$1,580,589,709	60,758,828	$26.0142
100240	33124 - Miami	$ 22,368,977	952,560	$23.4830	$1,580,589,709	60,758,828	$26.0142
100277	33124 - Miami	$ 3,754,380	79,222	$47.3906	$1,580,589,709	60,758,828	$26.0142
100284	33124 - Miami	$ 17,196,885	761,170	$22.5927	$1,580,589,709	60,758,828	$26.0142
100288	33124 - Miami						
		$ 1,580,589,709	60,758,828				

Calculated AHW	$26.0142
Published Miami AHW - Tables $4A_1$ & $4A_2$	$26.4214
Difference	$(0.4072)
National AHW (August 11, 2004 Federal Register)	$26.3570

Published Miami WIF - Tables $4A_1$ & $4A_2$	1.00220
Difference	(0.01521)

EXHIBIT B

Exhibit 3

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St. Suite 4T20
Atlanta, Georgia 30303-8909
(404) 562-7362

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

August 30, 2004

Mike Smith
Ernst and Young LLP
Phillip Point, West Tower
777 South Flagler Drive
West Palm Beach, Florida 33401

Your Reference: IPPS Hospitals in Palm Peach County

Dear Mr. Smith:

This letter is in response to your August 27, 2004 telephone inquiry regarding a listing of Inpatient Prospective Payment System (IPPS) hospitals in Palm Beach County Florida. The current IPPS hospitals in Palm Beach County are:

Bethesda Memorial
JFK Medical Center
Glades General Hospital
Boca Raton Community Hospital
Palm Beach Gardens Medical Center
Columbia Hospital
Jupiter Medical Center
Delray Medical Center
West Boca Medical Center
Palms West Hospital
Wellington Regional Medical Center
Good Samaritan Medical Center
Saint Mary's Medical Center

If you need anything else please let me know. I can be reached at (404) 562-7374.

Sincerely,

Michael Taylor
Health Insurance Specialist
Division of Medicare Operations

EXHIBIT B

Exhibit 3

Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St. Suite 4T20
Atlanta, Georgia 30303-8909
(404) 562-7262

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

August 30, 2004

Mike Smith
Ernst and Young LLP
Phillip Point, West Tower
777 South Flagler Drive
West Palm Beach, Florida 33401

Your Reference: IPPS Hospitals in Palm Peach County

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Delray Medical Center
West Boca Medical Center
Palms West Hospital
Wellington Regional Medical Center
Good Samaritan Medical Center
Saint Mary's Medical Center

If you need anything else please let me know. I can be reached at (404) 562-7374.

Sincerely,

Michael Taylor
Health Insurance Specialist
Division of Medicare Operations

EXHIBIT C

181

Jackson
PUBLIC HEALTH TRUST
MEMORIAL HOSPITAL
Jackson Health System

1611 N.W. 12th Avenue
Miami, Florida 33136-1094

June 20, 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: Comments on the Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates

Please note that we are submitting our comments on the regulations as published on the pages noted.

POST ACUTE CARE TRANSFER POLICY (pages 23411-58)

It is our belief that CMS should not implement an expansion of the post-acute care transfer policy. Expanding the transfer policy penalizes hospitals that ensure that Medicare patients receive care in the most appropriate setting. Also, expanding the policy undermines the fundamental principle of the prospective payment system, which is that some cases will cost more than the DRG payment, while others will cost less, but on average the overall payments should be adequate for the services provided. It is also important to note that to the extent that there are cost reductions associated with discharging patients to post-acute care facilities, such reductions will be reflected in lower DRG case weights during the DRG recalibration process.

OUTLIER PAYMENT THRESHOLD (pages 23424-426)

We believe that the threshold should be lowered since during the past two years, it was set so high that it resulted in outlier payments that were less than 5.1% percent of operating payments.

PROPOSED DECREASE TO THE LABOR-RELATED SHARE (pages 23391-394)

CMS proposed decrease of the labor-related share from 71.1 percent to 69.7 would have a negative impact for many teaching hospitals that are in large urban areas with wage indices greater than one. We ask that CMS evaluate the long-term effect of decreasing payments to teaching hospitals that serve the community by treating large numbers of patients that require tertiary care not provided elsewhere.

Sincerely,

Millie R. Gomez
Manager
Cost and Reimbursement Department
Jackson Memorial Hospital Provider 10-0022
Miami, Florida 33136

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RECEIVED
JUN 23 2005
BY:

RECEIVED
JUN 24 2005
BY:

Fishermen's HOSPITAL

June 23, 2005

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

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

Dear Sir or Madam:

Fishermen's Hospital is a 58 bed hospital located in Marathon, in the middle of the Florida Keys. Our resources are limited and employee turnover tends to be high due to the isolation of island living and the rapid escalation of housing costs. Our management team has averaged a sixty percent turnover rate the last few years and it is primarily for this reason, we missed our response deadline. In such a small, isolated community, qualified and experienced healthcare managers are difficult to find as well as retain. Manager vacancies can go unfilled for months while we seek a replacement. Such is the case at Fishermen's where we had a very experienced Director of HIM leave and the vacancy went unfilled for several months. Unfortunately our Risk Manager was trained for this interim time and then she too left the area before the HIM Director was hired. Our newly hired HIM Director was not aware of what was not being done and therefore our untimely response to your deadline.

Despite high employee turnover we continue to demonstrate excellent patient care evidenced by our 2003 JCAHO accreditation score of 96 and our continual Quality Service scores of 98%. We have significant concerns about the use of the QNet 3rd quarter 2004 Validation Assessment score in determining our FY 2006 Medicare rates (full market basket update).

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

3301 Overseas Hwy., Marathon, FL 33050 • (305) 743-5533 • Fax (305) 743-3962
www.fishermenshospital.com

Despite notifying our QIO of the appropriate addressee for correspondence related to this initiative, their requests were forwarded to an employee that was no longer at the facility, and therefore the appropriate attention to the validation request could not be given. We have explained this to our QIO and asked for the opportunity to send in the requested records late. We formally appealed the 3rd quarter Validation Results and sent the records at that time.

The QIO has asked that our next quarter's reports (4th quarter 2004) be sent in as much in advance of the deadline as possible. We have complied and submitted the 4th quarter's information nearly one month ahead of deadline.

More than 7% of the services we provide through our hospital are to a non-paying, indigent population. Medicare represents 47% of our business and a decrease in our rate would create a considerable negative impact on our ability to provide a quality, progressive health option to a community that, based upon its location, has very limited options for acute care.

It seems unjust that for the delinquency of five charts, a hospital that served 3,606 patient days to 739 Medicare patients in 2004 would have to see a decrease of any kind in its reimbursement. We incurred $7,000 in expenses in 2004 to have an outside audit agency review 100% of the in-patient charts that were sent to Medicare for reimbursement. This audit agency ensured that there were no coding errors on our submissions. Our charges are also run through a third party editor to ensure that charges not allowed by Medicare are not included in our bills. In 2004, we provided just over $2 million in care to the indigent people in this community and this amount is increasing every year. We served a total of 11,203 patients in 2004 that included out-patient surgery, in-patient, observation and Emergency Room visits. The delinquency of five charts is in no way an indicator of the level of service provided to patients in this community. I ask that you please reconsider our charts.

The long term impact to facilities, particularly sole community providers, can be devastating. To base such a severe consequence on the review of five charts seems unfair. The CMS proposal places a tremendous burden on sole community providers and we request that CMS delay until FY 2007, implementation of their proposal tying the market basket update to the validation assessment to allow rural hospitals adequate notice.

Once again, I ask your indulgence and reconsideration of the circumstances surrounding this issue. Thank you in advance for your consideration of our comments when making decisions relative to the CMS proposed rules.

Sincerely,

Michael G. Kissner,
Chief Executive Officer

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Susquehanna Health System
Divine Providence Hospital - Muncy Valley Hospital
The Williamsport Hospital & Medical Center

June 24, 2005

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

CMS Reclass
Hefter
Hartstein
Healy

Re: Comments to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates
Published in the Federal Register on May 4, 2005

Geographic Reclassifications

The following comments are being submitted on behalf of The Williamsport Hospital & Medical Center relating to the section of the FY 2006 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications."

