Submitter : Mr. David Smith **Date & Time:** 05/20/2004 04:05:23

Organization : Pocono Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

Issues 11-20

Post Acute Care Transfers

The proposed rule,pg.28272, includes in it's definition "Home Health Services provided by a home health agency". Do these services include activities of daily living, ie. those provided by a nursing assistant or is the intent of the regulation to consider only Skilled Services, as would be provided in a SNF,ie. Physical Therapy and Wound Care.

Submitter : Mr. Ed Smith **Date & Time:** 05/18/2004 12:05:00

Organization : N/A

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I like this regulation

Submitter : Mr. Liane Schubring **Date & Time:** 05/18/2004 12:05:00

Organization : Souhegan Home & Hospice Care

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

This proposed regulation would be extremely detrimental to the future of this agency if enacted without any type of consideration for home care to apply for reclassification of their wage index. We are very close to Boston and lose several nurses and therapists to Boston hospitals, homecare agencies and nursing homes. We also compete directly for staff with local hospitals. If the wage index reclassification goes into effect, not only will our reimbursement decrease allowing for us to have less money to purchase benefits and offer competitive wages, but we will have less money paid to us under Medicare. This will lead directly to an even greater loss for this agency, to include, a greater inability to cover the losses incurred by the state Medicaid program, private insurers and managed care organizations. I plead for the sake of the future of some of the oldest and best homecare agencies in the southern NH area, to reconsider the wage index changes to the Hillsborough county and Rockingham county area. If this regulation is passed, then I plead for the regulation to make allowances for home care agencies to apply for reclassification. I sincerely hope that this comment is read, heard and understood. I do not want to have to lose this business and have the community lose the services they so desperately need. Thank you for your time and consideration.
Liane Schubring, BSN, RN, MBA/MHA, CHCE

Submitter : Ms. Kathy Konishi **Date & Time:** 05/21/2004 12:05:00

Organization : IHC Heatlh Services, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

I am very supportive of CMS' proposed change in CMS-1428-P for "Hospital Reclassifications" that would allow ALL rural referral centers to use the 82-percent threshold to determine eligibility for geographic reclassification. The proposed revision appropriately provides for consistency in the treatment of rural referral centers physically located in both urban and rural areas. The revision should be adopted as final by CMS.

Submitter : Mr. Roger Breitrick **Date & Time:** 05/25/2004 12:05:00

Organization : St. Vincent Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

I am commenting in regard to CMS-1428-P, regarding Hospitals-Within-Hospitals. I am seeking clarification as to whether or not the proposed rules pertain to Rehab and Psych Hospitals in addition to Long Term Care Facilities. The proposed changes relate to provisions of 412.22(e). In section 412.22(f), it states that facilities in existance on or before September 30, 1995 are exempt from the provisions of 412.22(e). Is this still true? Do Rehab facilities exempt on or before September 30, 1995 need to comply with the proposed rule that requires 75% of the admission to a hospital within a hospital, to come from a source other than the host hospital?

Submitter : Dr. Lewis Domke **Date & Time:** 05/25/2004 12:05:00

Organization : N/A

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

May 25, 2004
Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850
Attention: CMS-1428-P; graduate medical education
Dear Dr. McClellan:
This letter concerns the draft regulations governing the Medicare inpatient prospective payment system (IPPS) and, specifically, information on the one-time reallocation of unused residency positions included in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). This provision of the MMA allows for a reallocation of unused resident positions to hospitals that apply for new positions from the unused slots pool and that receive a priority status from CMS. Within each of the six level priority categories for allocating slots developed by CMS, certain other criteria for evaluating the applications for increases in hospitals' FTE resident caps apply. One proposed criterion adds points for hospitals that use the additional slots to establish a new geriatrics residency program, or to add residents to an existing geriatrics program.
As a member of the American Geriatrics Society, I appreciate your inclusion of the geriatrics' specific language in the proposed rule. We agree that geriatrics, as "the one specialty devoted primarily to the care of Medicare beneficiaries," should be used as a criterion for evaluating applications. We urge CMS to maintain this criterion in the final rule.
Sincerely,
Lewis R. Domke, M.D.
Certified by the American Board of Internal Medicine with Added Qualifications in Geriatric Medicine

CMS-1428-P-13

Submitter : Dr. Eric Troyer **Date & Time:** 05/26/2004 12:05:00

Organization : N/A

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-1428-P; graduate medical education
Dear Dr. McClellan:
This letter concerns the draft regulations governing the Medicare inpatient prospective payment system (IPPS) and, specifically, information on the one-time reallocation of unused residency positions included in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA).
I appreciate your inclusion of the geriatrics' specific language in the proposed rule. We agree that geriatrics, as "the one specialty devoted primarily to the care of Medicare beneficiaries," should be used as a criterion for evaluating applications. We urge CMS to maintain this criterion in the final rule.
As evidenced in a recent study published in Health Affairs (Apr 7 2004), in states with higher concentrations of GP's, Medicare spends less money per beneficiary and gets better quality. And, the opposite is true for states with higher specialist concentrations. The obvious action for CMS is to train more primary care physicians, especially in programs with a strong geriatrics training presence.
I believe we must train geriatrician teachers who can then teach the principles of geriatrics to others in primary care. This is exactly what our training program does. I hope we can encourage more residencies to add this type of fellowship to their programs.
Sincerely,
Eric Troyer, MD
Geriatrics & Family Medicine Faculty

Submitter : Mr. Samantha Jouin **Date & Time:** 06/09/2004 12:06:00

Organization : Synthes (USA)

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

To supplement my letter dated 5/28/04 relative to CMS-1428-P, an additional public comment e-mail from the period following the 4-1-04 ICD-9 meeting has come to my attention. It was sent on 4-5-04. This was forwarded to me by a hospital that uses Norian SRS. It includes comment on both the ICD-9 issue and on the New Technology DRG Add-On application for Norian SRS.
Please take this into consideration.

CMS-1428-P-14-Attach-1.doc

CMS-1428-P-14-Attach-2.doc

Submitter : Mr. Kent Shisler **Date & Time:** 06/10/2004 12:06:00

Organization : The Brethren Home Community

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

See comments in attached file.

CMS-1428-P-15-Attach-1.doc

Submitter : Ms. Renee McIver **Date & Time:** 06/10/2004 12:06:00

Organization : Inova Fairfax Heart & Vascular Institute

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

To: Deb Lorenz, Manager
Boston Scientific Corporation
Lorenzd@bsci.com
From: Renee A. McIver
Revenue Analyst/CCS
Cath & EP Lab
Inova Fairfax Hospital
Renee.mciver@inova.com
Re: Proposal to CMS for modification of DRG 526 & DRG 527 for Drug Eluting Stents and modification of DRG 516 & DRG 517.

I work at Inova Fairfax Hospital, an acute care facility that is also a level one-trauma hospital. The Cardiology and Cardiovascular departments are moving into a new facility that will be geared specifically to care for cardiac patients. We currently have 5 Cath Labs but we are increasing the number to 9 Cath labs when we move into our new facility. We will have approximately 150 beds on our inpatient units and 39 beds for our short stay patients. We are very excited and pleased to offer this facility and optimum care to our community. Part of the optimum care is being able to offer state of the art technology to our patients.?i.e. drug-eluting stents.

My role as Revenue Analyst is to capture charges and ensure their accuracy, in addition to ensuring we are reimbursed accurately from our payers.

I would like to comment on the FY 2005 Inpatient Proposed Rule. I am in support of the proposed change of the stent DRGs to reflect the complex vs. non-complex case mixes. We use an abundance of resources to make sure we deliver the highest quality of care for our patients and this could be a mechanism to reflect all of the resources that are used.

We use approximately 1.54 DES per patient and over 200 + Drug Eluting Stents per month. We strive to give our patients optimum care by having an array of sizes available for our cardiologist to choose. Our facility recognized the need for this technology to be available to the public and made the investment and commitment to our community.

The proposed change to reflect the complex cases vs. the non-complex cases would help to capture some of the total resources that are involved in caring for this population of patients. I feel this is an opportunity to show by ICD*9 code the complex CHF, Renal Failure, CVA, or AMI patients and reflect the resources.

Thank you for your time.
Renee A. McIver
Revenue Analyst/CCS
Inova Fairfax Heart Institute

Submitter : Mr. Kenneth Huelskamp **Date & Time:** 06/10/2004 12:06:00

Organization : Inova Fairfax Heart & Vascular Institute

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

To: Deb Lorenz, Manager
Boston Scientific Corporation
Lorenzd@bsci.com
Re: Proposal to CMS for modification of DRG 526 & DRG 527 for Drug Eluting Stents and modification of DRG 516 & DRG 517.
I reviewed the document you left in my box. I think the designation that Boston Sci developed is appropriate. When we consider the lower restenosis rate associated with DES, approval of these DRGs will have an overall cost savings effect since we would anticipate less need for brachytherapy and surgical intervention. In addition, patient populations are becoming more and more educated about their options relative to treatments. Most patients we see are aware and expect to get a DES should they require a PCI. So, in order to find a balance between demand and its associated costs, a separate DRG with appropriate reimbursement is necessary to keep healthcare facilities financially viable.
Hope this helps.....Let me know if you need anything else. Thanks!
Ken Huelskamp, BS, RCIS, MSA
Cardiac Cath Lab Supervisor
Pager #73069

Submitter : Mr. David Travis **Date & Time:** 06/11/2004 12:06:00

Organization : East Texas Medical Center Athens

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

CMS-1428-P
"Hospital Redesignations?
For fiscal year 2005, East Texas Medical Center Athens located in Athens, Henderson County, Texas is a rural hospital and qualifies to be treated as being located in an adjacent MSA under section 1886(d)(8)(B) of the Act. However, the proposed rule has omitted East Texas Medical Center Athens from the tables showing such redesignations. We request that this omission be corrected in the final rule and East Texas Medical Center Athens be listed as redesignated to the Dallas-Fort Worth-Arlington, Texas MSA.
In part III.H.1. of the proposed rule there is a discussion concerning section 1886(d)(8)(B) of the Act that requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA to which the greatest number of workers in the county commute if: the rural county would otherwise be considered part of an urban area under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous MSAs.
In part III.H.3.c. there is a list of the eligible counties for this provision. This list (chart 6) includes the rural county Henderson, Texas to be included in the Dallas-Fort Worth-Arlington, Texas MSA. Our hospital, East Texas Medical Center Athens is located in Athens, Henderson County, Texas.
In part III.H.4 you state that the Table 9A shows hospitals that have been reclassified under either section 1886(d)(8) or section 1886(d)(10)(D) of the Act and the Table includes rural hospitals redesignated to urban areas under section 1886(d)(8)(B) of the Act for purposes of the wage index. This list does not include East Texas Medical Center Athens.
We request that this omission be corrected in the final rule and reflect East Texas Medical Center Athens as eligible to be redesignated to the Dallas-Fort Worth-Arlington, Texas MSA under section 1886(d)(8)(B) of the Act for purposes of the wage index.
Sincerely,
Patrick L. Wallace
Administrator
East Texas Medical Center Athens
David A. Travis
Chief Financial Officer
East Texas Medical Center Athens

Submitter : Mr. Eugene Leblond **Date & Time:** 06/17/2004 03:06:24

Organization : Pocono Health System

Category : Hospital

Issue Areas/Comments

Issues 1-10

DRG Reclassifications

June 15, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS - 1428 - P
Room C5-14-03, Central Building
7500 Security Boulevard
Baltimore, MD 21244-1850

Issue Identifier:
Federal Register/Vol.69, No.96/Tuesday, May 18, 2004/Proposed Rules Page#28261, H. Proposed revisions to the Wage Index Based on Hospital Redisignation 3. FY 2005 Issues b. Implementation of New MSAs

Attn: Jim Hart

Dear Mr. Hart:

Pocono Medical Center (PMC) provider number 39-0201 is an acute care hospital consisting of 192 licensed beds located in East Stroudsburg, PA in Monroe County. PMC was approved by the Medicare Geographic Reclassification Review BOard (MGCRB) and reclassified for wage purposes to the Newburgh, NY-PA MSA effective 10/01/02 for a three year period ending Spetember 30, 2005. The MGCRB reference number for the reclassificaiton is 01C0054.

In reviewing the proposed Hospital Inpatient PPS regulations for fiscal year 2005: PMC is in disagreement with your determination of the closest proximate county on which to assign us. The proposed regulations for fiscal year 2005, assign PMC to the CBSA of Allentown-Bethlehem-Easton, PA-NJ. PMC does not currently have in effect a MGCRB reclassifcation to the Allentown-Behtlehem-Easton, PA MSA. The fact that Warren County, NJ is part of the Allentown-Bethlehem-Easton CBSA is irrelevant since Warren County, NJ was not part of the Newburgh, NY-PA MSA to which PMC is reclassified to by the MGCRB through September 30, 2005.

Under the new CBSA definitions, the Newburgh, NY-PA MSA was disbanded. Orange County NY became part of the CBSA of Poughkeepsie-Newburgh-Middletown, NY and Pike County PA became part of the CSBA of Newark-Union, NJ-PA for a three year period effective October 1, 2002 through September 30, 2005. Following the example given in the Federal Register on page 28263, PMC should be assigned to either Poughkeepsie-Newburgh-Middletown, NY CBSA or Newark-Union, NJ-PA CBSA, depending on whether the hospital was closer to Orange COunty NY or Pike County PA. Because PMC is a reclassified hospital located closed to Pike County, PA, PMC should be assigned tothe Newark-Union, NJ-PA CBSA. This is based on Pike County PA's inclusion in the Newark-Union, NJ-PA CBSA.

Additionally, PMC is located in Monroe County, PA which is listed as reclassified to the New York-Newark, NJ-NJ-CT MSA in the table on page 28264 of the Proposed Rule under Section 1886(d)(8)(B) of the Act. The Newark-Union, NJ-PA CBSA appears to be a part of that MSA. Previously, hospitals reclassifed under Section 1886(d)(8)(B) of the Act were considered reclassified for purposes of both standardized amount and wage index. As discussed in the Proposed Rule on page 28263, there are no longer any reclasifcations for purposes of standardized amount so the reclassification under section 1886(d)(8)(B) is for wage index purposes only. Under long standing policy of CMS, hospitals reclassified for standardized amount are considered urban for all purposes while hospitals reclassifed for wage index purposes only are considered rural for all other purposes. Accordingly, since reclassification under Section 1886(d)(8)(B) of the Act is only for wage index pruposes in the future, PMC should be considered part of the New York-Newark, NY-NJ-CT MSA (we presume this means the Newark-Union, NJ-PA CBSA) for wage index purposes and rural for all other purposes without the need to apply for reclassifcation to the MGCRB in the future.

In review of the above facts, you will find that PMC should be reclassifed to the Newark-Union, NJ-PA CBSA for wage index and not the Allentown-Bethlehem-Easton, PA-NJ CBSA as indicated in the Proposed Rule for fiscal year 2005.

Please contact Mr. Ed Walsh, CPA, Chief Financial Officer at 570-476-3620 or Troy Armitage, Decision Support Manager at 570-420-4917 with any questions.

Sincerely,
Eugene A. Leblond, FACHE
President/CEO

CMS-1428-P-20

Submitter : **Date & Time:** 06/17/2004 08:06:51

Organization :

Category : Government

Issue Areas/Comments

Issues 21-30

IME Adjustment

Page 28284, second column, 13th line from the bottom - computation for IME adjustment factor should = 0.0539 instead of 0.0559.

Submitter : Mr. Anthony Lewis **Date & Time:** 06/15/2004 12:06:00

Organization : N/A

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

File code-CMS-1428-P
Issue: Graduate Medical Education
Dear Secretary: Thank-you for the opportunity to offer comments on the proposed rule entitled: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates
I wish to comment on the issue of agreements for residents that rotate to nonhospital settings. In the regulations, CMS is proposing to do away with agreements as long as providers can show that they bore the costs of the resident salaries and wages (benefits, etc.), as well as the teaching costs of the supervisory physicians at the nonprovider setting. I am requesting clarification on supervisory physicians who volunteer their time that is not compensated directly by the provider. What is very unclear is the statement made in the rule (p. 28317 of the Federal Register):
"We are aware that there are situations where, rather than providing direct financial compensation to the nonhospital site for supervisory teaching activities, the hospital is incurring all or substantially all of the teaching physician costs through nonmonetary, in-kind arrangements. We are proposing that, in order to be considered concurrent with the nonhospital site training, in-kind arrangements must be provided or made available to the teaching physician at least quarterly...
Would CMS please elaborate on these "in-kind" arrangements and give examples. Also, in the event that a hospital rotates residents to physician offices in town and the solo physician is devoting his/her time without compensation from the hospital solely on a voluntary basis, what type of in-kind arrangements are there in these types of situations?

Submitter : Dr. Michael Chaparro **Date & Time:** 06/16/2004 12:06:00

Organization : Palms West Pediatric Neurosurgery

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs:
I feel it is important to bring to your attention the difficulties that I have encountered in using Gliadel Wafers in the care of my patients with brain tumors. The cost to my institution is in excess of $10,000. Consequentially, the hospital (Palms West Hospital, in Loxtahachee, FL) will not stock the medication. In addition, I must obtain approval from the Hospital's CFO, Mr. Robert Preato, to use Gliadel Wafers. I have not been able to obtain permission to use this medication on Medicaid, Medicare, and some private payer patients. Only when the reimbursment covers the Hospital's cost of the drug have I been allowed to direct the pharmacy to order Gliadel Wafers. At least three patients to date this year were denied access to this treatment because of the costs to the institution. As I am sure you are aware, brain tumors are more common in our older patient population. Many of these patients will have Medicare as their soul source of funding. At my institution, these patients will be denied access to this medication, with proven benefits, until CMS moves the medication to a more favorable DRG.

Submitter : Mrs. Donna Badger **Date & Time:** 06/24/2004 12:06:00

Organization : Rhode Island Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Please refer to attachment below.

CMS-1428-P-27

Submitter : Mr. James Jackel **Date & Time:** 06/24/2004 12:06:00

Organization : Mercy Memorial Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Attached is the comment in a word doc.

CMS-1428-P-27-Attach-1.doc

CMS-1428-P-28

Submitter : Mr. Kenneth Tobias **Date & Time:** 06/24/2004 12:06:00

Organization : PricewaterhouseCoopers, LLP

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

CMS-1428-P ? ?Occupational Mix? The May FY2005 Proposed Rule states the purpose of the Occupational Mix Adjustment is to modify wage data in an effort to control the effect of hospitals? employment choices on wage index. However, in its current form, the calculation steps related to the Occupational Mix Adjustment will be relatively ineffective in application. This is due to the placement of the Occupational Mix Adjustment in the Medicare Wage Index Calculation. In the proposed calculation, the Occupational Mix Adjustment is made prior to the consolidation of individual hospital?s average wage rates into the MSA?s weighted average wage rate. In other words, the Occupational Mix Adjustment is made to the wage data and not to the calculated wage index. Therefore, each hospital is now at the mercy of the occupational mix of the hospitals in their Metropolitan Area. For example, if one hospital in a MSA of three hospitals utilizes a mix of high skilled patient care personnel equivalent to the national average and the other two hospitals utilize a higher mix of high skilled patient care personnel than the national average, the one hospital at the national average will be disadvantaged by the other two. Further, the placement of the Occupational Mix Adjustment prior to the consolidation of individual hospital?s average wage rates into the MSA?s weighted average wage rate dilutes the effect to the hospitals in the MSA which are out of line with the national average occupational mix. A better placement of the Occupational Mix Adjustment would be after the computation of the MSA?s weighted average wage rate. Placement at this point would, in effect, create a facility specific adjustment and directly impact only those facilities that fall outside of the national average occupational. Thereby, removing the disadvantage created in situations described above. This would also resolve the dilemma of enforcement for those hospitals who fail to report Occupational Survey Data. CMS could establish a hospital specific penalty such as weighting all occupational mix categories at some threshold level (i.e. 1.05). Placement of the occupational mix adjustment behind the MSA?s weighted average wage rate and a high occupational mix score would certainly create an incentive for hospitals to respond to CMS Occupational Mix Surveys. Although CMS states the purpose of the Occupational Mix Adjustment is to modify wage data in an effort to control the effect of hospital?s employment choices on the wage index, the true effect of the Occupational Mix Adjustment may be to lower the quality of care by creating an incentive to pay lower skilled labor higher wages and remove higher skilled labor from the market. Question? If it is true that the Case Mix Index Adjustment already and effectively controls employment choices, then isn?t the average wage rate for each facility already adjusted appropriately for occupational mix?

CMS-1428-P-28-Attach-1.doc

CMS-1428-P-29

Submitter : Mr. Kenneth Tobias **Date & Time:** 06/24/2004 12:06:00

Organization : PricewaterhouseCoopers, LLP

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

CMS-1428-P ? ?Wage Data? I have been working on several providers wage data over the past couple of years. This year we came across a provider with these Provider Based Clinics ("PBC") and noted the following observations: As you are probably aware, PBCs are nothing more than a physician private office that has received special treatment for Medicare and are reported on Worksheet A, Ln. 60 (not an excluded area cost center per the S-3 instructions) versus Ln. 98 (a typical cost center for Physician Private Offices - excluded area cost center per the S-3 instructions). Physician private offices bill two components (Professional and Technical) for their services under the physician fee schedule. When these private offices are determined to be "Provider Based" they bill the Technical component under certain Outpatient APCs and the Professional component is still billed under the physician fee schedule. Accordingly, these PBCs are not paid by Medicare under the Inpatient Prospective Payment System (IPPS). Interestingly, for FY2004, RHCs and FQHCs were removed from the Medicare Wage Index computation because they were determined to be services that Medicare paid outside of the IPPS. [FY2004 Final Rule, III.C.1. - August 1, 2003] For Medicare Wage Data purposes, the physician salaries and associated hours are required to be reported on line 5 of Worksheet S-3, Part II which gets removed for Medicare wage index purposes. The remaining salaries in these PBCs are typically lower average hourly wages that exist solely for the purposes of supporting the physician (not the hospital) and remain within the wage data computation. Another observation regarding PBCs is how infrequently they exist among hospitals. It appears that a majority of the providers do not have PBCs and due to the new provider based regulations the usage of PBCs appears to be diminishing quickly. However, for those majority hospitals within an MSA that don't utilize PBCs, a disadvantage is created in the wage index computation by the minority hospitals within the MSA that do since the MSA must absorb the relatively lower average hourly wages that are presently required to remain in the MSA's wage data. Therefore, I am puzzled as to the reasoning for not excluding these PBCs from the Medicare Wage Index computation. Is there any information you can provide me that will make it seem logical? If by some chance this seems to be an evolving issue, I would like to offer up a reasonable solution... Simply have Ln. 60 become another excluded area cost center. The FI's can easily identify the salaries on worksheet A and the associated hours from the providers paid hours report.

CMS-1428-P-29-Attach-1.doc

CMS-1428-P-34 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Christopher Guerin** **Date & Time:** **06/30/2004**

Organization : **Neurosugical Associates, Cassidy & Guerin, MD, PA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1428-P (Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates) Comment on Other DRG Issues
My malignant glioma brain tumor patients at Bon-Secours Venice Hospital, Venice, FL (a very high percentage Medicare population) are unable to receive Gliadel chemotherapy wafer implants due to lack of adequate reimbursement from CMS for the relevant DRG. The hospital cannot afford to absorb the large deficit it would incur, and thus is not able to allow Gliadel use. As you know, several phase 3 trials confirm the efficacy and safety of Gliadel. Older patients can particularly benefit from these implants, since they are less tolerant of, thus less likely to complete, reimbursed systemic chemotherapy. Unfortunately, CMS reimbursement policies are leading to Medicare beneficiaries' lack of access to this treatment for a disease with very little effective therapy. I request that CMS reconsider the DRG assignment/ reimbursement for Gliadel cases such that hospitals can afford to provide this effective treatment to our elderly and disabled.
Sincerely,
Christopher Guerin, MD

CMS-1428-P-35 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Steven Compton** **Date & Time:** **06/30/2004**

Organization : **Alaska Heart Institute**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am a clinical cardiac electrophysiologist, with an active cardiology rhythm practice. I'm writing to encourage CMS to improve Medicare payment to hospitals for CRT-D. Better reimbursement to hospitals will increase patient access to the therapy. A new technology add-on payment for CRT-D has been requested. If approved, an extra payment would be made to augment the basic reimbursement for DRGs 535, 536 and 515.
I primarily want to emphasize that CRT-D therapy represents a new and substantial improvement over previous device therapies, because CRT-D can dramatically improve patients' quality of life and stamina, in addition to improving survival. CRT-D has also been clearly demonstrated to reduce the risk of repeated hospital admissions for congestive heart failure. This therapy is substantially more difficult to deliver than previous pacing and defibrillation therapies, due to technical complexities in transvenous placement of left ventricular epicardial pacing electrodes. The therapy is clearly underutilized, in part due to poor reimbursement for the often substantial extra time involved in placing these devices (3-6 hours!). Improved reimbursement will improve patient access to this lifesaving therapy. I urge CMS to approve this proposal.

CMS-1428-P-36 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Benjamin Wallfisch** **Date & Time:** **07/02/2004**

Organization : **Medical Device Manufacturers Association**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

<see attached>

CMS-1428-P-36-Attach-1.doc

CMS-1428-P-37 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. patty parson** **Date & Time:** **07/02/2004**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

dlsnhewialkdmns

CMS-1428-P-38 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. test kj** **Date & Time:** **07/02/2004**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

k

CMS-1428-P-39 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Richard Wayne** **Date & Time:** **07/02/2004**

Organization : **CHRISTUS Santa Rosa Children's Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1428-P-39-Attach-1.doc

CMS-1428-P-40 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mrs. Linda Stones** **Date & Time:** **07/02/2004**

Organization : **Hospital for Extended Recovery**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

This is a comment on CMS-1428-P. See response attached.

CMS-1428-P-40-Attach-1.doc

CMS-1428-P-41 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Robert Charrow** **Date & Time:** **07/02/2004**

Organization : **On Behalf of Ovation Pharmaceuticals, Inc**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

See attached File with Comment.

CMS-1428-P-41-Attach-1.pdf

Greenberg Traurig

Robert P. Charrow
Phone: (202) 533-2396
charrowr@gtlaw.com

July 2, 2004

VIA ELECTRONIC MAIL AND USPS
http://www.accessdata.fda.gov/scripts/oc/dockets/ commentdocket.cfm?AGENCY=CMS or
www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

Subject: Inpatient Prospective Payment System FY 2005—Proposed Rule

Dear Sir or Madam:

We are writing on behalf of Ovation Pharmaceuticals, Inc. ("Ovation) with respect to the Proposed Rule for Inpatient Prospective Payment System FY 2005. *See* 69 Fed. Reg. 28196 (May 18, 2004). Ovation manufactures and distributes an orphan biologic intended to treat acute intermittent porphyria ("AIP") ("ICD-9: 277.1"), a rare metabolic disorder that affects fewer than 1,000 persons in the United States. Ovation is concerned that Medicare payments under part A for patients hospitalized with AIP do not accurately reflect the costs of the treatment. The proposed rule would continue that policy. For the reasons set forth below, we urge the Centers for Medicare & Medicaid Services ("CMS") to address the inequities with respect to AIP in the proposed DRG assignment scheme.

The treatment of choice for episodes of AIP is infusion of hemin. Panhematin, the trade name for injectable hemin, is a biologic approved by the Food and Drug Administration and designated as a orphan product under the Orphan Drug Act. *See* Federal Food, Drug, and Cosmetic Act §§ 525 *et seq.* Ovation is the only manufacturer of hemin.

There exists a great inequity between the established Medicare inpatient hospital payment for patients requiring Panhmatin infusions and the hospital costs typically associated with those admissions. The Social Security Act requires CMS to adjust DRG payments to reflect changes in hospital costs. *See e.g.*, SSA § 1886(d)(4). Ovation is requesting that CMS correct that inequity.