The Problem Today

In what we believe is only two areas of the United States today, there are individual urban hospitals[1] that are the sole hospital in their particular urban area (hospitals in single-hospital MSAs) that have historically found themselves surrounded by rural hospitals with whom they compete that receive higher Medicare payments because they have been reclassified to higher Medicare wage index areas or because the Centers for Medicare & Medicaid Services ("CMS") considers them rural referral centers, sole community hospitals, critical access hospitals or Medicare dependent hospitals (we will hereinafter refer to these hospitals as "Isolated Hospitals in Single-Hospital MSAs").[2] Because these Isolated Hospitals in Single-Hospital MSAs operate in urban areas that are not adjacent to any other urban area, they are unable to secure Medicare wage reclassification although they are at a competitive disadvantage because they are competing for labor with hospitals in nearby areas with higher wage indexes. They cannot secure Medicare wage reclassification on an individual hospital basis under 42 CFR 412.230 because, according to CMS standards, they are too far from the nearest urban area[3] and, by definition, the ratio of a hospital in a single-hospital MSA's average hourly wage to the average hourly wage of hospitals in the area in which the hospital is located is always 100% and therefore, these hospitals can not meet the 108% threshold for urban hospitals. Similarly, these unique hospitals cannot secure Medicare wage reclassification on a county-wide basis under 42 CFR 412.234 because they are not adjacent to any urban area, for fiscal year 2006, are not part of a consolidated metropolitan statistical

[1] Unless specified otherwise, the use of the term "hospital" or "hospitals" in this comment letter only refers to hospitals reimbursed under the prospective payment system.
[2] From our research, it appears that only The Williamsport Hospital & Medical Center, located in Williamsport, Pennsylvania, Lycoming County (Williamsport, PA MSA) and Community Hospital, located in Grand Junction, Colorado, Mesa County (Grand Junction, CO MSA) meet the definition of an Isolated Hospital in a Single-Hospital MSA.
[3] Urban hospitals must be within 15 miles of the urban area into which they seek reclassification for Medicare wage purposes.

1 Medical Campus, 777 Rural Avenue, Williamsport, PA 17701-3198
570-321-1000 Fax 570-321-3719

area ("CMSA") or combined statistical area ("CSA") that includes the urban area to which they seek redesignation, and for fiscal years 2007 and thereafter, are not part of a CSA that includes the urban area to which they seek redesignation.

Lower Medicare payments pose a major problem for these Isolated Hospitals in Single-Hospital MSAs. They must recruit health care workers from the same geographic area as the hospitals that surround them with whom they compete, but with their higher Medicare wage indexes, these competitor hospitals all have greater resources and can afford to pay higher salaries to their employees. In the long run, this makes it difficult, if not impossible, for Isolated Hospitals in Single-Hospital MSAs to recruit and retain the qualified health care professionals they need to serve their communities. This concern is especially significant given the fact that each of these hospitals is the only hospital in its urban area and therefore has an even greater obligation to the communities they serve. Without necessary assistance from CMS, the long term financial viability of these hospitals is questionable.

Despite the fact that CMS has specifically stated that geographic reclassification should be limited to hospitals that are disadvantaged by their current classification because they compete with hospitals that are located in the geographic area to which they seek reclassification,[4] and that the intent for its most recent proposed changes to the urban group hospital reclassification criteria was "to preserve the reclassification opportunities for urban county groups,"[5] we believe CMS has failed to adequately address the inequities facing a specific subset of urban county groups, namely Isolated Hospitals in Single-Hospital MSAs, in relation to the wage index and the rules governing geographic reclassification and is therefore failing to preserve the reclassification opportunities for all urban county groups.

Background on Urban Group Hospital Reclassifications:

On September 6, 1990, CMS published an Interim Final Rule in the Federal Register, implementing those provisions of Public Law 101-239, creating the Medicare Geographic Classification Review Board ("MGCRB") and specific guidelines for hospitals to request reclassification from one geographic area to another. Subsequently, on November 5, 1990, the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) was enacted which required CMS to make changes to its September 6, 1990 Interim Final Rule. Most notably, in developing guidelines to be used by the MGCRB in determining which hospitals could apply for reclassification from one geographic area to another, CMS limited group applications to all hospitals in a rural county seeking redesignation to an adjacent urban area. It did not provide for all hospitals in an urban county to be reclassified as a group to another urban area. The Conference Committee Report accompanying Public Law 101-508 demonstrated congressional intent that the Secretary establish guidelines for joint applications by urban hospitals classified as other urban to be reclassified to a large urban area. H.R. Rep. No. 964, 101st Cong., 2nd Sess.

[4] June 4, 1991 Final Rule - 56 FR 25469; See also June 2, 1995 Proposed Rule – 60 FR 29202.
[5] May 4, 2005 Federal Register.

715 (1990). Accordingly, in its June 4, 1991 Final Rule, CMS added a new section to provide guidelines under which all hospitals in an urban county may seek reclassification to another urban area.

In the May 18, 2004 Proposed Rule, CMS noted that representatives of individual hospitals expressed concern about the special circumstances of hospitals in single-hospital MSAs in relation to the wage index and the rules governing geographic reclassification. According to CMS, these hospitals contended that they are sometimes in the position of competing for labor with hospitals in nearby MSAs with higher wage indexes. CMS invited comment on the concerns raised by these hospitals and on possible methods of addressing these concerns. CMS stated that a new provision it was proposing to implement in the May 18 Proposed Rule may address these concerns. Section 505 of Public Law 108-173 provided for a new wage index adjustment for hospitals in lower wage areas in cases where significant numbers of hospital workers commute from the lower wage area to higher wage areas nearby. To the degree that hospitals in single-hospital MSAs experience disadvantages in competing for hospital workers with hospitals in higher wage index areas, CMS stated that it expected that the counties in which these hospitals are located would qualify for this adjustment. CMS further stated that it would actively consider whether to address the concerns of these hospitals more directly while analyzing the extent to which the new out-commuting provision would alleviate the concerns of these hospitals. CMS welcomed "comments on the special circumstances of hospitals in single-hospital MSAs and whether their special circumstances should be addressed by revisions to the regulations governing reclassification, or other measures."

In the August 11, 2004 Final Rule, CMS revisited the concerns raised by hospitals in single-hospital MSAs. In response to CMS's request for comments on this issue, a number of commenters recommended a variety of policy changes concerning the issue of single hospital MSAs. In determining not to adopt any of the policy changes proposed by the commenters at this time, CMS re-stated its belief that the new out-commuting provision is a promising vehicle for addressing the concerns raised by hospitals in single-hospital MSAs. Although CMS recognized that certain of the hospitals in single-hospital MSAs would not qualify for the adjustment, CMS stated that it believes that "it is appropriate to gain more experience with the workings of this new provision before we adopt any policy revisions designed to address separately [sic] reclassification by these hospitals."