Acute care hospitals receive a fixed fee for hospital stays based on the designation of "Inborn Errors of Metabolism" (DRG 299) under which the ICD-9 277.1 falls. That fee is adjusted for geographic variation, disproportionate share and indirect medical education. For example, for admitting and treating a patient with AIP, Medicare will pay a San Francisco teaching hospital about $6,300, while a rural Illinois hospital would receive about $3,700 for treating the same case. The DRG payment is supposed to be all inclusive. Subject to unusual

circumstances, Medicare part A does not pay extra for drugs. Thus, a hospital administering a costly drug to an inpatient receives nothing extra from Medicare to offset the price that it pays to purchase the drug.

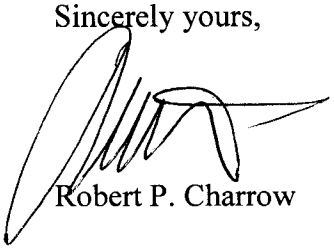
Ovation has conducted a preliminary informal survey of certain hospitals and compared the payments for hospital stays for the treatment of porphyria and the cost to the hospital for those hospital stays. Ovation found that on average, a hospital receives about $4,600 under PPS to treat an AIP patient. However, the hospitals spend more than $11,000 just to purchase the drug.

As of January 6, 2003, the average wholesale price ("AWP") of Panhematin, as reported in the Micromedex Red Book, was and is $2,437.50 for 313 mg (in powder form). In 2004, the part B payment level for hemin (Q2011) is $2,071.88 per vial or 85% of the AWP. Each vial contains 313 mg. This is an orphan drug and is only sold by the vial. In March, 2004, Ovation conducted an informal survey of five hospitals in both urban and rural locations. Those hospitals reported the following information regarding 2003 and 2004 admissions for the treatment of AIP under DRG 299:

Results of Informal Survey	
Hospital Stays for ICD-9 277.1 (DRG 299)	19
Average Length of Stay (days)	9
Average Number of Panhematin Vials Administered Per Stay	5.63
85 Percent AWP Per Vial of Panhematin	$2,071.88
Average Imputed Panhematin Cost Per Stay	$11,664.68
Average Hospital Charges w/o Panhematin for 4 Hospitals*	$13,377.00
Total Imputed Costs and Charges	$25,041.68
Average PPS Payment for DRG 299	$4,639.07

Based on these preliminary data, it would appear that assigning AIP to DRG 299 dramatically underpays hospitals for treating patients with AIP, especially where hemin injection is warranted. We believe that AIP ought to be moved to another more economically appropriate DRG, that DRG 299 be adjusted with a modifier to take into account those AIP cases requiring hemin, or that hospital stays for the treatment of AIP with hemin be assigned to a new, unique DRG.

Sincerely yours,



Robert P. Charrow

RPC/pb

* The fifth hospital did not report charges without Panhematin.

CMS-1428-P-56 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. James Sherwood** **Date & Time:** **07/07/2004**

Organization : **Henrico Doctor's Hospital**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

I support the movement of LVADs into DRG 103. Patient applications are increasing, and hospitals who want to do the right thing for their patients are aborbing increasing costs that are not reimbursed. The incremental payment for LVADs will help. Thank you, James Sherwood

CMS-1428-P-57 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Earl Kemp** **Date & Time:** **07/07/2004**

Organization : **Center for Family Medicine**

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

The moratorium on written provider agreements which require such details as certifying there is no added expense to teachers outside the home institution, or certifying that teaching is done on a volunteer basis, etc. is very helpful this year, and must be extended indefinitely. A great deal of education of family physicians is most appropriately provided in the ambulatory setting, and while we agree that the cost of resident stipends, benefits etc. are the responsibility of the sponsoring institutions, this can be paid only if there is stable financial support, a great deal of which comes through CMS. We urge CMS to limit the required agreement to one in which the program pledges to carry direct financial responsibility for resident expenses, but eliminate any requirement on the part of our teachers to certify volunteerism or absence of any out of pocket expenses on their part. This adds confusion to an already complicated situation in working with voluntary teachers, and has resulted in the loss of services of some good ones.

WE also urge CMS to eliminate the apparent trend toward requiring reimbursement of teachers regardless of whether or not they have any expenses resulting from teaching. Residency programs are being squeezed financially with out adding expenses which are totally unnecessary in the education of our residents, and places our programs at further risk of closure by sponsoring institutions whose immediate priority is direct care of patients, with graduate medical education being secondary.

Family pracitce residencies are in the greates jepordy because the majority of our programs are community based, and our institutions have smaller budgets, which are more susceptible to these forces.

Family physician training is critical to the health of our citizens because we provide the bulk of first contact health care, especially in underserved areas such as inner city and rural settings. For example, our program in Sioux Falls, SD has about 250 graduates, of whom about 160 are in rural practice settings. Several communities have been taken off the "critical health provider shortage" list because our graduates have opened or augmented practices in those areas. IME is a critical component of the funding of programs such as ours.

Finally, I would ask that CMS give clear recommendations to intermediaries that beyond the basic agreement to teach, on the part of faculty, and the basic agreement to fund resident expenses on the part of our programs, no other criteria are needed to approve funding of graduate medical education in the ambulatory setting. Some intermediaries have made arbitrary decisions on minute criteria and damaged programs in ways which were unintended in the law.
Thank you.

IME Adjustment

It is important that the IME be frozen at present levels for the survivial of community based residency programs. These are sponsored by hospitals with narrow operating margins, but are critical in the production of family physicians. Family physician training is critical to the health of our citizens because they provide the bulk of first contact health care, especially in underserved areas such as inner city and rural settings. For example, our program in Sioux Falls, SD has

about 250 graduates, of whom about 160 are in rural practice settings. Several communities have been taken off the "critical health provider shortage" list because our graduates have opened or augmented practices in those sites. IME is a critical component of the funding of programs such as ours. Reductions place our program in jepordy of being closed because the hospitals' first funding priority is direct patient care.

CMS-1428-P-58 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Randall Longenecker** **Date & Time:** **07/08/2004**

Organization : **The Ohio State University Rural Program**

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Section 713
It is imperative, for the survival of family medicine residency programs, especially those located in rural areas, that hospitals be allowed to count resident FTE's for training in non-provider settings when the hospital incurs the actual costs of that training. In most cases, the teaching physician in that setting teaches on a volunteer basis, and the costs for training, including (1) the resident physician's salary and benefits, (2) the administrative costs of scheduling, curricular planning, oversight, and evaluation, and (3) supervisory teaching faculty costs are borne by the teaching hospital. Approximately 40% of our residents' training (10% PGY1; 40% PGY2, and 70% pGY3) occurs in these settings and we are dependent upon the 40 volunteer faculty for the financial survival of our rural training track. If required to pay these faculty for their time in order to claim the resident's FTE in those settings, community-based medical education (the vision of the Institute of Medicine) is dead. What we get in GME/IME does not begin to cover the costs that we already bear.

Redistribution of unused residency slots:
Rural hospitals with less than 250 beds should be exempt from redistribution of unused resident positions. It has been extremely difficult to recruit students to these settings, and to take away positions that are unused thwarts the intent of legislation, which is to promote and foster training in these settings. Priority for new funding should favor rural and other underserved training sites. Although family medicine programs in general train physicians who locate in rural settings, no program does that better than those programs which are in fact rural-located or who require significant time in that setting. I support the current CMS definition of rural training developed by the Rural Medical Educators group of the NRHA. Similar definitions could be developed for other underserved communities, although urban definitions are subject to abuse by urban academic health centers located by not serving the communities in which they are present.

CMS-1428-P-59 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Daniel Border** **Date & Time:** **07/08/2004**

Organization : **Adventist Medical Center**

Category : **Hospital**

Issue Areas/Comments

Issues 31-40

Operating Payment Rates

Proposed Changes to Hospital IPPS Outlier Threshold for FY 2005.

We are very concerned with the proposed 16.4% increase in the Inpatient Outlier Threshold from $30,150 to $35,085, effective October 1, 2004.

CMS states in the proposed regulation (May 18, 2004 Federal Register, page 28377) that estimated FY 2004 outlier payments will be approximately 4.4% of total DRG payments. Thus, the current outlier threshold amount was set too high for the current fiscal year, resulting in outlier payments approximately 20% below the midpoint of the statutory required range of 5% to 6% of total DRG payments.

We believe that the assumptions used to calculate the proposed increase in the FY 2005 outlier threshold will likely result in continued underpayment of outlier amounts.

First, the estimated two-year increase in charges applied to FY 2003 MedPAR claims, is probably overstated at 31.1%. This increase is based on the change in MedPAR charges per case from FY 2001 to FY 2003. This was a period of charge restructuring in the industry to counter the negative effects on hospitals from the 1997 Balanced Budget Act provisions, intended to increase reimbursement from insurance payors and private parties. If hospitals do not increase their charges by at least 31.1% from 10/01/02 to 10/01/04 they will certainly lose part of their currently underpaid outlier reimbursement, assuming no change in case mix and utilization levels. The proposed rule would be a strong incentive to increase charges beyond the level that might otherwise be required.

Second, the proposed regulation is lacking the necessary update of cost-to-charge ratios from the December 2003 Provider Specific File (generally FY 2002 ratios), to account for the annual decline in such ratios. Since hospital charges increase at a higher rate than costs each year, cost-to- charge ratios decline over time. CMS will use cost-to-charge ratios that are one year newer (generally FY 2003 ratios) to calculate actual FY 2005 outlier payments. If CMS does not adjust the December 2003 PSF cost-to-charge ratios, the estimated FY 2005 outlier payments will be overstated, resulting in the need to set the outlier threshold too high. If the outlier threshold is set too high, based on overstated cost and outlier payment estimates, the outcome will be another year of outlier payments below the statutory required range of 5% to 6%.

Please consider our recommendations to correct the two problems identified above.

First, we recommend that paid FY 2004 claims should be analyzed to determine the percentage increase in average charges per case over FY 2003 levels. A small factor could be added, if necessary, to trend the FY 2004 amounts forward from 6/30/04 to 9/30/04 based on analysis of changes in the FY 2003 claims from 6/30/03 through 9/30/03. The resulting percentage increase in average charges per case from FY 2003 to FY 2004 could be doubled, and applied to the FY 2003 MedPAR claims to estimate FY 2005 charges. This approach should yield a more current estimation of

charges, since one year (FY 2004) of the two-year period is a known amount.

Second, we recommend adjusting the 2003 cost-to-charge ratios, for the purpose of estimating FY 2005 costs and establishing the FY 2005 outlier threshold. Since the ratios published in the December 2003 Provider Specific File are generally the ones used to calculate actual FY 2004 outlier payments, only one year of adjustment is needed to estimate the decrease in such ratios that will result from increasing charges at a higher rate of inflation than actual cost inflation. The FY 2005 update factor used to increase the IPPS standardized payment amount should be used as a proxy for the average increase in hospital allowable costs.

We appreciate the opportunity to comment on CMS proposed regulations for FY 2005, and hope that you will consider our comments to adjust the final regulations.

CMS-1428-P-59-Attach-1.doc

CMS-1428-P-60 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Allan Wilke** **Date & Time:** **07/08/2004**

Organization : **Medical College of Ohio**

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Non-hospital Settings:

Written Agreements:

We agree there is no need for CMS to require a written agreement, and we appreciate the attempt to lighten the regulatory burden for hospitals complying with the regulations surrounding graduate medical education. However, for the purposes of family medicine education, written agreements are already required by the Residency Review Committee (RRC) for Family Practice and are part of the accreditation process.

CMS?s proposal to replace the written agreement with a payment requirement is not a better solution. To expect an institution to pay within 30 days after the training has occurred adds a tremendous burden to the hospital. It makes more sense to require that payment, if any is incurred, be made within the cost reporting period, without any further restrictions.

We request that CMS to make very clear in regulation or intermediary instruction that if there are no payments made to the non-hospital site by the hospital, that is not an a priori reason to deny time spent by residents in that environment. If the hospital is paying the resident?s salary and benefits, travel costs, lodging, etc., there may in fact be no costs (hence payments) to the non-hospital site. This would frequently be the case in situations where the preceptor is volunteering his/her teaching or supervisory time.

Implementation of Moratorium:

We are extremely pleased that the agency interpreted the statute to include both audits undertaken during this calendar year, and agreements for this calendar year. However, we are still concerned that CMS is abrogating its own regulatory policy by denials of payment for time spent in nonhospital sites where the supervisory physician is volunteering his/her services. Again, we urge CMS to discontinue its audit denials on this issue in the future.

Redistribution of Unused Residency Slots:

Demonstrated Likelihood Eligibility Criteria:

For Criterion 1: Establishing a new program, a program/hospital must meet two requirements:

To meet this requirement, the hospital must document each of hospital?s existing programs has a fill rate of at least 95% in 2001 through 2003, OR submit a cover page of employment contracts with current or future residents, OR document that the specialty has a national fill rate of 95%.

We believe CMS?s use of the national fill rate is an appropriate measure. It is important for CMS to define fill rate in its final rule. The commonly used term fill rate is often confused with the match fill rate. We believe that the actual fill rate is the important criterion as it shows each year what positions are filled with actual residents; not what was offered, or what was filled initially, but where finally the residents actually are. We support CMS including in the final rule a definition that ?fill rate? is meant to be the number of residents training in a program or programs as of July 1st of each year. This information is widely available, perhaps most easily accessed through the annual educational issue of the Journal of the American Medical Association (JAMA) which is published in September, or in the ACGME Web Accreditation Data System.

CMS-1428-P-60-Attach-1.doc

CMS-1428-P-61 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Date & Time:** **07/08/2004**

Organization :

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

I believe that CMS should not require payment for supervising physicians as this would place an undue burden on teaching hospitals and residency programs that promote primary care. When supervising physicians offer teaching voluntarily, the institution typically continues to pay the resident salary and benefits, thus incurring much of the cost. In addition, this places an unnecessary amount of paperwork and documentation to determine the actual amount of time spent outside of the hospital setting.

CMS-1428-P-61-Attach-1.doc

CMS-1428-P-62 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Thomas Schwenk** **Date & Time:** **07/08/2004**

Organization : **University of Michigan**

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Non-hospital Settings:

Written Agreements:

? We agree there is no need for CMS to require a written agreement, and we appreciate the attempt to lighten the regulatory burden for hospitals complying with the regulations surrounding graduate medical education. However, for the purposes of family medicine education, written agreements are already required by the Residency Review Committee (RRC) for Family Practice and are part of the accreditation process.

? CMS?s proposal to replace the written agreement with a payment requirement is not a better solution. To expect an institution to pay within 30 days after the training has occurred adds a tremendous burden to the hospital. It makes more sense to require that payment, if any is incurred, be made within the cost reporting period, without any further restrictions.

? We request that CMS to make very clear in regulation or intermediary instruction that if there are no payments made to the non-hospital site by the hospital, that is not an a priori reason to deny time spent by residents in that environment. If the hospital is paying the resident?s salary and benefits, travel costs, lodging, etc., there may in fact be no costs (hence payments) to the non-hospital site. This would frequently be the case in situations where the preceptor is volunteering his/her teaching or supervisory time.

Implementation of Moratorium:

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? We believe CMS?s use of the national fill rate is an appropriate measure. It is important for CMS to define fill rate in its final rule. The commonly used term fill rate is often confused with the match fill rate. We believe that the actual fill rate is the important criterion as it shows each year what positions are filled with actual residents; not what was offered, or what was filled initially, but where finally the residents actually are. We support CMS including in the final rule a definition that ?fill rate? is meant to be the number of residents training in a program or programs as of July 1st of each year. This information is widely available, perhaps most easily accessed through the annual educational issue of the Journal of the American Medical Association (JAMA) which is published in September, or in the ACGME Web Accreditation Data System.

CMS-1428-P-62-Attach-1.doc

CMS-1428-P-63 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. e e** **Date & Time:** **07/07/2004**

Organization : **e**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

e

CMS-1428-P-64 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Bill Hawley** **Date & Time:** **07/07/2004**

Organization :

Category : **Critical Access Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Regarding Critical Access Hospitals and their ability to open Inpatient Rehab Facilities (IRFs)...if a IPPS hospital becomes a CAH after October 1 and wants to open an IRF with some of the beds that exist on their IPPS license, will this IRF open exempt since the CAH is a new provider and by definition these beds are new...or since the beds existed on the IPPS license will they be considered converted beds and the IRF will be required to go through 12 months non-exempt status? If the latter is true and the IRF must be non-exempt for 12 months...how are they paid since the rest of the hospital would be CAH?

Thanks

CMS-1428-P-65 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Michael Gramaglia** **Date & Time:** **07/07/2004**

Organization : **Health Allaince Of Greater Cincinnati**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

We would like to comment on the proposed outlier threshold. We are an Alliance of 6 hopitals in the greater Cincinnati area. The attached worksheet details the outlier payments received by our hospital from FY 2001 thru YTD 2004. You can see that outlier payments to our organization has decreased from $14,600,000 to $5,800,000. The % outlier has fallen from 8.99% to 3.5% over the last 4 years. We project that the proposed increase in the 2005 threshold will continue to reduce our outlier payments. You suggest that the average increase in charges over the last two years has been 14.5%. We have increased charges from 2002 Thru 2005 as follows, 4% 2002 8% 2003 9% 2004 and 8% 2005. We suggest that the relatively few hospitals that chose to increase charges for the purpose of gaming the oulier system, are resposible for the high % increase in charges over the last few years. If we are in any way represenative of the average hospitals across the country, then we think the outlier payments for FY 2005 will fall well short of the mandated 5.1% of total PPS payments. We ask that you reevaluate your proposed 2005 Threshold of $35,085. We believe that the careful monitoring of the cost to charge ratios by the FI's has accomplished the needed effect on the outlier payments. The continued increase in the thresholds is unnecessary.

CMS-1428-P-65-Attach-1.xls

CMS-1428-P-66 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. James T. Kirkpatrick** **Date & Time:** **07/07/2004**

Organization : **Massachusetts Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1428-P-66-Attach-1.doc

CMS-1428-P-67 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Andy Fitzgerald** **Date & Time:** **07/07/2004**

Organization : **Holy Rosary Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Holy Rosary is a 49 bed acute care hospital located in rural eastern Oregon. While we understand that Oregon as a state is not included in the original 10 states identified in this program, we feel consideration should be given to the fact that half of the patients we treat are from Idaho (which is one of the 10 listed low-density population states). Eastern Oregon also comprises a very broad geographical area and has counties which have less population than most of the original 10 designated states. The other half of our patient are from those low density counties. The difference between western and eastern Oregon is the difference between California and Nevada in terms of population density. Simply because of the Portland metropolitan area, Oregon is excluded from consideration in the demonstration project, and therefore all providers in Oregon which might gain from this project are likewise excluded.

As an example of its population density, the four county area of eastern Oregon which Holy Rosary serves is comprised of 27,619 square miles and a population density of approximately 2.0 people per square mile. By comparison, Wyoming has a population density of 4.7 and Utah 21.0, both states included in the project. Eastern Oregon is truly a rural geographic area of large proportion and would benefit by inclusion in the demonstration project.

According to the Social Security Act, Title 18 (defines as section 1886 (d)(2)(D), "the term "urban area" means an area within a Metropolitan Statistical Area (as defined by the Office of Management and Budget) or within such similar area as the Secretary has recognized under subsection (a) by regulation; the term "large urban area" means, with respect to a fiscal year, such an urban area which the Secretary determines (in the publications described in subsection (e)(5) before the fiscal year) has a population of more than 1,000,000 (as determined by the Secretary based on the most recent available population data published by the Bureau of the Census); and the term "rural area" means any area outside such an area or similar area."

Ontario Oregon is located in Malheur County, with a population of 31,248 for the entire county. The communities of Weiser (pop. 5367), Fruitland (pop. 3805), and Payette (pop. 7148), Idaho are also service areas. The population for the entire service area is less than 50,000. This population designates Holy Rosary to be in a federally designated rural area. We would request that eastern Oregon be given consideration in the demonstration project for Rural Community Hospitals as Critical Access Hospitals.

CMS-1428-P-67-Attach-1.doc

CMS-1428-P-68 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Andy Fitzgerald** **Date & Time:** **07/07/2004**

Organization : **Holy Rosary Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Pertaining to Volume 69, No. 96 of the Federal Register published on May 18, 2004; Section IV, subsection P. Rural Community Hospital Demostration Project.

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CMS-1428-P-68-Attach-1.doc

CMS-1428-P-69 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Date & Time:** **07/08/2004**

Organization :

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Non-hospital Settings:

Written Agreements:

? We agree there is no need for CMS to require a written agreement, and we appreciate the attempt to lighten the regulatory burden for hospitals complying with the regulations surrounding graduate medical education. However, for the purposes of family medicine education, written agreements are already required by the Residency Review Committee (RRC) for Family Practice and are part of the accreditation process.

CMS?s proposal to replace the written agreement with a payment requirement is not a better solution. To expect an institution to pay within 30 days after the training has occurred adds a tremendous burden to the hospital. It makes more sense to require that payment, if any is incurred, be made within the cost reporting period, without any further restrictions.

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Implementation of Moratorium:

We are extremely pleased that the agency interpreted the statute to include both audits undertaken during this calendar year, and agreements for this calendar year. However, we are still concerned that CMS is abrogating its own regulatory policy by denials of payment for time spent in nonhospital sites where the supervisory physician is volunteering his/her services. Again, we urge CMS to discontinue its audit denials on this issue in the future.

CMS-1428-P-70 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Daniel Sontheimer** **Date & Time:** **07/08/2004**

Organization : **Cox Family Practice Residency**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Non-hospital Settings:

Written Agreements:

? We agree there is no need for CMS to require a written agreement, and we appreciate the attempt to lighten the regulatory burden for hospitals complying with the regulations surrounding graduate medical education. However, for the purposes of family medicine education, written agreements are already required by the Residency Review Committee (RRC) for Family Practice and are part of the accreditation process.

? CMS?s proposal to replace the written agreement with a payment requirement is not a better solution. To expect an institution to pay within 30 days after the training has occurred adds a tremendous burden to the hospital. It makes more sense to require that payment, if any is incurred, be made within the cost reporting period, without any further restrictions.

? We request that CMS to make very clear in regulation or intermediary instruction that if there are no payments made to the non-hospital site by the hospital, that is not an a priori reason to deny time spent by residents in that environment. If the hospital is paying the resident?s salary and benefits, travel costs, lodging, etc., there may in fact be no costs (hence payments) to the non-hospital site. This would frequently be the case in situations where the preceptor is volunteering his/her teaching or supervisory time.

Implementation of Moratorium:

? We are extremely pleased that the agency interpreted the statute to include both audits undertaken during this calendar year, and agreements for this calendar year. However, we are still concerned that CMS is abrogating its own regulatory policy by denials of payment for time spent in nonhospital sites where the supervisory physician is volunteering his/her services. Again, we urge CMS to discontinue its audit denials on this issue in the future.

CMS-1428-P-70-Attach-1.doc

CMS-1428-P-71 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Larry Halverson** **Date & Time:** **07/08/2004**

Organization : **Cox Family Practice Residency**

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

See attached document.

CMS-1428-P-71-Attach-1.doc

CMS-1428-P-72 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Robert Dowling** **Date & Time:** **07/08/2004**

Organization : **University Cardiothoracic Surgical Associates**

Category : **Physician**

Issue Areas/Comments

Issues 1-10

DRG Reclassifications

We support the reclassification of 37.66 to DRG 103 and expansion of DRG 103 for heart transplants to include Destination Therapy and Bridge to Transplant LVAD procedures

DRG Weights

CMS should consider continuing to examine data within 37.66 and heart transplant procedures to confirm that weight is accurate. The hospital believes that weight may, in fact, need to be increased either in short term or next year.

CMS-1428-P-73 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Marc Strode** **Date & Time:** **07/08/2004**

Organization : **Methodist Healthcare System**

Category : **Hospital**

Issue Areas/Comments

Issues 1-10

DRG Reclassifications

Methodist Specialty and Transplant Hospital, a medicare-certied heart transplant center and destination therapy site, supports the proposal to reclass the implantation of ventriculart assist devices either as bridge to transplant or destination therapy from DRG 525 to DRG 103, thus increasing reimbursement from approximately $72,000 to $100,000 for our institution. VAD therapy is new technology, and we are of the opinion that the technology is far ahead of reimbursement policy and that transplant and VAD centers should play an active role in helping educate and provide data to support additional reimbursement.

While VAD therapy is expensive, it provides Medicare beneficiaries waiting for a heart transplant a chance at an organ they might otherwise not live long enough to receive. For DT patients, it provides a proven clinical option for Medicare beneficiaries who are ruled out for heart transplantation.

As it stands right now, the reimbursement under DRG 525 is only enough to cover the cost of the implant pump itself, which depending on the type of device (Thoratec or Heartmate) runs $72,000 per procedure--ironically the same amount as the DRG reimbursement for the entire course of treatment during the admission. While outlier reimbursement typically comes in to play with these admissions, our data supports that in most instances the reimbursement does not cover the hospital's cost per case. Methodist shared this data with CMS in 2002-03 which helped support its decision to create DRG 525.

Adequate reimbursement, both for inpatient and outpatient VAD services, needs to be in place to ensure that hospitals that are qualified and competent to offer this valuable service are financially able to do so.

CMS-1428-P-74 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Ellen Sakornbut** **Date & Time:** **07/08/2004**

Organization : **Northeast Iowa Medical Education Foundation**

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

We request that CMS make very clear in regulation or intermediary instruction that if there are no payments made to the non-hospital site by the hospital, that is not an a priori reason to deny time spent by residents in that environment. The two hospitals that support our foundation and pay all of our residents' salaries and benefits, travel costs, lodging, etc. have no costs to reimburse (hence payments) to volunteer faculty in a non- hospital site. Teaching by community physicians is an important component of all community-based Family Medicine residencies and is generally regarded by these physicians and the community as a public service, but it takes place during the normal process of that physician's practice. Nonetheless, the cost of the residents continues whether clinical experiences have moved to a non-hospital setting or remain physically on the hospital campus.

In addition, we would ask that CMS reconsider the concept of rural residency sites as a critical factor in training residents for rural practice. Iowa is a rural state with a limited number of metropolitan areas. Our Iowa residents frequently (approximately 40%)enter practice in this state and the region in rural locations, despite the fact that their training is based in a city of 100,000+ with only one month required rural rotation. Commitment to the underserved has been historically a defining aspect of the discipline of Family Medicine, and we would ask that CMS not impose further specifications for support of residency training. Our training programs often require a larger population to adequately provide the broad range of experiences needed by residents entering rural practice. They need more training intensity, not less, so that they will be prepared. To decrease the number of training slots available in such a setting could jeopardize in the very near future the availabilty of physicians to serve rural Iowa.

CMS-1428-P-75 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Gary Newkirk** **Date & Time:** **07/08/2004**

Organization : **Family Medicine Spokane**

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

I support the recommendations of the AFMRD regarding prospective payments for out-patient rotations. I feel that many of these principles should also apply to all programs who rely on volunteer teaching within medical communities.
Thank you,
Gary Newkirk, MD

CMS-1428-P-76 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Robert Garee** **Date & Time:** **07/08/2004**

Organization : **CHF Solutions Inc.**

Category : **Device Industry**

Issue Areas/Comments

Issues 1-10

New Technology Applications

To further support and answer any question regarding newness of the Aquadex S100 Fluid Removal System technology, CHF Solutions makes the following comments:
1. CHF Solutions has received numerous patents issued from the U.S. Patent Office for many aspects of our technology thus demonstrating the technology?s uniqueness and newness to the medical device arena.
2. The Company has already highlighted the proprietary design of the filter assembly and its unique low flow capability which may be continued over an extended period of time. These features provide safety and convenience to both patients and their clinicians in a wide variety of hospital and outpatient settings using the technology. No other technologies operate in this low flow range using automatic pressure control algorithms and peripheral vascular access while delivering ease of use and patient safety. These system attributes were recognized by the FDA as being a different technology when the device was not limited to use in the ICU or dialysis clinic.
3. The Aquadex S100 Fluid Removal System is a minimally invasive inpatient procedure. It is specifically designed to quickly, as compared to standard pharmacologic diuretic therapy, remove excess fluid from fluid-overloaded patients experiencing right or left sided heart failure. There remains a growing unmet clinical need for effective treatment modalities to better address the clinical needs of the congestive heart failure patient population. Clinicians need new state of the art tools to treat patients for fluid overload as demonstrated through the emerging data from the ADHERE registry. The percentage of heart failure patients discharged improved but still symptomatic with fluid overload is large, 39% which has increased 2% since the last quarterly update, Q2/2003. The percentage of patients who gain weight prior to discharge, obviously due to fluid onboard, [e.g. retention], is an incredible 20% and has not changed appreciably over the duration of the registry. The results of a retrospective review of 46,599 hospitalizations collected in the ADHERE registry concluded; ? 1). Renal insufficiency is associated with adverse patient outcomes in terms of resource utilization, symptom status and, survival, 2). Chronic diuretic therapy is an independent predictor of poor clinical outcomes and higher resource utilization, 3). The association of chronic diuretic therapy and poorer outcomes/greater resource utilization is seen in patients with and without renal insufficiency. Alternative therapies may provide better clinical and resource utilization outcomes.? The emerging body of knowledge for CHF patients suffering from fluid overload is clearly demonstrating the need for efficient and effective fluid removal.
CHF Solutions wishes to thank CMS for the opportunity to comment and for working with the Company representatives in completing the application and comment requirements in a timely and cooperative manner.
1 ADHERE Acute Decompensated Heart Failure National Registry, 3rd Quarter 2003 National Benchmark Report, January 2004, 2nd Quarter 2003 National Benchmark Report, November 2003.
2 Maria Rosa Costanzo, MD, FACC, et. al., Impact of Renal Insufficiency and Chronic Diuretic Therapy on Outcome and Resource Utilization in Patients with Acute Decompensated Heart Failure, American College of Cardiology, Poster Presentation #1069-114, March 8, 2004

Robert A. Garee
Vice President Operations
CHF Solutions Inc.