Why CMS's Proposed Fix for the Problem Won't Work

CMS's proposed fix for the concerns described above raised by representatives of hospitals in single-hospital MSAs – namely the out-commuting wage adjustment – does not help all of the hospitals located in a single-hospital MSA. In order for this "fix" to work, there is an assumption that significant numbers of the single-hospital MSA workers commute from the lower wage area to higher wage areas nearby. It does not recognize those hospitals in single-

hospital MSAs that must recruit health care workers from the same geographic area as the hospitals that surround them with whom they compete. It similarly does not recognize the unique circumstances of a specific type of hospital located in a single-hospital MSA, namely Isolated Hospitals in Single-Hospital MSAs. As explained previously, Isolated Hospitals in Single-Hospital MSAs are surrounded by rural counties that contain hospitals with whom the Isolated Hospital in a Single-Hospital MSA competes that have been reclassified into higher wage index areas. The out-commuting wage adjustment methodology looks at the *pre-reclassified* wage indexes of the hospitals located in these adjacent areas. Accordingly, even if an Isolated Hospital in a Single-Hospital MSA would meet the out-migration threshold, it would not be considered for the wage adjustment because the wage index of the MSA where the hospital is located is higher than the *pre-reclassified* wage index of the areas where the surrounding hospitals are located. In addition, utilizing the commuting data compiled by the U.S. Census Bureau is not the most accurate method to assess commuting patterns. Only one of every six households was asked to describe their commuting patterns and not all of these households responded to the Census Bureau's surveys. This is clearly the case in Williamsport, Pennsylvania (Lycoming County) where it has been recently announced that residents of Williamsport and Lycoming County who failed to complete the mail survey they received will be getting a visit from a representative of the U. S. Census Bureau over the next few months to obtain the necessary information

CMS specifically stated in its May 18, 2004 Proposed Rule that it would welcome comments on the special circumstances of hospitals in single-hospital MSAs and whether their special circumstances should be addressed by revisions to the regulations governing reclassification, or other measures. Clearly, the out-commuting wage adjustment will not help all of the hospitals in single-hospital MSAs and specifically fails to address the unique circumstances of Isolated Hospitals in Single-Hospital MSAs. These hospitals should not have to wait for CMS to gain more experience with the workings of the new out-commuting wage adjustment provision before it adopts any policy revisions designed to address separate reclassification by Isolated Hospitals in Single-Hospital MSAs.

Specific Example of Problem

The Williamsport Hospital and Medical Center located in Williamsport (Lycoming County), Pennsylvania is the only hospital in its county, which county has been designated an urban area. All of its recent applications for Medicare wage reclassification have been rejected because unlike the surrounding hospitals, it cannot meet CMS's distance requirement for reclassification as an individual hospital, nor can it qualify for county-wide reclassification because it is not adjacent to any urban area and is not part of a CMSA or CSA that includes the urban area to which it seeks redesignation. Historically, all of the hospitals located in the rural counties adjacent to Lycoming County with whom Williamsport Hospital competes received higher Medicare reimbursement. As a result, Williamsport Hospital has had and continues to have a difficult time competing for the services of a very limited pool

of qualified health care professionals in an environment in which the federal government has in effect provided greater resources to all of the other hospitals in its region.

Proposed Solution

As we explained above, only one other hospital in the United States faces similar circumstances today. They appear to meet CMS's wage criteria for wage reclassification, but are located too far from other counties to meet the proximity requirement or have no adjacent urban counties into which to reclassify. As a result, they receive lower Medicare payments, jeopardizing their ability to recruit and retain the health care professionals they need in order to meet their obligations as sole hospitals in their urban areas. Given these unusual circumstances, CMS should allow Isolated Hospitals in Single-Hospital MSAs such as these, that also meet CMS's wage standard for reclassification, to be reclassified into the nearest urban area which is part of a CSA located in the same state as the hospital for Medicare wage purposes. Reclassification into the nearest urban area that is part of a CSA located in the same state as the hospital is appropriate because that urban area will typically represent the relevant market for purposes of wage comparison in the context of employee recruitment and retention. In addition, reclassification into the nearest urban area that is part of a CSA located in the same state as the hospital is proper because that urban area will typically be the geographic area in which the hospitals with whom the Isolated Hospital in the Single-Hospital MSA competes are located or have been reclassified. As explained above, CMS has stated on several occasions that geographic reclassification should be limited to hospitals that are disadvantaged by their current classification because they compete with hospitals that are "located" in the geographic area to which they seek reclassification.

The proposed solution described above can be easily effectuated by making certain changes to the current regulations governing reclassification of all hospitals in an urban county (42 CFR §412.234). As described above, CMS has acknowledged that the special circumstances of hospitals in single-hospital MSAs may need to be addressed by revisions to the regulations governing reclassification. CMS has also acknowledged that it may need to address separate reclassification by these hospitals. Accordingly, set forth below is proposed regulatory language that would address the unique circumstances faced by Isolated Hospitals in Single-Hospital MSAs.

Proposed Regulatory Language (proposed language appears in **boldface**)

412.234 Criteria for all hospitals in an urban county seeking redesignation to another urban area.

(a) *General criteria.* For all prospective payment hospitals in an urban county, **except as provided in paragraph (a)(5),** to be redesignated to another urban area, the following conditions must be met:

(1) All hospitals in an urban county must apply for redesignation as a group.

(2) The county in which the hospitals are located must be adjacent to the urban area to which they seek redesignation.

(3) (i) For Federal fiscal years before fiscal year 2006, the counties in which the hospitals are located must be part of the Consolidated Metropolitan Statistical Area (CMSA) that includes the urban area to which they seek redesignation.

(ii) For fiscal year 2006, hospitals located in counties that are in the same Consolidated Statistical Area (CSA) (under the MSA definitions announced by the OMB on June 6, 2003) as the urban area to which they seek redesignation; or in the same Consolidated Metropolitan Statistical Area (CMSA) (under the standards published by the OMB on March 30, 1990) as the urban area to which they seek redesignation qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.

(iii) For Federal fiscal year 2007 and thereafter, hospitals located in counties that are in the same Consolidated Statistical Area (CSA) (under the MSA definitions announced by the OMB on June 6, 2003) as the urban area to which they seek redesignation qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.

(4) The hospital may be redesignated only if one of the following conditions is met:

(i) The prereclassified average hourly wage for the area to which they seek redesignation is higher than the prereclassified average hourly wage for the area in which they are currently located.

(ii) For fiscal years prior to fiscal year 2005, the standardized amount for the area to which they seek redesignation is higher than the standardized amount for the area in which they are located.

(5) Special Isolated Hospital in a Single-Hospital MSA Exception. The requirements of Paragraphs (a)(1), (a)(2) and (a)(3) of this section do not apply if the hospital seeking redesignation meets the following criteria:

(i) The hospital is the only hospital in its urban area.

(ii) The hospital is in an urban area that is not adjacent to any other urban area.

(iii) The hospital is seeking redesignation to the closest urban area which is part of a CSA located in the same state as the hospital.

(b) *Wage criteria.* In applying the following numeric criteria, rounding of numbers to meet the

(b) *Wage criteria.* In applying the following numeric criteria, rounding of numbers to meet the qualifying percentages is not permitted.

(1) *Aggregate hourly wage.* The aggregate average hourly wage of all hospitals in the urban county must be at least 85 percent of the average hospital hourly wage in the MSA to which the hospitals in the county seek reclassification; or

(2) *Aggregate hourly wage weighted for occupational mix.* For redesignations effective before fiscal year 1999, the aggregate average hourly wage for all hospitals in the county, weighted for occupational categories, is at least 90 percent of the average hourly wage in the adjacent urban area.

(c) *Appropriate wage data.* The hospitals must submit appropriate wage data as provided for in §412.230(d)(2).

We thank you for the opportunity to express our comments to the section of the FY 2006 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications" and appreciate your consideration of the issues we raised. We would welcome the opportunity to discuss with you in more detail the special circumstances facing Isolated Hospitals in Single-Hospital MSAs and our proposed revisions to the regulations governing reclassification to address these concerns.

Sincerely,

Steven P. Johnson, President/CEO
The Williamsport Hospital & Medical Center

cc: Rick Santorum, United States Senator, Pennsylvania
Arlen Specter, United States Senator, Pennsylvania
John Peterson, United States Representative, 5th District of Pennsylvania
Don Sherwood, United States Representative, 10th District of Pennsylvania

St. Francis Hospital

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THE HEART CENTER®

June 20, 2005

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

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

My hospital is a 279 bed acute care hospital located in Rosyln, New York. As a major health care provider in our area, we implant medical devices and perform other procedures on a significant number of Medicare beneficiaries, in the inpatient setting. Because inpatient services are a key component of what we provide, I am writing to express my concern with the proposed rule, " Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates", published by the Centers for Medicare and Medicaid Services (CMS) on April 25, 2005. My concern is on page 50 of the proposed rule where CMS proposes to modify the DRGs for ICD implants.