Suite 170, 7601 Northland Drive
Brooklyn Park, MN 55428
763.463.4680 direct line
763.463.4600 main line
763.463.4606 fax
rgaree@chfsolutions.com

CMS-1428-P-77 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Robert Garee** **Date & Time:** **07/08/2004**

Organization : **CHF Solutions Inc.**

Category : **Device Industry**

Issue Areas/Comments

Issues 1-10

New Technology Applications

To further support and answer any question regarding newness of the Aquadex S100 Fluid Removal System technology, CHF Solutions makes the following additional comments:
1. In the application for New Technology Add-on payment for FY2005 submitted by CHF Solutions, we detailed the significant technical, patient group and clinical setting differences between the Aquadex S100 Fluid Removal System and legacy hemodialysis and hemofiltration. The supporting information supplied with the application from the Company continues to satisfy the established criteria for New Technology.
a. The Aquadex S100 Fluid Removal System is clearly and distinctly different and new from any currently available technologies.
b. The Aquadex S100 Fluid Removal System provides clinical services to patients who previously were ineligible for in-kind therapy, or for whom such therapy was technically not available.
c. The Aquadex System 100 has been clearly demonstrated to treat a different patient population, Heart Failure vs Renal failure because 98% of patients with fluid overload are treated in a different DRG other than DRG 316 Renal Failure. This data was outlined in the MEDPAR analysis provided to CMS upon request and in the original New Technology Add-on Payment Application submitted in Dec 2003. Data was also submitted from an independent data source Premier Health Informatics which further confirmed these analyses.
d. The company believes that CMS should maintain the criteria and definition established in the Final Rule published in the Federal Register, Vol. 66, No.174, p.46915, September 7, 2001 for new technology. CMS stated if an existing technology is used for treating patients not expected to be assigned to the same DRG as the patients already receiving the technology, it may be considered for approval if it also meets the other cost and clinical improvement criteria.. According to this Final Rule definition the Aquadex System 100 Fluid Removal system meets the criteria and should be approved.

2. CMS has indicated that there are no large prospective randomized trials but acknowledges that clinical evidence has been provided that demonstrates this technology?s benefits. The company has confidentially provided the additional data and an abstract from the EUPHORIA trial which the company recently completed. The results of this trial have been accepted for presentation at the HFSA (Heart Failure Society of America) in September 2004. The trial results continue to demonstrate the clinical safety and effectiveness as well as the cost effectiveness of the Aquadex S100 Fluid Removal System in treating the fluid overloaded patient.

3. CHF Solutions believes the cost threshold calculations to be accurate and therefore has no additional comments for CMS. We agree with the confirmatory analysis performed by CMS published in the proposed rule CMS-1428-P.

CHF Solutions again wishes to thank CMS for the opportunity to comment and for working with the Company representatives in completing the application and comment requirements in a timely and cooperative manner.

Robert A. Garee

Vice President Operations

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CMS-1428-P-77-Attach-1.doc

CMS-1428-P-78 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Don Kalicak** **Date & Time:** **07/08/2004**

Organization : **St. John's Mercy Health Care**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-1428-P-78-Attach-1.txt

CMS-1428-P-79 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Mike Myers** **Date & Time:** **07/08/2004**

Organization : **Lincoln Medical Education Partnership**

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

Non-hospital Settings

CMS-1428-P-79-Attach-1.rtf

CMS-1428-P-80 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Larry Beaty** **Date & Time:** **07/08/2004**

Organization : **Broadlawns Medical Center**

Category : **Physician**

Issue Areas/Comments

Issues 21-30

Graduate Medical Education

-I agree there is no need for CMS to require a written agreement and appreciate the attempt to lighten the regulatory burden for hospitals complying with the regulations surrounding graduate medical education.
-CMS's proposal to replace the written agreement with a payment requirement is not a better solution.
-I request that CMS to make very clear in regulation or intermediary instruction that if there are no payments made to the non-hospital site by the hospital, that is not an a Priori reason to deny time spent by the residents in that environment. If the hospital is paying the resident's salary and benefits, travel costs, lodging, etc., there may infact be no costs (hence payments) to the non-hospital site. This is frequently the case when a preceptor is volunteering his/her teaching or supervisory time.
-I am pleased that the agency interpreted the statute to include both audits undertaken during this calendar year and agreements for this calendar year. However, I am concerned that CMS is abrogating its own regulatory policy by denials of payment for time spent in nonhospital sites where the supervisory physician is volunteering his/her services. Again, I urge CMS to discontinue its audit denials on this issue in the future.

CMS-1428-P-81 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. John Torley** **Date & Time:** **07/08/2004**

Organization : **Huterdon Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Revised MSAs

CMS-1428-P-81-Attach-1.doc

CMS-1428-P-82 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. John Torley** **Date & Time:** **07/08/2004**

Organization : **Huterdon Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Hospital Redesignations

CMS-1428-P-82-Attach-1.doc

CMS-1428-P-83 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Ms. PATRICIA O'CONNELL** **Date & Time:** **07/08/2004**

Organization : **LUTHERAN SOCIAL SERVICES**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

CMS' delay in implementation of a reclassification system for Medicare SNF providers places Gettysburg N&R Center and other SNF providers at risk. Though State regulations dictate required hours of nursing/resident/day, these regulations do not grant exceptions for a nursing crisis and lack of trained professional nurses. SNF providers recruit nurses from the same pool that hospitals do.

Fact is, however, hospitals in Adams and Franklin Counties can pay more for nurses because their PPS rates are based on the wage index for a MSA other than their own (Adams gets York County's; Franklin get Bethesda, MD's). Yet, SNF providers are not afforded the same rights and SNF PPS rates are still established using much lower statewide wage indexes for rural providers.

This wage index system places SNF providers at an unfair disadvantage in competing with reclassified Medicare hospital providers for professional nursing staff. Having to staff at certain levels and have less of a competitive edge to pay that staff is unfair and frustrating to those of us who have dedicated their careers to providing quality care for this generation of elderly now and the soon-to-be Baby Boomers. Reclassification is needed for SNF providers too and can and should be implemented now.

Very truly yours,

Patricia E. O'Connell, CPA
Vice-President for Financial Management
Lutheran Social Services
Gettysburg Nursing & Rehab Center

CMS-1428-P-84 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. John Torley** **Date & Time:** **07/08/2004**

Organization : **Hunterdon Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Hospital Redesignations

CMS-1428-P-84-Attach-1.doc

CMS-1428-P-85 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Peter Konrad** **Date & Time:** **07/08/2004**

Organization : **Vanderbilt University**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter.

CMS-1428-P-85-Attach-1.doc

CMS-1428-P-86 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Ronald Park** **Date & Time:** **07/08/2004**

Organization : **Somerset Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

The recent proposed changes to the Hospital Inpatient Prospective Payment System, included in the Federal Register of May 18, outline that Somerset Hospital will be designated as a rural hospital commencing on October 1, 2004. Formerly we had been included in the Johnstown, Pa. MSA and designated as other urban.

It appears based on reviewing the proposed rule that hospitals negatively impacted by such a change can maintain their previous designation for a three year period. We would request clarification on the process that will be used to provide hospitals this relief.

In addition, if we maintain our current MSA designation for this three year period (as other urban) would we be precluded from qualifying for other rural hospital benefits such as Sole Community Hospital and Medicare Dependent Hospital? Clarification on this issue would be very helpful.

I appreciate your consideration in this matter.

CMS-1428-P-87 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Scott Besler** **Date & Time:** **07/08/2004**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

As a NJ healthcare consumer. I urge the Centers for Medicare and Medicaid Services (CMS) to implement its proposal to utilize the new CBSA (core-based statistical area) adopted last July by the Office of Management and Budget (OMB) for purposes of calculating the Medicare wage index.

New Jersey is a unique labor market and the proposed rule demonstrates this fact. The lure of NYC and Philadelphia has contributed to the nursing shortage in New Jersey. NJ competes with both NYC and Philadelphia for not only nurses but other allied personnel. Also now a NJ hospital can offer a host of services that in the past they would not be able to. Thank you for your time and consideration.

CMS-1428-P-88 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mrs. Ellen Kugler** **Date & Time:** **07/08/2004**

Organization : **National Association of Urban Hospitals**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Comments from the National Association of Urban Hospitals re CMS-1428-P, Postacute Care Transfers

CMS-1428-P-89 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mrs. Ellen Kugler** **Date & Time:** **07/08/2004**

Organization : **National Association of Urban Hospitals**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Comments from the National Association of Urban Hospitals re CMS-1428-P, Postacute Care Transfers

CMS-1428-P-90 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Erwin Montgomery** **Date & Time:** **07/08/2004**

Organization : **University of Wisconsin Hospital and Clinics**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: New Technology Applications y Kinetra

I have been involved in deep brain stimulation for movement disorders and the post-operative management of these patients since 1997. I have been involved in over 200 cases. I supervise the post-operative management of these patients and I have seen the problems with the older technology (such as the Itrell II and the Soletra). The improvements provided by the newer Kinetra are significant for a substantial number of patients.

For example, the ability to inactivate the magnetic reed relay for turning the IPGys on and off will be a major improvement for many patients who are exposed to electromagnetic fields that would interfere with the operations of the older devices. The increasing number of new electronic devices in the environment, such as electronic dog fences, greatly increases the risks of sudden inactivation. Indeed, there are now several published case reports of serious morbidity due to sudden increases in disease symptoms from sudden device failure. This feature alone would be sufficient to warrant approval for many patients.

While the overall risk of infections is modest, the most frequent site of infection is the IPG site. Thus, the ability to reduce the number of IPG operative sites would significant impact the infection rates which translate to fewer hospitalizations and fewer systems that have to be explanted.

It is a matter of fact, that reimbursement rates for DBS surgery are marginal at best regardless of how the reimbursement is itemized or apportioned. I personally know of physicians and institutions who have elected not to offer this important therapy to patients because to the reimbursement rates. This means that Medicare and Medicaid patients are not having access to this new important therapy. Any means for improving the efficiency of these DBS-related procedures, such as having to implant a single Kinetra rather than two Soletras, has a significant impact of the cost-to-benefit ratio from the physician and hospital perspective.

My experience has lead me to be a strong advocate for performing a staged procedure with the leads implanted in the initial inpatient stay followed by a later surgery for IPG implantation. For the first few years, we implanted the entire system, leads and IPGs, during the same procedure. Over the last few years we have been doing the procedure staged. This has made a huge impact on the post-operative morbidity. Our patients recover much faster and can be discharged much sooner for the initial surgery in the staged procedure. I strongly suspect that this improvement is because the patient is not given general anesthesia at the end of the first initial surgery. Most of the patients already are severely compromised because their medications have been withheld. Added to this is the stress of the surgery. Now the patient, whose condition has been sorely tested, is going to be subjected to general anesthesia if the IPG is to be implanted during the same surgery as the leads were implanted.

On behalf of myself and my patients, I am grateful that CMS is considering a revision of its current policies.

CMS-1428-P-91 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Fred Kagarise** **Date & Time:** **07/08/2004**

Organization : **MidMichigan Health**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file for comments

CMS-1428-P-91-Attach-1.doc

CMS-1428-P-92 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. MICHAEL SHENDOCK** **Date & Time:** **07/08/2004**

Organization : **ALLIED SERVICES INSTITUTE OF REHABILITATION MEDICINE**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

THE ATTACHED COMMENT LETTER IS IN REGARDS TO DOCKET ID CMS 1428-P.

CMS-1428-P-92-Attach-1.doc

CMS-1428-P-93 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Harry Wolin** **Date & Time:** **07/08/2004**

Organization : **Mason District Hospital**

Category : **Critical Access Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Our comments regarding CMS. proposed changes to the inpatient payment system are found in the attached file.

CMS-1428-P-93-Attach-1.doc

CMS-1428-P-94 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Ms. Colleen Scanlon** **Date & Time:** **07/08/2004**

Organization : **Catholic Health Initiatives**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Comments of Catholic Health Initiatives are attached.

CMS-1428-P-95 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. David McClure** **Date & Time:** **07/08/2004**

Organization : **Tennessee Hospital Association**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attached file

CMS-1428-P-95-Attach-1.pdf

Tennessee Hospital Association

July 8, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS – 1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

Ref: CMS-1428-P — Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2005 Rates; Proposed Rule (69 *Federal Register* 28196), May 18, 2004.

Dear Sirs:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule establishing new policies and payment rates for hospital inpatient services for fiscal year (FY) 2005. The Tennessee Hospital Association (THA), established in 1938, serves as an advocate for hospitals, health systems and other healthcare organizations and the patients they serve. THA represents over 200 healthcare facilities, including hospitals, home care agencies, nursing homes, and health-related agencies and businesses and over 2,000 employees of member healthcare institutions, such as administrators, board members, nurses and the many health professionals. THA is the premiere organization in Tennessee that promotes and represents the interests of all health careers, hospitals and health systems.