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

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

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

Thank you for your consideration.

Sincerely,

William Abernathy
SR VP - CFO

c: Alan D. Guerci, M.D.
Lawrence A. Reduto, M.D.

ANS
LIFE GETS BETTER

June 13, 2005

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

Re: Proposed changes to the Hospital Inpatient Prospective Payment System for 2006:

Advanced Neuromodulation Systems, Inc. (ANS) is a medical device company located in Plano, Texas, that manufactures and markets spinal cord stimulation (SCS) systems, also known as neurostimulation systems. These are implantable devices that provide pain relief for chronic pain patients.

ANS appreciates the opportunity to comment on the proposed changes to the Hospital Inpatient Prospective Payment System for 2006, which was published in the Federal Register on May 4, 2005.

The following comments are in reference to CMS' response to Medtronic's application for new technology add-on payments for its Restore® rechargeable implantable neurostimulation system sited on pages 23,363 and 23,364 of the proposed rule.

SCS is not a new treatment for pain. In 1967 Dr. Norman Sheely of the University of Minnesota developed the concept of electrical stimulation as a pain therapy. Sheely found that pain relief could be achieved by implanting a spinal cord stimulator and an electrical lead with electrodes and using the implanted device to stimulate targeted nerve fibers of the spinal cord. The stimulation of these targeted nerve fibers diminishes or blocks the intensity of the pain message being transmitted to the brain and replaces the areas of intense pain with a more pleasing sensation called paresthesia. The objective of SCS is to reduce or eliminate a patient's level of pain so he or she can return to a more normal lifestyle and resume a roll as a functioning member of his or her family and community.

Generally, SCS is FDA-approved for the treatment of chronic intractable pain of the trunk and limbs.

Significant advances in technology, implantation technique, and patient selection criteria over the last 37 years have made SCS a safe and highly effective treatment for chronic intractable pain.

The standard SCS procedure calls for the implantation of an 8-electrode lead or two 4-electrode leads and an implantable pulse generator (IPG) system utilizing a non-rechargeable battery, which provides the power needed for electrical stimulation. Once a non-rechargeable IPG's power is depleted, the patient requires a surgical procedure to replace it. The non-rechargeable IPG systems offered in the marketplace today have a limited life expectancy, which depends on the amount of power required to provide adequate pain relief. Under average power usage, the life expectancy of a non-rechargeable IPG is approximately three years. However, for patients who have a higher-than-average power need in order to achieve pain relief, the IPG could deplete in less time than the previously stated three years. In fact, there are documented cases where these power supplies required replacement surgery in less than one year.

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SCS technology has evolved, and as a result, rechargeable SCS systems have been introduced to the market place. These new systems are rechargeable IPG systems, which power up to 16 electrodes (two 8-electrode leads). Rechargeable IPGs allow patients with high power needs to achieve adequate pain relief without the concern for premature power depletion. Additionally, the implantation of up to 16 electrodes provides broader stimulation coverage and offers several clinical benefits, including the reduction of additional surgeries required to rectify a common complication, lead migration. Lead migration occurs when a lead moves off the targeted nerve fibers and is usually caused by excessive patient movement. When this occurs, targeted stimulation and pain relief may be lost, requiring an additional surgical procedure to reposition the lead. With 16 electrodes, the physician has the flexibility to electronically retarget the nerve fibers that provide pain relief through non-invasive programming, thus eliminating the need for this revision surgery.

As mentioned on page 23,363 of the proposed rule, in July of 1999, ANS introduced the 16-electrode Renew® radio-frequency (RF) system with therapy capabilities comparable to those of the new 16-electrode rechargeable IPG systems. And while these systems provide similar therapy, an RF system demands a much greater level of patient ability and compliance than does an IPG system. In addition to the lead component, an RF system consists of an implantable receiver, an external transmitter, and an external antenna, which is connected to the transmitter and which must stay in constant contact with the receiver. With an RF system, patients have to affix the external antenna, generally with an adhesive pad, to their skin directly over the implanted receiver in order to receive pain relieving stimulation from the system. They must wear it continuously, even while sleeping, or forego pain relief. As a result of the external antenna, many patients develop skin irritations and skin erosion, leading to problems with therapy compliance and the need for additional medical care. Moreover, patients cannot wear the antenna when showering, bathing, or swimming. This means that chronic pain patients are unable to receive pain relief during these activities of daily living.

Until the recent introduction of 16-electrode rechargeable IPG systems, physicians were reluctant to prescribe 16-electrode systems because of the patient compliance issues with RF systems already stated. In turn, the majority of patients with complex chronic pain—patients who needed the higher power output and additional electrodes of the RF systems for adequate pain relief—received conventional IPGs. Due to these patients' high power requirements and resulting battery depletion, their conventional IPG systems had to be frequently replaced through additional surgery, as mentioned earlier.

The advent of totally implantable, 16-electrode rechargeable SCS systems represents an advance in technology that will significantly improve the treatment and quality of life of patients who suffer from complex chronic pain. These rechargeable systems provide the broad coverage and continuous high power output needed by this subset of patients and eliminate the complications that arise from being tethered to an external antenna. With them, physicians can meet these patients' long-term therapy needs, and patients can receive uninterrupted pain relief, without the need for frequent battery replacement surgeries. This new rechargeable IPG technology will address a complex clinical need and will result in a significant cost savings to the healthcare system over time.

ANS introduced an 8-electrode rechargeable IPG system in February of 2005 and was approved by the FDA to market a 16-electrode rechargeable IPG system in March of 2005.

Advanced Bionics introduced a 16-electrode rechargeable IPG system in April 2004, while Medtronic's 16-electrode rechargeable IPG system received FDA approval in the spring of 2005. These new rechargeable IPGs have been approved for having battery lives ranging from 5 to 9 years.

Clinical improvements provided by 16-electrode rechargeable implantable pulse generators

The 16-electrode rechargeable IPGs not only offer the benefits of rechargeability but also the benefits associated with increased frequency ranges and broader electrode capability. Frequency is a key parameter of stimulation and is measured in hertz (Hz), or pulses per second. As frequency is increased, more stimulation is delivered in the same amount of time. Currently, due to power limitations, the non-rechargeable IPG systems deliver lower frequencies when compared to rechargeable IPG systems.

Clinical Benefits

- The increased battery life of 16-electrode rechargeable IPGs will result in the reduction in the number of surgeries for stimulator replacement and other associated medical interventions. Patients requiring higher power to achieve pain relief (e.g., patients with chronic low back pain) can now use their system without concern for premature battery depletion. The reduced number of surgeries and other medical interventions will result in less patient trauma and a substantial cost savings to the healthcare system over time.[1]

- Implanting 16 electrodes provides broader stimulation coverage. This allows the physician the flexibility to retarget the selected nerve fibers that provide pain relief when the complication of lead migration or neuroplasticity occurs.[2] This, in turn, may result in a reduced number of surgeries and other medical interventions, minimizes patient trauma, and provides a substantial cost savings to the healthcare system over time.

- The broader stimulation coverage provided by the implantation of 16 electrodes, coupled with higher frequency stimulation, has been shown to provide improved pain relief for patients with Complex Regional Pain Syndrome (CRPS 1).[3]

- The broader stimulation coverage provided by the implantation of 16 electrodes powered by one system has proven to be beneficial for patients with both upper and lower extremity chronic pain. Currently there are a number of patients with both upper and lower extremity chronic pain who are implanted with two separate 8-electrode SCS systems. Implanting one SCS system results in one less pocket incision to the patient at the time of initial implant and also represents a significant cost reduction to the healthcare system.

In summary, rechargeable implantable IPG systems are the obvious evolution of SCS technology, and they offer both substantial clinical improvement and significant healthcare system cost savings (due to fewer surgical procedures and associated medical interventions) as referenced above. ANS agrees with and supports the Medtronic application for new technology add-on payments for rechargeable implantable neurostimulators (IPGs).

If you have any questions or require any additional information about ANS' rechargeable products (e.g., specifications/cost), please do not hesitate to call me at 800-727-7846, Extension 8034. Representatives of ANS are also available to meet with you at your convenience.

Thank you for your review of this information and your consideration in this matter.

Sincerely,

Mark P. Barulich
Director, Sales Support

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[1] Barolat, G. Current status of epidural spinal cord stimulation. *Neurosurgery Quarterly*. 1995;5(2):98-124. (See Attachment A.)

[2] Barolat G. A prospective multicenter study to assess the efficacy of spinal cord stimulation utilizing a multi-channel radio-frequency system for the treatment of intractable low back and lower extremity pain. Initial considerations and methodology. *Neuromodulation*. 1999;2(3):179-183. (See Attachment B.)

[3] Bennet DS, Alo KM, Oakley J, Feler CA. Spinal cord stimulation for complex regional pain syndrome 1 {RSD}: a retrospective multicenter experience from 1995 to 1998 of 101 patients. *Neuromodulation*. 1999;3:202-210. (See Attachment C.)

Attachment A

Neurosurgery Quarterly
5(2):98–124 © 1995 Raven Press, Ltd., New York

Current Status of Epidural Spinal Cord Stimulation

Giancarlo Barolat

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Summary: Spinal cord stimulation is the most widespread application of neurostimulation, which includes electrical stimulation of the sensory-motor cortex, thalamus, spinal cord, sacral roots, peripheral nerves, and vagus nerve. Its popularity, although with variable acceptance over the past two decades, has steadily increased and is now a well-established part of the pain specialist's armamentarium. Several published studies (none of which, however, is prospective) have consistently shown a 50% efficacy in producing a satisfactory degree of long-term pain relief in a variety of chronic pain conditions. In Europe the most widely accepted application is for the management of peripheral vascular disease in the lower extremities. The effects on ischemic pain have been reported consistently to be very positive. Intractable pain due to angina pectoris is also showing promising results. The role of spinal cord stimulation in the management of hypertonic motor disorders has been controversial and has recently been overshadowed by the development of intrathecal baclofen infusion. In the author's experience, spinal cord stimulation remains the procedure of choice for athetosis or dystonia. Some evidence also exists that spinal cord stimulation might have a role in regulating the blood flow to the brain. This has been confirmed by animal experimental studies. Isolated reports have also shown some beneficial effects in persistent vegetative status due to brain injury or stroke. **Key Words:** Spinal cord stimulation.

Spinal cord stimulation (SCS) has been around since the late 1960s, with varying acceptance in the medical community. After some initial skepticism, the procedure became extremely popular among neurosurgeons, particularly in the United States. In the late 1970s the procedure was performed in large numbers by a great number of physicians, very few of whom were qualified or truly dedicated to this field. Because of the poor knowledge of the underlying mechanisms of action, the still immature clinical experience, and the innumerable technical problems that plagued the implanted devices, the procedure fell out of favor. In the mid-1980s, thanks to the continuing high-quality work of a few dedicated neurosurgeons in the United States and Europe, the procedure regained acceptance, and its popularity has spread beyond the neurosurgical specialty. Anesthesiologists and, to a more limited extent, orthopedic surgeons and physiatrists have become involved with this technique. Several factors have contributed to its resurgence. Traditional indications have become better defined, and new applications have emerged strongly [such as peripheral vascular disease (PVD) in Europe]. Physicians have come to realize that proper follow-up after electrode implantation is just as important (if not even more important) than the initial surgery. Better guidelines have been put forward for preimplantation screening. Last, but certainly not least, the equipment has become more reliable and versatile. Types of pain that could not be addressed before, such as pain in the low lumbar area or widespread pain in the upper and lower extremities, can now be tackled with a more consistent degree of success.

This article reviews the current status of SCS and

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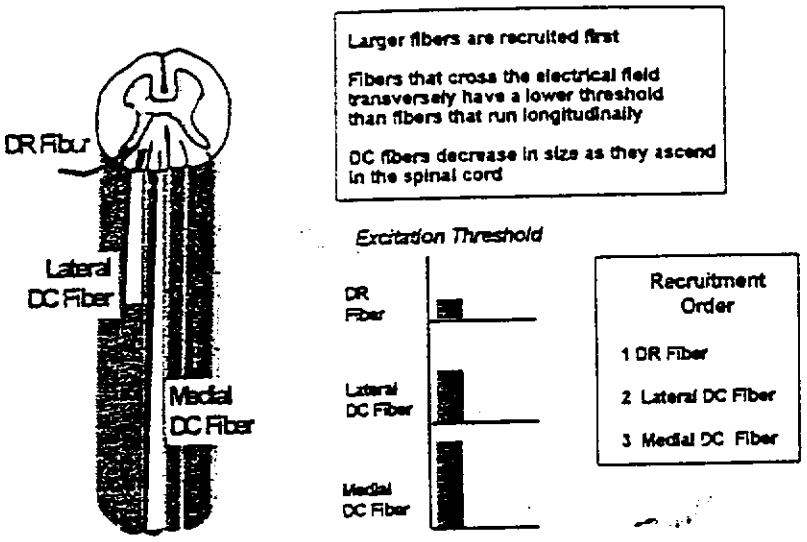


FIG. 1. Important factors that determine the electrical parameters of SCS. Modified from the work of Holsheimer and Strujik (1–6).

some applications that, although not yet established, seem to be promising. It also discusses some of the recent advances in the understanding of the basic mechanisms of action of the modality.

ANATOMICAL AND ELECTRICAL PROPERTIES OF THE INTRASPINAL STRUCTURES RELEVANT TO SCS

Some important work has been performed recently to shed light on the electrical properties of the intraspinal structures and on the electrical field potentials generated during epidural SCS. The work has been performed at the University of Twente, The Netherlands, by Holsheimer and Strujik, who have developed a computerized detailed volume conductor model of the spinal cord (Fig. 1). The data generated from the model were then validated by comparing them to a large number of data collected by the author in patients with implanted electrodes (1–6).

The spinal structures can be compared with an inhomogeneous volume conductor resulting of various compartments, each of which has a different conductivity. The highest conductivity belongs to the cerebro-spinal fluid (CSF), followed, at a distance, by the longitudinal fibers in the white matter (Table 1). The majority of dorsal root fibers, after entering the spinal cord, proceed toward the dorsal columns, where they bifurcate into an ascending and a descending branch. These branches enter the lateral part of the dorsal columns and gradually shift medially and dorsally. About 85% of the dorsal column fibers are primary afferents. All afferent fibers in the dorsal columns give out collateral branches into the gray matter. These collateral branches only occur at the nodes of Ranvier of the ascending or descending main fibers. Transmembrane potentials due to external monopolar stimulation at the node at which a collateral is attached are significantly affected by the presence of the collateral branches. Both the excitation threshold and the blocking threshold of dorsal column fibers are decreased up to 50% compared with unbranched fibers. In comparison with longitudinal dorsal column fibers, dorsal root fibers have a curved shape and differ in orientation with respect to the spinal cord and the implanted electrodes. Proximal to the dorsal ganglion, the dorsal root fibers fan out in an ascending dorsomedial direction to form the rootlets that enter the spinal cord at different angles. The curvature of the dorsal root fibers was found to significantly affect the activation threshold, particularly the angle that the fibers have when entering the dorsal root entry zone of the spinal cord. The threshold increases with increasing angle between the fiber and

TABLE 1. *Conductivity of the intraspinal elements*

Medium	Conductivity (1/Ω)
Gray matter	0.23
White matter	
Longitudinal	0.6
Transverse	0.08
CSF	1.7
Epidural fat	0.04
Dura mater	0.03
Vertebral bone	0.02
Electrode insulation	0.002

the transverse plane. In the model, dorsal column and dorsal root fibers also demontrated different electrical properties. Dorsal root fibers have a threshold stimulus less than half that of dorsal column fibers. The difference in the threshold is attributable to three factors: (a) the fiber is oriented differently with respect to the electrode; (b) dorsal root fibers are curved, whereas dorsal column fibers are straight; (c) dorsal root fibers travel across the interface between a low-conductivity (spinal cord) and a high-conductivity (CSF) compartment. Even though dorsal root fibers usually have a lower threshold, in the case of a small CSF width the dorsomedial dorsal column fibers might be stimulated first. These data correlate well with the clinical experience that paresthesiae are initially felt at the segmentary level. Occasionally, especially in the cervical area, a perfectly midline electrode, instead, will give paresthesiae in distal areas such as the feet.