The proposed rule would increase a hospital's patient PPS rates by 3.3 percent in 2005, if the hospital submits data on 10 specific clinical measures of quality care. Hospitals that do not submit quality data would receive a reduced payment update to reflect market basket less 0.4 percentage points, or 2.9 percent.

THA continues to urge adequate Medicare reimbursement to hospitals which reflects cost increases and applaud Congress and CMS for the full market basket increase for the upcoming year.

The THA is concerned about the redistribution of hospital payments due to the proposed revisions to metropolitan statistical areas (MSAs), the implementation of an occupational mix adjustment, and changes to geographic reclassification. **Specifically, the THA urges the agency to implement a 3-year "stop-loss provision" to protect those hospitals that would experience a decline in their wage index value due to the revised MSAs.**

THA is greatly concerned about those critical access hospitals (CAHs) that now would be designated as "urban" hospitals due to the new geographic boundaries. It is essential that these facilities maintain their CAH status, even though they may no longer be located in

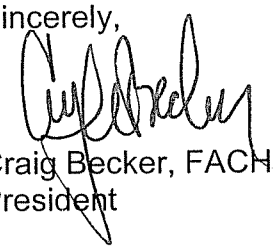
rural "statistical" areas. **THA strongly urges CMS to "grandfather" these CAHs so that they may seamlessly retain their current CAH status**. We also continue to strongly oppose CMS's 2004 proposal, reiterated in the 2005 rule, which "clarifies" that patients must be physically present in a critical access hospital when a laboratory specimen is collected in order for the hospital to continue to receive cost-based reimbursement. **This policy is shortsighted, not in the best interest of rural beneficiaries or hospitals, and must be retracted.**

Additionally, THA strongly opposes the increase in the outlier threshold to $35,085, which will make it more difficult for hospitals to qualify for these necessary payments. Given that CMS did not even spend the entire pool of funds set aside in FY 2004 – a loss of $7 million to hospitals – **THA urges CMS to lower the outlier threshold to appropriately reflect the significant changes to outlier payment policy in June 2003**.

Finally, THA is disappointed that the rule contains a proposal to further expand the post-acute care transfer policy, which would reduce hospital payments by $25 million in FY 2005 alone. There is no sound policy rationale for CMS' proposal to adopt a new set of "alternative criteria." **This provision must be withdrawn.**

Attached are THA's detailed comments regarding CMS's proposed changes to the inpatient payment system, including those related to the wage index, dominant hospital reclassification, outlier threshold, transfer policy, quality data submission, new technology, graduate medical education, end stage renal disease, critical access hospitals, Medicare DSH, and long-term care hospital provisions. The THA appreciates the opportunity to submit these comments on the proposed rule. If you have any questions about these comments, please feel free to contact me or David McClure, vice president of finance, at (615) 256-8240.

Sincerely,



Craig Becker, FACHE
President

Attachment

Attachment

Tennessee Hospital Association
Comments on FY 2005 Medicare Hospital Inpatient PPS

Revised MSAs

The Office of Management and Budget in releasing its revised standards for defining MSAs cautions that the new definitions "should not be used to develop and implement Federal, State, and local non-statistical programs and policies without full consideration of the effects of using these definitions for such purposes. These areas should not serve as a general-purpose geographic framework for non-statistical activities, and they may or may not be suitable for use in program funding formulas." **We question whether CMS has truly given full consideration regarding the effects of the revised definitions on hospital payments.**

But the re-drawing of lines due to decennial census data creates almost insurmountable challenges. These challenges are then augmented by the fact that hospitals' Medicare payments are intimately tied to their labor market area and their corresponding hospital wage index. In a budget neutral system, where any changes in the MSAs will create a significant redistribution in Medicare payments, it is unclear whether any one methodology would be better than the next – as all will create "winners" and "losers." To this end, for FY 2005, the THA is supporting a proposal that would limit the losses to those hospitals that are most significantly harmed by the census changes.

Specifically, the THA recommends that CMS adopt a 3-year "stop loss" provision for all hospitals that would experience a decline in their wage index value due solely to the MSA changes.

In addition, THA supports CMS' proposal to not adopt OMB definition of Micropolitan Statistical Areas for use in the Medicare payment system, as it would result in even more dramatic swings in hospital payment.

And, we support CMS' proposed 3-year "hold harmless" provision for urban hospitals that would be located in now rural areas. This provision would help fully alleviate the substantial decline in payments for hospitals currently classified as urban that would become rural, and will allow them to retain their current MSA assignment (and its corresponding wage index) for three years.

Finally, we are greatly concerned about those critical access hospitals (CAHs) that would be designated as urban due to the new geographic boundaries. We believe it is essential that these facilities maintain their CAH status. Even though they may no longer be located in "rural" counties, their physical location has not changed and these areas still have health care access concerns that can be adequately addressed only through protecting the local

hospital's CAH status. **We urge CMS to "grandfather" these CAHs so that they may seamlessly retain their current CAH status.**

Occupational Mix / Wage Data

CMS is required by law to perform an occupational mix adjustment to the wage index beginning in FY 2005, but we are concerned about the integrity of the data used to create the adjustment. Therefore, we recommend that a maximum of 10 percent of the wage index be adjusted for occupational mix.

Specifically, THA is concerned about the accuracy and completeness of the data used to conduct an occupational mix adjustment to the wage index, given that:

- Hospitals had a very short timeframe for collecting the occupational mix data. While advanced copies of the instructions were available in December 2003, at a time when many hospital employees were on vacation, the formal One-Time Notification was not released until January 23, 2004. Hospitals then had three weeks to gather and submit the data by the February 16, 2004 deadline.
- Hospitals were given a very short time to review and verify the accuracy of their hospital's occupational mix data as published by CMS. CMS made hospital specific occupational mix data available March 8 on its Website, and allowed hospitals less than three weeks to correct, revise, or actually submit their information if they missed the earlier deadline.
- Fiscal intermediaries were not requested or able to review the accuracy of the data collected, and were unable to correct obvious errors.
- Hospitals experienced great confusion in determining the proper category to place certain employees (i.e., an RN who also conducts administrative duties). We are concerned that hospitals treated these situations quite differently, especially in small rural facilities where an employee often has more than one role at the facility.
- As of March 15, only 90 percent nationally of qualifying hospitals completed the survey.
- Hospitals' data could be submitted either on a four-week prospective basis or a one-year retrospective basis. As the wage index is a relative measure of labor costs across geographic areas, it is important that the data collected from hospitals reflect a common period.

While we believe that CMS' theoretical methodology to determine an occupational mix adjustment has a sound basis, we are concerned that when CMS implemented the adjustment, they did not compare "apples to apples." Specifically, it appears that the total national hours for each of the occupational mix categories (published in Chart 5 of the proposed rule) were obtained from the March 8 occupational mix survey file. Yet there are an additional 263 hospitals in the May 12 occupational mix survey file. According to a recreation of CMS' analysis, it appears that these 263 hospitals received an occupational mix adjustment, but that their hours were not included in the national totals. Thus, the national totals were not recalculated based on the March 8 file amended with the May 12 file for the additional 263 hospitals. **We urge CMS to recalculate its analysis using all hospitals in its files.**

Since an occupational mix adjusted wage index will redistribute Medicare payments among hospitals using data about which we are seriously concerned, we believe that CMS should proceed with extreme caution on implementation. We support a blended wage index, in which a very small portion of the wage index is adjusted for occupational mix, and believe this portion should be no higher than 10 percent.

Hospital Redesignation

The THA applauds CMS' interpretation of Section 505 of the MMA that provides hospitals in lower wage areas a wage index adjustment if a significant number of hospital workers commute from the lower wage area to higher wage areas nearby. We support CMS' proposal to adopt the minimum requirement that at least 10 percent of the hospital workers in a county commute to a higher wage area(s) in order for the hospitals in the county to receive the adjustment. We also fully support CMS' proposal to not require a minimum difference between the wage index that applies to the county and the higher wage index areas. Both of these proposals will allow the maximum number of hospitals to qualify for the adjustment.

Hospital Reclassifications

We urge CMS to use its administrative authority to protect those hospitals that have been approved for reclassifications effective in FY 2005 from any decline in their wage index due to such reclassification. Specifically, we ask that CMS grant both rural and urban hospitals the most advantageous wage index value possible for 2005. In addition, the THA recommends that CMS allow reclassifying hospitals 30 days after publication of the 2005 inpatient PPS final rule to withdraw their reclassification request.

Dominant Hospital Reclassifications

Medicare adjusts payments to hospitals for services furnished to program beneficiaries to reflect labor cost differences among various labor markets. CMS categorizes labor markets using Metropolitan Statistical Areas (proposed Core Based Statistical Areas (CBSAs)). Each year, CMS develops a distinct geographic adjustment factor, known as the "wage index," for each CBSA in the country, and one for each rural portion of each state. In 1989, recognizing that many hospitals were disadvantaged by the assignment of wage indexes based on CBSAs, Congress established a process whereby hospitals could submit requests to the Medicare Geographic Classification Review Board (MGCRB) to receive the wage index of a nearby labor market, a process known as wage index reclassification. Pursuant to the statutory requirement, CMS promulgated a series of criteria and rules that hospitals had to satisfy to qualify for wage index reclassification.

Generally speaking, to qualify for wage index reclassification, a hospital must show that (1) its wage costs are higher than hospitals in its area, (2) its wage costs are comparable to hospitals in the area to which it seeks reclassification, and (3) it is proximate to the area to

which it seeks reclassification. For purposes of the first of these tests, the hospital's average hourly wage (AHW) must be greater than 108 percent of the AHW of all hospitals in its area, if the hospital is located in an urban area. Under this comparison, the applicant's AHW is included in both the numerator and denominator of the equation, because it is required to compare its AHW to the AHW of all hospitals in its area, including itself.

Most hospitals applying for wage index reclassification are not adversely affected by the fact that the applicant's AHW is included in both the numerator and denominator of the 108 percent test, because the applicant's AHW in the denominator is diluted by the AHW data from the dozens of other hospitals also located in its area. In other words, the applicant is comparing its AHW to the combined AHW of maybe 50 or 100 hospitals. Although the applicant's AHW is included to comprise the average AHW in the denominator, its AHW data does not have a controlling effect.

Where a hospital is the only hospital in its area, or one of just a few hospitals in its area, it cannot satisfy this 108 percent test, because its AHW has a controlling effect on the denominator of the equation. In the case of a hospital that is the only hospital in its area, it is actually comparing its own AHW to its own AHW. That equation will always equal 1.00, and will never approach 1.08. The same is true for hospitals that are one of two or three hospitals in an area. Here too, the applicant essentially is comparing its own AHW to its own AHW.

THA recommends that CMS resolve this situation in one of the following ways.

- **CMS could exempt dominant hospitals and hospitals in single hospital metropolitan areas from the 108 percent test.**

- **CMS could revise the way it administers the 108 percent test for all hospitals such that applicant-hospitals are required to compare their AHW to the other hospitals in their area; if the applicant is the only hospital in its area, it would be deemed to have satisfied, or be exempt from this requirement.**

- **CMS could broaden the existing Special Dominating Hospital Exception at 412.230(e)(4). Section 4409 of Balanced Budget Act of 1997 required CMS to establish a reclassification opportunity for hospitals and not have prior application as on criteria. This 1997 special opportunity, which became known as the "Special Dominating Hospital Exception," permits an eligible hospital to remove its wage data from the area AHW (i.e., the denominator of the equation) for purposes of the 108 percent test. To be eligible, a hospital must pay more than 40 percent of the hospital wages in its area and must have previously applied for reclassification each of fiscal years 1992 through 1997. This "Special Dominating Hospital Exception" was tailored in such a way as to be applicable to a single hospital.**

Outliers

The THA strongly opposes CMS' proposed increase in the outlier threshold. In the rule, CMS proposes setting the FY 2005 threshold at $35,085, a substantial increase of over the FY 2004 threshold of $31,000. This rise will makes it more difficult for hospitals to qualify for outlier payments and will put them at greater risk when treating high-cost cases.

CMS' estimate of the FY 2005 outlier threshold does not take into account its June 9, 2003 final rule that significantly changed outlier payment policy. The rule implements the use of more up-to-date data when determining a hospital's cost-to-charge ratio (CCR) – specifically, a hospital's most recent final or tentatively settled cost report. It eliminates use of the statewide average CCR when the hospital's CCR falls below established thresholds. And, it instructs fiscal intermediaries, in certain situations, to retrospectively reconcile outlier payments when a hospital's cost report is settled. Implementing these very significant changes has decreased overall outlier spending, and the outlier threshold must be reduced to account for these more accurately calculated payments.

In fact, CMS estimates that actual outlier payments for FY 2004 will be 4.4 percent of actual total inpatient payments, which is 0.7 percentage points less than the 5.1 percent withheld from hospitals to fund outlier payments. A national industry estimate is that the FY 2004 threshold should have been set at $26,565, rather than $31,000, to result in outlier payments of 5.1 percent.

CMS' proposed methodology for determining the threshold is flawed. The 2005 threshold would be based on the two-year average annual rate of change in charges per case from FY 2001 to FY 2002 and FY 2002 to FY 2003. CMS estimates this increase to be 31.1 percent over two years. Yet this timeframe does not take into account those substantial changes to outlier payment policy that result in lower cost-to-charge ratios. The data that CMS is using represents rates of increases that are higher than the rates of increases under its new policy, resulting in a higher than appropriate outlier threshold.

An appropriate outlier threshold reflecting these changes is needed to ensure the accuracy of prospective outlier payments. THA supports the AHA recommendation of either:

- Using data projections such as the hospital market basket (rather than actual data) to update charges for purposes of determining the outlier threshold, or
- Returning to its previous methodology that measured the percent change in costs using the two most recently available hospital cost reports.