Interesting data were obtained when the values predicted by the model were compared with the values obtained in humans (6). Three main aspects were investigated:

Paresthesiae Threshold as a Function of the Spine Level

The perception threshold is lowest in the cervical area and highest in the mid-thoracic area. This was found to correlate well with the width of the dorsal CSF layer. As predicted by the model, three factors influence the order of recruitment of the fibers, namely, the width of the CSF and the orientation and size of the fibers. The order of recruitment is therefore dorsal root fibers followed by lateral dorsal column fibers and then by medial dorsal column fibers. These predictions were confirmed by clinical observation.

Paresthesiae Threshold as a Function of Electrode Separation

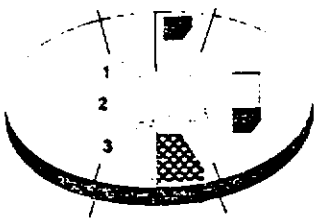
The model showed that for dorsal column fibers the minimum activation threshold occurred with an electrode separation of <10 mm; the threshold increased with increasing separation. This was confirmed by the clinical data. Increasing the interelectrode distance also increased preferential stimulation for the dorsal root fibers, which is usually an undesirable effect.

Paresthesiae Threshold as a Function of the Lateral Position of the Electrodes

The clinical data showed that there is a definite difference in threshold between midline and laterally located electrodes. In the author's series the average perception threshold for midline located electrodes was 1.7 V, whereas for electrodes placed >5 mm from midline it was 0.8 V. These data were also confirmed by the model, which showed that the clinical results can be explained by the preferential activation of dorsal root fibers as one moves the electrodes laterally.

Although initially the term dorsal column stimulation was applied to the procedure, with the assumption that most if not all of the observed effects (paresthesiae and pain relief) were attributable to direct stimulation of the dorsal columns, it has now become clear that applying electrical fields to the dorsal epidural space activates a larger number of neural structures both inside and outside the spinal cord (Fig. 2). Because the paresthesiae are always ipsilateral to the stimulating electrodes and because they are perceived as a tingling sensation, the clinical effects are most likely due to stimulation of large afferent myelinated fibers. The most likely involved structures include the dorsal columns, dorsal roots, dorsal root entry zones, and dorsal horns.

On a clinical basis, distinction between stimulation of a dorsal root versus a dorsal column is feasible although not always possible. A segmentary distribution of paresthesiae with a low electrical threshold and early motor recruitment is indicative of stimulation of a dorsal root. A more widespread distribution of paresthesiae with bilateral involvement and a slightly higher threshold instead is more indicative of activation of the dorsal columns. Stimulation of the dorsal root entry zone or dorsal horn should give a pattern closer to the one of the corresponding nerve root. In reality, the problem is even more complex because often more than one structure is simultaneously stimulated. For example, when the electrodes are placed at the T11–L1 level, the nerve roots of the cauda equina come in close contact with the spinal cord and follow it for a distance of several centimeters. In this area it is common to have a mixture of dorsal column/dorsal root stimulation, and it might be practically impos-



Clinical Characteristics of Intraspinal Structures Activated by SCS

1	Motor Neurons	Motor contractions ipsilateral and at the level of the electrode
2	Sensory Neurons	Tingling ipsilateral and at the level of the electrode
3	Interneurons	Reduction of hypertonia and involuntary movements (?)
	Dorsal Columns	Tingling ipsilateral and below the level of the electrode
	Pyramidal Tract	Motor contractions ipsilateral and below the level of the electrode
	Reticulo-Spinal Tract	Reduction of hypertonia and involuntary movements (?)
	Sympathetic Tracts (Inhibition)	Feeling of warmth

FIG. 2. Clinical characteristics of the nervous structures stimulated by dorsal epidural electrodes.

sible to differentiate them on a clinical basis. Another conflictual situation occurs when the electrode is placed 3–4 mm from midline and could simultaneously stimulate the dorsal column, dorsal root, and its correspondent entry zone.

Motor structures also can be stimulated with dorsally placed electrodes. Stimulation at a rate of <5–10 Hz will preferentially stimulate the segmentary motor pathway, either by direct stimulation of the motor neurons or by activation of the monosynaptic reflex arc.

MAPPING OF SENSORY RESPONSES TO EPIDURAL SCS

One of the main factors in assuring the success of the stimulation procedure is the ability to cover with stimulation-induced paresthesiae the area of

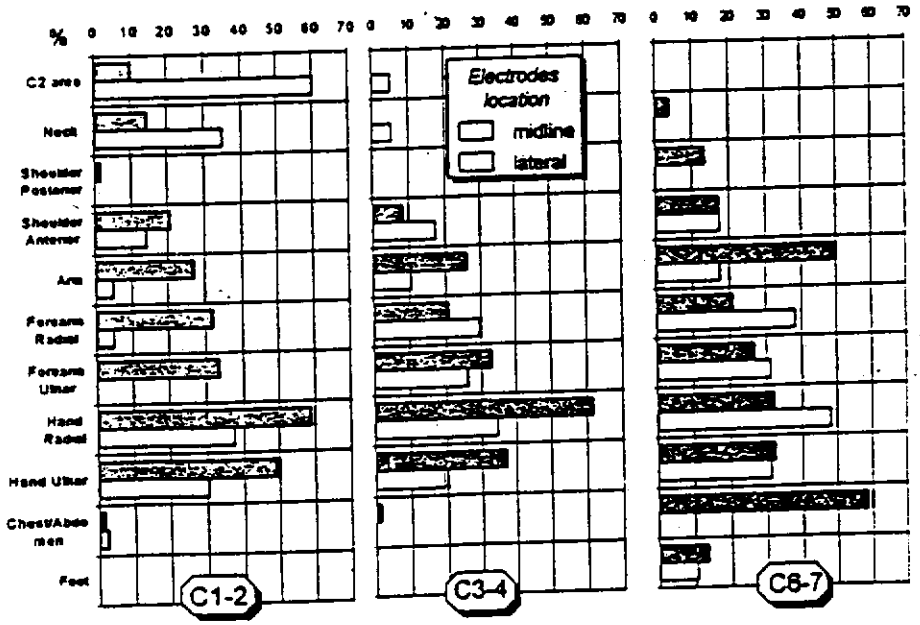


FIG. 3. Distribution of stimulation-induced paresthesiae at various cervical spine levels at perception threshold. The percentages indicate the probability that an electrode at that spine level will elicit paresthesiae in the appropriate body area [for further details on the methodology see Barolat et al. (9)].

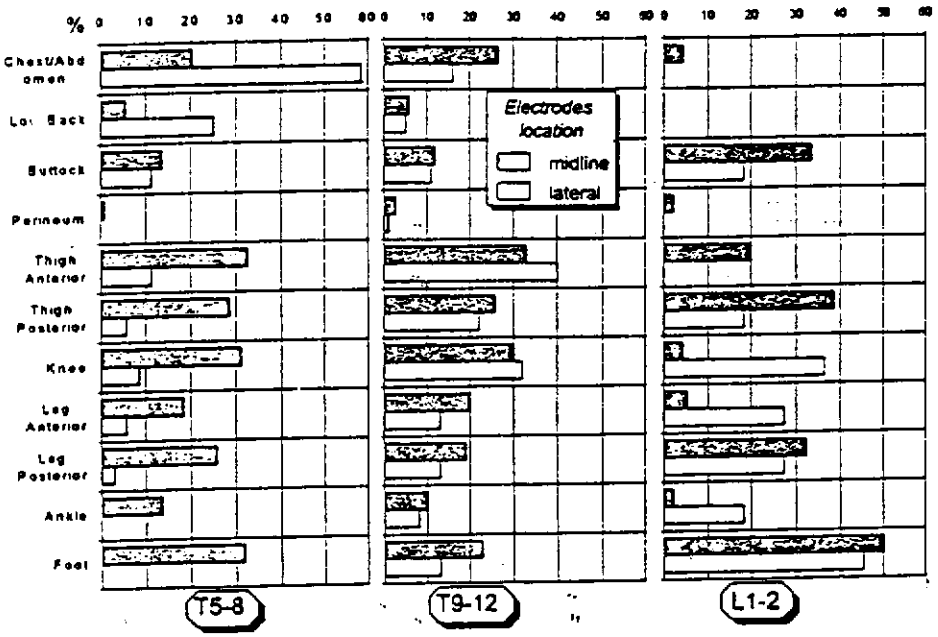


FIG. 4. Distribution of stimulation-induced paresthesiae at various thoracic spine levels at perception threshold. The percentages indicate the probability that a electrode at that spine level will elicit paresthesiae in the appropriate body area [for further details of the methodology see Barolat et al (9)].

pain (7,8). This can only be achieved if one positions the electrode(s) in strategically correct locations on the spinal cord. This strategy has been the object of systematic data collection and analysis by the author. A study on extensive mapping of the spinal cord levels has been published previously (Figs 3–4). Knowledge of the correlation between spinal levels of implanted electrodes and stimulation-induced paresthesiae, based on the analysis of thousands of combinations, has made it possible to more consistently and successfully place epidural electrodes at the desired spine levels.

The following paragraphs contain a discussion on how the various body areas that constitute common targets can best be stimulated with epidural electrodes. A more complete discussion of this work has been published elsewhere (9).

C2 Area

The C2 distribution covers the ipsilateral posterior occipital area and angle of the jaw. The C2 contribution to the angle of the jaw and the mandible is variable. In some individuals it covers only a small portion of the angle of the jaw; in others it covers a large portion of the mandible almost reaching midline. Paresthesiae in the C2 distribution are obtained with the electrode placed either under the arch of C1 or under the lamina of C2. The electrode has to be placed slightly off midline on the affected side. An excessively lateral placement stimulates the nerve root and generates undesirable motor contractions. In our experience the best arrangement to obtain paresthesiae in the C2 distribution is to have two electrodes side by side at C1–2, one in midline and one ~3 mm off midline.

Neck

Neck stimulation is difficult to obtain. The cathode must be at least at the C3 level. No major differences were found between midline or lateral contacts.

Shoulder

The anterior shoulder can be stimulated with electrodes in the upper cervical area (C1–3). The posterior shoulder is much more difficult to stimulate. Even with proper placement, shoulder stimulation is not obtained as consistently as are other areas, such as the hand.

Hand

Stimulation of the median aspect of the hand is elicited from the large percentage of combinations with electrodes placed from C1 down to C6. The ulnar side of the hand is stimulated more consistently when the electrode is at C7–T1. To obtain complete coverage of the hand, the electrode optimally should be placed at C3–5.

Chest/Abdominal Wall

Stimulation of the chest/abdominal wall is, in most instances, viewed as an undesirable side effect of stimulation directed to other parts of the body, most frequently the low back. Chest wall stimulation is often accompanied by motor contractions and is perceived as an unpleasant constrictive band. Both sensory and motor activation are often obtained at the same threshold, denying any therapeutic effect of the stimulation. Stimulation of the chest/abdominal wall unfortunately is a prominent feature of stimulation through electrodes placed in the thoracic spine. This might be due to the fact that the diameter of the spinal cord is at its narrowest at that level. Strict midline placement can minimize but not eliminate it. Even with a perfect midline electrode placement, in time chest/abdominal wall stimulation might become the most prominent feature, even if not so at the time of implantation.

Foot

The foot is one of the areas that display the highest likelihood of being covered by stimulation-induced paresthesiae. An electrode in the lower thoracic–upper lumbar area has >70% odds of activating the foot fibers. This reaches almost 100% when the cathode is at the L1 spine level. Foot fibers can also be more easily activated from higher spine levels, such as the cervical cord. Our usual target for pure foot stimulation is T12–L1.

Perineum

This area is difficult to stimulate. Only a small percentage of combinations elicits paresthesiae in the perineum/genitalia. Most of them come from electrodes located at T11–L1. To enhance the possibilities of stimulating this area, the electrodes have to be located in midline. Stimulation is also often simultaneously perceived in the anterior thigh area. Of the combinations that elicited paresthesiae in the perineum, a strikingly larger percentage was located in midline.

Low Back

This area is difficult to stimulate individually without intervening chest or abdominal wall stimulation. The spine levels for low-back stimulation overlap with the spine levels for the chest/abdominal wall. The chest and abdominal wall have a higher percentage of fiber recruitment and a lower stimulation threshold than does the low back. The low-back fibers seem to be buried medially and deep in the dorsal columns (Fig. 5). Stimulation through a dorsally placed midline electrode will activate the incoming dorsal roots before reaching the dorsal columns. The pioneering work of Law has shown that one can substantially enhance the penetration of the stimulation into the medial aspect of the dorsal columns by using narrowly spaced parallel electrode arrays (10). In Law's construct, he usually placed two parallel quadripolar or octapolar electrodes 1–2 mm on each side of midline at T9–10

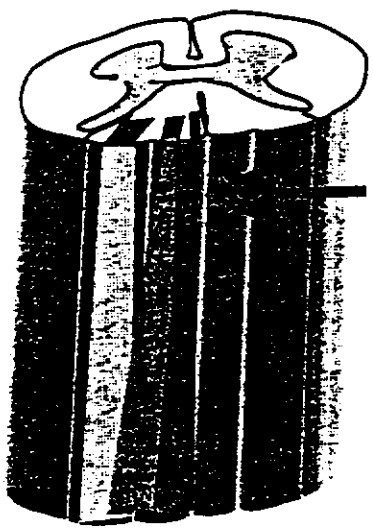


FIG. 5. Possible factors involved in SCS for low-back pain.

(Fig. 6). This configuration has allowed a more successful implementation of SCS for intractable low-back pain (11,12).

EQUIPMENT

Electrodes

Currently available electrodes are of two types: percutaneous and plate-type. The first percutaneous electrodes were unipolar, with only one electrical contact. Subsequently, bipolar, quadripolar, and, more recently, octapolar electrodes have been introduced (Figs. 7–8). Introduction of multipolar electrodes, paired with the possibility of noninvasively switching the electrical combinations, has substantially increased the flexibility of the procedure. Currently available percutaneous quadripolar electrodes include the Medtronic Quad, the Medtronic Quad Plus (the contacts are more widely spaced), and the Neuromed Quattro. The substantial difference between the Medtronic and the Neuromed line of percutaneous electrodes lies in the fact that the Medtronic electrodes are soft and require a stilet inserted in the electrode at the time of implantation that is removed when the electrode is in place. Different types of stilets exist, both straight and curved, that allow precise manipulation of the electrode in the epidural space. The Neuromed electrodes, instead, are inherently semi-stiff and do not require a stilet for insertion. Each type presents advantages and disadvantages, the discussion of which goes beyond the scope of this article. The only currently available octapolar electrode is the Neuromed Octrode. The Neuromed Cervitrode has seven unevenly clustered contacts and was developed specifically to treat complex upper extremity/upper thoracic area pain problems. Currently available plate-type electrodes that are approved by