The outlier threshold must be lowered to reflect CMS' modifications in outlier payment policy. It is absolutely necessary to ensure hospitals receive the full 5.1 percent of payments that will be withheld from base inpatient payment in 2005, and ensure that hospitals have access to these special payments to cover extremely high-cost patients. **The THA urges CMS to lower the outlier threshold.**

Post-acute Care Transfers

The THA opposes any expansion of the post-acute care transfer policy to additional DRGs. The expansion of the transfer policy undercuts the basic principles and objectives of the Medicare PPS, and penalizes hospitals for ensuring that patients receive the right care at the right time in the right place.

Last year, after "an extensive analysis to identify the best method by which to expand the transfer policy," the agency adopted four specific criteria that a DRG must meet, for both of the two most recent years for which data are available, in order to be added to the post-acute care transfer policy:

1. The DRG must have at least 14,000 cases of post-acute care transfers;
2. The DRG must have at least 10 percent of its post-acute care transfers occurring before the mean length of stay for the DRG;
3. The DRG must have a length of stay of at least three days; and
4. The DRG must have at least a 7 percent decrease in length of stay over the past five years (1998 – 2003).

This resulted in expanding the provision from 10 DRGs in FY 2003 to 29 DRGs in FY 2004. Now, only a year later, the agency is proposing to adopt an additional set of alternative criteria that would be applied to a DRG if it failed to qualify for the transfer provision under the FY 2004 criteria. The new criteria state that the DRG only needs to have 5,000 cases of post-acute care transfers, and the percentage of transfer cases that are short-stay transfer cases is at least two standard deviations above the geometric mean length of stay across all DRGs. It also adds to the four items listed above, to state "or contains only cases that would have been included in a DRG to which the policy applied in the prior year."

The agency clearly is adopting the new criteria solely to capture cases currently in DRG 483 (Tracheostomy with Mechanical Ventilation) as they also propose splitting this DRG into two new DRGs 542 and 543, based on whether or not the case had a major operating room procedure. Given the split of the DRG, cases currently subject to the policy would no longer qualify. Yet given the proposed new criteria, the transfer policy also would capture DRG 430 (Psychoses) and reduce hospital payments by an additional $25 million in FY 2005 alone.

If CMS' proposed split of DRG 483 into two more specific DRGs now better accounts for variation in length of stay and cost per case, then the historically stated need for a transfer policy for these two new DRGs is no longer valid. If CMS' creation of the two new DRGs for tracheostomies with and without surgical procedures do not create less variation in length of stay and cost per case, then there is no need to split DRG 483 and no need to expand the transfer policy criteria.

The agency cannot change its rules and criteria year by year in order to ensure certain DRGs are included in the transfer policy. **The THA objects to the implementation of**

alternative criteria for which there is no sound policy rationale. This provision must be withdrawn in its final rule.

Hospital Quality Data

CMS has proposed a data submission process for quality data that is consistent with the process already underway for the voluntary reporting of hospital quality data, except that a few additional forms must be completed. Hospitals appreciate the fact that CMS has kept the process consistent with the one in which many already were engaged. We applaud this decision, which has helped to reduce confusion and burden.

To ensure the hospital data submitted are accurate, timely and complete, CMS has proposed a validation process in which a contractor would re-abstract a sample of patient records. Hospitals' data would be considered acceptable if there is an 80% agreement or better between the data abstracted by the hospital originally and the data abstracted by the CMS contractor for the most recent four quarters, beginning with the data that are submitted for patients discharged during the first quarter of 2004 (data that are due to the warehouse by August 2004).

We agree with CMS that the usefulness of the public reporting is contingent upon having accurate, timely and complete data submitted. We favor having checks on the accuracy of the data, but there are several problems with CMS' proposed methodology for validation:

- Identifying the correct data. First, if the contractor re-abstracts data from a sample of a hospital's patient records, and there are significant differences between the information as recorded by the contractor and that recorded by the hospital, this merely tells us that there is a disagreement between the two parties. We do not know if the hospital is correct, the contractor is correct, or neither is correct. There must be an opportunity for the hospital and the contractor to review and reconcile their differences, or for a third party to review and determine what data are correct.

- Differences should be significant. CMS has called for an agreement between their contractors' abstraction of all data elements and the hospital's abstraction of the same information, without regard to whether the difference in information is consequential or not. Some disparities in the information recorded may make absolutely no difference in the reported performance of the hospital on the selected measures. For example, if a hospital provided an antibiotic to a pneumonia patient 24 minutes after that patient's arrival at the hospital, but transposed the numerals and recorded 42 minutes instead, there would be a difference in the data elements, but it would have no effect on the actual total of patients recorded as having received their antibiotic within an hour of arrival.

- Phase-in of validation. While over half of the eligible hospitals have been submitting data on some of these 10 measures, less than 25 percent have been submitting data on all 10, and a substantial proportion of the smaller hospitals have not previously had to collect and submit the data. Hospitals will begin submitting data on all 10 measures

starting with patients discharged during the first quarter of 2004. Even with the best of intentions, it is unlikely that the data will be abstracted perfectly the first time. CMS has not indicated that the hospitals or the re-abstraction contractors will get any feedback or help to improve the accuracy of their abstractions, so it is unclear how the data collection will be improved over time. Even if such a mechanism were established, hospitals may find it difficult to achieve the desirable level of data accuracy if they encountered significant problems in their data submission during the first quarter. Thus, we encourage CMS to consider allowing 60 percent agreement for the data that will affect the FY 2006 payment rate and phasing up to 80 percent agreement for FY 2007.

CMS also has indicated that it would assess the completeness of a hospitals' data submission by checking to see if the number of cases submitted corresponds to the number for whom they have bills. Since the cases reported for quality purposes are for all patients, regardless of payor, and the bills submitted to CMS are only for Medicare patients, it is clear that the number of cases reported should not be congruent with the number billed to CMS except in rare cases. CMS needs to reevaluate their process to assess completeness and provide greater clarity about how it will assess the completeness of the data submission.

New Technology Threshold

The THA strongly urges CMS to raise the add-on payment level for new technologies from 50 percent to 80 percent of the difference between the standard DRG payment and the cost of the procedure using the new technology. This change is supported in the MMA's report language. In addition, it would mirror the current 80 percent marginal cost factor for inpatient outlier payments.

ESRD Discharges

The THA opposes CMS' proposed change declaring that only discharges involving End-Stage Renal Disease (ESRD) Medicare beneficiaries who have received a dialysis treatment during their inpatient hospital stay are to be counted toward whether a hospital qualifies for additional Medicare payment because it treats a higher percentage of ESRD patients.

Currently, hospitals with at least 10 percent of its patients as ESRD discharges are able to receive an additional add-on payment under Medicare. CMS proposes revising its policy to reduce the number of hospitals that will qualify for this additional payment. Specifically, CMS proposes that only discharges involving ESRD Medicare beneficiaries who have *received a dialysis treatment* during an inpatient hospital stay would be counted toward qualifying for this adjustment, rather than all ESRD discharges. These payments were established because of the higher cost of treating patients who are critically ill, even though they may not receive a dialysis treatment during their inpatient admission. The adjustment is used to help defray the extra costs of treating ESRD patients in their entirety,

not just to defray dialysis costs. CMS has not explained why it proposes the change in policy, nor presented a sound argument for doing so – except to say that the effect of the change would be reduced Medicare program expenditures. This is a real cut to hospitals treating these very ill and costly patients. **The THA opposes any change to this provision, which was put in place to protect access to care for Medicare beneficiaries and help offset the financial losses associated with hospitals treating a high concentration (10 percent or more of a hospitals total Medicare discharges) of dialysis patients**.

Graduate Medical Education

In addition to the comments below, the THA supports those comments submitted by the American Hospital Association.

The THA urges CMS to ensure that the initial residency period (IRP) for specialty physicians who complete a preliminary year in general clinical training is assigned based on the specialty the resident enters in their second year of training.

The rule discusses a potential change – but does not propose a change – in how CMS would "weight" the direct GME resident count for residents that pursue specialties requiring an initial year of broad-based training. Currently a number of programs, such as anesthesiology and radiology, require a year of generalized clinical training in internal medicine as a prerequisite to subsequent training in their chosen specialty. This requirement can be met by, either spending the first year in internal medicine, pediatrics, or surgery, or participating in a one-year, freestanding "transitional year" program. CMS policy, however, bases direct GME payments on the resident's first year of training, without factoring in the specialty in which the resident ultimately seeks board certification. For example, an anesthesiologist who does a base year of generalized clinical training would be labeled with a three-year training period – which is the time required to be board eligible in internal medicine – rather than the four years it takes to be board eligible in anesthesiology. The result is that the resident is eligible for only partial direct GME reimbursement in the fourth year.

Current CMS policy violates the statute, does not reflect congressional intent, and results in inequitable payments to teaching hospitals for residents training in certain specialties. The MMA conference report language clearly states, "The initial residency period for any residency for which the Accreditation Council on Graduate Medical Education (ACGME) requires a preliminary or general clinical year of training is to be determined in the resident's second year of training."

CMS discusses the possibility of reweighing these residents to allow hospitals their full direct GME payments. Given that it has been CMS' longstanding policy to allow an appropriate calculation of the full residency period for those residents training in "transitional year" programs; we also feel strongly that this interpretation should be

extended to those spending their first year in internal medicine, pediatrics or surgery. **The THA believes that this issue needs to be addressed and corrected in the final regulation.**

Dual-Eligible Patient Days

The THA is in opposition to CMS' proposed changes last year in the counting of dual-eligible patient days for the purpose of calculating the DSH patient percentage. CMS did not finalize its proposal last year, but indicates in this year's proposed rule that it will respond to last year's comments and make a decision in its FY 2005 final rule.

The DSH patient percentage is a sum of two fractions, the "Medicare fraction," calculated as the number of patient days attributable to patients eligible for both Medicare Part A and SSI benefits divided by total Medicare days, and the "Medicaid fraction," calculated as the number of patient days attributable to patients eligible for Medicaid but not entitled to Medicare Part A benefits divided by total patient days. CMS proposes changing how it treats dual eligible patients who have exhausted their Medicare coverage. Rather than continue to include these patients as part of the Medicare fraction, CMS proposes to exclude them from the Medicare fraction and count them in the Medicaid fraction.

There are important reasons not to make this change. First, CMS clearly states in the FY 2004 proposed rule that the current formula is consistent with statutory intent. Second, the proposed change would place a significant new regulatory and administrative burden on hospitals. CMS indicates, "it is often difficult for fiscal intermediaries (FIs) to differentiate days for dual-eligible patients whose Part A coverage has been exhausted. The degree of difficulty depends on the data provided by the States, which may vary from one State to the next." The shift of this administrative burden to hospitals is unjustified, especially given the inability of hospitals to access this information. Government agencies, specifically the FIs and the states, have records regarding the Medicaid and Medicare status of patients as well as whether they have exhausted their benefits.

It also is likely that this proposed change would result in reduced DSH payments to hospitals. Any transfer of a particular patient day from the Medicare fraction (based on total *Medicare* patient days) to the Medicaid fraction (based on *total* patient days) will dilute the value of that day, and therefore reduce the overall patient percentage and the resulting DSH adjustment. **The calculation of dual-eligible days must not be changed.**

Excluded Hospitals and Units

THA has deep concern and strong opposition to two proposed rules which would severely restrict the ability of long term care hospitals in Tennessee which share a building or campus with another hospital ("co-located long term care hospitals") to provide necessary hospital services to Medicare beneficiaries. These proposed rules would unfairly alter the manner in which co-located long term care hospitals participate in the Medicare program.

One proposed rule would limit to 25%, the number of Medicare beneficiary admissions to a co-located long term care hospital from the hospital with which it is co-located. The creation of a rigid statistical barrier to beneficiary access to hospital services is unprecedented, and is contrary to a primary directive of the Medicare program which guarantees Medicare beneficiaries freedom to choose covered services from any participating Medicare provider.(Section 1802(a) of the Social Security Act). We note that Congress has repeatedly represented to the American people that attempts to reform the Medicare program will not be at the expense of Medicare program beneficiaries' right to choose freely their provider of medical services. The 25% admission limitation is inconsistent with this representation. Medicare beneficiaries would be diverted from a co-located long term care hospital with no assessment of whether the specialized programs of long term hospital care they require are otherwise available to them. A 'predictable' effect of the proposed rule is to divert Medicare patients from family members, physicians, and other caregivers of their choice. Also, the proposed 25% admission cap would undermine the ability of acute care hospitals and co-located long term care hospitals Tennessee to consider the best interests of Medicare program beneficiaries in making patient admission and discharge decisions. For these reasons, the 25% admission limitation appears to be fundamentally flawed.

CMS indicates the reason for this proposal is to prevent inappropriate patient admissions to co-located long term care hospitals. At its April, 2004 public meeting, MedPAC addressed this question by voting to recommend to Congress that the Medicare program review the medical necessity of patient admissions to co-located long term care hospitals through Quality Improvement Organizations which Congress has authorized to perform that function. The Secretary has ongoing authority to include this type of review within the scope of work for Quality Improvement Organizations, and THA believes it is more appropriate to measure the appropriateness of an admission based upon medical need rather than a rigid statistical barrier based upon the source of the admission. **THA recommends CMS adopt the MedPac recommended approach if there are any questions concerning the appropriateness of patient admissions to co-located long term care hospitals.**

The imposition of a 25% admission cap will deprive some co-located long term care hospitals in Tennessee of the critical mass of patients they need to provide patient care, and even the proposition of this rule has a current destabilizing effect on the ability of these co-located hospitals to attract and retain medical personnel who are essential to the maintenance of ongoing patient care programs.

THA is additionally concerned about a second proposed rule which would prohibit common ownership of co-located acute care and long term care hospitals established subsequent to June 30, 2004. This proposed rule would preclude hospitals and health care systems from providing long term care hospital services in their own community. THA is concerned that application of this proposed rule would adversely affect hospital organization's ability to participate as Medicare providers. We understand that the stated reason for the

proposed rule on common ownership is the same concern voiced in connection with the 25% admission cap – namely, inappropriate admissions to co-located long term care hospitals. Here again, MedPAC's recommendation sets forth a compelling reason not to pursue this proposed rule.