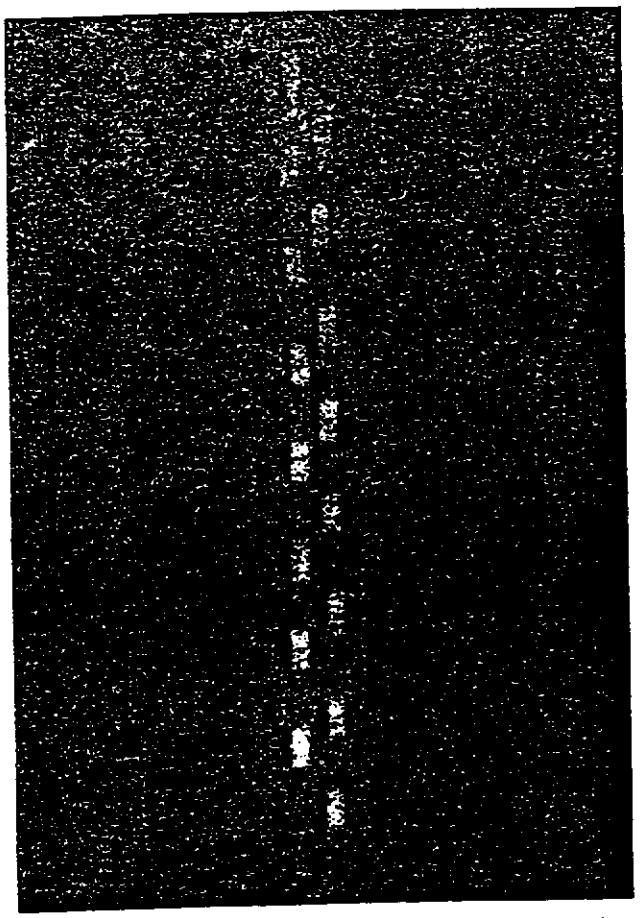


FIG. 6. Two Neuromed Octrode electrodes in a parallel arrangement at T9–10. This matrix gives a small intercontact distance (<7 mm). This allows the creation of an electrical field that selectively stimulates the dorsal column fibers located near midline. This arrangement, pioneered by Law, is optimal to stimulate the fibers innervating the lower lumbar area.

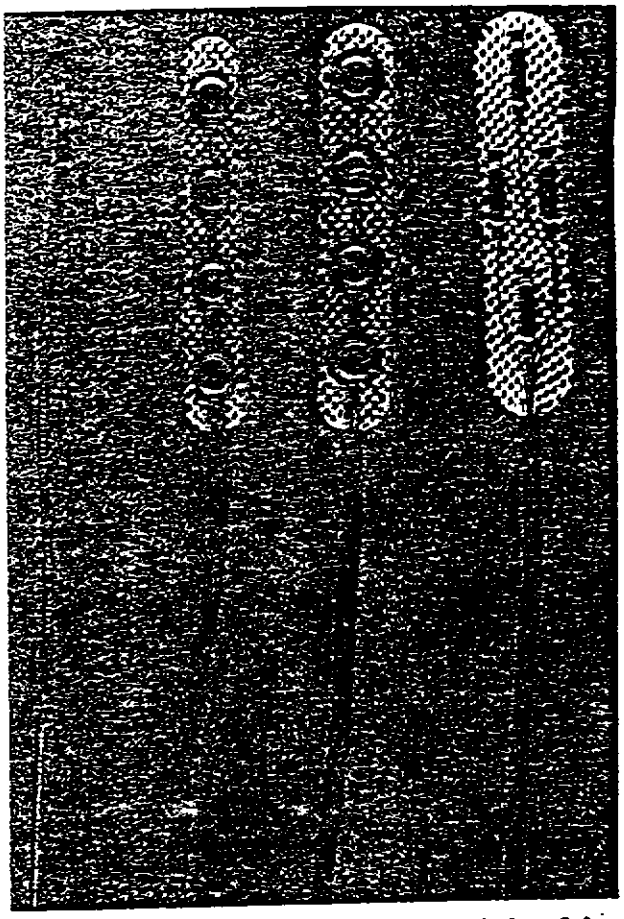


FIG. 7. Electrodes manufactured by Medtronic Inc. (left to right: Pisces Quad, Resume TL, Resume, Symmix).

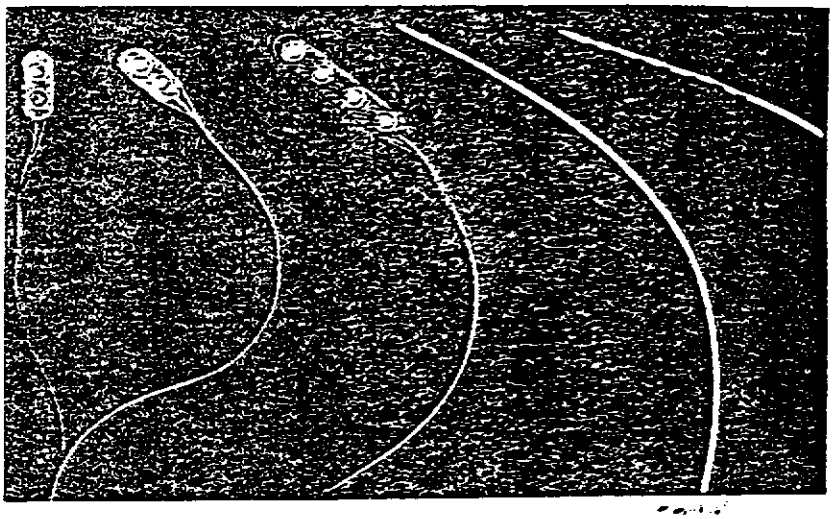


FIG. 8. Electrodes manufactured by Neuromed Inc. (left to right: Peritrode, Lamitrode, Quattro, Octrode).

the U.S. Food and Drug Administration are all quadripolar. They include the Medtronic Resume, the Medtronic Resume-TL, the Medtronic Symmix, the Neuromed Lamitrode, and the Neuromed Peritrode. A review of a large series of implanted plate electrodes recently has been reported (14). The Neuromed Peritrode consists of two small paddles, each of which contains two contacts. The two paddles, joined at the connector site, can be placed at different levels or in different locations on the spinal cord. In selected instances, this allows more flexibility. In the Medtronic Symmix the contacts are arranged in a diamond pattern in order to maximize the possibility of stimulating simultaneously both lower extremities. Other configurations are being designed and tested to optimize the patterns of stimulation.

Law found that narrowly spaced dipoles provide a more selective stimulation within the dorsal columns than do other electrode configurations (10). This major advance has made possible direct stimulation more selectively toward the low-back fibers, without incurring deleterious stimulation of the segmentary nerve roots. Law's observations were also confirmed by the author and coworkers in an extensive analysis of his implanted series (15). Law found the optimal spacing to be 7 mm. The Neuromed Octrode electrode was therefore built with a 7-mm intercontact spacing. Another way of obtaining such a narrow intercontact distance is to implant two percutaneous electrodes parallel to each other, one within 1–2 mm on each side of midline. This arrangement has proved to be extremely versatile and effective in obtaining and modifying the patterns of stimulation and has been endorsed by most experienced implanters.

Pulse Generators/Receivers

Two types of systems are currently available. The totally implantable pulse generators contain a lithium battery in the pulse generator. They are activated and controlled by outside transcutaneous telemetry and, once activated, they do not require any patient input to function. They can be turned on and off through a small magnet that the patient is advised to carry with him or her. The magnet also allows some control over the stimulation parameters. Life span of the battery greatly varies with usage and with the parameters applied (voltage, rate, pulse width, etc.). With average use, most patients can expect the battery to last 2.5–4.5 years. Available lithium-powered pulse generators allow stimulation to be given in increments of 0.1 V and with rates up to 130 Hz. With the currently available systems, electrode combinations cannot be modified by the programming device given to the patient.

Radio frequency (RF)-driven systems consist of a passive receiver implanted under the skin and a transmitter worn outside the body. RF-driven systems can deliver stimulation with a rate up to 1,400 Hz and can be customized to deliver more power than the corresponding lithium-powered systems. The patient has full access to all the features available, including changing the electrode combinations.

Both systems present advantages and disadvantages. The main disadvantage of the RF systems is the inconvenience of having to wear the antenna and the radio receiver. This might be a significant barrier for individuals who have weakness or poor motor coordination in the upper extremities and