End of Attachment
CMS-1428-P — THA Comments - Medicare IPPS Fiscal Year 2005; Proposed Rule
July 8, 2004

CMS-1428-P-96 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Grant Leidy** **Date & Time:** **07/08/2004**

Organization : **Deborah Heart and Lung Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

please see the attached file for our comments related to this issue

CMS-1428-P-96-Attach-1.doc

CMS-1428-P-97 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Grant Leidy** **Date & Time:** **07/08/2004**

Organization : **Deborah Heart and Lung Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached file for comments on this issue.

CMS-1428-P-97-Attach-1.doc

CMS-1428-P-98 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Richard Cowart** **Date & Time:** **07/08/2004**

Organization : **Baker Donelson Bearman Caldwell & Berkowitz**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Re: File Code: CMS-1428-P
Issue Identifiers: Revised MSAs, Hospital Redesignations, Hospital Reclassifications

Comment Letter is attached but Exhibit A is not. Complete Letter with Exhibit A will follow via Federal Express.

CMS-1428-P-98-Attach-1.pdf

CMS-1428-P-99 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Cully White** **Date & Time:** **07/08/2004**

Organization : **Midwest NeuroScience**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: New Technology Applications . Kinetra

I'm a neurosurgeron that has been working with Parkinson's patients for 3 years now implanting Activa deep brain stimulators. I believe that Kinetra is sufficiently different from the previous technology Soletra. Here are 3 reasons why:

Reduced Invasiveness. Less invasive than implanting two single-array neurostimulators, Kinetra requires tunneling down only one side of the neck and only one subcutaneous pocket, eliminating two incisions and subcutaneous trauma.

Reduced Complications. The fewer incisions and eliminating the second device implant may reduce the probability a patient will experience complications.

Improved Environmental Compatibility. The older technology is subject to inadvertent switching off of the device by environmental magnetic fields . resulting in unexpected return of underlying disease symptoms. New technology encompassed in Kinetra substantially mitigates this issue.

For these reasons I believe that CMS should condsider new-technology ambulatory payment classification for Kinetra in the outpatient propsetcitve payment system as quickly as possible. Thank you for your full consideration of Kinetra payment issues and I strongly urge you to approve the inpatient add-on payment for our patients that have and will continue to benifit from Activa deep brain stimulation therapy with the use of Kinetra.

CMS-1428-P-100 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Ms. Patricia Marlinghaus** **Date & Time:** **07/08/2004**

Organization : **Riverside Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

July 8, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

Subject: Hospital Reclassifications
To Whom It May Concern:
Riverside Medical Center is a short-term general acute care hospital. The hospital is licensed for 341 beds, of which 238 beds (excluding Level II Nursery, Rehabilitation (Chemical) and Nursery bassinets) are currently staffed. In addition, our facility is a state certified Level II Trauma Center and a state certified Resource Hospital.
Riverside Medical Center is located in Kankakee County Illinois, which is a two-hospital county 55 miles south of Chicago. Currently, Riverside Medical Center comprises approximately 60% of the hospital wages in Kankakee County. Based on the current regulations, Riverside Medical Center has been unable to qualify for Dominant Hospital status for the purposes of wage index.
Dominant hospitals (i.e., hospitals that pay a substantial proportion of all the wages paid by hospitals geographically located in their area) and hospitals in single-hospital Metropolitan Statistical Areas are unable to qualify for geographic reclassification because CMS includes the applicant.s average hourly wage data in both the numerator and denominator of the 108/106 percent equation. We encourage CMS to revise the Medicare regulations in a manner that would allow dominating hospitals and hospitals in single hospital MSAs to qualify for geographic reclassification. Specifically, we urge CMS to either (1) exempt these hospitals from the 108/106 percent test, or (2) exempt just hospitals in single-hospital areas from the 108/106 percent test, and revise the 108/106 percent test for dominant hospitals such that they are required to compare their AHW to the AHW of other hospitals in their area.
We believe that the provision to only allow hospital groups that are in a metropolitan division of a large urban area should be modified to also allow reclassification of a county included in a large urban Combined Statistical Area (CSA) to reclassify to another contiguous metropolitan division included in the CSA.

Under the 1990 standards, the Kankakee MSA (Kankakee County) was included in the Chicago-Gary-Kenosha Consolidated Metropolitan Statistical Area (CMSA) as a Primary Metropolitan Statistical Area (PMSA). Under those OMB/Census standards, CMS extended the group

reclassification criteria to Kankakee County and allowed for a countywide reclassification to the contiguous Chicago PMSA, if all criteria were met.

Under the 2000 standards, Kankakee County has been excluded from being a metropolitan division of the Chicago-Naperville-Joliet MSA, as a result of the increased commuting threshold. The CMS proposal would deny group reclassification to the two hospitals in this county since the proposal requires groups to be within a metropolitan division.

The economic and social interaction of Kankakee, with the expanded Chicago metropolitan area, has not decreased. The need to offer competitive salaries to attract and maintain professional employees within the CSA is just as important, or even more important today as in prior years. By utilizing counties within the newly defined CSAs for countywide reclassification purposes, CMS would preserve the integrity of the group reclassification process as it currently exists and allow hospital groups that meet the historical criteria to seek group reclassifications if they meet the other geographic reclassification criteria in future applications to the MGCRB.

Again, I would urge CMS to revise the Medicare regulations to eliminate the applicant from both the numerator and denominator of the equation to qualify as a Dominant hospital and to allow counties included in a CSA to seek group reclassification to a contiguous metropolitan division in the CSA.
Cordially yours,
RIVERSIDE MEDICAL CENTER

Patricia K. Marlinghaus

CMS-1428-P-100-Attach-1.doc

CMS-1428-P-101 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Dr. Philip Starr** **Date & Time:** **07/08/2004**

Organization : **University of California, San Francisco**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am writing to support increases in reimbursement for surgical implantation of the Medtronic Kinetra implantable pulse generator (IPG), reflecting a substantial technological improvement compared to prior IPG.s. The Kinetra is used as the battery and control unit for bilateral deep brain stimulation in the treatment of Parkinson.s disease.

At UCSF, we have implanted over 500 deep brain stimulator systems since launching our movement disorders surgery program in 1998. We therefore have substantial experience with all stages in the development of the implantable generator, including the original Itrel 2 single channel IPG, the subsequent Soletra single channel IPG, and most recently the Kinetra dual channel IPG.

The Kinetra represents a major advance in the following ways:

1.) For the first time, the Kinetra allows patient control over the stimulation parameters, within limits that are set by the physician, using a simple hand-held device (Access Review). In the effort to optimize stimulation parameters for best motor function in Parkinson.s disease patients, it is often necessary to make many small changes in stimulation voltage. This is impractical to do in the office, since the result of programming changes may not be fully manifest for hours or days, and it is not possible for most patients to make numerous trips to their neurosurgeon or neurologist for this purpose. With the patient control feature, a patient may make prescribed changes, assess the result for their symptoms in a relaxed environment, performing normal activities, over an extended time. This has resulted in much greater patient satisfaction, far fewer physician visits, and better optimization of stimulation parameters.
2.) Because the Kinetra powers two DBS leads instead of one, it substantially reduces the number of incisions and operative time for bilateral deep brain stimulation.

It is important to note that at times, a bilateral DBS implant must be staged into two separate procedures separated by weeks or months. This is the case for the more frail or elderly patients, for whom recovery from simultaneous bilateral surgery would be prolonged. In these cases, surgeons need to have the option of placing the Kinetra as an outpatient after both DBS lead implants are done, or as an inpatient in the same operative session as the placement of the second DBS lead.

Please do not hesitate to contact me if I can be of further assistance.

Sincerely yours,

Philip A. Starr MD, PhD
Associate Professor of Neurosurgery, UCSF

CMS-1428-P-101-Attach-1.doc

CMS-1428-P-102 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Ms. Kathy Nelson** **Date & Time:** **07/08/2004**

Organization : **Marshall Medical Center North**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

RE:CMS-1428-P-Medicare Program;Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2005 Rates;Proposed Rule(69Federal Register 28196), May 18,2004

CMS-1428-P-103 **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates**

Submitter : **Mr. Allen Van Driel** **Date & Time:** **07/08/2004**

Organization : **Harlan County Health System**

Category : **Critical Access Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter

CMS-1428-P-103-Attach-1.pdf

Harlan County Health System

Proudly Serving Harlan County for 25 Years

717 North Brown
P.O. Box 836
Alma, Nebraska 68920
Phone: (308) 928-2151
FAX: (308) 928-2774

July 7, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing in response to the proposed rule regarding changes to the FY 2005 Inpatient Prospective Payment System (IPPS), published in the May 18, 2004 Federal Register. Specifically, these comments relate to the section of the proposed rule addressing Critical Access Hospitals (CAHs).

In the proposed rule, you state that Section 405(e) of Pub. L. 108-173 amended sections 1820(c)(2)(B)(iii) and 1820(f) of the Act to allow CAHs a maximum of 25 acute care beds for inpatient services, regardless of swing bed approval. Further, you state that it is your interpretation that this provision of the law is to be applied prospectively after April 1, 2004, regardless of when the CAH was designated, and that (in accordance with your Survey and Certification Letter 0414, dated December 11, 2003) all CAHs may maintain up to 25 inpatient beds, effective January 1, 2004. While this statement, and your proposal to amend Sections 485.620(a) and 485.645(a)(2) to reflect this provision of law are in agreement, they are at odds with recently issued changes to the State Operations Manual (dated May 21, 2004), which continue to state a maximum of 15 acute care beds. This discrepancy in direction to state survey agencies needs to be corrected with all due haste, in order to help prevent further confusion.

I also wish to comment once again regarding the provisions dealing with Payment for Clinical Diagnostic Laboratory Tests. The proposed rule restates a position first elucidated in the FY 2004 IPPS Final Rule regarding the requirement for outpatients of a CAH to be physically present in the CAH when the specimen is obtained in order for the CAH to be paid on the basis of reasonable costs. The position taken in the FY 2004 rule was wrong, and the reiteration of that position in the FY 2005 Proposed Rule compounds the error originally made, fails to address information provided by numerous parties to CMS in the interim, and clearly defies Congressional intent on this matter. Language contained in Pub. L. 108-173 indicates the intent of Congress to require reimbursement of Clinical Diagnostic Laboratory tests performed for outpatients of CAHs on the basis of reasonable cost. The interpretation that CMS has placed on this language, namely that an

outpatient must be physically present in the facility, is not only a change in customary service patterns, it clearly defies the intent of those Senators and Representatives who inserted the language in the law. In the arena where CAHs normally function, the staff of the CAH are truly very often the only personnel properly trained and equipped to perform blood sampling services for Medicare beneficiaries who are residents of group homes, assisted living facilities, or Intermediate Care Facilities. The CAH certainly does not incur less cost in the process of performing laboratory tests for beneficiaries in those settings than for outpatients who come to the facility. To illustrate this point more clearly, perhaps some scenarios would be helpful.

Suppose that a Medicare beneficiary is a resident of an Intermediate Care Facility located in the same community as, but not adjacent to or owned by the CAH. The patient (beneficiary) is transported to a physician's office (also not adjacent to or owned by the CAH) by staff of the ICF for evaluation of a medical problem. The physician orders clinical diagnostic laboratory testing be performed. Because the physician does not have the capability of performing clinical diagnostic laboratory testing in his office, the patient is transported to the CAH, registered as an outpatient, and has a specimen drawn for analysis. The results are reported to the physician, who orders medication for the patient as a result of the examination and laboratory findings. Subsequently, to evaluate the effects of the therapy, the physician orders a repeat of the clinical diagnostic laboratory tests one week later. The staff of the CAH is notified of the order, and qualified staff from the CAH go to the ICF and perform sampling for clinical diagnostic laboratory testing. Because the patient is not physically present in the CAH when the specimen is obtained (although the patient is under any logical definition, again an outpatient of the CAH), the performance of the clinical diagnostic laboratory test is reimbursed at a much lower rate (fee schedule) than when the first (identical) test was performed. There is no difference in cost of performance of the tests on the two different occasions, there is some additional cost to the CAH to provide the staff to go to the ICF to perform the sampling, BUT THE CAH IS REIMBURSED LESS! The alternatives to this method of providing service to the Medicare beneficiary is for the ICF staff to transport the patient (beneficiary) to the CAH, or for the physician to go to the ICF, perform another examination of the patient, and, incident to this covered visit, draw the specimen for repeat testing. If the ICF staff transports the patient to the CAH for sampling, this represents additional un-reimbursed cost to the ICF, unnecessary movement of a perhaps frail elderly Medicare beneficiary, and overall a much less satisfactory solution than having the CAH staff draw the specimen in the beneficiary's place of residence. The other solution suggested in the FY 2004 Final Rule is to have the ICF staff draw the specimen and transport it to the CAH for analysis. However, in most instances, the ICF would not have a CLIA Certificate and would likely not have staff qualified to perform blood drawing in any event. Again, the best (and in many cases ONLY) solution is for CAH staff to provide service to patients who are not physically present in the CAH.

This is a scenario repeated on a daily basis in hundreds of rural communities located across the United States. It is not a theoretical situation, nor is it a situation of a CAH attempting to inappropriately expand their service area. It is an example of how Critical Access Hospitals provide service to the residents if the communities they serve. The Medicare beneficiaries in these communities are neighbors, long time acquaintances, and, in many cases, relatives. Providing health services to them is a way of life, but it cannot and should not be viewed by CMS as being less worthy of adequate reimbursement than services provided to Medicare beneficiaries in another setting.

CMS has requested examples of "actual verifiable documentation as to any actual access problems being generated by this policy…". It has proven extremely difficult to provide existing examples of changes in service patterns resulting in decreased access for beneficiaries. This is because, as noted above, most CAHs SERVE the communities in which they are located. Despite the negative financial impact produced by the ill-advised policy change made by CMS a year ago, these facilities have chosen NOT to abandon their communities. CAHs across this country have refused to negatively impact the quality of care delivered in their communities simply in order to demonstrate to CMS that an impact could result. As has been stated previously, the only way that CMS staff will understand what this means is to spend time (more than an hour or two) WALKING IN THE SHOES OF CAH STAFF and observing first hand how care is delivered. As I have in the past, I again gladly extend the invitation for CMS staff to visit my community and see how we deliver care in a CAH.

I thank you for your attention to these comments and look forward to your response.

Sincerely,

Allen E. Van Driel, CHE
Administrator